Vol. 1, no. 1

network

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Dear Colleagues:

The International Fertility Research Program was established in 1971 to increase the safety, effectiveness and acceptability of fertility control methods. A worldwide network of collaborators in nearly 50 developing and developed countries is the backbone of IFRP. This publication is dedicated to them.

Currently, the scope of IFRP functions is expanding. Studies have broadened to include evaluations of the use and acceptance of family planning methods, programs and services. New initiatives are planned in the study of contraceptive safety. We continue to conduct a unique global survey on childbirth and its outcome and to train doctors and allied health personnel in the latest techniques of fertility control. The IFRP also sponsors seminars and workshops on various aspects of family planning to help decision-makers identify and provide the most effective services possible.

As we enter the decade of the 1980s, the IFRP will continue its worldwide quest to improve the quality of life for women, children and families through family planning. We feel it is essential to share relevant findings and maintain communication with others striving to make safe and effective contraceptive choices available to those in greatest need. While major research results are published in appropriate scientific journals, information exchange on a broad scale is also crucial if we are to respond efficiently to the challenges ahead.

With this in mind the IFRP is introducing **network**. It will be published quarterly to keep IFRP collaborators and other interested professionals informed of our activities. Each issue will highlight current research and projects and include other items of interest. We are eager to receive reader response and welcome your ideas and opinions about **network**.

Malcolm Potts, MB, BChir, PhD
Executive Director

Fimbrial prosthesis trials continue

An experimental fimbrial prosthesis for temporary or reversible female sterilization is being tested in simultaneous trials in Leuven, Belgium, and San Antonio, Texas, according to IFRP Medical Director Leonard E. Laufe. The devices are being designed and fabricated at the IFRP. This work is a continuation of a pilot study performed by Dr. Laufe at Battelle Institute in Columbus, Ohio, in 1971. The project is being funded by the Program for Applied Research in Fertility Regulation, in cooperation with the University of Leuven, where Ivo Brosens, and Willie Boeckx, are conducting prototype studies of the prosthesis in rabbits, and with the University of Texas at San Antonio, where Carlton Eddy is carrying out morphologic and efficacy studies in subhuman primates.

"Results are preliminary," Laufe stressed, "but in Leuven, in those few rabbits in whom the devices have been in place 8-12 months, no adhesions, infections or hydrosalpinx have been found. Moreover, the devices have proven easy to remove and scanning electron microscopies (SEMs) of the rabbit fimbria after prosthesis removal have shown no alteration in patterns." The earliest data from the prosthesis studies in a few rabbits show that when the device has remained in place and ovulation has been determined by laparoscopy, no pregnancies have occurred when the females were placed with the male.

Laufe hopes that in humans, the prosthesis can be applied to and removed from the fallopian tubes via minilaparotomy. He suggested that the fimbrial prosthesis approach would find large acceptance in family planning programs if it can be developed to offer an 80% opportunity for fertility restoration.

At Leuven, Brosens and Boeckx began the fimbrial prosthesis work with rabbits to test promising materials in different configurations and to test a variety of delivery systems. Their primary objective was to evaluate tissue response to identify a satisfactory device. Three

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candidate devices were tested first—all designed to fit the fimbria of the rabbit. The three devices were designed and fabricated at the IFRP workshop by bioengineer Robert G. Wheeler, who also developed the delivery system (Fig. 1) by which the prosthesis could be attached to the rabbit fimbria. The delivery system can be compared to that which delivers the tubal ring in the female sterilization procedure.

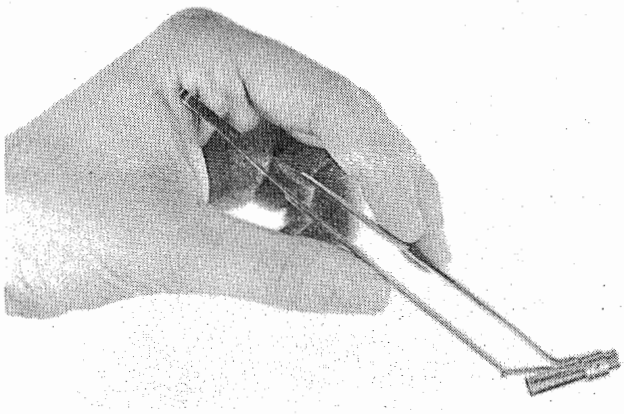

Fig. 1. Fimbrial hood applicator.

The first two of the three devices were made of silastic, an inert material that has the approval of the US Food and Drug Administration. The first device was 0.002 of an inch thick, and the second was 0.006 of an inch thick. The third candidate device was made of a Teflon polymer, a material suggested by William Droegemueller, and Milos Chvapil, both of the University of Arizona.

Results of the early trials of the three devices showed that the second, with a thickness of 0.006 of an inch, was too heavy to be held in place with simple suturing techniques. The Teflon device, which wrinkled when in place and showed a tendency to collapse, was found to be too thin; it also invited excess peritoneal overgrowth. The first device, 0.002 of an inch thick, proved to be biocompatible. In the few rabbits in whom this device was in place for 8-12 months, the results at removal showed the device to be covered by an acceptably thin peritoneal coating, having a single mesentery with one small artery.

The major problem in the testing of the prosthesis has been the development of a proper fixation technique. A variety of fixation techniques were tried, including purse-string sutures and 2-, 4- and 6-stitch sutures. All of these proved unsuccessful, Laufe stated, because of the motility of the rabbit tube. The last group of rabbits in the Leuven studies will have the 0.002-inch thick device implanted with the continuous suture technique, which the investigators believe will prove consistently successful.

Early efforts in monkeys have shown that an appropriately fitting prosthesis can be held in place using a multiple interrupted suture technique. The prosthesis (Fig. 2) will be placed in 20 monkeys in the San Antonio trials. When impending ovulation has been determined by hormonal assay, the female will be placed with the male each month for six months. The prosthesis will be removed and SEMs used to evaluate the fimbria.

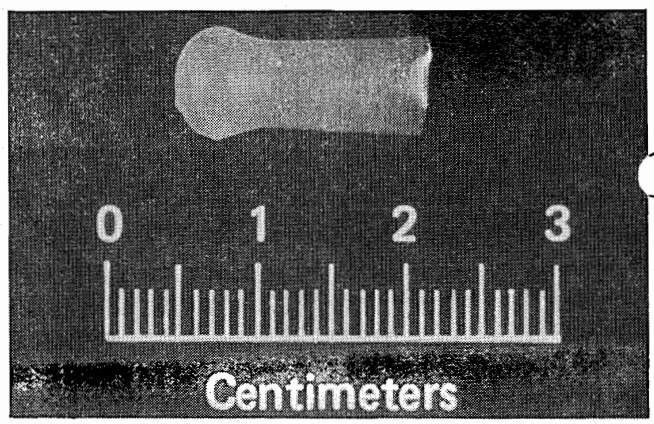

Fig. 2. Fimbrial hood used in monkeys.

DMPA for contraception discussed by international forum of experts

For some, depot medroxyprogesterone acetate (DMPA) is an ideal contraceptive. Some experts say that when injected in three- and six-month doses, DMPA can provide highly effective, long-lasting protection from pregnancy, with comparably fewer and less serious side effects than those associated with the use of oral contraceptives, intrauterine devices and voluntary sterilization.

For others, DMPA is a dangerous drug, associated with menstrual irregularities in humans, breast cancer in beagles and uterine cancer in monkeys. The possible risks to women of birth defects in offspring conceived during its use, of prolonged infertility or sterility after discontinuing DMPA and of developing cancers while using it for long periods are also cited by its detractors.

In March 1978, the US Food and Drug Administration denied a request to approve the marketing of Depo-Provera, a DMPA product manufactured by The Upjohn Company for contraception in the USA. DMPA is used as a contraceptive in 69 other countries throughout the world and is available for the treatment of cancer in the USA.

The continuing controversy over the use of DMPA for contraception is discussed in detail by an International Forum of experts in issue 16(5) of the *International Journal of Gynaecology & Obstetrics (IJGO).*

David A. Edelman, IFRP Associate Director for Research, provides an overview of the controversy and Forum participants from four countries discuss their extensive experience with the drug and its effects on thousands of users. These experts include:

- Paul C. Schwallie, a Clinical Research Physician in Fertility Research at The Upjohn Company, Kalamazoo, Michigan, USA;
- Edwin B. McDaniel, the Head of the Obstetrics and Gynaecology-Family Planning Department of McCormick Hospital, Chiang Mai, Thailand;
- H. J. S. Rall, and W. A. Van Niekerk, of the Department of Obstetrics and Gynaecology, Tygerberg Hospital and the University of Stellenbosch, Tygerberg, Republic of South Africa; and
- Prof O. A. Ojo, of the Department of Obstetrics and Gynaecology, University College Hospital, Ibadan, Nigeria.

"We believe that this timely, thoughtful, scientific discussion by a distinguished panel of experts provides considerable insight and new information about the risks and benefits of DMPA used as a contraceptive for prolonged periods by large groups of women in different parts of the world," said Edelman.

"Regardless of the outcome of the current DMPA controversy," Edelman added, "there remains a great need for a safe, highly effective, long acting contraceptive that can be widely, and inexpensively administered to those people most in need of contraception, especially the poor in developing countries where limited medical resources and skyrocketing birthrates create a continuing crisis in the availability and adequacy of maternal and child health care."

Malcolm Potts, Executive Director of the IFRP, believes that it is necessary to focus attention on injectable contraceptives. He noted that "the IFRP is aware of the need for more information on the many thousands of women who have used shots continuously for 8 or 10 years, and is actively discussing possible new studies with several research centers around the world."

The *IJGO* is cosponsored by the IFRP and the International Federation of Gynaecology and Obstetrics (FIGO) and published bimonthly by the IFRP in Research Triangle Park, North Carolina.

A free copy of the International Forum discussed above may be obtained by writing the Information Coordinator, International Fertility Research Program, Research Triangle Park, NC 27709, USA.

Tunisia: rural contraceptive distribution project has impact

Planning Familial à Domicile (PFAD), a small pilot project in rural Bir Ali ben Khalifa in the Governorate of Sfax, Tunisia, has departed from the country's clinic-based family planning program and demonstrated the feasibility of making contraceptives available on a door-to-door basis.

Launched in early 1976, PFAD, under the directorship of Dr. Liliane Toumi, recruited and trained a small corps of nonmedical personnel who visited all households within the area, offered oral contraceptives to married women aged 15 to 44, and referred those desiring IUDs or sterilizations to a clinic where these services were provided at no charge. Following two years of intensive household distribution, contraceptive use among women in Bir Ali increased from 6.6% to 17.7%, a relative increase of 168%. Nearly eight out of every ten women visited said that PFAD provided their first information about family planning.

PFAD was designed to help the Office National du Planning Familial et de la Population (ONPFP) identify acceptable, cost-effective contraceptive distribution methods for use in rural areas such as Bir Ali, where the terrain has caused the small population of 30,000 to live in widely dispersed settlements. The success of this pilot activity has influenced efforts by the ONPFP to extend family planning services throughout rural Tunisia.

Two current household distribution projects are building on the PFAD experience to test integrated delivery of family planning and maternal and child health services. The Planning Familial Par le Couple (PFPC) project was initiated in 1977 among a population of 144,000 and includes additional health components, a lower canvasser-household ratio than PFAD, a greater contraceptive mix and more effective resupply methods. Household visits were completed in September 1979 and a governorate-wide contraceptive prevalence study is now being conducted. The Planning Familial en Milieu Rural (PFMR) project, initiated in 1978, is surveying a population of 400,000 to measure the impact and cost-effectiveness of offering services through mobile clinics and the use of social assistants as family planning educators and motivators.

Population growth objectives of the Tunisian National Development Plan call for a 40% reduction in the growth rate by the year 2000. ONPFP's current five-year plan is directed at making the delivery of contraceptive information and services more efficient and widespread throughout rural Tunisia. PFAD has taken an important step forward in showing that household delivery can substantially increase contraceptive prevalence. Results of the three-year project will be valuable to the ONPFP as it evaluates the different household and community-based distribution experiences in its continuing efforts to provide the best possible family planning program for all of Tunisia.

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Contraceptive safety studies discussed

Unmet needs for contraceptive safety studies, particularly in the developing world, were discussed June 25 and 26 in a two-day meeting conducted by the IFRP at its Research Triangle Park headquarters.

Participants included senior IFRP staff and 14 international experts on fertility regulation and family planning from 12 different organizations involved in conducting or funding research on contraceptive safety.

"We found that there is a great need to tackle the key question as to whether contraceptives, such as birth control pills or intrauterine devices, are more or less dangerous when used by women in developing countries," said IFRP Executive Director Malcolm Potts.

"Studies are urgently needed to put all the risks related to reproduction in perspective. The meeting prepared the IFRP to meet these challenges."

Potential problems likely to be encountered in planning and implementing such studies in developing countries were also discussed. They include:

- quality and availability of maternal health care and trained personnel to provide family planning services,
- adequacy of the local record keeping system to keep track of contraceptive users and any method-related illnesses they may experience,
- accuracy of diagnosis of patient complaints and symptoms and their relationship to contraceptive use.

"The extensive experience of the meeting participants in designing special research strategies to overcome such problems and to collect and analyze sufficient data to accurately evaluate the safety and effectiveness of various contraceptives proved most helpful," said David A. Edelman, the IFRP's Associate Director for Research.

"Based on our useful discussions of the need for and problems associated with conducting new contraceptive safety studies," he added, "we have decided to explore further the feasibility of conducting a large-scale, long-term prospective study to determine the risks associated with contraceptive use in developing countries."

A study comparing the relative risks of various contraceptives to that of uncontrolled reproduction will provide a perspective on the risk-benefit ratio of contraceptive use in developing countries, where diet deficiencies and parasitic infestation present additional problems for pregnant women," explained Potts.

Meeting participants included professionals from the IFRP and the following organizations: Center for Disease Control, Public Health Service, US Department of Health, Education and Welfare; Ford Foundation; International Development Research Centre; International Planned Parenthood Federation/London; Kaiser Foundation Research Institute; National Institutes of Health; Office of Population, US Agency for International Development; Population Council; Program for Applied Research in Fertility Regulation; Program for the Introduction and Adaptation of Contraceptive Technology; Rutgers Medical School; and University of Oxford.

Recent publications by the IFRP staff

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To request a free copy of any of these articles, or a complete list of IFRP publications (1971-78) write Information Coordinator, IFRP, Research Triangle Park, NC 27709, USA.

Investigation of quinacrine hydrochloride

Extensive research is being conducted to develop a simple method of nonsurgical female sterilization that can be offered by paramedical personnel in large-scale sterilization programs. Nonsurgical methods of sterilization investigated include: systemic approaches, tubal plugs and chemical agents.

Among the most promising of the chemical agents is quinacrine hydrochloride. It is hypothesized that quinacrine disrupts the epithelium of the intramural portion of the fallopian tube without altering the histology of the endometrium.

The IFRP is proceeding with the following studies to further evaluate quinacrine:

1. Absorption levels of quinacrine are currently being evaluated from blood and saliva samples taken from 25 women who have undergone quinacrine pellet insertions. Additional pharmacologic and toxicologic tests in subhuman primates will be undertaken. Key factors will be the absorption of the drug by various organ systems, and the drug's mutagenicity and teratology.
2. The safety and effectiveness of the transcervical insertion of quinacrine hydrochloride pellets as a method of nonsurgical female sterilization will be evaluated in four studies of 150 subjects each. Pellets containing a total of 250 mg of quinacrine hydrochloride will be inserted at admission and again at one month and two months after admission.
3. Alternate delivery systems, such as a quinacrine IUD, are being explored. A mixture of 80% quinacrine and 20% polythyleneoxide has been molded over a Cu-T IUD to deliver quinacrine directly to the tubal ostia (Fig. 1). These IUDs will be inserted in 25 patients awaiting hysterectomy for uterine prolapse. Tubal specimens will be examined to determine the presence of sclerosing lesions. Other IUDs, such as the Ypsilon IUD, are being considered to improve drug delivery.

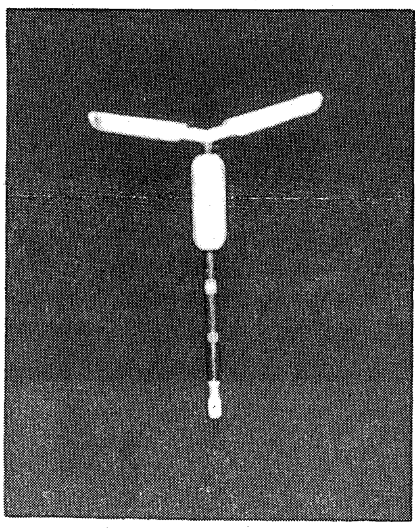

Fig. 1 Quinacrine-T IUD.

IFRP receives $80,000 grant from The Hewlett Foundation

The IFRP recently received a two-year grant of $80,000 from The William and Flora Hewlett Foundation, a Palo Alto, California-based charity.

"The purpose of the grant is to help the IFRP increase access to birth control methods and implement family planning programs for those in need of such services in developing countries around the world," reported IFRP Executive Director Malcolm Potts.

"This generous grant provides a much-needed supplement," Potts added, "to the predominantly federal funding that the IFRP now receives, and it will allow us to undertake several important new projects and activities that we could not otherwise pursue.

"This grant also demonstrates The William and Flora Hewlett Foundation's continuing concern in the area of family planning and population control. Moreover, it illustrates the great significance that private donations have in underwriting important research that may have far-reaching impact not only for the relatively small overseas population who are directly affected, but also for thousands of others all over the world who will eventually benefit from the development of safer, more effective fertility regulation methods."

The William and Flora Hewlett Foundation was incorporated as a charity in 1966 in California, with assets built on gifts of stock in the Hewlett-Packard Company, of which William Hewlett was a co-founder. The foundation has concentrated its resources on support of activities in the arts and humanities, education, the environment and population.

IFRP researchers win ACOG prize for postpartum IUD paper

An IFRP paper on the development of a postpartum intrauterine device (IUD) recently won the First Prize for Papers on Current Clinical and Basic Investigation awarded by the American College of Obstetricians and Gynecologists (ACOG).

The paper, "Modification of IUDs for Postpartum Use" by Medical Director Leonard E. Laufe, bioengineer Robert G. Wheeler and IUD Project Coordinator Patrick G. Friel, was selected as the most significant of 36 papers presented in its category at ACOG's 27th Annual Clinical Meeting, March 31- April 5, in New York. It was published in the April 21 issue of *Lancet*.

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Reported were preliminary data from four international trials of a Lippes Loop D modified with biodegradable chromic sutures affixed to its upper crossarm so it can be more readily retained in the enlarged postpartum uterus. Field trials were conducted in Egypt, Bangladesh, the Philippines and Chile.

According to Laufe, the six-month net life-table expulsion rate for the IFRP's postpartum suture loop was 5.3 ± 1.3 per 100 women (based on 341 insertions).

Laufe explained that the modified IUDs, which can be inserted by hand immediately after delivery, represent a technology that is both adaptable to other devices and easily transferable to the developing countries where the IFRP concentrates its efforts.

Contraceptive prevalence survey conducted in São Paulo

The IFRP believes that family planning programs can provide the best possible services only when the specific contraceptive needs of the populations they serve are identified. Recently, the IFRP and the Center for Disease Control in Atlanta, Georgia, provided the Catholic University of Campinas with the technical and financial assistance necessary to conduct a survey of fertility levels and contraceptive use in the State of São Paulo, Brazil. The objectives of the survey were to:

- estimate the level and pattern of fertility in specific urban and rural areas of the State,
- assess the level and pattern of contraceptive use by area, education, income and age,
- identify women for whom pregnancy involves a high risk to health, and
- investigate why some women who want to plan their families are not using contraception.

Results of the São Paulo survey show that although a high proportion of married women in urban centers use contraception, many are still in need of services. Low-income women, especially those living in rural areas, are likely to use less effective contraceptive methods or none at all and have more unwanted pregnancies.

Although women in the rural areas of São Paulo express as much interest in using contraception as their urban counterparts, they are less likely to know about available services. Moreover, the long distances rural women must travel to receive services, combined with the lack of transportation, create a significant deterrent to contraceptive use.

As might be expected, interest in programs to make contraceptives more widely available is greatest in rural areas and among the poor.

The survey yielded abundant information that can be used to improve the availability of family planning services in São Paulo. The IFRP welcomed the opportunity to contribute its expertise and hopes that similar surveys will be conducted in the future.

Vasectomy: the need to expand availability

Research and experience clearly indicate that voluntary sterilization is the most desirable method of permanently ending the fertility of couples who decide that their families are complete. Although male and female sterilization procedures have been proven to be safe and effective, there is no doubt that vasectomy is considerably easier to perform and is associated with fewer serious complications than the currently available methods for female sterilization. A successfully performed vasectomy has no disadvantages for the person who finds the method an acceptable means of achieving permanent sterilization. The advantages are:

- the procedure is safe, effective and simple to perform,
- the excision and ligation method has been refined to a point where further improvement is unlikely,
- a significant amount of research has not identified any long-term adverse effects of vasectomy and
- paramedics can deliver reliable vasectomy services.

The current demand for the more complex, but available, female sterilization procedures appear to exceed the demand for male sterilization primarily because vasectomy is not available in most developing countries or is available from only a few physicians. In Korea and the United States, where both male and female sterilization services are easily accessible, they are provided in approximately equal numbers.

The IFRP feels that it is essential to expand the availability of vasectomy services without placing additional strains on the world's physicians. It is one of the IFRP's goals to demonstrate that carefully trained paramedical workers are entirely capable of performing safe and effective vasectomies.

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Hope for the living—Dacca 1979

Dacca is the capital of Bangladesh, the world's poorest and most congested nation. Pwrano Moghal Toli is a slum district within the city of Dacca, and down an alley in this district stands the one-room home of Jebunnessa and her family.

If you stand in the center of Jebunnessa's home, you can touch the four walls without moving your feet and feel the leaky ceiling scraping your head. Nearly all of the living space is taken up by a crudely built wooden bed covered with a thin straw mat. Jebunnessa, her husband and four children sleep on the bed; Jebunnessa's mother-in-law crawls under the bed to sleep on the dirt floor. This shack of woven straw, pieces of discarded wood and scraps of corrugated iron is one of two dozen similar dwellings crowded into a narrow and irregular alley between a pair of dilapidated two-storied houses.

Jebunnessa drinks only a cup of weak tea for breakfast; she last purchased an egg a year ago. Like the other women living in her alley, Jebunnessa will cook only one meal a day and it will be mainly rice. Then, she will scour her small aluminum cooking pot with the black mud from under her feet, walk to the end of her alley and wait her turn to rinse the pot once in water from the single tap that serves fifty households.

Jebunnessa's life is lived within the boundaries of her home and the narrow alley to the water tap. Her husband does the shopping and conducts all interactions with the world beyond his home. This is purdah, the Moslim seclusion of women that is virtually universal in Bangladesh. Although Jebunnessa's life is severely constricted by culture and poverty, she is not totally without hope. An organization known as the Concerned Women for Family Planning in Dacca has provided that hope through their efforts to improve life for the living. Among Jebunnessa's few valued personal possessions stored in a rusty tin on a high shelf are oral contraceptives supplied by the Concerned Women. With the help provided by this outstanding group of volunteers, Jebunnessa and thousands of other women like her have learned that they can plan their families and by doing so perhaps improve the immediate future for themselves and their children.

There are people who suggest that oral contraceptives should only be dispensed by a physician after a complete physical examination has been conducted. There are international committees who sit in air conditioned buildings in Geneva, London and New York agonizing over so-called medical standards. The door-to-door delivery of oral contraceptives in Dacca is conducted by lay-women who are not accompanied by a physician, but their work is easily justified. Most women in the slums of Dacca will never see a trained physician, as such a luxury is not possible for most of the world's poor. The Concerned Women in Dacca are courageously and intelligently providing an option for those women who will never know luxury and who, until now, never had a choice.

If you joined the Concerned Women on their rounds through the slimey alleys between the hovels of the poor, you discover that most women respond to the suggestion of adopting family planning with the phrase, "Let me ask my husband." Usually the husbands agree, but if they do not, then the field workers return on Sunday when they can be sure the husbands will be at home and they can argue the case for family planning.

A 30-year-old woman living in one of the alleys is known as Zaman-er-ma or "the mother of Zaman." She has lived all her life in poverty with little feeling of individual self-worth. She hesitates when asked her

Members of the Concerned Women for Family Planning conducting a course in nutrition.

(left) The poor age quickly from too much work, too little food and too many children. These two women are 35 and 50 years of age.
(below) The main street in Pwrana Moghal Toli.

name as opposed to that of her children because she genuinely has a problem recalling that it is Joshana. She was married when she was 13 and has had ten pregnancies since that time. Three of her children have died. She is weary, anemic, malnourished and spends nearly the whole of her day in her dark hovel. With the help of the Concerned Women, Joshana had a tubal ligation about six months ago and she hasn't noticed any side effects from the procedure. It solved one of life's many problems for her.

Westerners sometimes raise long-term questions about voluntary sterilization. What if our children die? What if we get divorced? For the very poor, these are intellectual questions that have nothing to do with the reality of how to eat today. The very poor can intellectualize about the possible disadvantages of an irreversible operation, but they will not identify with them as a genuine problem. They are just grateful for the immediate and real advantage of not having to worry—"Am I pregnant again this month?"

Hawa Bibi, another woman in the alley, lives on a starvation diet but spends a sixth of her meager income on a private tutor for her three children. The Concerned Women, who teach courses in nutrition and the treatment of dehydration in children with severe diarrhea, offered to run literacy classes for the mothers, but the idea was rejected in favor of expending the effort on educating their children. The women feel that their lives are already lost. Their bodies are prematurely aged from too much work, too little food and too many children born too close together. The best that family planning can do for them is to put an end to one of the miseries of their lives and help create a world where their children may have some glimmer of hope. Without family planning, the children of the Dacca slums will be condemned to the same destructive cycle of poverty as their parents. With the help of the Concerned Women, backed by the strength of maternal responsibility and ambition of women like Hawa Bibi, these children may have more of a chance than their parents.

Old Dacca is not a nice place, but it is no different than a hundred other cities on the Indian subcontinent. People living in abject poverty with no sense of personal value want and need these services. They rarely get them. Concerned Women for Family Planning has set up a model of service delivery that is succeeding. Field workers trudge through the slums every day delivering oral contraceptives, providing information, conducting classes, offering choices and providing the only hope available to the woman trapped forever in poverty. It is not easy work. It requires physical and emotional stamina and an intense commitment to the belief that the most disadvantaged of people need the greatest care. There are two million people in Dacca and perhaps 200,000 women in the worst of the slums. Concerned Women has enrolled 58,000 in their family planning program and 30,000 continue to use the pill. The number of women undergoing voluntary sterilization increases everyday. More and more volunteers are lining up to join the Concerned Women. Perhaps in Dacca, the capital of the poorest nation on earth, there is hope for the living.

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Immunology to provide new fertility control methods?

Researchers have long thought that perhaps the best hope for improved methods of contraception lies in the discovery of a means of enchancing nature's own physiologic barriers to conception. The concept of an immunologic method of fertility control, which by definition must be specific, nontoxic, immunogenic and non-cross-reactive, is thought to have a number of advantages: (a) such a method would be likely to require only infrequent administration; (b) its administration would not be physician-dependent; and (c) a natural rather than artificial physiologic agent would be used to intensify the body's own attempts to prevent conception.

Immunologic methods are being studied by numerous investigators, many of whom met in St. Louis, Missouri, on October 22-23,1979, for a workshop on "Immunologic Aspects of Infertility and Fertility Regulation." The workshop was sponsored by the Reproductive Biology Study Section, Division of Research Grants of the National Institutes of Health. Dr. Pouru Bhiwandiwala, a member of the IFRP's scientific staff who attended the meeting, cites the following as among the most promising methods or concepts reported on:

- A study of the secretory immune system by Dr. T. B. Tomasi of Mayo Medical and Graduate School, Rochester, Minnesota, has shown what Tomasi describes as the "homing patterns" of lymphoid cells. He has demonstrated that cells that are sensitized in the intestine can migrate to the breast and locally produce the antibodies found in the milk. This process is controlled by hormones (progesterone, estrogen and prolactin). Sensitized cells can also migrate to the salivary and lacrimal glands, lungs, cervix and vagina. It is theorized that it may be possible to sensitize cells in one area of the body (by aerosol in the lungs, for instance) and have the cells migrate to the cervix or uterus and produce antibodies that would act as a method of fertility control.
- A study of antigens of spermatozoa and their environment by Dr. M. G. O'Rand of the University of Florida College of Medicine, Gainsville, Florida, has resulted in the isolation of an autoantigen to sperm and the production of a specific antisperm serum. When used in an experiment in eight rabbits, the administration of antisperm serum reduced fertility by 70%. In vitro experiments showed that when the antiserum is used, spermatozoa are unable to bind to the zona pellucida of the ovum.
- A study of antigens of oocytes and their environment by Dr. C. A. Shivers of the Department of Zoology, University of Tennessee, Knoxville, Tennessee, has shown that oocyte antigens are found in theca and granulosa cells, vitelline membrane, follicular fluid and the ovum. When the ova were exposed to the antiserum produced in this study, the number of sperm attached to the zona pellucida was drastically reduced. In an experiment, one horn of a rabbit uterus was treated with the antiserum. No pregnancy occurred in the exposed horn, whereas normal fertilization and implantation occurred in the other horn. Since its antigens have been identified, the zona pellucida seems a practical target for immunologic fertility regulation. A mode of delivery for the antiserum must still be found, however, and this study is only preliminary. Further studies to isolate and purify the zona antigen are necessary, as are safety and toxicity evaluations of the antiserum. It is also hypothesized that the oocyte antibodies, located on the surface of the zona pellucida in a fenestrated arrangement, may be responsible for some cases of infertility: the production of the antiserum may occur naturally in some women.

Proceedings of the entire workshop, which featured eleven speakers, are forthcoming from Elsevier Press by mid-1980.

Seminar on high-risk pregnancy planned for May in New Orleans

"High-Risk Pregnancy: Diagnosis, Management, Prevention" will be the topic of a seminar for Latin American physicians to be held May 8-11, 1980, in New Orleans, LA. The seminar is being jointly sponsored by The Department of Obstetrics and Gynecology of Tulane University School of Medicine, New Orleans, LA, and the International Fertility Research Program.

This Seminar, to be presented in Spanish, is directed to the Latin-American physician whose practice involves the care of women and their pregnancies. The latest concepts in the identification of a potential high-risk pregnancy will be presented along with a thorough update on the management of the mother at risk. The most current methods available to prevent high-risk pregnancies will be reviewed, as will the growing problem of adolescent pregnancy. The practical application of clinical principles will be presented from both the hospital and private office setting.

As an organization accredited for continuing medical education, the Tulane University School of Medicine has designated this continuing medical activity as meeting the criteria for 14 credit hours in Category 1 of the Physician's Recognition Award of the American Medical Association.

For more information, contact: Director, Tulane Medical Center, Office of Continuing Education, 1430 Tulane Avenue, New Orleans, LA 70112, or the Seminar Coordinator, Dr. Marcos J. Pupkin, Department of Obstetrics and Gynecology, Tulane University School of Medicine, New Orleans, LA 70112 (telephone: 504-588-5217).

Patterns of adolescent pregnancy seen in the developing world

Adolescent pregnancy, characterized by some as epidemic, is widely recognized as a problem in the US, where almost one fifth of deliveries and one third of abortions are to teenagers. Although less publicized in the developing world, adolescent pregnancy is common and follows two patterns. In traditional societies young women marry at a very early age and begin childbearing immediately. Premarital sexual activity is strictly forbidden, and premarital pregnancy seldom occurs. However, in transitional societies, opportunities for education and employment are expanding and women are choosing to marry at later ages, while at the same time menarche is occurring earlier. When adolescent pregnancies occur in such societies, they are likely to have been conceived premaritally.

Among the factors determining the proportions of adolescent pregnancies in transitional societies are the large number of women in this age group, the decreasing age at menarche, the increasing age at marriage and the stage of social transition. Many studies have documented a declining age at menarche, generally associated with improved nutritional status. In rural, traditional populations the mean age at menarche is 15-16 years, while in transitional populations it is approaching 12-13 years. There is also an overall trend of increasing age at marriage. Comparison of the mean age at first marriage for the groups of women whose current ages are 25-29 and 40-44 reveals an increase of as much as three years in this mean age, although in the Asian countries for which data are available it was generally less than two years. The mean was generally higher among the Latin American than the Asian countries in both groups.

In traditional societies, early marriage and early childbearing are encouraged. High infant and childhood mortality support the perception that the maximum possible number of children must be produced to ensure survival to adulthood of a few children. One way of accomplishing this is to begin producing offspring early in life. Because virtually no other alternatives are available to young women in traditional societies, they usually comply with the society's expectations. Bangladesh, where the mean age at first marriage among women aged 25-29 is 12.8 years, typifies this situation. Once married, girls are anxious to prove their fertility. Failure to produce children is often grounds for divorce, leaving a woman with no means of support. The few girls who delay marriage in traditional societies are not likely to engage in premarital sexual activity because of the strong sanctions against it.

The most important of societal changes, in terms of its effect on adolescent fertility, is the expanding role for women in the economic life of the society. The rapid changes in the economic structure of societies in transition are associated with a large influx of young people seeking employment in metropolitan areas. The increased opportunity for sexual contact in the towns and cities, together with earlier age at menarche and later age at marriage, leaves many adolescent women exposed to the risk of premarital pregnancy.

Medical consequences of adolescent pregnancy include lower birth weight infants, higher perinatal mortality, increased incidence of toxemia, hemorrhage and prolonged labor and maternal mortality. The younger the mother, the greater the chance of problems. Older teenagers (18- and 19-year-olds) appear not to experience increased obstetric difficulties. All too often, an adolescent mother will have additional pregnancies, closely spaced, with one or more of the successive pregnancies also occurring during adolescence. The risks of age are then compounded by the risks of short pregnancy intervals.

In countries where induced abortion is legal, it has been documented that teenagers comprise a large proportion of the women obtaining abortions. Because of inexperience, ignorance, legal restrictions, social barriers and economic restraints, adolescents often seek abortion later than older women. Thus the abortion procedure becomes more complicated and the risks of adverse medical (including perhaps psychologic) consequences are increased.

The most obvious demographic consequence of adolescent pregnancy is short time periods between generations. If each generation bears its first child at the age of 16, there will be six generations per century. Delaying the first childbirth to the age of 25 reduces them to four. The population grows even faster if, as is frequently the case, early reproduction is associated with larger completed family size. The reproductive behavior of the large number of adolescents and soon-to-be adolescents will largely determine the population growth during the next 20 years. Their decisions will be crucial in determining the future of the human race on this planet.

The generation whose reproductive behavior will determine population growth in the next two decades.

IFRP encouraged by success of national fertility research programs

A grant from US/AID has enabled the IFRP to help a number of developing countries establish their own fertility research programs (FRPs). The national FRPs evaluate contraceptive methods and delivery systems to aid health personnel in providing the family planning services most suitable to their country's population. Staff at the national FRPs establish the safety, effectiveness and acceptability of various contraceptive methods and train local service providers in the latest procedures and techniques of fertility control. Through support of these programs, the IFRP hopes to increase local awareness, understanding and availability of contraceptive methods to all those who wish to practice family planning. The IFRP currently supports six national FRPs:

1. Mexico Biomedical Research Program. This research program aims to achieve a greater acceptability of and continuity in contraceptive use. It is involved with studies of injectable contraceptives, postpartum IUD insertion, voluntary sterilization, abortions treated in hospitals (especially threatened, inevitable and incomplete abortions) and maternity care monitoring (MCM), a unique global survey of childbirth and its outcome for the mother and her baby.
2. Programa Regional de Investigaciones en Fecundidad—Colombia (PRIF). PRIF is achieving self-sufficiency and has initiated several independent research projects, including MCM, the distribution of barrier contraceptive methods by traditional birth attendants and a study of the acceptability of female sterilization. PRIF is currently developing the capacity to process its data locally.
3. Bangladesh Fertility Research Programme (BFRP). Over the last year, the BFRP conducted studies on female sterilization, IUDs, female barrier contraceptive methods, oral contraceptives, MCM and abortions treated in hospitals. The program has followed up vasectomy cases and carried out studies of community-based distribution of oral contraceptives, the long-term effect of oral contraceptive use and the use of injectable contraceptives. Various conferences, seminars and workshops concentrating on problems and issues of health and family planning programs have also been organized by the BFRP.
4. Indonesia Fertility Research Program (BKS PENFIN). Since the beginning of 1979, BKS PENFIN has initiated studies of MCM, abortions treated in hospitals, systemic contraceptives and postpartum IUDs. Plans have been made to evaluate a training program in the techniques of male sterilization and to establish an in-country data processing capability. To help achieve this capability, the Central Office staff provided contributing physicians throughout Indonesia with training in research methodology and the use of standardized data collection instruments.
5. Malaysia Fertility Research Programme (MFRP). The MFRP was recently established as part of the Research and Evaluation Division of the National Family Planning Board in response to a rapid rise in the demand for and use of various contraceptive methods. Plans for first-year activities include studies of MCM in selected state hospitals, abortions treated in hospitals and systemic contraceptives. The MFRP also plans to conduct training courses in the techniques of sterilization. In September 1979, two programmers from the MFRP were trained at the IFRP as a first step toward the development of an in-country data processing and analysis capability.
6. Sudan Fertility Control Association (SFCA). Under the IFRP's first year of sponsorship, the SFCA's studies have focused on MCM and abortions treated in hospitals in three centers in Khartoum; similar studies are planned for rural centers later in the year. The SFCA also studies female sterilization, IUDs and oral contraceptives in an effort to increase their acceptability in the Sudan. The SFCA's data collection coordinator recently spent two weeks at the IFRP learning to tabulate and analyze data.

IUD use and PID discussed by experts

The relationship between the occurrence of pelvic inflammatory disease (PID) and the use of intrauterine devices (IUDs) has received a large amount of recent publicity. This topic is discussed in detail by an International Forum of experts in the March/April issue 17(5) of the *International Journal of Gynaecology & Obstetrics (IJGO)*. Forum guest editor, Dr. David A. Edelman, Associate Director of Research for the International Fertility Research Program, will provide an overview of this controversy and the other Forum participants will address the following questions: Do the available data confirm the existence of a causal relationship between IUD use and PID? If such a relationship exists, what are the responsible factors? Is such a relationship associated with all, or only some, IUDs? Is the risk of PID associated with IUD use the same for all users, or is it greater for women in certain age and parity groups? What sociodemographic factors are associated with an increased risk of PID? What steps can be taken to minimize the risks of PID among IUD users?

The eight Forum participants, in addition to Edelman, will include: Max Elstein, Professor of Obstetrics and Gynaecology at the University Hospital of South Manchester, University of Manchester, Manchester, England; Stellan Osser, Percy Liedholm and Nils-Otto

Sjöberg of the Department of Obstetrics and Gynecology, University of Lund, Malmo, Sweden; Robert Snowden, Co-director of the University of Exeter's Institute of Population Studies, Exeter, England; Martin P. Vessey of the Department of Social and Community Medicine, Oxford, England; Lars Westrom, Associate Professor of Obstetrics and Gynecology, University of Lund, Lund, Sweden; and Nicholas H. Wright of the Department of Community Medicine, Rutgers Medical School, College of Medicine and Dentistry of New Jersey, Piscataway, NJ, USA.

A single copy of the issue 17(5) will be obtainable for US $6.50 from the *IJGO,* PO Box 12037, Research Triangle Park, NC, USA. Subscription information is also available from the above address.

Recent publications by the IFRP staff

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To request a free copy of any of these articles, or a complete list of IFRP publications (1971-78), write: Information Coordinator, IFRP, Research Triangle Park, NC 27709 USA.

National sterilization campaign a success

The results of a follow-up study of the 1977 Bangladesh national sterilization campaign have shown that sterilization services that are well provided in a campaign situation are highly acceptable in Bangladesh and that a large demand exists for such services in the future. The follow-up study was carried out by the Bangladesh Fertility Research Programme (BFRP) and was jointly sponsored by AID/Dacca and AID/Washington.

Survey respondents were a large probability sample of those sterilized (by both tubectomy and vasectomy) in the national campaign, as well as neighborhood controls. Interviews were successfully completed for 402 male and 417 female sterilization clients.

Results of the study showed that there was a high level of satisfaction (90%) among recipients of sterilization. The quality of service offered by the sterilization clinic was apparently good, as evidenced by the respondents high opinion of the clinic: 93.5% of the men and 89.2% of the women reported there was "nothing disliked" about the clinic.

Over 90% of the respondents stated that their reason for obtaining sterilization was "not to have more children." Only about 5% of those interviewed cited the financial reimbursement (from non-AID funds) as their main reason.

Most notably, the study showed a high level of current explicit demand for sterilization (about 10%) among the controls. The study's summary notes that this suggests "an immediate demand for well over one million additional sterilizations" in Bangladesh.

The BFRP report is entitled "Sterilization Campaign of 1977—A National Long-Term Follow-Up Survey" and was written by M. Nawab Ali, Douglas H. Huber, Atiqur Rahman Khan and Syed Waliullah. It is available from the BFRP, 3/7, Asad Avenue (1st floor), Mohammadpur, Dacca-7, Bangladesh.

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Barrier contraceptives reviewed for consumer

The use of barrier contraceptives has increased during the last decade in response to the well-publicized adverse side effects associated with the use of oral contraceptives and intrauterine devices. In response to consumer demand for reliable barrier contraceptives, increased research efforts are being directed toward the development of barrier products that are safe, effective, convenient and acceptable for the consumer.

According to David A. Edelman, IFRP Associate Director for Research, "There is a need for additional data on the effectiveness of most available barrier products, and it is important that the consumer is given adequate and accurate information." Such information is provided by Edelman in Barrier Contraceptives—An Update, an article soon to be published in *Advances in Planned Parenthood.* The review article provides data on the effectiveness of three spermicidal suppositories commercially available in the United States and presents preliminary data on two experimental barrier products currently being evaluated by the IFRP in multiclinic trials.

Encare Oval (Easton-Merz Laboratories, NY, USA), Semicid (Whitehall Laboratories, NY, USA), and S'positive (Jordan Simner, Inc., FL, USA) are the only spermicidal (nonoxynol-9) foaming tablets or suppositories commercially available in the United States. Although data from three studies of Encare Oval and from one study each of Semicid and S'positive indicate that all three products have high rates of effectiveness, Edelman warns the consumer that each study was limited by one or more design or procedural problem, as well as by insufficient data on the frequency of allergic reactions or vaginal inflammations following product use. Further careful study is needed to obtain reliable data. Edelman cites a National Institutes of Health-funded comparative study of Encare Oval and the diaphragm with spermicide as one that should yield reliable data on the effectiveness of the Encare Oval within the next two years.

Neo-Sampoon (Eisai Company, Tokyo, Japan), a spermicidal (menfegol) foaming tablet (Fig. 1) commercially available in Asia and Latin America is being studied by the IFRP in Bangladesh, Colombia, Egypt and Mexico. In the one completed study of 150 users in Bangladesh, the six-month (gross life table) pregnancy rate was 3.4 per 100 women. The overall six-month pregnancy rate for all studies was 4.9 (±2.0) per 100 women. The most frequently reported reason for discontinued use was discomfort caused by a burning sensation. Edelman notes that the time from insertion of any foaming or melting spermicidal tablet or suppository into the vagina to the time the tablet has foamed or melted varies among women and among products.

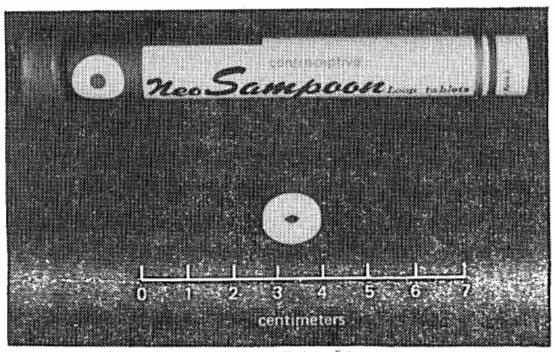

Fig. 1. Neo-Sampoon spermidical foaming tablets.

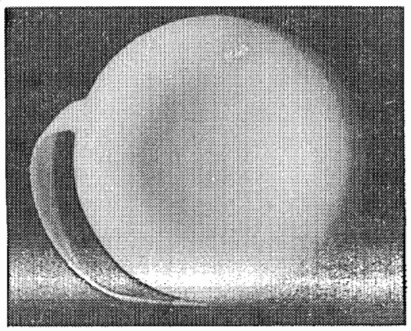

Fig. 2. Collatex polyurethane spermicidal sponge.

The Collatex (Vorhauer Laboratories, CA, USA), a polyurethane sponge (Fig. 2) containing the spermicide nonoxynol-9, is being studied by the IFRP in Bangladesh, Colombia, Egypt, Mexico and Yugoslavia. In the one completed study of 100 users in Yugoslavia, the six-month (gross life table) pregnancy rate was 1.1 per 100 women, and one of the most frequently reported reasons for discontinued use was unplanned pregnancy. The overall six-month pregnancy rate for all studies was 3.6 (±1.6) per 100 women.

Edelman asserts that, based on IFRP's findings, the effectiveness of Neo-Sampoon and Collatex compares favorably with the effectiveness of the diaphragm.

Disposable MR kits exceed advertised durability

Disposable plastic menstrual regulation (MR) kits, if properly cared for, can safely be used for more procedures than advertised by the kits' manufacturers. This finding, the result of an IFRP study by Judith A. Fortney and D. Vengadasalam soon to be published in *Contraception*, directly affects the kits' use in developing countries, where manufacturer's directions are frequently ignored and no piece of equipment is discarded until it is useless.

MR is widely practiced in many of the developing countries. The procedure usually is performed to treat a missed menstrual period but can also be used to obtain endometrial biopsies or to treat incomplete abortions. The disposable kits of plastic equipment are not only reusable, but offer additional advantages to the physician in a developing country: a kit costs less than US $10.00, and the equipment (Fig.1) is hand-operated, so no electricity is necessary.

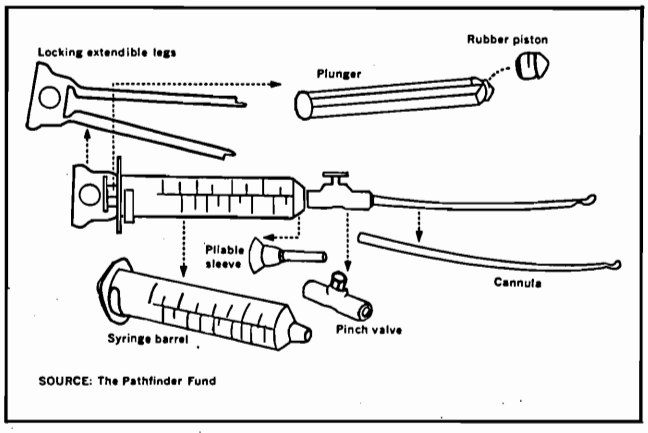

Fig. 1. Menstrual regulation equipment.

In the IFRP study, the durability of MR kits produced by three manufacturers (IPAS, Chapel Hill, NC, USA; Rocket of London Inc., Branford, CT, USA; Burnett Instruments, Lawrence, KS, USA) was evaluated at a Singapore hospital where a large number of MR procedures are done annually. Dr. Vengadasalam, who performed all the procedures in the study, was chosen for his skill and experience in this particular procedure.

Dr. Vengadasalam used each kit until it was no longer considered safe to use, or for 100 procedures, whichever came first. Each kit contained one syringe, five 4-mm cannulae, five 5-mm cannulae and five 6-mm cannulae (Fig. 2). In some instances, additional cannulae were provided so that kits of each brand contained the same number of cannulae.

Of the 18 syringes (six of each brand were used in the study), only two remained usable after 100 procedures. Both of these were manufactured by IPAS. The mean number of procedures for the three brands of syringes

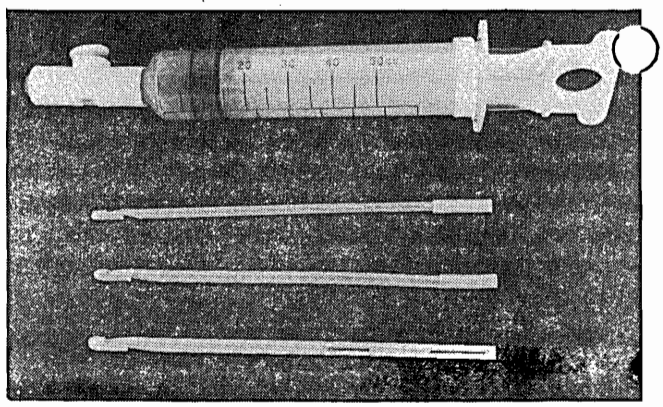

Fig. 2. Contents of each MR kit included one syringe, five 4-mm cannulae, five 5-mm cannulae and five 6-mm cannulae; a syringe and three sizes of cannulae are shown above.

was 84.3 for the IPAS model, 80.8 for the Burnett and 51.7 for the Rocket. While the Burnett and IPAS syringes lasted substantially longer than the Rocket syringes, the manufacturer's directions with the Rocket kit specifically state that it is intended for one use only.

There was little difference in the durability of the three brands of cannulae: the Burnett cannulae averaged 23.5 procedures each, the Rocket cannulae 24.1 procedures and the IPAS cannulae 25.3 procedures (only 5-mm cannulae were used with enough frequency to permit analysis).

The study also showed that different soaps and disinfectants had a negligible effect on the durability of both the syringes and cannulae.

Results of the study underscore the need for proper care of the MR kits. The useful life span of the equipment can be significantly prolonged if medical personnel follow the manufacturer's directions for maintenance. The plastic kits should never be boiled or autoclaved for purposes of sterilization. Soaking the syringe in iodine, as some have done, can cause the rubber tip on the piston to stick inside the barrel so that it cannot be withdrawn to provide an adequate vacuum. Sterilization of the syringe is unnecessary; after each use, the syringe should simply be washed in hot, soapy water, then air-dried. The cannula should be similarly washed, then soaked in a disinfectant for at least 15 minutes.

New finding added to debate on postvasectomy semen examination regimen

New evidence may soon be added to the ongoing debate over which postvasectomy semen examination regimen should be used to determine sterility in a vasectomized man. Some physicians and clinics base their regimens on obtaining a sperm-free ejaculate specimen after a specified period of time, others after a

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certain number of ejaculates. Still others combine both criteria.

Current work by Stephen D. Mumford, a member of IFRP's research staff, and urologist Joseph E. Davis, a leading authority in vasectomy research, has shown that differences in the construction of the ampulla of the vas among individuals accounts for most of the wide variation in the length of time required to reach azoospermia postvasectomy. In different men, between 32% and 99% of sperm appearing in the ejaculate comes directly from the epididymis, with the rest coming from sperm storage sites. Since the ampulla of the vas serves as the principal storage site for sperm, the implications of the individual variations in retention capability of the ampulla are considerable.

Mumford and Davis have found that the ampulla of different individuals typically is one of three types. At one extreme, the ampulla is cavernous with a mucosa consisting of a considerable number of highly convoluted folds and crevices where sperm can be temporarily retained. This type of ampulla would have maximal sperm retention capability. At the other extreme, the ampulla is noncavernous or nearly so, with a mucosal lining almost devoid of folds and crevices. This ampulla has the appearance of a solid-walled tube with a relatively smooth inner surface; it would have only a minimal, if any, capability for sperm retention. The third type would fall somewhere between the other two and would have a moderate sperm retention capacity.

According to Mumford, "Identification of these differences in the ampulla, which have been confirmed by microscopic examination of sections of ampulla specimens, represent a new anatomical finding not previously described in classical anatomy literature."

Because it appears that the differences in the construction of the ampulla affect the number of sperm stored in the individual and more importantly, the ease with which they are flushed out, there will be wide variation in the length of time required to reach azoospermia postvasectomy. Vasectomized men with ampullae having maximal storage capacity will most likely require longer periods of time and higher numbers of ejaculations before reaching azoospermia.

Mumford and Davis have concluded that there are a number of basic unanswered physiological questions (eg, Are immotile sperm capable of fertilization? Is a motile sperm that has been stored in the ampulla for several months still capable of fertilization?) that must be answered before a semen examination regimen can be formulated on strictly medical considerations. They resist therefore, the notion that any regimen beyond a single azoospermic specimen as a sign of sterility is defensible on physiological/medical grounds. "Social considerations, such as convenience, economics and patient apprehension, cloud this issue once the clinician ventures beyond this basic minimum requirement," Mumford states.

Cameron to work for the United Nations

Catherine Cameron, IFRP's International Projects Administrator, will be returning to work overseas as Programme Officer for the United Nations Fund for Population Activities (UNFPA) in Bangladesh. Before assuming administrative responsibilities at the IFRP, Cameron worked as a technical consultant to the Institute of Community and Family Health in the Philippines. She is enthusiastic about the challenge the new assignment offers and feels that her public health degree, combined with previous field experience and the administrative skills acquired at the IFRP, have prepared her for this undertaking. A significant amount of Cameron's time will involve monitoring a budget of some 50 million dollars, and providing technical support in the identification, preparation and evaluation of proposals and projects requesting UNFPA support. She expects to assume duties in Bangladesh by the first of May.

Peng leaves IFRP for post in Hawaii

J. Y. Peng, who has been involved in the development of international activities for the IFRP, has accepted an appointment at the University of Hawaii's School of Public Health. A long-time proponent of the use of ancillary personnel to extend and enhance the delivery of family planning services, Peng will be Regional Director of the newly established Regional Training Service Agency/Asia to be based in Honolulu. The Program is one of three projected globally by the Office of Population of USAID.

"We will address problems related to delivery of family planning services, particularly to the rural and urban poor," Dr. Peng stated in explaining his new position. "By intensifying the training of paramedical, auxiliary and community (PAC) personnel and working to change attitudes and conditions that inhibit their functioning, we hope to effect considerable improvement in these services in lesser developed countries." Peng will assume his new position by May 1.

High- and low-dose pills studied in Sri Lanka

The IFRP is helping the Family Planning Association of Sri Lanka conduct a research and demonstration project that promises to have worldwide implications. The project, which is supported by a contract from USAID, is intended to explore a number of important research questions: is there a difference in the continuation rate for women who use high- or low-dose oral contraceptives? What is the impact of providing vitamin supplements to oral contraceptive users? Answers to these and other questions are being gathered through a series of clinical trials in Colombo and in two rural areas of Sri Lanka. Acting as home visitors, indigenous women will collect data in the rural areas on pill acceptance and continuation rates. Their ability to motivate their peers to accept contraception will also be evaluated.

The clinical trials are underway at the Family Planning Association's headquarters clinic in Colombo and in the two rural project sites of Matara and Puttalam. At the Colombo clinic, women are randomly assigned to a regimen of high- or low-dose oral contraceptives with or without vitamin supplements. The same procedures are followed in the rural areas, but the home visitors and nurses provide the service instead of the licensed medical doctors employed in the Colombo clinic.

The project is important because it attempts to answer crucial questions for family planning managers. Available evidence seems to indicate that low-dose pills have few side effects. The effect of vitamins is far more complex and disputed. There is evidence suggesting that vitamins have a therapeutic impact in lowering oral contraceptive side effects. However, placebos also have a measurable impact sometimes equal to that of vitamins. Moreover, several studies suggest that doing anything or even simply waiting will cause the oral contraceptive side effects to diminish. Still, providing the women with the vitamins (or with extra attention, at any rate) may be sufficient to encourage more of them to accept oral contraceptives.

Most of the work for this project is being done by the staff of the Family Planning Association. The IFRP is providing research support and technical assistance. Two US drug companies, Syntex and Hoffman-LaRoche, have helped by providing the low-dose pills and the vitamins, respectively. Preliminary results from this study are expected by the end of the year.

Mexican medical schools to introduce course in family planning

The Coordinación Nacional del Programa de Planificación Familiar, the government agency responsible for the implementation of all family planning programs in Mexico, recently organized a successful three-day Workshop for the Deans of medical schools throughout the country. One of the Coordinación's goals has been to improve the quality of family planning services by encouraging medical schools to include in their curricula a separate course on contraceptive technology and the demographic problems that may result from a lack of knowledge about family planning. The workshop, which was supported by the IFRP, provided the forum necessary to discuss how best to implement such programs.

The deans of 75% of the universities offering medical training were invited to participate in the January 31-February 2 workshop, as were directors of the largest service providers in Mexico. According to Christine Colven, Senior Regional Coordinator in the International Projects Department at the IFRP who attended the workshop, the participants were enthusiastic and the program and the planning groups were effective and productive.

The Coordinación, in cooperation with the Mexican Association of Faculties and Schools of Medicine, will prepare prototype manuals, models and audio-visual materials for use in the development of the training program that will be implemented in the fourth, fifth and sixth years of medical school.

It is anticipated that this program, which will cover approximately 40 hours of course work, will be implemented during the current academic year.

Medical students in 28 universities will receive specialized training in family planning and contraceptive technology during the program's first year. Upon completion of their medical education, all health care professionals spend one year in social service. Those who have received special training will have the opportunity, the information and the motivation necessary to foster acceptance of the family planning concept and to improve the services provided.

The careful planning and preparation accomplished by the Coordinación and the contributions of the medical school deans during the workshop were and will continue to be vital to the success of this program. Their efforts are to be commended and can serve to encourage other family planning organizations and medical institutions to pursue similar solutions to the common need for specialized training in contraceptive technology.

Study to evaluate PID and the IUD string

The strings attached to the base of many intrauterine devices (IUDs) were designed to provide a means of retrieval and a simple, easy way for the physician and woman to determine whether or not the device is still properly positioned. Although they serve this purpose well, there is a possibility that IUD strings may also contribute to a high incidence of pelvic inflammatory disease (PID). By conducting clinical trials of Cu-T-200LB devices with and without strings (Fig. 1) in clinics reporting a high incidence of PID among IUD users, the IFRP hopes to determine the role of IUD strings in the development of upper genital tract infections.

Study participants will return for regular follow-up visits over a 12-month period where the physician will perform a thorough pelvic examination. If the woman exhibits excessive adnexal tenderness, profuse purulent discharge, acute cystitis, an adnexal mass or swollen edematous labia or if she complains of frequent urination, dysuria, fever or abnormal uterine bleeding, cultures will be done to determine the presence of *N. gonorrhoeae* and *Chlamydia*. Laboratory tests will also be performed to determine her erythrocyte sedimentation rate and the total and differential white blood count. Physicians in each participating clinic will diagnose PID according to the criteria they normally use.

When necessary, a special forceps-type instrument will be used to retrieve the stringless IUDs; the same instrument has been used in the past to locate and remove "lost" devices. The removal procedure is simple, safe and relatively painless.

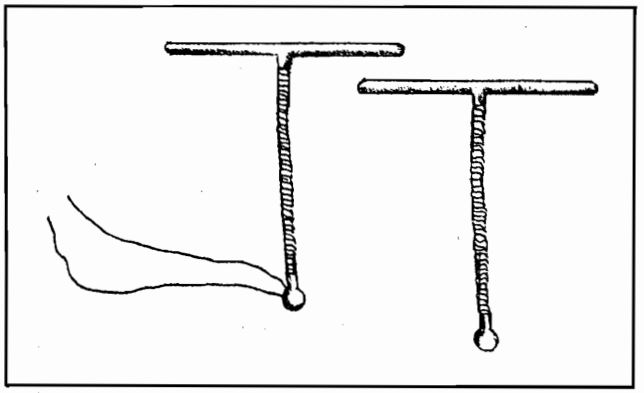

Fig. 1. Cu-T-200LB with and without string.

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Chilean associate visits the IFRP

Dr. Pablo Levine of Santiago, Chile, recently traveled to the IFRP's headquarters in North Carolina to discuss analysis of data from two large postpartum intrauterine device (IUD) studies he has completed in collaboration with this organization. Levine is a deputy administrator of the maternity section of the Hospital Barros Luco Trudeau, Santiago, a major center for family planning research. Currently he is completing another IFRP study, a clinical trial of the three-year Progestasert device, and is scheduled to initiate a comparative study of the Cu-T-220 with and without sutures.

Levine has extensive experience in postpartum IUD insertions, including various comparisons of the Lippes Loop, intrauterine membrane, Progestasert, Cu-T-200, Cu-T-220 and the Population Council's postpartum "T" device. His studies have also evaluated both hand and standard inserter techniques of IUD insertion.

International symposium on PID held April 1-3 in Atlanta

An International Symposium on Pelvic Inflammatory Disease (PID) was held at the Center for Disease Control in Atlanta, Georgia, USA, on April 1-3, 1980, with 500 clinicians, scientists and public health officials from more than 40 countries attending. Highlights of the presentations and discussions, which focused on the consequences of PID, its diagnosis, etiology, prevention and control, included the following:

- Two serious consequences of PID, in addition to patient morbidity at the time of infection, were emphasized: the possibility of infertility and a higher risk of ectopic pregnancy for women who are able to conceive.
- The difficulty of accurate clinical diagnosis of PID without the use of laparoscopy was stressed. A major point of disagreement among participants was whether there is justification for use of routine diagnostic laparoscopy. For many clinics throughout the world, this is not a matter of choice; diagnosis must be performed without the aid of laboratory or surgical confirmation. In such clinics, PID is generally diagnosed and treated if a woman has three of the following symptoms: lower abdominal tenderness, rebound tenderness, cervical motion tenderness, adnexal tenderness, adnexal fullness or mass.
- Most investigators classified PID as gonococcal or nongonococcal on the basis of the presence or absence of *N. gonorrhoeae* in cervical specimens. Recent studies suggest that *Chlamydia trachomatis* plays a larger role in PID infection than *N. gonorrhoeae*. Often a patient has both, but only the gonococcal infection is diagnosed and treated. Nongonococcal infections such as *Chlamydia* are harder to treat, more recurrent, more likely to result in infertility and contribute more to overall morbidity than gonococcal PID. It is impossible to differentiate gonococcal from nongonococcal PID without the aid of laboratory tests. Gonococcal PID is usually managed with penicillins and nongonococcal PID usually responds to tetracyclines.
- Presentations and discussions on the relationship of PID and contraceptive use indicated an apparent increased risk of PID among IUD users, particularly among young nulliparous women. Oral contraceptives, however, seem to have a protective effect, perhaps because they maintain the cervical mucus barrier. The risk of ectopic preganacy is lower for users of any contraceptive method than for users of no method. For IUD users, the risk of ectopic pregnancy increases with duration of IUD use, but is not higher than that of a nonuser.
- More than 38 gonococcal strains have been identified and each has its own specificity. An antigenic substance of the bacterium is represented by pili, fingerlike projections surrounding infectious strains. Experimental vaccines made from pili are now undergoing preliminary evaluation. It may be possible to develop a vaccine to protect against gonococcal infection.

The symposium was sponsored by the World Health Organization, Center for Disease Control, Pan American Health Organization, American College of Obstetricians and Gynecologists, American Veneral Disease Association, International Union Against the Veneral Diseases and Treponematoses, International Planned Parenthood Federation and the International Federation of Gynaecology and Obstetrics. Many of the papers presented will be published in a proceedings of the meeting.

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Postpartum IUDs: a boon to family planning

For many women who live in the developing world, the moment of childbirth may be their only contact with a physician or other health care professional. Thus, this occasion offers many women a rare opportunity to obtain family planning advice and contraceptive services.

The possibility of being able to offer an effective contraceptive method, such as the IUD, immediately postpartum is very attractive. At the time of childbirth, most women are receptive to the idea of planning their family and are desirous of a reliable method. In addition, the bleeding that naturally follows childbirth coincides with and masks any bleeding that results from wearing the IUD, an important factor since IUD-related bleeding is one of the most common complaints of women using IUDs and, in some cultures, is a deterrent to their acceptance. A further benefit is that either the nonmedicated or copper-bearing IUD provides safe contraception to the woman who plans to breast-feed her infant because the device affects neither the quantity nor the quality of the mother's milk.

Recognizing the merits of this idea, researchers at the IFRP began developmental work in 1975 to modify a standard IUD for postpartum use. This effort eventually resulted in the adaptation of the Lippes Loop D (LLD) and the Copper-T-220C (TCu-220C) devices.

Modification of the TCu-220C or LLD for postpartum insertion is a relatively simple and inexpensive technology that is easily transferable to any part of the world. The names given by the IFRP to these modified IUDs are the Delta-T and Delta-Loop. Strands of moistened, biodegradable chromic suture material are tied through holes drilled through the upper crossarm of the LLD or around the copper bands on the crossbar of the TCu-220C; this material is secured to the copper bands with a commercially available, biocompatible adhesive. When dry, the suture material becomes stiff, and the projecting ends of the knots are trimmed to 0.5 cm and directed to a downward 45° angle. These projections enhance the retention of the IUD in the enlarged postpartum uterus. After six weeks, when the uterus has returned to its normal size, the suture material will have dissolved, leaving a standard IUD in position.

Both devices can be inserted by hand (Fig. 1) within 10 minutes after the placenta has been expelled. If more than 10 minutes have elapsed, or if the physician prefers to use a mechanical means of insertion, the Delta-Loop can be inserted with uterine dressing forceps (Fig. 2) and the Delta-T with an inserter (Figs. 3 and 3a).

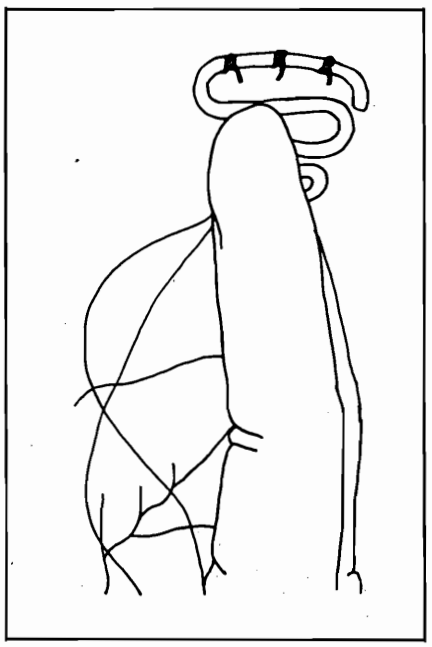


Fig. 1—Insertion by hand (left)
The sterile IUD is held between the second and third fingers so that the device is horizontal. One hand is placed on the abdomen to palpate and control the uterus. The IUD is inserted into the uterine cavity while the strings are kept uncoiled along the side of the hand. The IUD is then pushed up to the fundus with the index finger while the uterus is controlled through abdominal palpation. When the IUD is in place, the hand is withdrawn.

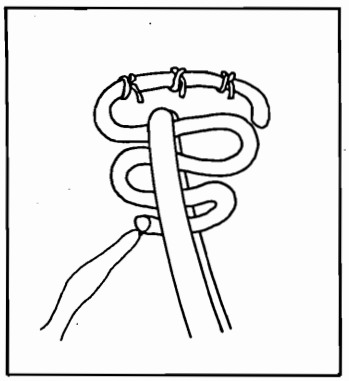
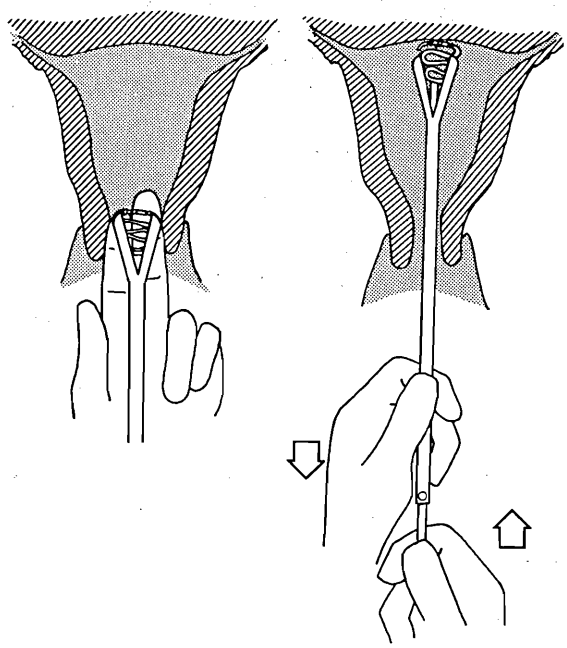


Fig. 2—Insertion by forceps (left)
The sterile IUD is placed in the jaws of the dressing forceps; to avoid crushing the IUD, the forceps are not locked completely. The forceps are inserted through the cervix up to the uterine fundus, guided by the fingers of one hand if necessary. The abdomen is palpated to control the uterus as delivery of the IUD is completed. The forceps lock is opened, releasing the IUD, and the forceps are withdrawn gently.



Figs. 3 and 3a—Insertion by inserter
The uterus is stabilized by grasping the lip of the cervix with a ring forceps, or other appropriate instrument. Slight downward traction is applied on the forceps as the preloaded inserter is inserted into the cervical canal, causing the arms of the Delta-T to collapse (Fig. 3). The device is then delivered to the uterine fundus (Fig. 3a) while the uterus is palpated abdominally to ensure correct placement of the IUD. Finally, the IUD strings are released from the notch at the base of the inserter, which is then withdrawn.

Preliminary data from clinical trials of the Delta-T and Delta-Loop indicate that they may significantly reduce the high expulsion rate usually associated with immediate postpartum IUD insertion. The three-month gross life-table expulsion rates are 7.3 ± 1.0 and 8.1 ± 1.4 per 100 women for the Delta-Loop device (based on 935 insertions) and the Delta-T device (based on 545 insertions), respectively. Continuation rates were 89.7 and 88.7 per 100 women at three months.

Recently, the IFRP applied to the US Food and Drug Administration (FDA) for approval of both devices for investigational use. Approval for the Delta-T has been obtained (IND 16952), and it is expected that approval of the Delta-Loop will follow shortly. The FDA approval of the devices will permit the conduct of clinical trials in the United States and lend support to their acceptance in other countries. If warranted by clinical results, the next step will be to promote wider availability of the postpartum IUDs in developing countries by training medical personnel in the techniques of their insertion and by supplying family planning programs with the devices.

Further investigation of quinacrine hydrochloride and of the Collatex sponge

In the continuing effort to develop safe and effective family planning methods, the IFRP hopes to initiate further studies of a nonsurgical female sterilization technique and of a new female barrier method of contraception.

Two subcontracts awarded to The Johns Hopkins University School of Medicine will fund research to determine the safety and efficacy of using quinacrine hydrochloride as a chemical means to permanently occlude the fallopian tubes. Such a nonsurgical tubal occlusion method would enable trained paramedical personnel to offer female sterilization services.

The proposed studies will provide data on the toxicologic and teratologic effects of quinacrine hydrochloride administered transcervically (in the form of pellets) in monkeys and via intrauterine injections in rats. It is anticipated that the data collected from these studies will result in approval from the US Food and Drug Administration for the use of quinacrine hydrochloride in controlled clinical trials.

The IFRP also plans to study a new vaginal contraceptive. Data from the National Reporting System for Family Planning Services show a two- to threefold increase in the use of barrier contraceptives. In an effort to help meet this demand, the National Institute of Child Health and Human Development (NICHD) will contract with the IFRP to evaluate the Collatex sponge (Vorhauer Laboratories, Inc, Costa Mesa, CA, USA).

Development of the Collatex sponge began in early 1976. About 5.5 cm in diameter, 2 cm thick and slightly concave, the polyurethane sponge contains the spermicide nonoxynol-9. A polyester loop attached to the bottom of the sponge facilitates removal from the vagina.

The efficacy of the Collatex sponge does not depend on its ability to provide a physical barrier to the sperm. During intercourse, the spermicide is released from the sponge. Tests indicate that only small amounts of spermicide leach out of the sponge. The Collatex sponge compared to the diaphragm with spermicide affords a number of additional benefits:

- It does not require application of a spermicide with each use;
- One size can be used by all women;
- It is intended to be supplied as a nonprescription contraceptive; and
- It can be inserted up to 24 hours before coitus.

The IFRP, under contract to the NICHD, proposes a multiclinic evaluation of use of the Collatex sponge compared with that of the diaphragm when used with a spermicide. The two contraceptive methods will be randomly assigned to 1600 women (800 for each method) to determine the sponge's comparative use-effectiveness and continuation rate at one year, incidence of adverse side effects, regularity and ease of use and acceptability.

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Egyptian pharmacists and physicians to receive family planning technical bulletins

Beginning in the summer of 1980, approximately 4000 pharmacists and 6000 private physicians in Egypt will be the recipients of a bimonthly family planning technical bulletin. The one-year bulletin project, sponsored by the Egypt Fertility Care Society, PIACT/Assiut University and the IFRP, is intended to upgrade the family planning services offered by these two private sector groups. In addition, the IFRP will sponsor a pre- and post-bulletin project survey to evaluate the knowledge, attitudes and practices of the pharmacists and their assistants. Dr. Mahmoud Fathalla, PIACT Coordinating Committee member in Egypt, will supervise both the bulletin project and the surveys.

It is generally thought that the family planning effort in Egypt has not fully tapped the potential of the pharmacists and private physicians in the delivery of contraceptive services. Both groups are in a position to provide a large part of family planning services available in Egypt; pharmacists are allowed to sell contraceptive commodities, including pills, without prescription and are frequently approached for advice on contraceptive methods. Both groups of service personnel, however, often have inadequate access to or have outdated technical information. The lack of up-to-date information on contraceptive technology results in poorly informed users. The aim of the bulletin project is to improve the capability of the target groups to discuss and explain the contraceptive products available to the Egyptian population. With an estimated annual population growth rate of 2.5%, the Egyptian government hopes that the project will encourage increased use of family planning methods through better information and education.

The bulletins will be published in English and in Arabic and will feature information on current contraceptive products and methods, contraindications, side effects and their management, promotional ideas and articles by prominent Egyptian and international leaders addressing topics of special interest to providers of family planning technology. PIACT/Seattle will supply the articles, studies and sales material for publication; production of the bulletins will be managed by a bilingual Egyptian editor.

The pre- and post-bulletin survey will be conducted in metropolitan Cairo, Upper Egypt and the Delta. A total of 450 interviews, 150 in each area, will be conducted prior to the initial distribution of the technical bulletins. One year later, after six bulletins have been received, the same 450 practicing pharmacists will be reinterviewed, along with 180 who were not previously interviewed. The study sample will be randomly selected from a comprehensive list of Egyptian pharmacists supplied by Dr. Ahmad Sami, President, Planning Sector, Egyptian State Pharmaceutical Trading Company, Cairo, and the National Family Planning Program of Egypt.

Personal interviews will be conducted by three teams, one in each area, consisting of one superior and four interviewers. Interviewers will be selected from among pharmacy and medical students and female draftees of the Egyptian Ministry of Social Affairs. At each selected pharmacy, the interviewers will record the name, age, education and work experience of the employees. One of the pharmacy workers will then be selected by random method for an interview that will obtain information on the employee's knowledge and attitudes toward family planning and behavior with respect to family planning counseling and the sale of various contraceptives.

It is anticipated that the results of the survey will show that the product-oriented bulletins have ensured the regular provision of relevant technical information and that they have improved the ability of the pharmacists to provide family planning counseling.

IFRP to sponsor session at Xth World Congress of Fertility and Sterility in Madrid

"Contraceptive Technology—1980 and Forward," a pre-congress session, will be sponsored by the IFRP at the Xth World Congress of Fertility and Sterility in Madrid, Spain, July 5-11, 1980. The session will be co-chaired by IFRP's Executive Director Malcolm Potts and Medical Director Leonard Laufe. Highlighting the program will be a presentation by Dr. Liu Guo-zhen of the Chinese Academy of Medical Sciences in Peking on "Family Planning in the People's Republic of China." Other participants and topics include Dr. David Edelman, IFRP, Research Triangle Park: Nonprescription Contraception; Dr. John Guillebaud, Margaret Pyke Center for Study and Training in Family Planning and Middlesex Hospital, London: IUDs—Present and Future; Dr. John Hearn, Wellcome Laboratories of Comparative Physiology, London: Immunologic Aspects of Fertility Control; Dr. Leonard Laufe, IFRP, Research Triangle Park: Nonsurgical Female Sterilization; Dr. Malcolm Potts, IFRP, Research Triangle Park: Drug Approval and Surveillance; Dr. Andrew Schally, Veterans Administration Hospital, New Orleans: LH-RH Agonists and Atagonists; and Dr. Sheldon Segal, The Rockefeller Foundation, New York: Hormonal Contraception—New Routes of Administration.

The proceedings of this session will be published in an upcoming issue of the *International Journal of Gynaecology & Obstetrics*, which is cosponsored by the International Federation of Gynaecology and Obstetrics and the IFRP.

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Recent publications by the IFRP staff

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Sudanese to study prevalence and effects of female circumcision

Female circumcision (FC) is the complete or partial removal of the female external genitalia, usually performed as a ritual involving young, prepubertal girls. The practice, which is now receiving much attention in the international press, is the focus of two current IFRP research efforts. For one cooperative study now in process, the IFRP is supporting analysis of the data collected in a project originated by the Sudanese Fertility Control Association (SFCA) in conjunction with the University of Khartoum to survey FC as it is practiced in the Sudan. In another, proposed project, the IFRP plans to study childbirth complications in circumcised Sudanese women.

The emphasis on the Sudan is intentional. Despite 1946 legislation making FC illegal, it is generally estimated that from 75% to 90% of Sudanese women are circumcised, and the practice continues. FC apparently exists on every continent, but it is particularly prevalent today in Africa (Fig. 1). Its origins are largely obscured, but the practice was known to ancient Egyptians, Romans and Arabs. Three types of FC are in most common usage in Africa. *Sunna circumcision* is the removal of the prepuce of the clitoris and the larger, posterior parts of the labia minora. The clitoris is preserved. The second type, *excision or reduction*, removes the prepuce and glans of the clitoris, together with either adjacent parts or the whole of the labia minora. *Infibulation*, known in the Sudan as *Pharaonic circumcision*, consists of the removal of the entire clitoris, labia minora and adjacent medial part of the labia majora. The introitus is obliterated by sewing together the two raw sides of the vulva, leaving only a small opening to allow urinary and menstrual flow.

It is sometimes necessary to partially "open" an infibulated woman to permit sexual intercourse. Thus, on a typical "wedding night," the new husband will use a knife on the toughened scar of his bride or call on a midwife to provide the same assistance. Further, the woman must also be cut open completely for each birth and then reinfibulated.

FC is said to be necessary to ensure the girl's purity and the honor of her family and that of her future husband; the bridegroom, who pays for his bride, is thus assured of her virginity. Although among some African tribes FC takes place at about 15-16 years of age or even during the first pregnancy, most of the rituals are carried out on very young girls. The majority of Sudanese girls are thought to be circumcised by age six.

The actual operation is most often performed by an older woman, many times a trained or untrained midwife. The procedure, especially in rural areas, is done without anesthesia. The girl is usually kept uninformed about what to expect, and may even look forward to the day, encouraged in this by her mother. The child is held down by female relatives and other women (men are seldom involved) with her legs spread apart while the incision is made by razor or some other frequently unsterile, sharp instrument.

In Pharaonic circumcision, the edges of skin will be threaded together with thorns or clamped together between a split cane. Catgut is sometimes available for the suturing, but string and hair are also used for this purpose. A match stick is often inserted between the edges of skin so that after the wound heals, a tiny opening will remain to allow the flow of urine and future menstrual blood. The girl's legs are then bound together to promote hemostasis and union of the two sides of skin.

Immediate and delayed complications of FC include hemorrhage from unligated clitoral blood vessels; shock, often the result of hemorrhage; urine and/or menstrual blood retention because of the tightly closed introitus; damage to the urethra, anus or other adjacent structures because of a poorly trained operator or because of the girl's uncontrollable movements; chronic pelvic infection resulting from unsanitary conditions at excision; lack of sexual satisfaction; infertility, a result of damage to vital organs and infections; and obstetric complications during delivery of infibulated women, such as large perineal tears, fistulae and puerperal sepsis in cases of reinfibulation performed at the time of home deliveries.

In treating an infibulated woman for one of these complications, the physician faces additional problems: it is extremely difficult, if not impossible, to perform a pelvic examination. The infibulation scar must be split for speculum insertion and the patient resewn after

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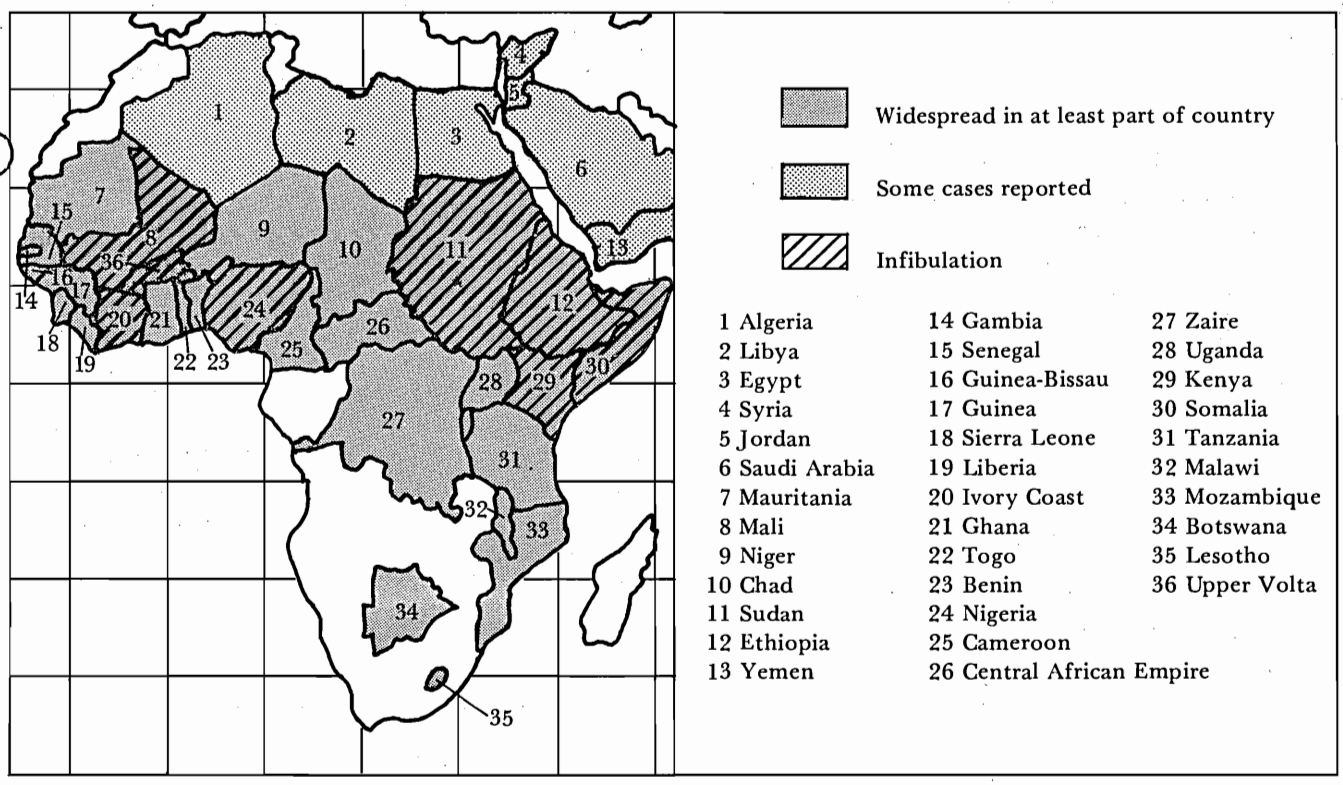

Fig. 1. Female circumcision is known on every continent; it is reportedly practiced in some parts of eastern Mexico, Brazil, Russia and Australia, but is most commonly performed in Africa. The map indicates African and Middle Eastern countries where some degree of the practice has been documented. Infibulation, the most extreme form of female circumcision, is most often seen in the Horn of Africa.

each examination, something demanded by almost all of the circumcised women. Without a pelvic examination of a pregnant woman, the physician is unable to differentiate between threatened and inevitable abortion, nor can the degree and progress of cervical dilation of a woman in labor be assessed. The attendant must always split the scar of Pharaonic circumcision to permit birth; the splitting may be necessitated earlier in labor if the physician must make an examination or an internal manipulation. Splitting the scar in the first stage of labor, however, may result in excess blood loss and may increase the risk of infection.

The IFRP's involvement in two studies of female circumcision is aimed at gaining a more complete understanding of the practice in the Sudan. The SFCA cooperative study is collecting data on the prevalence of FC, type of circumcision practiced, age at circumcision, immediate and delayed complications of the practice, cultural and religious attitudes toward the practice and basic sociodemographic characteristics of those surveyed. The SFCA, under the direction of Dr. Hamid Rushwan, projects that questionnaires will be completed for a total of 15,000 Sudanese (10,000 women and 5000 men). About 5000 questionnaires have been completed to date. The IFRP hopes that preliminary analysis will be available in early 1981. The World Health Organization, the Sudanese Ministry of Health, the Dutch Ministry of Foreign Affairs, International Planned Parenthood Federation and the Shell Oil Company are also involved in supporting the SFCA study. The resulting data may be used to make recommendations about ways to abolish the practice.

In a second research effort, the IFRP is proposing a study of the clinical complications associated with childbirth in circumcised Sudanese women. This study is proposed for several reasons. The literature presents mostly survey data on FC, with little focus on its effect on childbirth. Further, a special question on the practice was added some months ago to the IFRP's Maternity Record used in a number of Sudanese maternity centers. The data confirm that large numbers of Sudanese women are circumcised: results from a typical month in which 875 maternity cases were recorded have shown that 95.2% of the women were circumcised. A two-part questionnaire will be used in the childbirth complication study; the birth attendant will complete one part, and the second part will be completed in the course of an interview with the mother. The questionnaires are still in draft form.

FC, which has been effectively abolished in Egypt and is only rarely seen in some other Muslim nations of the Middle East, still persists in much of Africa. In the Sudan, the government health officials and medical community are making large efforts to study and stem a traditional practice that flourishes despite prohibiting legislation.

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Seminar on contraceptive technology held in Mexico

Each year, the Universidad de Yucatán in Mérida, Mexico, graduates approximately 200 physicians who, like all physicians in Mexico, spend one year in public service at rural health centers. These new doctors, like many of their colleagues worldwide, have not received extensive training in the importance of offering and providing family planning services and have received only limited training in the field of contraceptive technology. These two factors combine to limit both the acceptance of the family planning concept and the quality and extent of contraceptive services provided.

To help meet the new physician's needs in this area, the IFRP in cooperation with Dra. Thelma Canto de Cetina, Head of the Department of Biology of Reproduction at the Universidad de Yucatán, conducted a two-and-a-half-day seminar on contraceptive technology for 18 physicians either involved in their undergraduate year of social service or already working at rural health centers throughout the Yucatán.

Dr. Rodolfo Quiñones, of the Dirección General de Atención Médica Materno-Infantil y Planificación Familiar in Mexico City, and Dr. Roberto Rivera, Director of the Instituto de Investigación Científica of the Universidad Juárez joined Dra. de Cetina in conducting the seminar. Areas covered included the problems confronted in the practice of rural medicine and possible solutions, an overview of the national family planning program, as well as training in the safe and effective use of oral contraceptives, barrier methods of contraception, IUDs and female sterilization via minilaparotomy. A multimedia approach involving films, lectures, discussion periods, small-group workshops and printed handouts was used throughout the seminar to present the material in the most informative, useful and interesting manner possible.

Over the past year and a half, the government of Mexico has consistently supported the IFRP's involvement in programs of this type. Upgrading graduating physicians' training in contraceptive technology will promote the availability of family planning services to a population that relies on the rural health centers for medical care.

network review requested

This fourth issue of **network** completes our first volume year of publication. The IFRP and the **network** staff want to know your reactions to the material we have presented so that we might continue to provide you with information that is of greatest interest, value and use. Please take a moment to respond to the queries below, then clip and return this card to: **network**, International Fertility Research Program, Research Triangle Park, NC 27709 USA.

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Thank you for your valuable assistance.

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RAMOS study planned for Bali

Users of modern contraceptive methods in the developing world far outnumber those in industrialized countries. Yet little is known about the risks and benefits of family planning in traditional societies where contraceptives are available, sometimes without involvement of trained clinicians. How can the impact of sharply contrasting habitats, climates, nutrition, medical care and customs on the contraceptive practices of these populations be measured? To address these questions, the IFRP has designed RAMOS—Reproductive Age Mortality Survey—a study to identify the causes of death among women in the fertile age group who live in these traditional societies. The study data will be used to compare the mortality of women who do and do not use contraceptives and to establish maternal and age-specific death rates for all causes.

Cover, RAMOS monograph. The IFRP has prepared a descriptive monograph that presents the philosophy behind and the need for a study of this type. The monograph, one of a series to be published by the IFRP, is available, free of charge, by writing the Information Coordinator, IFRP, Research Triangle Park, NC 27709 USA.

The IFRP will conduct the RAMOS study initially in Bali, Indonesia. A questionnaire in both Balinese and Indonesian has been devised for data collection. The first section will be used to record the symptoms from which the cause of death will be determined; the second section deals with demographic characteristics. The third section, which will be completed by the Project Director and an Advisory Panel, consists of a checklist of potential causes of death and a written report of the most probable cause of death. The study will extend over a period of two years and is expected to begin shortly.

Judith Fortney, PhD, a demographer in the IFRP Research Department and the principal investigator of the study, observes that, "The balance of risks and benefits of various kinds of fertility control has been clearly established for the developed countries, but very little is known about any of the components of the equation in the developing world." Fortney also emphasizes that "the hazards of pregnancy and childbirth are greater than in a developed country and the risks of dying from causes unrelated to either of these have yet to be determined. The basis of fundamental decisions about contraceptive management tends to be data gathered in developed countries. But it cannot be inferred that the risks of oral contraception and IUDs, for example, are the same for the diverse populations of the developing world as they are for women in the US and Britain, where both obesity and smoking are associated with increased risk when oral contraceptives are used. Indonesian women are more likely to be malnourished than overweight, and smoking is rare."

The size of Bali's population lends itself to mortality research; approximately 2000-2500 deaths per year to married women of reproductive age are expected, a number sufficient for statistical analysis, but not considered to be unmanageable. The island itself is quite

small, making investigation of all deaths feasible. Logistically, the site is attractive to demographers because contraceptive prevalence is high and because the Family Planning Board of Bali has a well-organized system of family planning "group leaders" who have available transportation. The mortality investigation will be added to their duties as they visit the villages.

"A pretest in Bali clearly demonstrated that the decision to use nonmedical personnel to collect information on signs and symptoms of disease was justified," Fortney states. "The family of the deceased showed no reluctance in discussing her illness within a short time after the death. They report the symptoms with an apparently high degree of accuracy, so that a cause can be determined with relative confidence in most cases."

Family planning pamphlets to be adapted for Mayan culture

Theirs is a history of extraordinary achievement dating from the third century. Their ancient astronomers accurately calculated the solar year and precisely predicted solar eclipses. Their remarkable architectural, calendrical and mathematical accomplishments made them the most advanced pre-Columbian civilization known. These are the Mayans, an Indian people chiefly of Yucatán, Guatemala and Belize.

Despite an exceptional history, including the most sophisticated form of writing developed by an Indian people of North America, most Mayans today remain illiterate. To encourage the acceptance of contraceptive methods and the practice of family planning among this group, the IFRP will fund developmental work required to adapt existing family planning pamphlets to Mayan needs and culture. The project will be conducted by PIATA, a Mexican civil association that is affiliated with the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT), a nonprofit organization based in Seattle, Washington, that will provide administrative support for the project.

During the past two years, PIATA has developed and tested six family planning pamphlets designed for the illiterate rural population of Mexico: Two of the pamphlets describe IUDs, two explain oral contraceptives (Fig. 1), one covers female sterilization, and one explains injectable contraceptives. Based on the findings of research to determine contraceptive preference and to identify appropriate symbols and images, staff at PIATA will adapt three of these pamphlets specifically for the Mayan people. Data will be provided by Dra. Thelma Canto de Cetina, Head of the Department of Biology of Reproduction at the Hideyo Noguchi Research Center in Mérida, by the Ministry of Health and by a previously conducted contraceptive prevalence study. With the assistance of a local interpreter, individual interviews and group sessions will be conducted and photographs of Mayan women will be taken to illustrate the pamphlets. Prototypes of the revised pamphlets will be tested for comprehension among the Mayans before final copies are printed. It is anticipated that work on the project will begin this fall.

PIACT Executive Director Dr. Gordon W. Perkins and Ms. Maria Elena Casanova, Manager of PIATA, will act as consultants to the project. Additional support for the project will be provided by USAID.

If the pamphlets prove successful, the National Family Planning Program of Mexico will incorporate them into its program, distributing them to midwives and other health personnel for use as support materials in instructing Mayan women on the use of different contraceptive methods. Each woman who accepts a contraceptive method will be given a pamphlet after she has received a thorough verbal explanation of the method chosen and instructions on its use. It is hoped that the pamphlet will serve as a reminder of the instructions given at the health center.

Fig 1. A page illustrating "La Pildora Anticonceptiva," one of the pamphlets on oral contraceptives prepared by PIATA for use among the illiterate rural population of Mexico.

IFRP awards two subcontracts to study health and contraceptive methods

In its commitment to research that contributes to improved knowledge of the safety and efficacy of contraceptive methods, the IFRP has recently awarded several subcontracts to support studies of the relationship between health and various methods of contraception. Most recently, two separate projects have been funded to evaluate the effects on health subsequent to vasectomy and to the use of the three-month injectable depot medroxyprogesterone acetate (DMPA) as contraceptive methods.

Through one IFRP subcontract, the Kaiser Foundation Research Institute in Oakland, California, will examine the relationship of prior vasectomy to the risk of a large number of illnesses that require hospitalization. Included in the study will be approximately 6200 vasectomized men who have received multiphasic health checkups at the Oakland and San Francisco Kaiser-Permanente Medical Centers from July 1977 through July 1980.

Each man included in the study will be matched by age and race with two nonvasectomized men who have had similar checkups. The occurrence of hospitalized illness from the date of the checkup until December 31, 1980, will be determined from the computerized hospital discharge records of the Northern California Kaiser-Permanente Hospitals.

Rates of hospitalized illnesses and relative risks of individual diseases and diseases grouped by organ system and by underlying pathophysiologic mechanisms will be examined in relation to the presence or absence of vasectomy, to the amount of time elapsed since the vasectomy was performed and to age at vasectomy. It is estimated that almost half of the vasectomized men in the study population underwent vasectomies at least ten years prior to the beginning of the study, which produces a good probability of identifying both beneficial and adverse health effects of vasectomy.

Publishable reports on the association of vasectomy with the risks of certain diseases are expected to result from the study. Principal investigators for the study at the Kaiser Foundation Research Institute are Dr. G. D. Friedman and Dr. D. B. Petitti.

The second subcontract will support a two-part research effort of the Emory University School of Medicine in Atlanta, Georgia, which will first determine the feasibility of conducting a case-cohort study of women using different methods of contraception at the University's Grady Memorial Hospital. If feasible, such a study will be designed and conducted with the principal purpose of determining if women who have ever used DMPA are at an increased risk of severe adverse effects compared to women who have used other contraceptive methods. The Emory University School of Medicine was selected for this study because the family planning clinic of the university-affiliated hospital has a data bank of more than 50,000 contraceptive users that includes the largest number of DMPA users (+7000) in the United States.

The Emory study will estimate loss-to-follow-up rates by contraceptive method and will evaluate the adequacy of the Grady Memorial Hospital's medical records by selecting the records of 400 women from the computerized tapes (1967-1973) of the hospital's family planning clinic. The study will then identify and locate the clinical records of all women of childbearing age who have attended the Grady Family Planning Clinic from 1967 to 1979 with any of the following conditions: all types of cancer, endometriosis, ectopic pregnancy, hepatocellular adenoma of the liver, gallbladder disease, hypertension, myocardial infarction and thromboembolic phenomenon. A report summarizing the findings of this study will be prepared and is expected to be released by mid-1981. Dr. R. A. Hatcher and Ms. Aliza Greenspan of the Emory Grady Family Planning Program will act as principal investigators of the study.

Early data indicates low infection rate for Delta Loop

The fear of an increased risk of infection is one reason some physicians hesitate to insert an IUD into a woman's uterus during the moments immediately following expulsion of the placenta. Preliminary data from the IFRP's clinical trials of the postpartum Delta Loop (*see* Vol. 1, No. 4) when compared to experience with interval insertions of the Lippes Loop D show no basis for this fear. Infection rates reported are similar for the two groups, as shown in the table below.

Inflammation/infection reported at follow-up for the Delta Loop and the Lippes Loop D.

Inflammation/ Infection*	Immediate Postpartum Insertion Delta Loop (N = 870) No.	%	Interval Insertion Lippes Loop D (N = 1217) No.	%
Adnexitis	2	0.2	22	1.8
Endometritis	6	0.7	10	0.8
Trichomonas	11	1.3	20	1.6
Cervicitis	19	2.2	37	3.0
Vaginitis	3	0.3	11	0.9
Other and unspecified**	31	3.6	35	2.9
Total number of women with 1 or more inflammation/ infection	63	7.2	120	9.9

*Multiple events may be recorded for the same woman.
**Leukorrhea is often reported as a symptom.

Abortion in Latin America: a summary report

"Abortion in Latin America," a recently published IFRP report, describes the organization's nine-year experience with 27,722 women who were treated for incomplete abortions in selected hospitals in nine Latin American countries. The 79-page report, available in English and soon to be available in Spanish, provides a summary of the pooled data accumulated from 53 hospital abortion studies conducted from 1971 to 1979 (Fig. 1).

The data were analyzed to obtain a demographic profile of the patients, to compare pre- and postabortion contraceptive use and to determine the type of medical treatment routinely given to incomplete abortion patients in Latin America. Further analysis produced an overview of hospital resources used to treat the abortion patients.

Analysis of the demographic data collected showed that women in these studies were markedly younger and of lower parity than were women in similar studies reported in the literature for the 1960s. Further, it was evident that abortion was being used as a family planning method, as almost a quarter of the women were nulliparous. At the same time, almost half the women indicated that they wanted no additional children. For them, abortion was a means to limit family size, a size that is notably smaller than that for women described in the literature of the previous decade.

When pre- and postabortion contraception use was compared, great variation was found among countries. While many hospitals in some countries provided excellent contraceptive services to these patients, facilities in a few countries failed noticeably to encourage the use of any contraceptive method. In countries where contraceptives are not available elsewhere, hospitals that do not encourage and provide contraceptives for postabortion patients increase the future burden for the fertile woman and ensure a continued drain on often scarce hospital resources.

Of the 39 hospitals involved in the studies, the vast majority treated incomplete abortion patients by sharp curettage with general anesthesia. On an average, an incomplete abortion resulted in two-three days of hospitalization, 15-20 minutes of operating room time and the dispensation of antibiotics, anesthetics and, quite frequently, a blood transfusion. In two comparative studies, however, outpatients experienced no more complications than inpatients. The report concludes that the shorter hospital stay is safe for the patient without complications and could result in significant savings to the hospital.

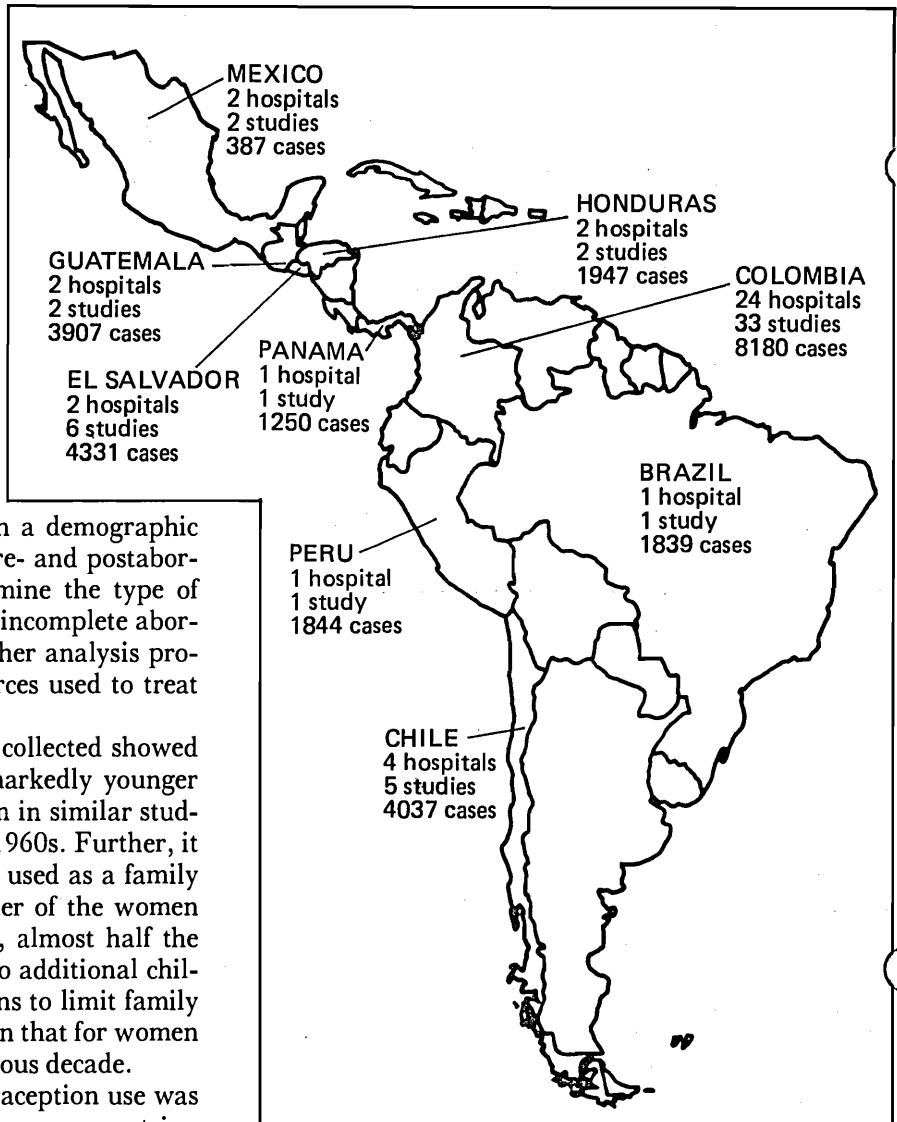

Fig. 1. The map shows the participation of the nine Latin American countries where the IFRP has supported studies of incomplete abortions treated in hospitals (1971-79).

The report suggests that the ideal management of an uncomplicated, aseptic incomplete abortion appears to be suction curettage under local anesthesia with only a few hours of hospitalization. Adoption of this treatment as policy would increase efficiency and the cost-effectiveness of the clinical management of incomplete abortion. The report also concludes that the burden on hospital resources would be greatly alleviated if the incidence of illegally induced abortion were reduced, which can be accomplished if all women treated for incomplete abortions are provided with an acceptable and effective means of family planning.

Copies of "Abortion in Latin America" in English or Spanish may be obtained by writing the Information Coordinator, IFRP, Research Triangle Park, NC 27709 USA.

Indonesia hosts workshop on fertility regulation methods

A workshop on "Advances in Fertility Regulation" will be held December 18-20, 1980, in Surabaya, East Java, Indonesia. Cosponsors of the workshop include the Indonesian Family Planning Program (BKKBN), the IFRP, the Program for Applied Research on Fertility Regulation (PARFR), the Foundation Yayasan Kusuma Buana and the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT).

The IFRP will conduct a two-hour session that will include a presentation by IFRP's Executive Director Malcolm Potts on menstrual regulation and one by Medical Director Leonard E. Laufe on instrumentation in fertility regulation. Invited speakers are Rudi Hendrawidjaja, a private physician from Indonesia who will speak on female sterilization services; Tongplaew Narkavonkit, a staff member of Thailand's Ministry of Public Health who will present her experience with massage abortion in Thailand; and Kotha Panikkar, a private physician from Malaysia whose presentation will be on her extensive clinical experience with menstrual regulation and various uses of the gynecologic syringe.

Topics to be presented during PARFR's session are advances in intrauterine contraception, benefits and risks of oral and injectable steroids, new developments in vaginal contraception, advances in male and female surgical contraception and contraception in the postpartum period. PIACT will conduct a panel presentation on the social marketing of contraceptives and on the introduction of new fertility regulation technology.

Bound copies of all papers to be presented at the workshop will be edited at PARFR, printed by the IFRP and distributed to each participant at the beginning of the workshop.

Female sterilization accessibility study underway in Honduras

More than 70% of the 18,523 women who were delivered at hospitals in Tegucigalpa and San Pedro Sula, Honduras, during the last three years said that they did not want more children. Over 23% (3063) of these women stated that they planned to be sterilized to terminate their fertility, but only 306 women received postpartum sterilizations.

IFRP Research Department staff member Barbara Janowitz, PhD, and Joaquín Nuñez, MD, the Medical Director of the Family Planning Association of Honduras, want to know why only 10% of the women who wanted to be sterilized actually had the procedure performed during their hospital stay.

Although a contraceptive prevalence survey has not been conducted in Honduras and little is known about contraceptive use there, the IFRP's Maternity Record has been used to collect detailed data about deliveries and their outcomes for mothers and their infants. The Record also collects pertinent information about each mother's obstetric history and her past and planned contraceptive practices, including whether or not she received postpartum sterilization. An analysis of these data from the hospitals in Tegucigalpa and San Pedro Sula clearly indicates that women are not receiving requested sterilization services for reasons other than lack of information and the Honduran "rule of 80," which requires that the number of living children multiplied by the mother's age exceed 80 before she is eligible for sterilization. It appears that insufficient operating room space may have been a major factor affecting the availability of services, but new facilities and equipment are now in place, and it is anticipated that the increase in facilities will have a positive impact on the demand for sterilization.

To determine who receives sterilization services, as well as where and why they receive them, Nuñez and Janowitz have initiated a six-month study to collect specific information about service accessibility. A questionnaire will be completed for approximately 6000 consecutive delivery patients over a period of three months at the hospitals in Tegucigalpa and San Pedro Sula, and a carefully planned follow-up system will monitor sterilizations that occur during the three months subsequent to delivery.

An analysis of the questionnaires and follow-up records is planned for early 1981. The resulting report will present data on how many women who delivered in the two study hospitals had heard about female sterilization and were aware of its availability prior to delivery, and the sources of that information. The number of women sterilized at delivery and during the three months following delivery will be available, as will specific information about where they obtained sterilizations. The contraceptive methods, if any, used by the women who failed to obtain sterilizations will be identified, as will the reasons why women who intended to be sterilized were not. Information will be available on how the facilities, equipment and their patterns of use at the two hospitals affect each institution's ability to meet the demand for sterilization.

The information collected in this study will not only identify why mothers who request sterilization do or do not receive services, but also will provide the Family Planning Association of Honduras with a solid foundation of facts to support future initiatives to improve the availablity and accessibility of sterilization to all mothers who request it.

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Dr. Liu Guo-Zhen, cottonseed oil and the male pill

Dr. Liu Guo-Zhen, a urologist involved in research at the Capital Hospital in Peking, visited colleagues at the IFRP recently and provided firsthand information about the remarkable progress of the People's Republic of China in curbing its population growth rate. Dr. Liu traveled to Research Triangle Park after presenting a paper at an IFRP-sponsored workshop at the Xth World Congress of Fertility and Sterility in Madrid, Spain. The paper, to be published soon in the *International Journal of Gynaecology & Obstetrics,* presents an overview of the family planning philosophy and programs that have led to a steady decline in China's population growth over the last ten years.

Participants in the Madrid workshop and the IFRP staff were most interested in learning about Dr. Liu's research on a male contraceptive pill. During his examination of the causes of infertility among Chinese who consumed large quantities of cottonseed oil, Liu discovered that the ingestion of gossypol, a component of the oil, caused a reduction in the sperm count. This led to the development of a male contraceptive pill that, according to Liu, has been proven to be 98% effective. Although testing and refinement of the pill continues, Liu sees this simple, nonhormonal contraceptive method as a major breakthrough in the field of contraceptive development.

The IFRP hopes to continue an exchange of information with Dr. Liu and looks forward to a greater involvement with contraceptive research being conducted in China during the years to come.

In memorium: Gaines B. Turner

The sudden death of Gaines B. Turner on May 31, 1980, was a great personal and professional loss for all who knew or worked with this much admired and multitalented man. As the IFRP's Associate Director for Administration since 1977, Gaines served the organization fully and well in a wide variety of roles. His negotiating skill and ability to take decisive action were largely responsible for the continuing stability of the IFRP. His administrative talents often required him to serve as the final reference point for many questions of policy and practice, and he was frequently called upon to make the most difficult decisions. The success of the IFRP as an organization is a tribute to Gaines' talents; the unfailing affection the staff feel for him is a tribute to his warmth and spirit. We are grateful that, for a time, Gaines was among us. He is sorely missed.

Riaño-Gamboa joins IFRP staff

Dr. German Riaño-Gamboa, Colombian obstetrician/gynecologist, has recently joined the IFRP staff as Senior Program Development Associate for South America. As Director of the Colombia Regional Fertility Research Program for many years (PRIF), Dr. Riaño's collaboration with the IFRP has covered a wide spectrum of studies and projects in the field of family planning. His new responsibilities will include identification of local family planning needs on the South American continent and will address the problems of delivery of services to these populations.

IFFH selects new president and relocates Secretariat

The International Federation for Family Health (IFFH) announced in July that it will relocate its Secretariat to Bandung, Indonesia, and appoint Professor Sulaiman Sastrawinata as Executive Secretary in January 1981. Dr. Elton Kessel, Founder of the IFRP, will continue as Executive Secretary of the IFFH until the Secretariat is relocated.

The 13 member nations of the IFFH are active research collaborators of the IFRP and include Bangladesh, Brazil, Colombia, Egypt, India, Indonesia, Korea, Malaysia, Nepal, Singapore, Sri Lanka, Sudan and Thailand. At their Third General Assembly, held July 12, 1980, representatives of the member nations and past president Dr. C. L. Jhaveri welcomed Dr. Guillermo Lopez of Bogota, Colombia, as the newly elected President of the Federation.

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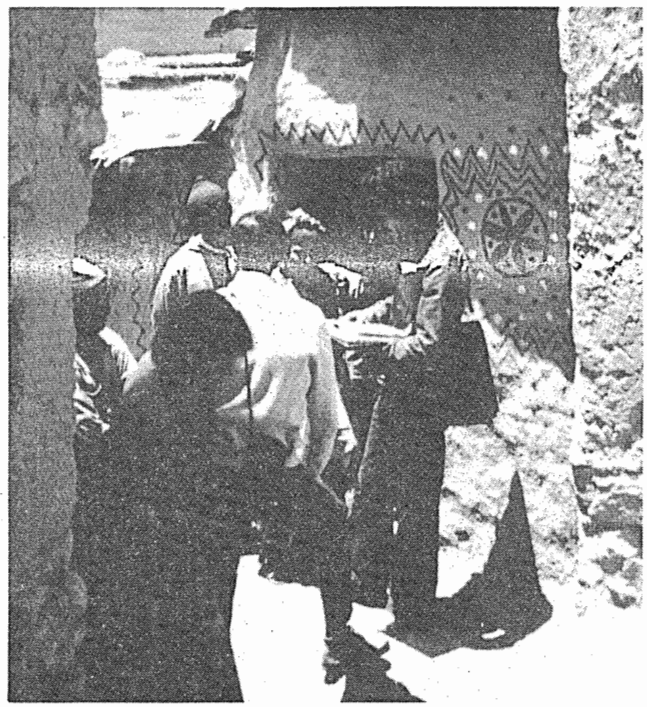
Household distribution of contraceptives in Marrakech proves successful

A pilot project recently completed in Marrakech Province, Morocco, to test the acceptability and effectiveness of distributing family planning services on a door-to-door basis has been found to be highly successful in increasing the use of contraception among women in both urban and rural areas. Beginning in Marrakech City in 1977, the project, Visites à Domicile de Motivation Systématique (VDMS), was gradually extended to the entire province and ultimately reached 150,000 households. Based on provincewide data available through 1980, modern contraceptive methods offered by the program (pills and IUDs) were accepted by nearly two thirds of the eligible population, resulting in a near doubling (from 28% to 53%) of the rate of contraceptive prevalence among women visited twice by VDMS household agents.

Marrakech is one of 39 provinces comprising Morocco, a country whose varied geography has allowed a diversity of populations to maintain their cultural integrity. The population of Marrakech Province is 1.2 million, about 40% of whom live in urban areas. Because of the vast expanses of desertlike terrain, most of the remaining 60% are widely dispersed. In an attempt to make medical care more easily accessible to the rural Marrakechi, health dispensaries have been established close to the *souks*, or open-air markets, that many people attend weekly. However, despite the existence of these dispensaries, comprehensive delivery of health care services has not yet been achieved in Marrakech.

VDMS was developed using the same basic principles of a similar project conducted in Tunisia (*see* Vol. 1, No. 1, October 1979). Launched in 1977 under the direction of Dr. Zarouf Mohamed, Médecin-chef of Marrakech Province, VDMS recruited and trained fieldworkers from existing public health personnel.

During the first of two visits, the trained health workers visited 150,000 households, reaching nearly 165,000 women. Their goals were to identify all women eligible for family planning services (those aged 15-44 years), to collect basic information on the reproductive background and contraceptive status of each woman, to offer oral contraceptives or condoms to all eligible women and to refer those desiring an IUD to the appropriate health facility.



Trained health workers collected information on the reproductive history and contraceptive status of nearly 165,000 Marrakechi women.

The purposes of the second visit, which occurred three to five months after the first, were to assess the acceptability of the door-to-door delivery system, to provide more pills or condoms to initial acceptors, to encourage others to accept a method offered by the program and to record additional information about attitudes toward the use of contraception by Marrakechi women.

Findings from the project demonstrate conclusively that household distribution is a highly acceptable and effective means of increasing contraceptive use, even in a society in which the traditional belief in large families is deeply rooted. Two of every three women who were offered oral contraceptives at the initial visit accepted them from the VDMS health worker. Pills proved to be the most popular method, with almost 90% of initial acceptors continuing to use them at the time of the second visit and with fewer than 1% reporting side effects and consequent discontinuation.

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The increase in contraceptive use among the women visited twice during the project was dramatic: overall use of contraception increased from 49% to 65% in urban Marrakech, and from 13% to 46% in the rural remainder of the province *(see table)*. Even more impressive was the proportional increase in the use of pills: 50% in the urban sector (from 36% to 54%), and over 300% in the rural sector (from 9% to 37%).

For Morocco, a country of 172,000 square miles with a population of 21 million, the average completed family size of 6.8 children and the youthfulness of the people (47% are under age 15) are concerns of vital importance for national development. The country's current 3% population growth rate is among the highest in the world and results from a relatively low death rate (14 per 1000) coupled with a persistently high birthrate (43 per 1000). At such an annual rate of increase, Morocco will double its current population in less than 25 years.

There is evidence, however, that Moroccan couples do want to control their fertility. The idea of family planning, almost unheard of in Morocco 15 years ago, is now officially recognized as an integral part of national health policy. The VDMS project was conducted on a large scale to determine the feasibility and desirability of expanding such a household-based contraceptive delivery system nationwide during the 1980s. As a means of spreading knowledge about family planning and of offering effective methods of contraception, household distribution as implemented by VDMS has proved a valuable strategy toward the goal of reducing the population growth rate.

A final report of this successful pilot project has been prepared by Douglas Nichols, PhD, a demographer in the IFRP's Research Department, and Miriam Labbok, MD, Office of Population, USAID. A complimentary copy of the report, *VDMS: Household Distribution of Contraceptives in Marrakech, Morocco,* is available on written request.

Marrakech: Contraceptive Prevalence (%) Before and After VDMS Activities*

	Before	After
Urban		
Contracepting	**49**	**65**
Pills	36	54
Other methods	13	11
Not contracepting	**51**	**35**
N = 37,877		
Rural		
Contracepting	**13**	**46**
Pills	9	37
Other methods	4	9
Not contracepting	**87**	**54**
N = 54,551		

* Tabulations limited to women visited twice during the program.

Surgical family planning methods and the private physician

The IFRP announces publication of its latest monograph, *Surgical Family Planning Methods: The Role of the Private Physician*. Reports of current social and legal attitudes toward sterilization, menstrual regulation and pregnancy termination in several countries provide an overview of the types of problems confronting the acceptance and practice of surgical family planning methods and the involvement of the private physician. Also presented are examples of national family planning programs that provide sterilization services through the use of private practitioners and government subsidy, as well as a review of the latest technical advances in of surgical contraception.

The IFRP monograph was prepared from selected papers presented at a workshop held during the IX World Congress of Gynecology and Obstetrics in Tokyo in October 1979. This meeting was one of the first to bring together private practitioners, government representatives and persons affiliated with international population agencies to discuss the basic problems of involving private physicians in providing family planning services.

According to IFRP's Executive Director Malcolm Potts, "When governments support an extensive sterilization program and choose to use the private sector for service provision, truly spectacular results can be obtained." For example, Taiwan's national family planning program functions within the framework of government health facilities and is supported by contracted physicians. Because of this system, the number of persons voluntarily sterilized per year increased from 7000 in 1974 to more than 50,000 in 1979.

The articles presented in the monograph all indicate that to increase the availability, acceptance and practice of surgical family planning methods, it is necessary to disseminate information to educate the public; provide government subsidies for sterilization procedures to low-income families and provide training courses and sterilization equipment for physicians.

"One of the reasons for confidence in the involvement of private physicians," said Potts, "is that they have played the key role in providing family planning services in Europe and North America for several generations. The problem facing the developing world is to accelerate the adoption of effective methods of family planning to meet individual health problems and national economic problems posed by a much more rapid decline in mortality than exists in the West." It is clear that the private practitioner will play an immensely important role in making the available methods and services more accessible to the public.

A complimentary copy of the monograph is available on written request.

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Traditional birth attendant studied in rural Brazil

Most of the babies being born this minute in developing countries are coming into the world without the aid of a physician or trained health care professional. A large percentage of these births are occurring at home with the assistance of traditional birth attendants (TBAs).

In rural areas of Brazil where many village populations suffer from poor health care services and high mortality, the TBA often provides the only maternity care available. Recognizing the need to provide improved maternity services in these areas, Professor José Galbo de Araujo, Head of the Assis de Chateaubriand Maternity School (MEAC) in Fortaleza, and Professor of the Center of Health Sciences, Federal University of Ceara, developed and coordinated a program to train TBAs and provide maternity facilities in rural areas using human and material resources available in the target communities.

Beginning in 1975, the program coordinated the building or restoration of maternity facilities in villages near the city of Fortaleza, then recruited TBAs from each community and provided them with a three-month training course at MEAC. Each completed three-or four-room facility includes an out-patient clinic, delivery room and postpartum room with five to seven beds. Simple medical instruments are supplied, and a physician and nurse supervise activities and monitor prenatal control and the care of high-risk patients. The facility remains open and staffed and ambulance service is available around the clock.

The IFRP has initiated a six-month pilot study at four of these maternity facilities and in the rural areas surrounding them to collect data on approximately 4000 TBA-assisted deliveries. Because many of the TBAs have little or no formal education, a pictorial form (Fig. 1) has been developed to enable them to record data during home deliveries. Nurses will assist TBAs in completing the IFRP Maternity Record during deliveries occurring at the maternity facilities. The Maternity Record will also be used to collect data on approximately 5400 inhospital deliveries occurring at MEAC during the same six-month period. The IFRP will analyze the data collected and prepare a report summarizing the results of this study at the completion of the project in April 1981.

According to IFRP Project Leader Barbara Janowitz, "the study will evalute the feasibility of monitoring TBA deliveries and will compare TBA deliveries with those attended by a physician or occurring in a hospital."

In addition to providing experience with organizing TBA data collection system, Janowitz states that, "Some basic questions about maternity care will be addressed, including the TBA's ability to recognize and appropriately refer high-risk patients, a comparision of hospital and nonhospital deliveries in terms of maternal and infant morbidity and mortality and an evaluation of complication rates to suggest areas where additional TBA training or services can be provided."

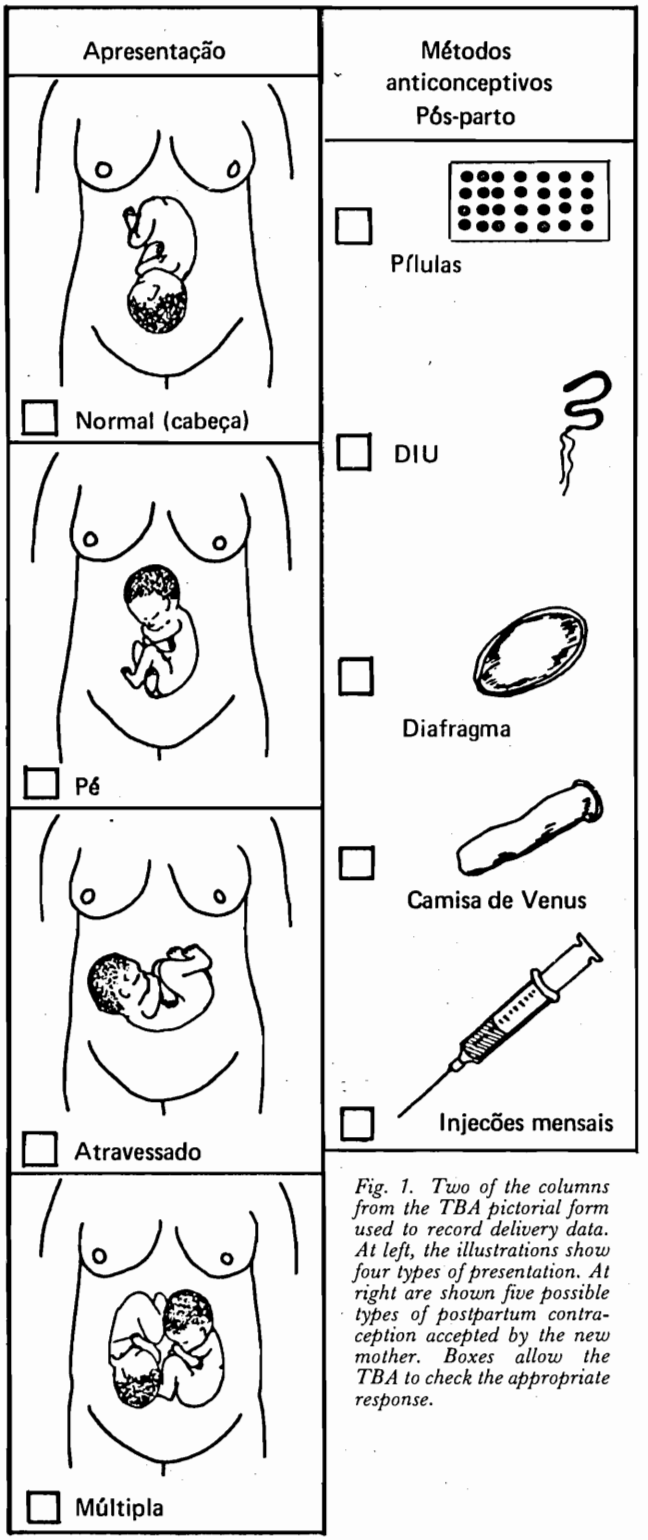

Fig. 1. Two of the columns from the TBA pictorial form used to record delivery data. At left, the illustrations show four types of presentation. At right are shown five possible types of postpartum contraception accepted by the new mother. Boxes allow the TBA to check the appropriate response.

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CONTINUING IUD RESEARCH

TEN-YEAR RETROSPECTIVE STUDY. An IFRP-supported study of IUD use in approximately 10,000 women is being conducted in Ljubljana, Yugoslavia. The study covers a ten-year period and the data were collected at Ljubljana's Family Planning Institute. The project is being directed by the Institute's Professor Lidija Andolsek and Dr. Mateja Kozuh-Novak. Study data will be analyzed to determine rates of ectopic pregnancy, cervical dysplasia and pelvic inflammatory disease. The data are particularly valuable because women with multiple IUD insertions are included. The customary data collected on side effects such as bleeding, pain and infection, and on events such as expulsion, termination and pregnancy can be related to a woman who has had a number of IUDs inserted over the ten-year period.

A broad range of IUDs were inserted over the study period, but the majority were Lippes Loops. IUDs inserted during the latter part of the study were usually copper devices.

A series of reports based on analyses of this data set is expected, as is a monograph, which will be published by Dr. Andolsek and Dr. Kozuh-Novak later this year.

NEW METHOD FOR STERILIZING IUDs. The IFRP and the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT) cooperate in a number of projects in which their combined efforts are more effective than the single efforts of either organization. PIACT de Mexico, for example, fabricates the postpartum Delta-T and Delta-Loop IUDs that are used by IFRP's network of collaborators. A new project of mutual interest is the evaluation of chemical disinfectants to sterilize copper-bearing IUDs.

In many developing countries, adequate facilities for sterilizing IUDs with standard methods of gas, heat or radiation either are not available or functional. In the absence of these options, the only potentially feasible approach to sterilizing IUDs in many countries is the use of chemical disinfectants.

Earlier this year the IFRP obtained the services of Jerry J. Tulis, PhD, Professor of Public Health, and Mr. Eugene C. Cole, Research Assistant in the Public Health Department, University of North Carolina, Chapel Hill, North Carolina, to select and evaluate various cold sterilization solutions for use with IUDs.

After carefully screening potential solutions, Tulis and Cole selected six for further study. Their study produced valuable information on the germicidal and spermicidal effects of the disinfectants, as well as on their corrosive properties and utility.

Although no one disinfectant meets all the requirements for IUD decontamination or sterilization without some untoward or adverse reactions, the findings of the study indicate that the aldehyde, formaldehyde, glutaraldehyde and chlorine-liberating compounds merit further testing. Iodine and iodine-liberating compounds are not suitable for this approach because they corrode copper.

The IFRP is now selecting appropriate medical facilities for the next phase of the study in which one or more of the selected chemical disinfectants will be tested under the working conditions that prevail in family planning clinics in developing countries.

NYLON T DEVICE. To evaluate the hypothesis that the effectiveness of a copper IUD is attributable to the increase in surface area of the device rather than to the copper itself, the IFRP is replicating an original study by Dr. Ibrahim Kamal of Cairo, Egypt. Dr. Kamal, a professor of obstetrics and gynecology on the medical faculty of Cairo University, designed a nylon-device and performed insertions in 98 not-recently-pregnant women.

Kamal's experimental IUD, a T device wrapped with 200 sq mm of nylon on the vertical stem, was inserted in the same manner as the TCu-200. Two-year pregnancy and other event rates for the nylon T were highly favorable (pregnancy rate, 5.5 ± 2.4; continuation rate, 83.2).

The IFRP is replicating Kamal's efforts in comparative studies underway at medical facilities in Yugoslavia and Puerto Rico. In each study, the nylon-wound T and the TCu-200 are being randomly assigned to 200 not-recently-pregnant women.

Design for contraceptive distribution achieved in rural Colombia

When Colombia's National Federation of Coffee Growers approached Dr. Gonzalo Echeverry in 1970 to ask why there were no family planning programs in the rural areas of Colombia, they struck a responsive chord. Echeverry, Director of ProFamilia, a voluntary organization in Colombia then making contraceptive services available in strictly clinical settings, was sympathetic to the desire of the marketing association to improve the living standards of people engaged in coffee production in the rural highlands. The subsequent efforts of Echeverry and ProFamilia were so successful in rural Colombia that their system has become a model for all of Latin America.

By the mid 1970s, ProFamilia began to address itself to the needs of the urban poor and set up distribution centers to reach these segments of a rapidly growing population. "The results have been gratifying," Dr. Echeverry said in a recent visit to the IFRP. "There are, by now, 3500 combined rural and urban distribution posts, delivering 150,000 cycles of pills every month."

Recognizing that clinic-based programs were not reaching the rural poor of the country, ProFamilia elected to experiment with a community approach for the projected rural programs. Basic to their premise was the conviction that a family planning program must be taken to the people, and that the service facility was to be completely nonclinical and quite separate from a health center. The rural programs were, therefore, immeasurably aided by Colombia's lack of strongly enforced legal barriers to dispensing oral contraceptives without a doctor's prescription.

A promotion campaign was mounted, stressing the importance and the possibility of limiting family size. Fieldworkers were hired and trained for work in remote areas, where scattered small villages characterize the settlements in coffee-growing regions. The fieldworker was trained to stimulate a community's interest in establishing a depot in a shop or home and to train the village worker, elected by the community, to dispense contraceptives. "Since these distributors were the natural leaders of their communities, the enterprise gained greater credibility than if they had been appointed by an outsider," Dr. Echeverry stated.

Each month, fresh supplies are sent to the depots from Bogotá. Everyone must pay for whatever contraceptives (pills or condoms) are purchased, because ProFamilia has found that things received gratis often are not valued. The distributor is thereby also restrained from disposing of the supplies instead of properly distributing them to interested customers. Payment also precludes acceptance of the contraceptive by those who do not intend to use it, but courteously do not refuse whatever is offered. On the other hand, if the cost is beyond a villager's means, the depot operator will consider the amount "owed," and not press for payment.

The distribution of oral contraceptives without prescription stratagem has now been replicated throughout Latin America. Dr. Echeverry believes that clinical services are important for some women who accept oral contraceptives, but for many who have no perceived need for a pelvic examination and cannot arrange an appointment with a doctor, the depot system is the answer. The distributors refer women experiencing uncomfortable side effects to a physician.

John L. Ganley appointed deputy director of IFRP

Malcolm Potts, Executive Director of the IFRP, announced in October the appointment of John L. Ganley as Deputy Director of the organization. In making the announcement, Potts stated that "John Ganley's 18 years with the federal government, combined with his corporate executive experience, will be a tremendous asset in effectively mobilizing all the professional and fiscal resources of IFRP and in negotiating with national and international agencies."

Ganley was President of Safetran Traffic Systems, Inc., of Colorado, and a Group Vice-President at the Safetran Systems Corporation in Louisville, Kentucky, where he was responsible for its corporate acquisition program until he assumed responsibilities at the IFRP. As a corporate-level financial and management executive in private industry, Ganley has also served as Senior Vice-President of Superior Manufacturing and Instrument Corporation, Director of Administration and General Manager with Weston Instruments Inc. and Director of Management and Purchasing at AVCO Corporation.

During his years with the federal government, Ganley served in a variety of high-level positions including: Deputy Director and Chief Executive Officer of ACTION, the 200 million dollar federal agency responsible for fostering volunteer service through such programs as the Peace Corps and VISTA; Auditor General of the Agency for International Development; Deputy Assistant Secretary for the Department of Housing and Urban Development, with responsibility for the operations of the Federal Housing Administration with its insuring organization; and senior staff member in the Office of the Secretary of Defense, where he was responsible for program review and operations analysis.

Ganley, a native of Lawrence, Massachusetts, attended Boston University and is a graduate of George Washington University.

Cabbages and condoms

Condoms being blown up like balloons. T-shirts sporting the ancient Buddhist slogan, "Too many children make you poor." School children singing family planning songs. Rice farmers and shopkeepers distributing oral contraceptives. Today, as a result of the overwhelming success of Mechai Viravaidya's Community-Based Family Planning Services (CBFPS), these sights are common in Thailand.

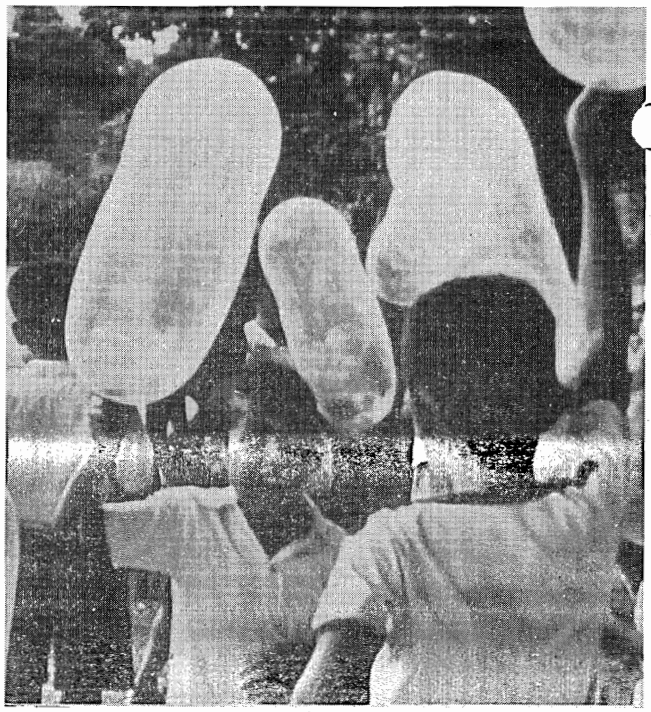
Mechai, the founder and director of CBFPS, Thailand's private, nonprofit family planning program, recently visited the IFRP and presented a history of his organization's work. An economist by training and a supersalesman by nature, he has revolutionized family planning in Thailand by involving the population in a program devoted to taking birth control to the remote areas of the country. The success of CBFPS is largely due to the villagers' role as active participants in the program, and to Mechai's philosophy that condoms and other contraceptives should be bought in the same way a villager buys a cabbage — from a friend, whenever there is need.

According to Mechai, "All economic development includes the improvement of facilities and the standard of living. To achieve this for the majority of people in Thailand, we need to change the patterns of consumption, create savings, develop agriculture and control the birth rate."

The "pig program," suggested by villagers and organized by CBFPS, is one example of Mechai's ability to link economic development and family planning. To increase the food supply, improve individual earnings and promote family planning, CBFPS offers to mate a villager's sow with CBFPS's prize boar. If the villager practices contraception, the mating is free; if not, the villager must pay CBFPS with one piglet from the resulting litter. The piglets earned by CBFPS are then given to the most economically disadvantaged family planning acceptors to raise and sell.

For the urban population, Mechai's organization has opened a Clothes, Cabbages and Contraceptives store, the CC&C Shop. The convenience of the first shop attracted such response that sales doubled in the first few months, and CBFPS is now pursuing the possibility of opening a chain of CC&C Shops where nearly all the basic necessities—food, clothing and contraceptives—can be bought in one-stop shopping.

Mechai believes that all the power, drive and energy necessary to achieve a better way of life in Thailand rests with the individual who has been provided with a meaningful opportunity to participate in positive change. One need only listen to this singular man speak of condoms and cabbages, clothing and contraceptives, pigs and the pill to believe that it is so.



Children in a village south of Bangkok play with balloons blown from condoms. CBFPS has played a large role in revolutionizing family planning in Thailand.

Elsevier to publish IJGO

IJGO Editor Dr. Harold Kaminetzky and IFRP Executive Director Malcolm Potts are pleased to announce that, beginning with the bimonthly publication of Volume 19 in January 1981, the *International Journal of Gynaecology & Obstetrics* will be published by Elsevier/North-Holland Biomedical Press.

Elsevier is a first-rank international publisher of excellent reputation in the biomedical field. The firm publishes 360 journals from its headquarters in Amsterdam, including the *European Journal of Obstetrics and Gynecology* and *Obstetrics and Gynecology*.

As publisher of the IJGO, Elsevier will manage all matters relating to subscriptions and other reader services, printing and distribution, promotion and advertising.

The Journal remains the official publication of both the IFRP and the International Federation of Gynaecology and Obstetrics (FIGO). Dr. Kaminetzky will continue to serve as Editor of the IJGO, and all manuscripts should be submitted to him for review.

The IFRP and FIGO look forward to their association with Elsevier and anticipate that the IJGO will continue to be an informative, timely communication among professionals in the field of obstetrics and gynecology and family planning.

"I'd rather my wife have an operation."

Vijaya Wijenaike is a rice farmer in the dry, north central region of Sri Lanka. He and others like him have migrated from the rainy but overcrowded south because the government has provided newly irrigated land from the Mahaveli Development Project. Vijaya and his wife have completed their family and do not desire more children; yet, when he is asked why he has not had a vasectomy, he responds, "I'd rather my wife have an operation."

This same explanation can be heard in many countries as the reason for the apparently low demand for vasectomy services. Dr. Ranjit Weerasinghe and Sri Lanka's Family Planning Association reason otherwise; the overwhelming success of their mobile vasectomy clinic proves that the provision of high-quality services yields high-level demand.

An IFRP staff member recently visited Dr. Weerasinghe and his associate Dr. Susil Jayasekera at their clinic stop in the Mahaveli Development Project's work camp. The van and doctors arrived on Thursday night, but a group of vasectomized men called "motivators" had been on the site since Monday visiting and talking with men in the surrounding villages.

On Friday morning, more than 300 men arrive at the camp seeking vasectomies. Most of them are in their late twenties and thirties and have two to five children. The two surgeons, taking turns in the single mobile operating theatre, can only perform 250 vasectomies at the most in the two-and-a-half days they will be working, so as many as a hundred men may be turned away.

Weerasinghe starts operating around 9:00 AM, while Jayasekera observes and helps organize the intake, then takes over in mid-afternoon and works until about 8:00 PM. After dinner, Weerasinghe returns to the camp, and by 4:00 AM 126 vasectomies have been completed.

At 8:00 Saturday morning, Jayasekera takes his place at the operating table and Weerasinghe begins the 24-hour follow-up. The men who live nearby have come back to the camp and are examined for possible complications, reassured about normal short-term discomfort, instructed as to what symptoms might require medical attention and referred to the hospital for a later free semen test and checkup. For those who live farther away, appointments have been made for men to gather at a particular place in their villages where Weerasinghe will travel to meet them.

By Sunday noon, two-and-a-half days after they began surgery, Weerasinghe and Jayasekera have performed 221 vasectomies and have brought a vital service to a population that is clearly ready to accept it.

Fewer than 2000 vasectomies were done by the entire government program during the first five months of 1980. This suggests that there isn't much demand, but the crowd at the Mahaveli camp sends a different message. They come to the mobile clinic in great numbers partly because it is convenient. They also come because the government's 100 rupee ($6.50) vasectomy incentive is paid on the spot by the FPA, while at the government hospital there is delay and red tape. But mostly they come because of the clinic's reputation. The first time the vasectomy van visits an area, the motivators have to scramble to get the required minimum of 40 acceptors. Gradually the word spreads, and men learn from each other that the operation is simple, complications are rare, and their sex lives are likely to improve as a result. They also learn that Weerasinghe runs a dependable, efficient and caring service.

The weekend's 221 vasectomies, of course, are of no demographic significance. Even with three such camps per month, Sri Lanka's population problem cannot be solved by two surgeons, however dedicated. What they do show is that in Sri Lanka, as in most places, the demand for vasectomy has much to do with the quality of services offered.

Contraceptive technology reviewed in Argentina

The first of three seminars to introduce recent contraceptive technology to physicians practicing in rural areas of Argentina took place in Rosario in October. Conducted under the auspices of the Asociación Argentina de Protección Familiar (AAPF) and the IFRP, the course emphasizes clinical practice and management of side effects of various contraceptive methods. Although the population growth rate in Argentina is relatively low, demographic problems resembling those of its neighbors still exist.

The AAPF has a unique commitment in the country. Among its important undertakings are operation of family planning clinics, training of physicians in contraceptive methods, inclusion of sex education in the official school curriculum and production of educational materials for wide dissemination.

The organization's considerable experience in designing and teaching enhanced the collaboration with IFRP on these seminars. Intensive training was provided to 20 physicians in a course lasting for three days. At its conclusion, the participants received a variety of pertinent reference material and a supply of contraceptives to distribute in their rural practices.

The second and third seminars will take place in the western provinces of Argentina later in 1981.

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Director of major US pill study presents new results at IFRP

New results from a long-term US study indicate that the risks to women from the use of birth control pills may be considerably lower than previously suspected and that diseases previously associated with taking them may actually be related to factors such as smoking, drinking and number of sexual partners. The well-known ten-year study by the Kaiser-Permanente Medical Center at Walnut Creek, California, examined 16,683 women and was able to follow up 92% of them. Almost all of the women were young, white, Protestant, married, middle-class Californians who had easy access to superior medical care. "For this group," according to Dr. Savitri Ramcharan, research director for the study, "the risks of oral contraceptive use are negligible." Dr. Ramcharan was a recent visitor to the IFRP, where she met to discuss her study with members of the Research Department who are concerned with similar contraceptive investigation.

The major conclusion of the Walnut Creek study is that an oral contraceptive (OC) user's life-style may enhance her risks of heart disease and various forms of cancer. A woman who smokes and has heavy exposure to sunlight and a sex life with multiple partners—and also uses OCs—may have a higher risk of lung, skin and cervical cancer than she would if she did not take the pill.

The study found no evidence of an increased risk of cancer of the breast, endometrium or ovary among OC users. Furthermore, OC users have a lower incidence of nonmalignant fibrocystic breast disease than do nonusers. The study also found no increase in risk of cervical cancer among OC users, except among women whose initial intercourse was at an early age and who had had multiple sexual partners, both factors that have been linked to cervical disease.

No increase in risk from circulatory disease was seen among OC users who did not smoke, but the combination of OC use and heavy smoking was found to compound the risk of circulatory disease.

Family planning training set for Honduran physicians

Eighty graduate physicians in Honduras who are spending the mandatory one year in social work at rural health centers will receive IFRP-sponsored training in family planning and demography. The training is expected to prepare the physicians to serve as opinion leaders in the community and to help solve some of the development problems facing Honduras today. Scheduled to begin in January 1981 and lasting through the calendar year, the training will be provided by the Asociación Hondureña de Planificación de Familia (Ashonplafa). Founded in 1963, Ashonplafa is a private, nonprofit organization that offers family planning services through a network of clinics and supports information and education programs.

By supplying recent medical school graduates with adequate family planning knowledge, Ashonplafa hopes to improve the quality of services that physicians provide and, therefore, increase contraceptive acceptance rates in Honduras.

Four 9-day courses are planned over the one-year training period and will be conducted at Ashonplafa clinics and surgical units in Tegucigalpa and San Pedro Sula.

Anek Hirunraks of Thailand visits IFRP

Dr. Anek Hirunraks of Thailand recently spent three months at the IFRP analyzing data collected by the Community-Based Family Planning Services (CBFPS) from the perspective of consumer and distributor characteristics. Dr. Anek, who received a PhD in statistics from Oregon State University in 1969 and was a postdoctoral fellow in population studies at the University of North Carolina at Chapel Hill in 1974, visited the IFRP to familiarize himself with the computer technology that is critical to his responsibilities on the faculty of public health in Mahidol University in Bangkok. Especially interested in the utilization and analysis of the IFRP's Maternity Record data, Dr. Anek will be collaborating with Robert Wheeler and I-cheng Chi of the IFRP staff on a number of papers dealing with the demographic profile of Thai women.

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Three IFRP studies investigate breast-feeding and contraception

The role of breast-feeding in both developing and developed countries has been undergoing intense reappraisal for more than a decade. New information has appeared on an unprecedented collection of topics ranging from the biochemical composition and antiviral properties of breast milk and the specific nutritional needs of infants and mothers to the economics of formula vs breast-feeding and its impact on global food supply and infant health. The new knowledge strongly underscores the old slogan "breast is best."

It has been well established that human milk is more readily digestible and is nutritionally superior to cow's milk, which is the basis of most infant formulas. Human milk has properties that protect against childhood asthma, food allergies and allergic dermatitis, and breast-fed babies have a lower incidence of respiratory and diarrheal diseases than infants fed cow's milk formulas.

In addition to being nutritionally superior, breast-feeding has another important benefit: it provides partial contraceptive protection against pregnancy by prolonging the postpartum anovulation amenorrhea that is common to all new mothers. It is this aspect of breast-feeding that the IFRP is currently exploring.

Whereas ovulation and menstruation return relatively rapidly for the nonbreast-feeding mother, ovulation in the breast-feeding woman is suppressed by endocrinologic actions that are stimulated by her infant's suckling. The more frequent the suckling, the higher the levels of serum prolactin and the more prolonged the postpartum anovulation. The introduction of supplementary foods, which results in partial breast-feeding, appears to allow a more rapid return to the ovulatory state.

Until now, there has been no longitudinal study in the developing world aimed at exploring the relationship between breast-feeding and the return of ovulation and fertility after childbirth. The IFRP is initiating a study to determine whether the early introduction of supplementary food stimulates the early resumption of ovulation. The relationship of factors such as resumption of menses and sexual practices on the return of ovulation after childbirth will also be investigated.

The study has been designed by Drs. Peter Howie and Alan McNeilly of Edinburgh and Dr. Pouru Bhiwandiwala of the IFRP Research Department, who is the study's Project Monitor. The study will be conducted at four geographical sites and will include a total of 100 women who are breast-feeding their babies and a control group of 40 women who have decided not to breast-feed for nonmedical reasons. The 100

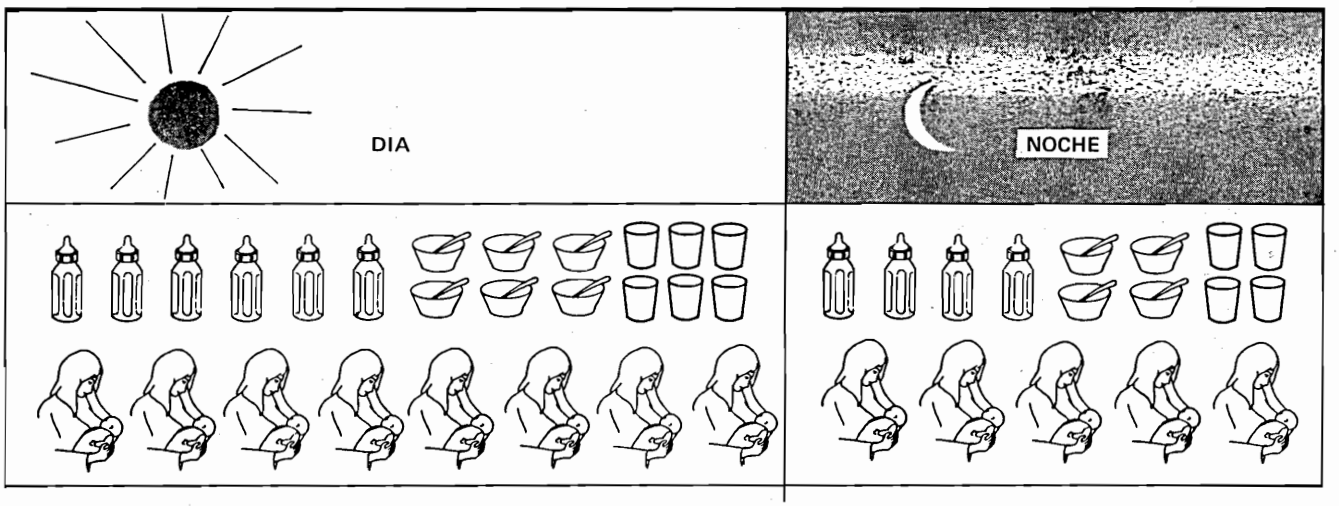


Fig. 1. Pictorial chart designed to enable the women studied to maintain detailed records of infant feeding. Each time the volunteer feeds her infant by any method she will cross out the appropriate symbol on the chart for that particular day or night.

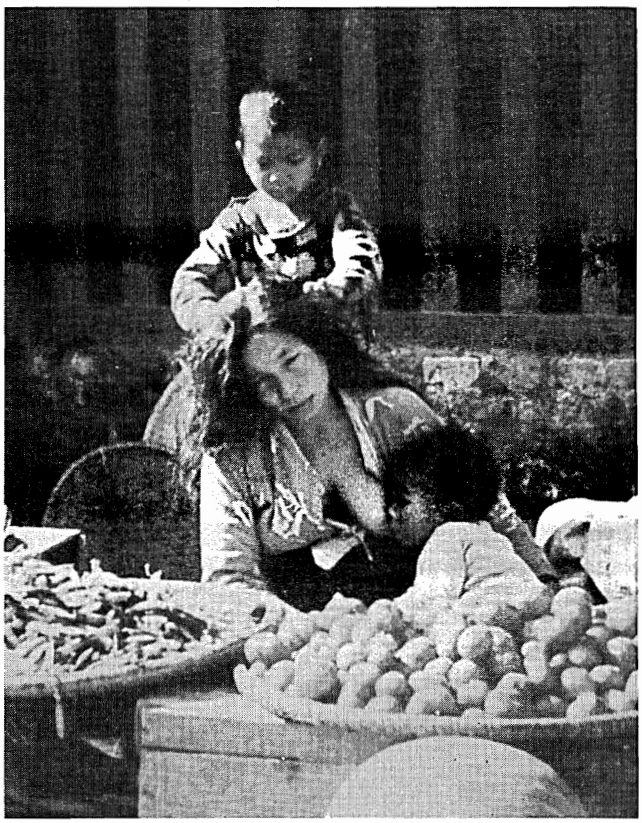
volunteers will be healthy women who wish to breast-feed and who do not intend to initiate supplementary foods for a minimum of three months.

A special pictorial chart (Fig. 1) has been designed, using different symbols, to enable the volunteer to maintain a detailed record of infant feeding. All the women will be visited weekly by a trained nurse who will obtain a detailed history of infant feeding from the volunteer's chart and coital frequency (also recorded by the volunteer on the chart); will inquire about resumption of vaginal bleeding; and will assess the health status of the woman. The nurse will also determine the infant's rate of growth and health status.

The levels of certain female sex hormones will be measured monthly to determine the time of ovulation and incidence of pregnancy, if any.

According to Bhiwandiwala, "The data from this study will be used to provide information and advice to breast-feeding women that will help maximize the antifertility effect of breast-feeding and help develop simple policies and guidelines to determine the optimum time for breast-feeding women with different cultural needs to start using contraceptives."

The first of the four studies has been initiated in Durango, Mexico, with Dr. Roberto Rivera, Director, Instituto de Investigación Cientifica.



In some cultures, breast-feeding continues for lengthy intervals, providing natural contraception for child spacing. Here, a breast-feeding mother in Nepal.

The duration of postpartum amenorrhea varies greatly from one individual to another and from country to country, but its impact on child spacing is great: many researchers think that more births are prevented by lactation than by all other forms of contraception combined. There is one drawback to lactational amenorrhea as a contraceptive, however: because a woman cannot predict when she resumes ovulation, the nursing mother is, at some point, at risk of pregnancy unless other contraceptive measures are taken. IUDs, foams and condoms, all safe for contraceptive use in lactating women, may be particularly appropriate choices. The use of combined oral contraceptives (OCs) has been debated, but progestogen-only OCs may have certain advantages for the lactating woman.

Hopeful of the demographic impact of a highly effective method of contraception that is acceptable to nursing mothers, the IFRP is currently conducting clinical trials of progestogen-only OCs and their relationship to lactation. The trials, underway in India, Malaysia, Argentina and Egypt, will compare a total of 1000 lactating women who will use progestogen-only OCs with an equal number who will use non-hormonal contraception.

The study will determine the initial acceptance and continued use of progestogen-only OCs among breast-feeding women; any significant differences over time in the weight of breast-fed infants whose mothers are using progestogen-only OCs, as compared to the weight of infants whose mothers are not using hormonal contraceptives; and the side effects experienced by women taking progestogen-only OCs.

A third IFRP study will survey breast-feeding patterns in relation to changing child-spacing trends in a traditional developing country. Analysis of data from a survey of contraceptive use, breast-feeding patterns and sexual abstinence of a sample of 4000 women in Lagos, Nigeria, is expected to yield preliminary results in mid-1981, according to Dr. Douglas Nichols, the IFRP Research Department staff member who is monitoring the project. Among the principal research questions to be answered by the survey are the proportion of women who are using modern methods of family planning, the proportions protected from unwanted pregnancy by the traditional practices of prolonged breast-feeding and sexual abstinence, and the relationships among these practices. Breast-feeding behavior will be examined in detail to detect recent changes in its prevalence and duration, reasons for termination, the contribution of breast-feeding to lengthening pregnancy intervals, the use of contraception among breast-feeding women, and its impact on infant survival probabilities. The survey was directed and coordinated by Dr. Paulina K. Makinwa, Senior Research Fellow of the Centre for Social, Cultural and Environmental Research at the University of Benin, Benin City, Nigeria.

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Microcomputers hasten transfer of technology to developing world research facilities

Helping fertility researchers in the developing world achieve autonomy has been a long-standing policy of the IFRP. The recent advent of microcomputers opens new options for the transfer of data analysis technology to IFRP collaborators overseas.

Much of the data collected by the IFRP is analyzed through the use of standardized computer programs, and the IFRP has received numerous requests to transfer these programs to local facilities.

However, in the past, the attempt to fulfill these requests has frequently met with technical difficulties. Often, the local computer facilities do not match the capacity of the IFRP's computer. When compatible facilities do exist, other problems arise: the time-consuming modifications of the IFRP's computer programs needed to compensate for differences in local computers; the scarcity of trained programmers to maintain the programs; the inconvenience of using facilities across town or in another city; and the lack of priority given to the work at the local computer center. In short, the IFRP and its collaborators generally encountered numerous problems that made the transfer of the latest analytical programs extremely difficult.

Microcomputers can greatly alleviate these problems. These computers are inexpensive, will be compatible from site to site and will require little space or environmental control (Fig. 1).

Technical advantages offered to users of the microcomputers include the ability to run standard tables instantly on any set of data, thereby allowing monthly, weekly or even daily monitoring of a hospital's performance, as well as immediate access of data by clinicians working on scientific analysis. By using computer programs that are compatible with current IFRP software, the users of the microcomputer systems can incorporate some of the same programs used to analyze data for research purposes at the IFRP. According to Edward Whitehorne, Systems Analysis and Programming Manager at the IFRP, "The use of microcomputers will simplify the collection of data and make data analysis quicker and more accurate, instantly upgrading a program's overall research capabilities."

Staff at the IFRP are currently designing and developing a microcomputer system for use in collecting and analyzing data from clinical trials. Initially, only one microcomputer will be installed overseas to allow the IFRP to resolve logistic problems and evaluate training methods before making the computers available to other collaborators. Consultants will test the system, provide technical evaluations and comment on the procedures and logistics associated with its use.

This approach will allow the IFRP staff to foresee and solve potential problems, and will guarantee a product that is tailored to the needs of its future users. The IFRP's present plans call for the purchase of a very limited number of microcomputers, which have already been allocated to carefully selected sites.

The use of microcomputers, combined with the ability to retrieve data from the field via magnetic diskettes, will greatly simplify the IFRP's methods of data collection and will significantly upgrade the research capabilities of those using the system.

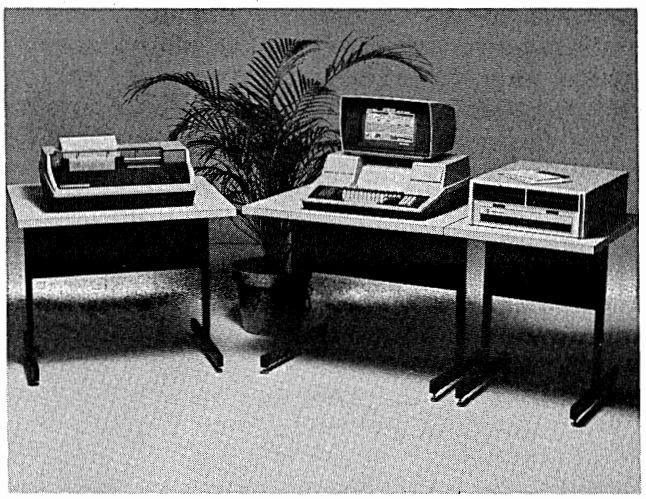

Fig. 1. The complete microcomputer unit, which includes a Cathode Ray Tube (CRT) terminal, twin floppy disks and a printer, easily fits on a table. The IFRP's present plans call for the purchase of a very limited number of microcomputers, which have already been allocated to carefully selected sites.

Evaluation of new vaginal contraceptive shows favorable early results

Preliminary results from the IFRP's multicenter trials of the Collatex sponge (*see* Vol. 1, No. 4, July 1980) show a six-month life-table pregnancy rate of 6.0 per 100 women. This early finding indicates that "the Collatex compares quite favorably with other female barrier contraceptive methods," according to David A. Edelman, Associate Director of Research at the IFRP.

The polyurethane sponge is about 5.5 cm in diameter, 2 cm thick, slightly concave and contains the spermicide nonoxynol-9. A polyester loop attached to the bottom of the sponge facilitates removal from the vagina. During intercourse, the spermicide is released from the sponge. Tests have indicated that only small amounts of spermicide leak out.

The sponge is produced by Vorhauer Laboratories, Inc, of Costa Mesa, California, under the trade name, "Secure." The National Institute of Child Health and Human Development has awarded a contract to the IFRP to evaluate the contraceptive's use-effectiveness and continuation, incidence of side effects, regularity and ease of use and acceptability. The IFRP's clinical trials are expected to continue through 1981.

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Nonsurgical female sterilization: expert committee provides future direction

How much time is required for quinacrine hydrochloride, a sclerosing agent being tested for nonsurgical female sterilization, to produce a lesion that will occlude the fallopian tubes? How important is the proximity of quinacrine to the tubes for successful occlusion? What are the toxicologic and teratologic effects of quinacrine? Are there other agents that will safely and completely occlude the tubes?

These are a sampling of questions that were addressed during a two-day meeting on chemical female sterilization held at the IFRP on January 15 and 16. The meeting brought together researchers involved with the development of a nonsurgical method of female sterilization to review the current status of chemical methods presently being tested. This review will aid the IFRP in determining its long-term policies to further develop and evaluate the use of quinacrine as an agent to occlude the fallopian tubes.

For more than ten years, Dr. Jaime Zipper of the University of Chile in Santiago has evaluated various doses and concentrations of quinacrine and vehicles for delivering the agent to the tubes in several thousand women. Based on the results of Zipper's research, quinacrine hydrochloride pellets (Fig. 1) have been developed to provide a delivery system that will bring the chemical into prolonged contact with the tubal ostia and increase the possibility of successful occlusion. The table shows the gross life-table pregnancy rates at six and 12 months for women who were administered quinacrine via solution or pellets during clinical trials.

After consulting with those present at the meeting in January, the IFRP has developed a strategy for continued research of nonsurgical female sterilization via quinacrine. Future research to be conducted by the IFRP will determine such things as the importance of proximity of quinacrine to the tube for successful tubal occlusion; the spermicidal properties of quinacrine, if any; the most efficacious release rate; the optimum number of insertions required and time needed between repeated insertions; and the most appropriate delivery system. Potential delivery systems other than the pellets include the No Gravid IUD loaded with quinacrine and a biodegradable device that will release quinacrine over a seven-day period.

Under a subcontract from the IFRP, researchers at the Johns Hopkins University School of Medicine continue to conduct animal studies to evaluate the toxicologic and teratologic effects of quinacrine. It is anticipated that the data collected from these studies will result in approval from the US Food and Drug Administration for use of quinacrine hydrochloride in controlled clinical trials.

Gross Life-Table Pregnancy Rates for Women Who Completed Three Administrations of Quinacrine Hydrochloride

	6-month Rate	Woman-Months	12-month Rate	Woman-Months
Quinacrine solution *(N = 124)*	5.7 ± 2.1	729	9.1 ± 2.6	1375
Quinacrine pellets with sodium thiopenthal *(N = 124)*	0.8 ± 0.8	741	2.5 ± 1.4	1422
Quinacrine pellets without sodium thiopenthal *(N = 249)*	1.5 ± 0.9	1217	1.5 ± 0.9	2035

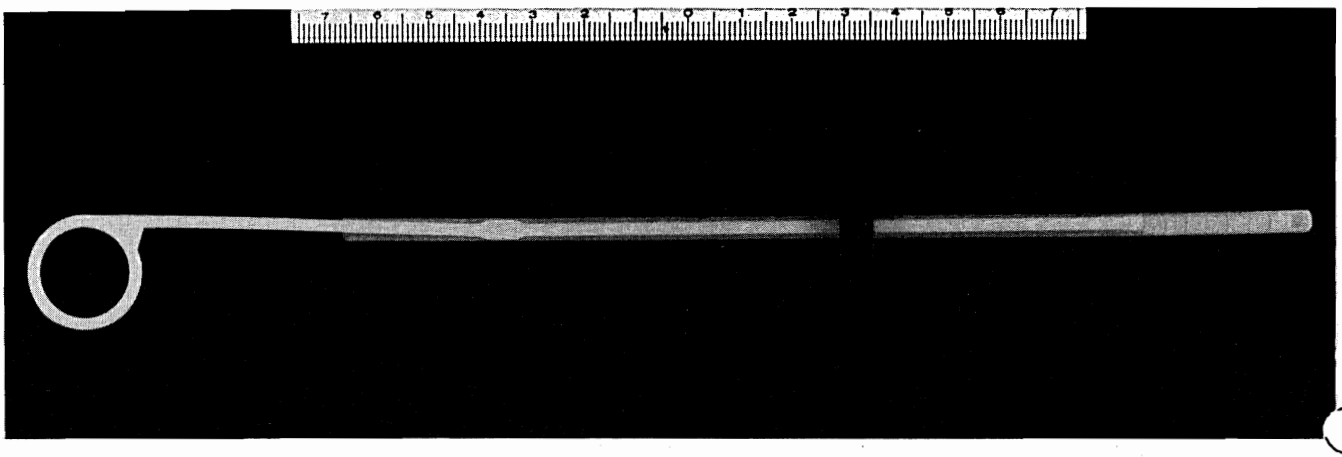

Fig. 1. Quinacrine pellet inserter loaded with seven pellets.

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One-year data in on fimbrial hoods

One-year data from rabbit and monkey trials of the fimbrial prosthesis for temporary or reversible sterilization are now available and show promising results, according to IFRP Medical Director Dr. Leonard Laufe. In both the rabbits and monkeys who retained the fimbrial hood for one year, no morphologic alterations of the fimbrial epithelium and their cilia were seen in scanning electron microscopies (SEMs) (Fig. 1). Further, experimental placement of the device in the 57 rabbits resulted in only one case of infection. Earlier data (*see* Vol. 1, No. 1, October 1979) showed an absence of adhesions and that no pregnancies occurred in the animals when the devices remained properly attached to the fimbria.

Laufe is convinced that "we have a completely biocompatible device. The only significant problem encountered in both animals has been device retention." The interrupted suture technique originally used in fixing the devices proved unsuccessful, and detachment occurred frequently, especially in the first three months after placement. The results of the detachments, however, have strongly implied that the technique is truly reversible: a high pregnancy rate was seen among those animals whose devices slipped off. A continuous suture technique and a collar for the hood that has specific points of fixation are being explored in an attempt to solve the detachment problem.

The development of a successful fixation technique is the last problem to be solved before human trials of the fimbrial hood can begin. Prototype devices for use in humans are being developed at the IFRP. The prototype fimbrial hood for use in humans consists of a mushroom-shaped bag made of a semipermeable, solution-cast silastic membrane .002 inches thick. According to Laufe, "it will probably have to be available in at least two or three standard sizes" because of the variance in size among women. It is hoped that the device can be applied to and removed from a woman's tubes via minilaparotomy.

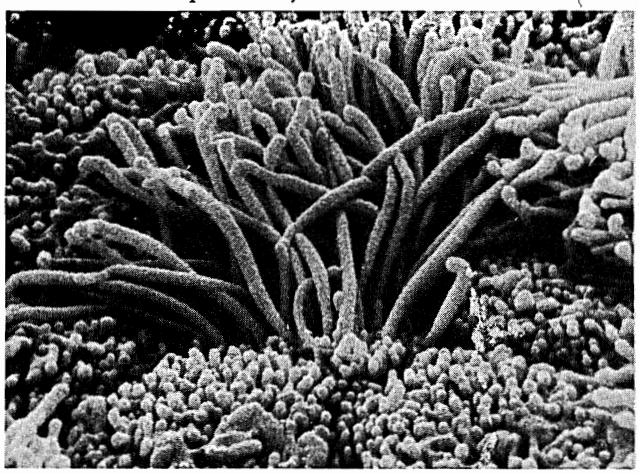

Fig. 1. SEM showing normal cilliation of rabbit fimbria after one year of fimbrial hood attachment (X 6500).

Female sterilization procedures compared

By the beginning of the 21st century, more than 400 million couples will have selected sterilization to limit the size of their family. Between 1951 and 1979, the numbers choosing sterilization had risen from 3 million to 90 million couples. Apparently more liberal attitudes among physicians and the evolvement of safer techniques that permit the procedure to be performed under local anesthesia on an outpatient basis have contributed to this trend. Reviewing data collected from studies conducted by IFRP in many countries, Drs. Stephen D. Mumford, Pouru P. Bhiwandiwala and I-cheng Chi, scientists in the IFRP Research Department, have compared three methods of female sterilization: occlusion by the tubal ring via laparoscopy and via minilaparotomy and occlusion by the modified Pomeroy technique via minilaparotomy.

Their findings appear in a recent article in *The Lancet* (*2:*1066, 1980). The 15,167 cases on record in 23 countries constitute the largest existing series of female sterilization cases with common protocol and definitions. The main body of the analysis consists of 14,910 cases. The incidence of complications at the time of surgery was 20/1000 for women undergoing sterilization via laparoscopy/ring, compared to 15/1000 for minilaparotomy/ring and 8/1000 for minilaparotomy/Pomeroy. Of the 7,680 women who were followed up, it was estimated, using life-table methods, that in a 12-month period, approximately 6/1000 became pregnant after sterilization by laparoscopy/ring, 5/1000 after minilaparotomy/ring and 3/1000 after minilaparotomy/Pomeroy.

The authors have suggested that many women seeking sterilization in the developing world would probably do better with a minilaparotomy than with a laparoscopy procedure. Minilaparotomy seems to have considerable advantages as regards safety, efficacy and ease in dealing with complications, making it the most appropriate method for nonspecialists outside large, well-equipped hospitals.

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Illegal abortion practices in traditional settings

The IFRP's newest monograph, *Traditional Abortion Practices*, to be published next month, presents an insight into the problem of illegally induced abortion in three developing countries. The findings are an important addition to the limited literature on illegal abortion and present a particular challenge to policymakers. Surveys recently conducted in the Philippines, Thailand and Mexico on abortion seekers and traditional service providers show that the traditional practice is both an important variable in fertility control and a significant public health problem. The surveys provide information on cultural attitudes toward induced abortion and on diverse perceptions regarding the decision-making process women use when confronting options for an unwanted pregnancy.

The overwhelming impression obtained from the research conducted to prepare this monograph is that induced abortion is common, practitioners of abortion are widespread, and the practice is commonly accepted as an established part of the culture. At the same time, the physical, emotional and financial costs of illegal abortion are usually greater than those of adopting modern methods of contraception. The monograph underscores the fact that the demand for accessible family planning services continues to far exceed availability in most of the developing world.

Two of the surveys deal exclusively with rural or small provincial towns. The data from the Philippines cover both rural and urban sectors, including inner-city slum areas. Each survey involved extensive interviews with traditional abortion practitioners, noting their attitudes, status within the society, fees charged and relationships established with the women seeking their services.

The monograph also presents epidemiologic evidence indicating that the practice of induced abortion has been widespread in every society that has experienced a significant decrease in the birthrate. Usually, the high incidence of induced abortion begins to decline first among those who are socially and economically privileged as they secure better access to modern contraceptives and practice contraception more efficiently. At the same time, the incidence of induced abortion continues to increase among the less privileged as they become aware of the advantages of limiting family size but remain hampered by economic, geographic or cultural limitations from ready access to family planning services. One chapter of the monograph deals with 19th-century evidence from Europe and North America that supports this phenomenon.

According to Dr. Malcolm Potts, Executive Director of the IFRP, "There is something arresting about the fact that, while politicians, government officials and family planning administrators talk about rapid population growth endangering economic and social progress, and while they mount complex programs to extend contraceptive programs to populations all too often believed to be reluctant to accept them, millions of women continue to risk the pain, danger and expense of illegal abortions, sometimes literally giving their lives in a wasteful demonstration of the strength of their desire to control family size."

It is recommended that policymakers in countries where abortion is illegal openly acknowledge and confront the significance of traditional abortion practices as a key variable in fertility control in their societies. The large number of women who resort to induced abortion demonstrates a powerful demand for fertility control. Appreciation of this trend should direct policymakers' attention to the need for more effective and accessible family planning services.

A limited number of copies of the monograph are available without charge on written request.

São Paulo data show unmet demand for family planning services

Results of a 1978 survey in the state of Sao Paulo, Brazil, have shown a sizeable unmet need for birth control services among reproductive-age women. Nine percent of all women aged 15-44 years were not using any contraceptive method and were exposed to the risk of unintended pregnancy. This unmet need amounts to an estimated 477,000 women in São Paulo State.

The survey was conducted under the auspices of the Pontifical Catholic University of Campinas; data analysis was sponsored by the IFRP. Major results of the analysis have been published in *Studies in Family Planning*, Volume 11, No. 7-8, July/August 1980 (Janowitz, Anderson, Morris et al) and in *International Family Planning Perspectives*, Volume 6(1), 1980 (Nakamura, Morris, Janowitz et al).

Older age and higher parity were both associated with an increased unmet need for family planning services: about one fifth of women aged 40 or older and nearly one quarter of those with five or more children were not using any method despite exposure to the risk of unintended pregnancy. The unmet need was distributed approximately as the population is distributed in São Paulo State: 33% of the need (roughly 156,000 women) was found in the Municipio of São Paulo; 50% (239,000 women) was found in other urban areas; and 17% (82,000 women) was in rural areas. The picture of São Paulo State is similar to that in many other developing countries: the unmet need for family planning services is concentrated among women who are poor, uneducated, older and of relatively high parity.

Researchers gather to discuss once-a-month injectable contraceptives

On January 23, 14 researchers and physicians from around the world met with staff at the IFRP to discuss the current status of once-a-month injectable contraceptives and the direction of future studies.

Participants familiar with conditions in developing countries remarked on the need for a once-a-month injectable contraceptive, a method used by 300,000 women in Mexico alone. Experience with monthly injections of a steroidal contraceptive has shown a lower rate of amenorrhea and better menstrual regularity than that associated with the three-month and six-month injections. It is speculated that a monthly injection will also result in fewer cases of temporary post-treatment infertility.

Topics discussed at the meeting included two delivery systems currently being tested to administer steroids intramuscularly. Dr. Harry Rudel, Centro de Investigación Sobre Fertilidad y Esterilidad in Mexico City, has developed a compound that consists of a dry powder of micronized crystals of norethindrone (NET) and mestranol. The mixture is suspended in saline and is injected intramuscularly. Current testing of this drug has already shown that there are few side effects of nausea or menstrual spotting and no irritation or inflammatory reaction at the site of the injection.

Another delivery system was developed by Dr. Lee Beck, University of Alabama, and researchers at the Southern Research Institute, Birmingham, Alabama, with support from PARFR. This system consists of microcapsules made of a biodegradable polymer in which NET is homogeneously dispersed. The microcapsules are injected intramuscularly; the steroid is slowly released by diffusion from the polymer matrix.

Among compounds being tested is Cyclo-Provera (medroxyprogesterone and estradiol cypionate, The Upjohn Company, Kalamazoo, MI, USA). The World Health Organization (WHO) has been studying Cyclo-Provera for about five years and will publish its results shortly.

Another potential injectable contraceptive under study by the WHO, currently known as the WHO Task Force Cocktail, is a combination of NET and estradiol valerate. Each steroid is injected separately and provides effective cycle control.

Following discussions of the current research being conducted on different delivery systems and steroids, all participants agreed that further research of a once-a-month injectable contraceptive is needed. It was unanimously agreed that only those steroids approved by the US Food and Drug Administration would be tested, with the drug of choice being NET. The delivery system using microcapsules of NET was thought to be the most promising for further evaluation. Although the technology of microencapsulation is well advanced, it is still at the stage where quality control of individual batches is required to confirm the drug's release rate and duration of action.

Further investigation of a monthly injectable contraceptive was deemed important in light of the advantages offered by this method—many of which may be of particular importance to women and family planning programs in developing countries:

- The drug is easy to administer.
- In many developing countries, injections are associated with safe, effective modern medicine, making them a culturally acceptable form of contraception.
- Because the drug is long-acting, it is a convenient method of birth control.
- The formulations do not inhibit lactation.
- The method is independent of coitus.

Invited participants of the one-day meeting were Lee Beck and Charles Flowers, University of Alabama, Birmingham, Alabama; Giorgio Benagiano, Rome, Italy; Robert Chatterton, Northwestern University, Chicago, Illinois; Harry Rudel and Vicente Diaz-Sanchez, Centro de Investigación Sobre Fertilidad y Esterilidad, Mexico City, Mexico; Henry Gabelnick, National Institute of Health, Bethesda, Maryland; Alfredo Goldsmith, PARFR, Chicago, Illinois; Dowon Hahn, Ortho Pharmaceuticals, Raritan, New Jersey; Peter Hall, WHO, Geneva, Switzerland; Harold Halverson, Upjohn International, Kalamazoo, Michigan; John Kent, Syntex Laboratories, Inc, Palo Alto, California; Daniel Lewis, Southern Research Institute, Birmingham, Alabama; and Allen Rosenfield, Center for Population and Family Health, New York, New York.

Seminar on IUDs planned for Brazil

The IFRP and PARFR have scheduled a seminar in Bahia, Brazil, for June 8-9. The conference will deal with the mechanism of action and evaluation of performance of various types of IUDs, insertion techniques and clinical management of associated side effects and complications. Ample opportunity for discussion of the risks and benefits involved will be an important aspect of the seminar, which will be directed by Dr. Elsimar Coutinho, who will also address the participants. The roster of speakers includes Anibel Faundes, David Edelman, John Guillebaud, Leonard Laufe, Elizabeth Connell, Daniel Mishell, Howard Tatum and Gerald Zatuchni.

Further information concerning the seminar may be secured by writing to **network**, at the IFRP, Research Triangle Park, North Carolina 27709, USA.

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Fertility regulation symposium in Tunisia

An international symposium on contraception will be held in Tunis June 1-3, 1981. Organized by l'Office National du Planning Familial et de la Population (ONPFP), the meeting is also sponsored by the IFRP, which with the ONPFP will conduct nationwide postpartum/postabortion studies in Tunisia.

Tunisia was one of the first Muslim countries in Africa to undertake a national program of family planning. As early as 1962, President Bourguiba was expressing his apprehension regarding the population growth that would inevitably frustrate efforts to raise living standards in Tunisia. A two-year experimental program of fertility regulation was begun in 1964 and proved so encouraging that the services were made an integral aspect of government policy.

The collaborative effort of the IFRP and the ONPFP in the first nationwide trial of the IFRP's two postpartum/postabortion intrauterine devices, (Delta-T and Delta-Loop), will evaluate the effectiveness of 3500 insertions at ten centers in Tunisia for one year. Preliminary results of the studies, which began in November 1980, will be reported at the International Symposium in June. The conference is expected to provide a useful forum for exchange of ideas and experiences among the professionals working in this field throughout the world.

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A free copy of any of these articles, or a complete catalog of IFRP publications (1971-80), is available upon request.

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Ten-Year Anniversary

network

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Dear Colleagues:

This July marks the tenth anniversary of the International Fertility Research Program. It also marks a decade of enormous progress in the global response to uncontrolled population growth. Ten years ago, world population was growing faster than at any time in history; today, birthrates are declining in almost every part of the world except Africa. Although our successes will not prevent another doubling of world population over the next 50 years, they do give us hope that human ingenuity can conquer this most devastating of mankind's current problems.

The IFRP has responded effectively to the population challenge. First, through the combined efforts of its staff in North Carolina and the organization's colleagues overseas, the IFRP has contributed to the increased safety, effectiveness and availability of less costly contraceptive technology. These contributions include new methods of surgical and nonsurgical female sterilization and improved designs for IUDs and other clinical equipment used in family planning. These innovations have particular application in the Third World, where there is a serious shortage of medical facilities and trained personnel.

Second, the IFRP's computerized data base of over 500,000 individual medical records from facilities throughout the world enables the organization to respond quickly and accurately to questions about the comparative safety, efficacy and acceptability of existing contraceptive methods. The IFRP is proud to serve as a resource to family planning policymakers in the US Government and international agencies.

Perhaps most important, the IFRP has helped to transfer crucial scientific skills to medical and research institutions in developing countries, where 90% of future population growth will occur and where ultimate responsibility for population programs must lie. Through its international network of scientific colleagues in 250 research centers in 47 countries, the IFRP has helped to ensure that policymakers in countries such as Brazil, Mexico, Egypt, India, Bangladesh, Thailand and Indonesia can now make timely and culturally and economically acceptable decisions about family planning.

Such institution-building in the world's poorest countries may be IFRP's most lasting contribution. Locally generated data on risks and benefits have provided Third World leaders with the courage to move forcefully on family planning programs and thereby enabled hundreds of thousands of women who might have died as a result of unwanted, unplanned pregnancies to make informed choices about childbearing. That these leaders have moved forcefully is in no small part a result of the IFRP's efforts.

Today, after a decade of dedicated work, the population problem is still urgent, but no longer hopeless. If we can sustain the same level of global energy and enthusiasm that now exists, we may celebrate our second decade in a world where existence is no longer threatened by overpopulation and where people enjoy new and more equitable opportunities.

Sharon L. Camp, PhD, Chairperson
Board of Directors

IFRP awarded contract to test new custom-fitted cervical cap

The IFRP has been awarded a contract from the National Institute of Child Health and Human Development to begin testing a newly developed vaginal contraceptive, a custom-fitted cervical cap that will be known as the Contracap. The device, which acts as a physical barrier to sperm and is designed for *continuous* wearing, will be fitted in 300 women who will be followed up for six months. The trials, expected to take about 18 months to complete, will evaluate ease of fitting, use and removal of the caps, as well as their safety and effectiveness.

The Contracap (Fig. 1) varies in size because of its custom design, but averages about 30 mm in diameter. It is made of flexible, rubberlike co-polymer material.

When in place, the device completely covers the outer surface of the cervix, but does not cover part of the vaginal space, as the diaphragm is designed to do. A valve built into the cap opens downward to permit discharge of menstrual and cervical fluids.

Contracap has a number of advantages over existing cervical caps commercially available. These existing caps are manufactured in a limited number of sizes, but Contracap's custom fit results in better retention and dispenses with the need for a spermicide recommended with other caps. The exact fit of the new device also helps prevent dislodgement during intercourse, a problem that occurs sometimes with the conventional caps and also with the diaphragm.

The Contracap's built-in, one-way valve that permits menstrual and cervical fluids to flow downward allows it to be worn continuously; no removal for menstruation or following intercourse is required. Contracap does not have a heavy rim, but is molded to the cervix, which reduces the risk of irritation.

Contracap was developed by dentist Robert A. Goepp, a professor of oral pathology at the University of Chicago and Director of the University's Zoller Dental Clinic, and Dr. Uwe Freese, Chairman of the Department of Obstetrics and Gynecology at the Chicago Medical School, who began work on the device in 1975. The two men applied dental technology, with its emphasis on exact fit, to create an impression to make a plaster replica of the cervix. Then the cap itself is fabricated by vacuum forming the co-polymer material around the plaster cervical model.

The commonly used, inexpensive dental casting material known as alginate is employed in making the cervical impressions. Alginate is nontoxic and is used to replicate the surface of the eye for custom-made contact lenses.

To get the unset alginate to the site of the cervix, Dr. Goepp designed a special "tray" (Fig. 2) that is placed over the cervix and supports the alginate until it sets, about one minute. A speculum keeps the lips and walls of the vagina open while the cuplike tray is slipped into the canal. An impression of the cervix can be made by this method in about 3-5 minutes. The procedure requires no local anesthetic and can be done in a doctor's office.

Once the impression is taken, a plaster cast is made from it, and then the cap can be fabricated in about 20

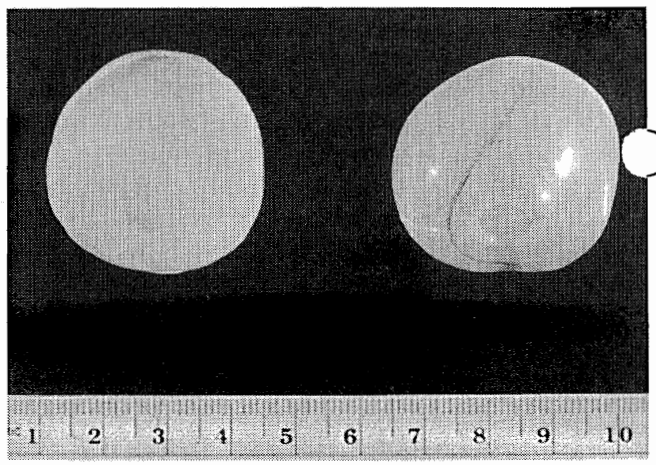

Fig. 1. The Contracap (right) and the plaster cervical model used in fabricating the cap. The line of ink on the cap emphasizes the location of the one-way valve.

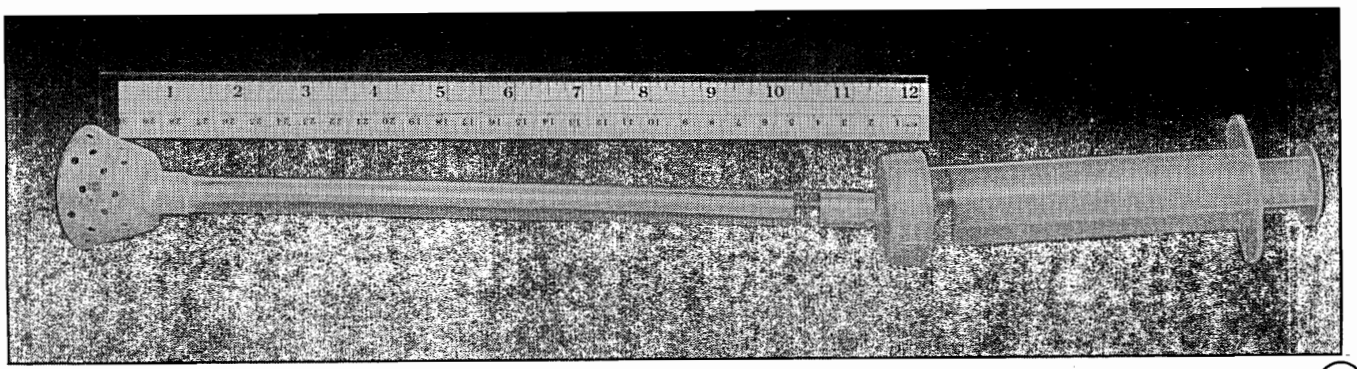

Fig. 2. One of the developers' early prototypes of the special cup-like tray designed to be placed over the cervix to support the plaster material until it has had time to set — about one minute.

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minutes. The final product is placed on the cervix either manually or with ring forceps. The developers, who have completed trials with approximately 140 volunteers, note that only a minimal amount of expertise is needed to operate the vacuum-casting machine that molds the plastic-like material over the cast to produce the cap.

The developers also say from their experience with the volunteer patients that the insertion procedure is not only simple, but painless. Goepp and Freese point out that Contracap mitigates against malodor, a problem with existing caps. Mucus flows freely underneath their device; it does not accumulate in stagnant pools.

Data from the initial users show that one woman has worn the Contracap continuously for more than 26 months without irritation, odors or any other detectable adverse effects. No cervical anomalies, vaginal infections or allergic reactions have been reported among the 138 volunteers who have used the cap to date. Clinical observation has noted that cervicitis found in women at the time of fitting has cleared more rapidly with the cap in place than would have occurred without it. It is speculated that this occurred because the Contracap rests on a layer of cervical mucus that flows continuously under it, insulating against exogenous organisms.

Popularity of barrier methods of contraception has increased in the past few years in the United States, possibly in reaction to concerns with hormonal and intrauterine methods of contraception. In theory, vaginal contraceptive methods have an acceptable rate of use-effectiveness. But among users of the diaphragm, for example, failure to use the method properly results in high rates of unintended pregnancy. Consumers need vaginal contraceptive methods that meet three standards: they should have high rates of actual use-effectiveness, be simple to use and should allow greater user compliance

The IFRP trials of Contracap will specifically examine the incidence of accidental pregnancy; the incidence of allergic reaction, vaginal infections and other complications, if any; the rates of and reasons for discontinuation; and the ease and regularity of use and acceptability to users. The IFRP study data will help decide whether or not to initiate large-scale clinical trials to collect information that could be used by drug regulatory authorities in deciding to make the Contracap commercially available in the United States.

Peter Lamptey to establish IFRP regional office in Africa

Dr. Peter Lamptey has been appointed IFRP's Senior Program Development Associate for Africa and will be establishing a regional office in Accra, Ghana. He recently spent three weeks in orientation at IFRP headquarters in North Carolina.

Lamptey, a native of Awaso, Ghana, will maintain a teaching appointment with the Department of Community Medicine, University of Ghana at Legon. A physician with a degree from the University of Ghana Medical School, Lamptey also holds master's and doctor's degrees in public health from the University of California at Los Angeles and Harvard University, respectively. As a United Nations Research Fellow, he has also trained for two years in the Massachusetts Institute of Technology's International Nutrition Policy Program.

Lamptey's double background has resulted in multiple professional experiences in both family planning and nutrition. He has been a consultant in family planning to the Pathfinder Fund; in nutrition to the Educational Development Center, Newton, Massachusetts; and in primary health care to Ghana's Ministry of Health Planning Unit, involving a project with traditional birth attendants and village health workers. He also served as Medical Officer for Ghana's well-known Danfa Project.

Lampety has organized the delivery of family planning services to a rural population; has trained village volunteers, nurses and administrators in family planning; and has evaluated overall family planning programs, including a drugstore training program in Latin America. He has also evaluated nutrition rehabilitation centers in Ghana and the Philippines and has organized and supervised rural nutrition programs.

His research includes the evaluation of male contraception in Ghana; analysis of the selection, training and supervision of village health workers and traditional birth attendants; analysis of the practices of infant feeding and weaning in both rural and urban populations; and an investigation of the impact of contraception on breast-feeding, birth intervals, nutritional status and child survival in rural Ghana.

Lamptey's new responsibilities as the IFRP's regional representative in Africa include the development of IFRP-sponsored projects to respond to the needs and interests of health professionals and population policymakers in Subsaharan Africa. He will also work to strengthen IFRP's network of African collaborating investigators.

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Meeting the family planning needs of the urban poor

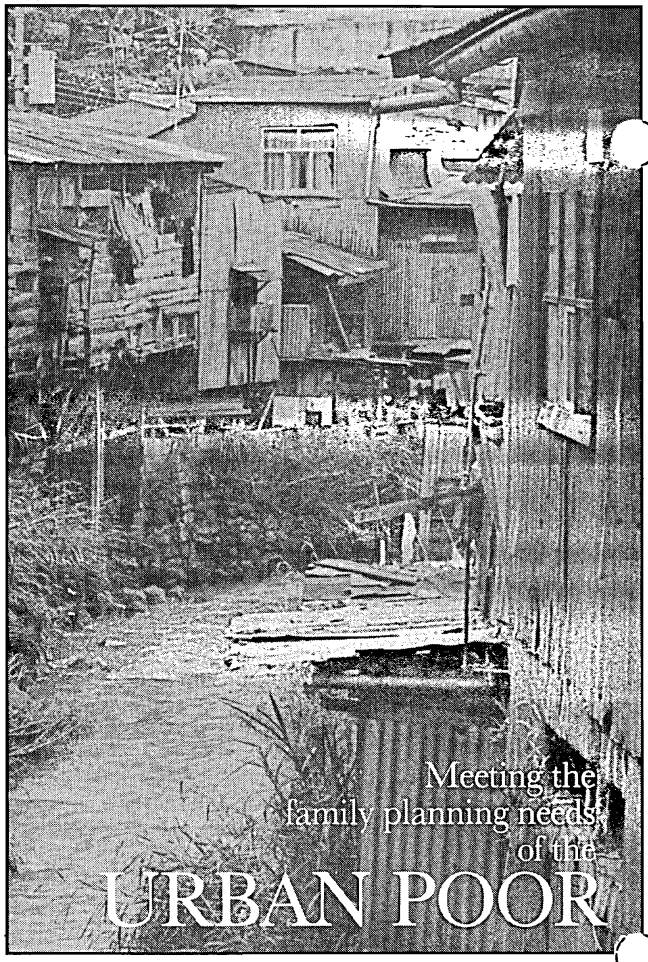
In September 1980 the IFRP sponsored a meeting to evaluate the most appropriate ways to deliver family planning services to the people in the peripheral slums and shantytowns of the rapidly expanding cities of the developing world. The small, intensive workshop, hosted in Juarez, Mexico, by IFRP Board member Mrs. Maria Guadelupe de la Vega, was attended by 11 invited professionals and three IFRP staff members.

The participants met specifically to review current technologies and to document successful urban family planning programs; analyze common factors that might help identify and replicate successful programs; review problems and opportunities that distinguish urban from rural family planning programs; and compare cities with and without effective family planning programs to determine the factors in design and implementation that led to a successful program.

The workshop discussions yielded a plan of action that included the following recommendations to help meet the family planning needs of the urban poor:

- Make oral contraceptives available without a physician's prescription;
- Provide greater access to injectable contraceptives and voluntary sterilizations;
- Promote condoms through advertisements and point-of-purchase displays and encourage their distribution by people with considerable public contact (eg, barbers, bartenders and motel desk clerks);
- Introduce family life education in schools;
- Involve pharmacists by including family planning in their training and by providing practicing pharmacists with promotional material;
- Enhance the status and visibility of field-workers;
- Involve industry and business offices in the distribution of family planning materials;
- Increase the involvement and responsibility of men in family planning;
- Establish community-based distribution of contraceptives, backed up by additional services from family planning clinics and private physicians, clinics and hospitals.

The IFRP's Executive Director Dr. Malcolm Potts and Dr. Pouru Bhiwandiwala, Medical Associate and Deputy Associate Director for International Projects, have coauthored a report that draws on the discussions at the Juarez meeting and further explores the opportunities and barriers of providing family planning services to the urban poor. Over the past 15 years, 600 million people—almost equal to the population of India—have left a traditional way of life to live in the exploding cities of the developing world. By the end of the century, they are likely to be joined by another 1500 million.



Cover, **Meeting the family planning needs of the urban poor.** *This publication is the fourth in a series of reports published occasionally by the IFRP on selected topics of interest to those concerned with population, family planning and the ultimate well-being of all people. A limited number of copies are available upon written request.*

Rapid urbanization results in unemployment, poor housing, unsanitary conditions and overcrowding. To ameliorate these problems, it is essential to provide people with family planning choices that will allow them to control the natural population growth that occurs in areas with rapid inward migration.

However, the lack of an established infrastructure and the multitude of social and physical problems that surround life in shantytowns often result in a disparity between needs and services. Although the upper and middle classes have always been able to turn to private physicians and pharmacies to meet their needs, relatively few programs have been developed to fulfill the particular needs of the urban poor.

According to Potts and Bhiwandiwala, "One of the most important aspects of urban family planning programs is the opportunity to involve the community."

Before people can adopt family planning, they must have access to services and information about those services. The authors discuss those contraceptive meth

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ods most suitable to urban family planning programs and present various effective channels for delivering services and different promotional approaches for providing necessary information and education on family planning.

In addition to presenting the opportunities and barriers to establishing family planning programs for urban slum dwellers, Potts and Bhiwandiwala highlight existing programs in similar areas that have proved successful. For example, the social workers of the Concerned Women for Family Planning distribute contraceptives, refer people for immunizations, IUD insertions, voluntary sterilization procedures and treatment of various diseases and infections, and promote good nutrition to the poorest of the world's poor in Dacca, Bangladesh.

Another successful urban program, Neighbors Population and Development Services, was organized in 1968 with support from World Neighbors to provide the urban poor of Zamboanga in the Philippines with access to contraceptives. Over time, the program has grown and expanded and now offers classes that provide health education, nutrition counseling and instruction on food preservation and food production.

The urban environment particularly lends itself to the door-to-door distribution of contraceptives. Such an experiment undertaken in Marrakech City, Morocco, increased overall use of contraception from 49% to 64%.

Another example of a successful urban program is Bombay's *Streehitakarani* (women's welfare), which was established in 1964. Although it began as a community development program concerned with immunization, nutrition and ways of generating income for women, *Streehitakarani* eventually incorporated family planning into its program. Between 1969 and 1973, 67% of the women in the most fertile age group (18-32 years) were using a contraceptive method; by 1979 the number had grown to 82%.

The publication by Potts and Bhiwandiwala, *Meeting the Family Planning Needs of the Urban Poor*, will be published this fall. A limited number of copies will be available upon written request.

Insertion technique improved for postpartum IUDs

One year of experience with clinical trials of the IFRP's postpartum Delta devices (*see* Vol. 1, No. 4, July 1980) has led to an improvement in the insertion technique. The modification is expected to keep expulsions to a minimum, according to IFRP Medical Director Leonard Laufe.

The IFRP is now recommending the use of uterine ovum or ring forceps for the IUD insertion. The improved technique calls for using the ovum or ring forceps to grasp the anterior lip of the postpartum cervix at the 12-o'clock position (Fig. 1). A second sterile ovum or ring forceps is then used to grasp the IUD, as shown in Fig. 2. After the vagina and cervix surface are cleansed with an antiseptic, the IUD may be guided with one hand through the cervical canal, while the other hand maintains gentle downward traction on the anterior lip of the cervix.

Laufe emphasizes that simple hand palpation of the abdomen will confirm when the IUD reaches the fundus. The strings of the IUD should be observed carefully during the insertion procedure. Once it has been determined that the fundus has been reached, the ring forceps holding the IUD should be released, and then the blades separated and withdrawn from the uterine cavity.

During this last maneuver, the strings of the IUD should not move; if the strings appear to lengthen, it must be assumed that the IUD has dropped from its fundal placement and should be removed and reinserted. The forceps grasping the cervix should be removed following removal of the forceps holding the IUD. The strings should then be trimmed 1.5 cm from the cervical os.

Major bleeding points should be controlled prior to IUD insertion. Lacerations or episiotomies should be repaired *after* the IUD insertion to avoid breakdown of the suture lines.

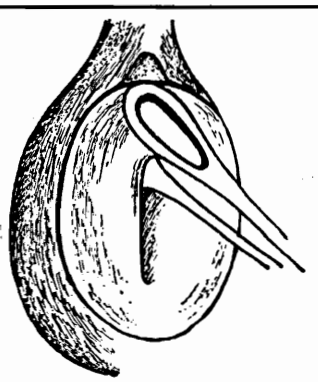

Fig. 1. To insert the Delta IUDs, ovum or ring forceps are now being used to grasp the anterior lip of the postpartum cervix at the 12-o'clock position.

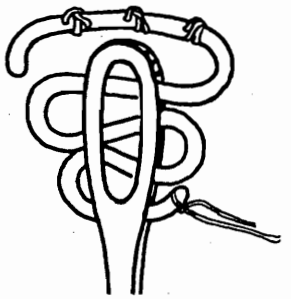

Fig. 2. A second ovum or ring forceps is then used to grasp the IUD (here, the Delta-Loop) and guide it into position.

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The future is NOW: international development in 1981

Over 675 professionals involved in all areas of international development convened in Washington, DC, May 12-14, to participate in the 1981 International Development Conference. Since 1952, this Conference has served as a forum for the exchange of information, experience and ideas on international economic, technical and social development.

Persons from the US and 17 countries who work for the US Government, international agencies, business, universities and government and nongovernment organizations met to discuss the stake of the US in world development. The success of this year's Conference was largely due to the efforts of Mr. Lawrence R. Kegan, Chairman of the International Development Conference and President Emeritus of the Population Crisis Committee.

Speaking during the first evening, the Honorable M. Peter McPherson, Administrator of USAID saw two clear signals in the issue of development: the need to slow population growth and the fact that the US recognizes its role of leadership. Citing the need to keep long-term goals in sight while addressing immediate problems, he named four objectives:

1. To help less developed nations set their own policies;
2. To emphasize institution-building and the transfer of technology so that developing countries can better solve their problems;
3. To set the priorities of projects according to potential economic growth; and
4. To encourage the private sector to become more involved in all areas of development.

Representing the IFRP was Medical Associate and Deputy Associate Director for International Projects Dr. Pouru Bhiwandiwala, who presented a paper titled "Population and Development" in which she avowed that, "To recognize family planning and economic development as complementary is practical, realistic and essential to the advancement of society."

While the importance of socioeconomic development, the development of energy sources, the conservation of natural resources and increased food production was emphasized by most speakers, population agency representatives stressed the need to integrate family planning into all development plans. Even though the global fertility rate has gone from 2% to 1.7%, the existence of at least 500 million starving people has worldwide economic and political implications.

According to Rafael A. Salas, Under-Secretary of the United Nations and Director of the UNFPA, there are several factors that have contributed to the recent success of government family planning programs. First, there has been a dramatic change in the concept of family planning programs, and almost every country now has an official population policy. Second, population programs have become better managed and thus more effective. And third, improved communication and education have greatly increased the understanding and acceptance of family planning.

Ambassador Richard Benedick, Coordinator of Population Affairs for the US Department of State, also noted several elements that have increased the effectiveness of population programs: the use of mass media for promotion and education; the decentralization of family planning programs; person-to-person contact as a way of reaching out to the consumer; local decision making to vary programs for specific needs; improved education for women; improved literacy rates; and programs on income generation for women.

Dr. William Hubbard, President of The Upjohn Company, Kalamazoo, Michigan, stressed the need to target contraceptive drug studies to the people to be served, stating that results from any one study cannot be applied to all populations and that obtaining informed consent from volunteers should be more important than approval by the US Food and Drug Administration. Hubbard thinks that the range of contraceptive choices is inadequate and that research and development are desperately needed. Contraceptive research has been supported by the government only since 1965. Today, two thirds of all such research is funded by government, 20% by industry and 10% by private foundations.

According to Bhiwandiwala, "Experts from developing countries estimate that at least 360 million couples in the world live without even the opportunity to choose family planning. What is needed is a strong commitment to the provision of family planning services and to improvements in education, food supply, job opportunities and other elements of socioeconomic development to the extent that resources allow."

Among the other speakers who stressed the importance of a population factor in development were the Honorable Phoebe Asiyo, Member of Parliament, Kenya; Dr. Sharon Camp, Director, Education and Public Policy, Population Crisis Committee; Mr. Philander Claxton, President, World Population Society; Mr. Thomas Donnelly, Population Office, USAID/Mexico; Ms. Merle Goldberg, President, International Women's Health Coalition; Ambassador Marshall Green, former Assistant Secretary of State for Asian and Pacific Affairs; Mrs. Kaval Gulhati, President, Centre for Population Activities; Mrs. Aziza Hussein, President, International Planned Parenthood Federation; Mr. Luis de la Macora, Secretary-General, Profam; Mr. Hira Malaney, Jan Mangal Sanstha, India; and Ambassador Edwin Martin, former Assistant Secretary of State for Inter-American Affairs.

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RAMOS: current status reviewed by panel of experts

On April 13, five invited experts met with 11 IFRP staff members to review the status of the IFRP's RAMOS studies and to provide recommendations for their conduct.

RAMOS—the Reproductive Age Mortality Survey—was designed to assess the relative benefits and risks of contraception when used by women who live in developing countries. The RAMOS studies will identify the causes of death among reproductive age women living in traditional societies of the developing world where modern medical care is scarce. The data from these studies will be used to estimate age-specific death rates for contraceptive users and nonusers and will also contribute to existing information on causes of death from pregnancy and childbirth in rural areas.

The first RAMOS study was initiated in Bali, Indonesia, in September 1980. A similar study was recently started in Egypt, and plans are underway to conduct the study in Sri Lanka as well.

IFRP staff anticipated problems in obtaining interviews with the bereaved, in the ability of lay interviewers to collect medical data, in accurately diagnosing the cause of death and in establishing the correct age of the deceased. Contrary to expectations, none of these problems occurred in Bali. Experience has shown that the families of the deceased seem to report symptoms quite accurately, and in most cases, the cause of death can be diagnosed wih confidence. However, it was suggested that a panel of physicians be formed in the United States to review a random sample of death reports and to review those cases for whom the cause of death was difficult to diagnose. It was also recommended that a physician or other medical professional reinterview a random sample of families to validate data collected by the lay interviewer.

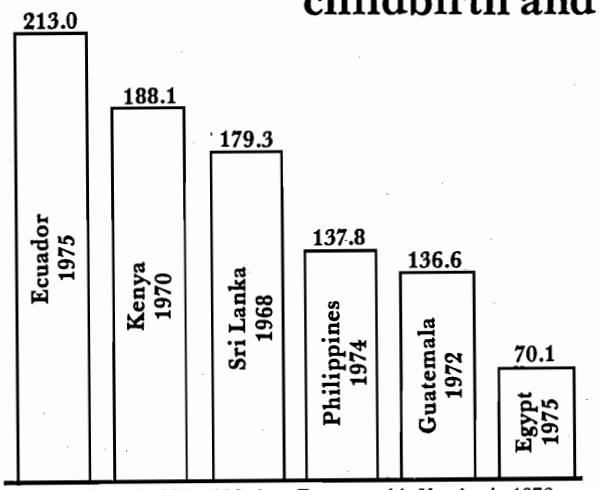
The panel recommended a system of independent checks to ensure as accurate a reporting of deaths as possible. One suggestion called for the organization of monthly meetings in selected areas. The meetings would be held in a *desa* (village), and all *kelians* (those who maintain the records for each *banjar*, or subvillage) would attend. The group leader would collect the number of all births and deaths that occurred in each *banjar* during the previous month.

Another possibility is for the IFRP to hire one person for each district to visit one or two *banjars* a day, collecting information on births and deaths during the previous month. Information obtained from these two approaches could be compared to the data collected through the registration system. The estimated number of expected deaths should also be recalculated using data from the most recent census.

As a result of another of the panel's suggestions, the IFRP will hire a consultant to live in Bali and participate in the review and management of the RAMOS study. All other panel recommendations will also be implemented.

The panel, included Janet C. Edmondson, Columbia University, New York, New York; Herbert Peterson, Center for Disease Control, Atlanta, Georgia; Diana Petitti, Kaiser Foundation Research Center, Oakland, California; Jeremiah Sullivan, Population Laboratories, University of North Carolina, Chapel Hill, North Carolina; and Bradley Wells, Bowman Gray School of Medicine, Winston-Salem, North Carolina.

Deaths of reproductive-age women (per 100,000 live births) from complications of pregnancy, childbirth and the puerperium



Data from the United Nations Demographic Yearbook, 1978. New York, 1979, Table 21.

In developing countries, the risk of death due to the use of oral contraceptives (OCs), even by women with predisposing conditions, is much lower than the risk of death due to complications of pregnancy, childbirth and the puerperium.

In developing countries, risk of death to OC users with predisposing conditions (per 100,000): aged 15-29, 1.0; aged 30-34, 6.0; aged 35-39, 13.0; aged 40-44, 63.0. Risk of death to OC users without predisposing conditions (per 100,000): aged 15-29, 0.8; aged 30-34, 1.3; aged 35-39, 3.0; aged 40-44, 5.5.

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Tunisia and Turkey to evaluate IFRP's Delta IUDs

Large-scale national programs in Tunisia and Turkey are now a part of the IFRP's clinical trials of its postpartum IUDs, the Delta-Loop and Delta-T (*see* Vol. 1, No. 4, July 1980). An 1800-case trial of both Delta IUDs in ten centers is underway in Tunisia, and a similar trial of 6000 cases with the Delta-Loop is expected to begin shortly at ten maternity hospitals in Turkey. The nationwide trials in both countries were instituted by the IFRP at the request of the two governments' Ministries of Health.

In both countries, the trials of the Delta IUDs will determine expulsion and continuation rates, the acceptability of the devices as a family planning method and the rates of accidental pregnancy and side effects associated with use of the devices. The IUDs will be inserted immediately postpartum. A woman who agrees to participate in the studies must have had a normal vaginal delivery, have no evidence of infection and agree to have the insertion performed during her hospitalization for delivery. Follow-up will take place at one, three and six months postpartum. Studies in both countries are expected to run for approximately one year.

Family planning work accelerates in Senegal

The head of a national family planning association in Senegal recently visited IFRP headquarters in Research Triangle Park, North Carolina, to discuss possible cooperative projects between the two organizations. Mr. Khouraïchi Thiam, the new Executive Secretary of the Association Sénégalaise Pour le Bien Etre Familial (ASBEF), emphasized his country's need for training and evaluation in the family planning field. The ASBEF, an affiliate of the International Planned Parenthood Federation, and the IFRP are designing projects that involve a series of seminars for community leaders in the three rural regions and a two-month instructional program for trained midwives, Senegal's *sage-femmes*, who carry the major responsibility for maternal and infant care.

Family planning is a new thrust in health care for Senegal. In December 1980, the new government under President Abdou Diouf (the former Prime Minister) repealed the 1920 law that had restricted development of family planning programs. Although the old law had permitted the sale of contraceptive products, it forbade publicity about them. The 1980 legislation allows such publicity. Thiam was particularly enthusiastic about Senegal's move toward family planning. "The average Senegalese mother may have as many as eight children, sometimes as many as 12, so we urgently need to educate our people about contraceptive methods," he informed us.

The ASBEF, which was created in 1975 and began active work in 1980, is a nongovernmental agency, but operates under the authority of Senegal's Ministry of Social Affairs. ASBEF's Scientific Committee, composed of physicians in private practice, evaluates and advises the association on matters concerning the safety of family planning methods and education of the community in limiting the number of children in each family.

Recent publications by IFRP staff

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M Potts. Drug Approval and Surveillance. Int J Gynaecol Obstet 18(5):313, 1980. (EVAL-67)

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Sri Lanka pill and vitamin trial produces important data

Preliminary results of a large-scale clinical trial of two different oral contraceptive (OC) preparations, with and without multivitamin supplements, have recently been made available by the IFRP and the Family Planning Association of Sri Lanka. Initiated in 1978, the project was jointly carried out by the Family Planning Association of Sri Lanka, with technical support from the IFRP and funding by the US Agency for International Development.

Three double-blind clinical trials conducted in three different sites in Sri Lanka were undertaken to determine (1) whether currently used oral contraceptives with standard doses of estrogen and progestogen should be replaced in Sri Lanka and other developing countries by lower-dose pill preparations and (2) whether a multivitamin tablet taken daily in conjunction with the OCs would reduce the side effects generally associated with OC use, and thereby improve rates of acceptance and continuation.

The clinical trials, which took place in one urban site (Colombo) and in two rural sites (the Matara and Puttalam Districts), consisted of a four-part comparative trial of two OC preparations with and without vitamin supplements. The four OC treatments, which were assigned blindly and at random, included Brevicon (0.5 mg norethindrone and 0.05 mg mestranol; Syntex, Humaçao, Puerto Rico) with multivitamin supplement; Brevicon with placebo; Norinyl (1.0 mg norethindrone, 0.05 mg mestranol; Syntex) with multivitamin supplement; and Norinyl with placebo. Norinyl is the standard OC in Sri Lanka; its side effects are known and widely tolerated.

Treatments were provided in two packets, one for the contraceptives, the other for the vitamins/placebos. The packets were identical except for contraceptive content and alphabetic code markings.

In Colombo, where women were recruited for the study at the Family Planning Association's clinic, acceptors were limited to 500 physically healthy women, 18 to 40 years old, from low-income areas who had reasonable access to the clinic to facilitate follow-up. Acceptors participated for 12 menstrual cycles of treatment, with women being selected for the study according to a detailed protocol. The urban study was directed by Dr. Sriani Basnayake, Medical Director of the Family Planning Association of Sri Lanka.

In Matara, 1635 women participated in the trial; there were 1186 acceptors in Puttalam. The rural trials were managed by Mr. S. Victor de Silva, Director of Evaluation and Research of the Family Planning Association.

Follow-up took place systematically and detailed information on 24 possible side effects was collected at each follow-up visit. In addition, a selected group of the urban acceptors kept daily symptom records during the course of the treatment; each of these women was visited at home to ensure that proper recording procedures were carried out.

A number of preliminary conclusions have been drawn from the data. The lack of effect of the vitamin supplements in all areas of the investigation was consistent and striking. According to the project monitor, Mr. Peter Miller of the IFRP, "The quantity and quality of information is sufficient to justify a firm conclusion on this topic: in the populations studied, the provision of a daily multivitamin supplement taken in conjunction with either of two types of OCs made no difference in either continuation or side effects associated with OC use."

A puzzling phenomenon in the data makes it difficult at this point to ascribe clear superiority to either the standard or the low-dose OC. In the urban study, the continuation rates for Norinyl were far higher than for Brevicon, but the difference is entirely explained by dropout for reasons that were apparently unrelated to the contraceptives themselves. Whether or not this is a genuinely method-related difference is under continuing study.

Rural differences in continuation rates between Norinyl and Brevicon are small. Urban side effect data show that Brevicon was, as expected, associated

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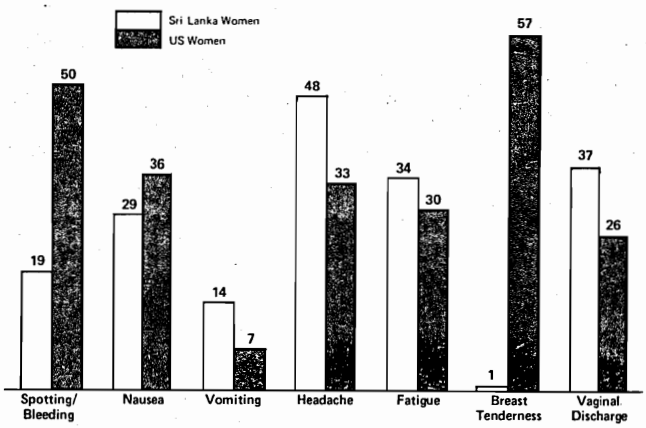
Male sterilization discussed 5

PERCENT OF SRI LANKA AND US NORINYL® USERS REPORTING SIDE EFFECTS DURING FIRST CYCLE FROM DAILY SYMPTOM RECORDS



Sources: For US data, RT Ravenholt *et al:* A comparison of symptoms associated with the use of three oral contraceptives: a double-blind crossover study of Ovral®, Norinyl® and Norlestrin®, Advances in Planned Parenthood *12:* 222, 1978. Sri Lanka data are from Colombo women who filled out daily symptom records.

with higher levels of breakthrough bleeding, and Norinyl was associated with higher levels of most other common side effects, with the notable exceptions of nausea and vomiting. Rural data were less conclusive, but there seemed to be more complaints of menstrual side effects among Brevicon users.

Differences among study sites in both side effects and continuation were generally far larger than differences among treatments, and some rather subtle variations in study execution were also associated with substantial differences in program results. This, Mr. Miller says, confirms the clinician's standard judgment: quality of care is usually more important than fine points of pharmacology.

For all treatments combined, headache was the most commonly reported symptom, with a variety of other symptoms commonly reported but at a somewhat lower level. Breast discomfort was surprisingly rare. Depression was also rather uncommonly reported—a fact that may result from the makeup of Sinhalese culture: there is no Sinhalese word for depression.

Most striking was the decline in reported symptoms over time for nearly all symptoms. These data, like others, suggest that for women who continue using the pill for several months, side effects become increasingly less obtrusive. Levels of reported side effects were also compared with a previous Sri Lanka study and one US study that used comparable methodology. The levels obtained in the previous Sri Lanka study were generally confirmed. The figure shows a comparison of recorded side effects from the US study with data from women in the Colombo study site.

Mr. Miller comments, "In all three sites, complex, large-scale clinical trials were executed with a high level of fidelity to sound research principles. The urban data, in particular, are of sufficiently good quality to be of international importance. The quality of these data is a high tribute to the competence and integrity of the Family Planning Association of Sri Lanka." A final comprehensive report on the Sri Lanka pill and vitamin project will be available in February 1982.

IFRP studies child-spacing trends in subSaharan Africa

In late 1980 the IFRP conducted a study of the changing patterns of breast-feeding, postpartum sexual abstinence and use of modern contraceptive methods among women of reproductive age living in metropolitan Lagos, Nigeria. Directed and coordinated by Dr. Paulina K. Makinwa, Senior Research Fellow of the Centre for Social, Cultural and Environmental Research at the University of Benin, Benin City, Nigeria, and monitored by IFRP Research Associate Douglas Nichols, the survey set out to:

- calculate cumulative and current fertility levels,
- assess the impact of breast-feeding and postpartum sexual abstinence on birth intervals,
- examine the use of and demand for modern methods of child-spacing and
- evaluate the consequent implications for fertility levels and use of family planning in the 1980s.

In many of the rapidly growing urban areas of subSaharan Africa, traditional child-spacing practices of prolonged breast-feeding and postpartum sexual abstinence are breaking down more rapidly than modern methods of family planning are being adopted to replace them. In traditional societies in which modern contraceptive methods are unknown or unavailable, prolonged breast-feeding and the widespread practice of postpartum abstinence have resulted in average birth intervals of up to three years.

As Africa modernizes, however, these long-standing practices are changing. The popularity and successful marketing of infant formula has effected a tremendous increase in bottle-feeding: not only are fewer women breast-feeding their babies, but those who do are breast-feeding for shorter periods of time. Postpartum abstinence from sexual relations is also becoming less common and of shorter duration. These changes are occurring most rapidly in urban areas, and particularly among educated women and those who work outside their homes.

Lagos is the largest city in tropical Africa and the capital of the continent's most populous country. The changes now occurring in Lagos are likely to ensue in other African cities in the near future, making the understanding of the dynamics of child-spacing obtained from this survey both of regional and local importance.

The existing division of Lagos into well-mapped Census Enumeration Areas enabled the investigators to conduct individual household interviews with all women aged 15-49 years from a representative sample (N = 3178) of the entire metropolitan population. Household interviewing began in August 1980 and continued for approximately three months. Interviewers were recruited from the nursing staffs of two Lagos hospitals and were given a week-long training course in interviewing techniques by Dr. Makinwa.

A total fertility rate of 6.56 was calculated from the data. When compared with a mean cumulative fertility of 6.19 among women aged 45-49, it does not appear that fertility in Lagos is on the decline. On the

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contrary, preliminary findings suggest that fertility is, in fact, increasing. The high level of cumulative and current fertility among women in the sample is reflected in the respondents' low levels of awareness and practice of modern family planning methods.

The interviewers collected information from women aged 15-49 regardless of marital status. However, because fertility behavior and patterns of contraceptive use differ substantially between married and unmarried women, the preliminary analysis of the data is limited to the 2352 women (74% of the total sample) who are currently married. A separate examination is planned on the use of and attitude toward family planning among the 710 women in the study who have never been married.

Nearly half of the married women had heard of a modern method of family planning, and almost two thirds knew of one or more traditional child-spacing practices. Although many were aware that breast-feeding and sexual abstinence are associated with a reduced likelihood of pregnancy, they did not tend to consider either as a means of contraception.

Slightly fewer than one fourth (23%) of the women were currently using a method of family planning. Of these, 7% were using a modern method (mostly pills); 3%, a conventional method (condoms); and 14%, a traditional method only. Interestingly, many women reported that they were currently breast-feeding or abstaining from sexual relations for *other* than contraceptive reasons: 70% of those breast-feeding and 65% of those abstaining did not consider the practice as a method of family planning.

Among women whose last pregnancy resulted in a surviving live birth, breast-feeding was practiced by over 85% during the first two months, and declined slowly until a rapid drop at 9-11 months. Only 25% were still breast-feeding after 12 months postpartum. Abstinence was practiced by fewer women in the immediate postpartum period (55%-60% in the first six months), but did not show the sharp decline at the end of the first year as did breast-feeding. As a result, more women were practicing abstinence in the second and subsequent postpartum years than were continuing to breast-feed.

In response to the question, "Why do you practice family planning?", 84% answered "to postpone the next pregnancy," and only 15% answered "to avoid a future pregnancy." Almost all of the 15% were aged 40 and over and already had large families. Among women in Lagos, it is clear that family planning is desired more as a means of spacing wanted children than as a means to limit fertility.

For women who are abandoning the traditional child-spacing practices, there is an urgent need for alternative methods of family planning. The availability of safe and effective modern contraceptive services is today far from a reality in the rapidly growing urban areas of subSaharan Africa, but it must be recognized as a compelling need if couples are to be able to have the number of children they wish tc have and to space pregnancies adequately to ensure the optimal health of both mother and children.

Levonorgestrel-releasing IUD to be compared with copper device

The IFRP has awarded the Population Council a subcontract to study a levonorgestrel-releasing IUD (Fig. 1). Levonorgestrel is a synthetic progestin, formerly known as d-norgestrel. The new device was developed to combine the long-lasting effectiveness of subdermal implants with the ease of placement and removal of an IUD.

The levonorgestrel IUD uses the polyethylene body of the Nova T device to support a silastic cylinder that consists of two components: one is a core containing levonorgestrel dispersed throughout, and the other is a covering of silastic tubing that slips over the core to control the rate of levonorgestrel release. Preliminary investigations by the World Health Organization and the Population Council have shown that the new device is associated with a low volume of blood loss, a factor important in many developing countries where anemia is a frequent problem.

The Population Council will evaluate the performance and safety of the levonorgestrel IUD in comparison with the Council's TCu 380 Ag device. The TCu 380 Ag IUD carries two sleeves of solid copper on the crossbar and a coil of copper wire, with a core of silver, around the stem. A total of 1100 insertions (550 of each device) will be randomly assigned to women at three study locations.

Study volunteers will be physically healthy, menstruating women who desire IUD contraception. Prior to admission to the study, each potential subject will receive a routine physical examination, which will include breast and pelvic examinations and a Papanicolaou smear, to screen for contraindications.

All the women in the study will be followed for one year. Follow-up visits will be scheduled at 1, 3, 6 and 12 months postinsertion and at any other time should an individual problem arise.

At one year postinsertion or at termination of IUD use for any reason prior to one year of use, the women will be questioned on their perception of changes in menstrual patterns, side effects and their likes and dislikes about the levonorgestrel and TCU 380 Ag IUDs.

The study is expected to take two years to complete.

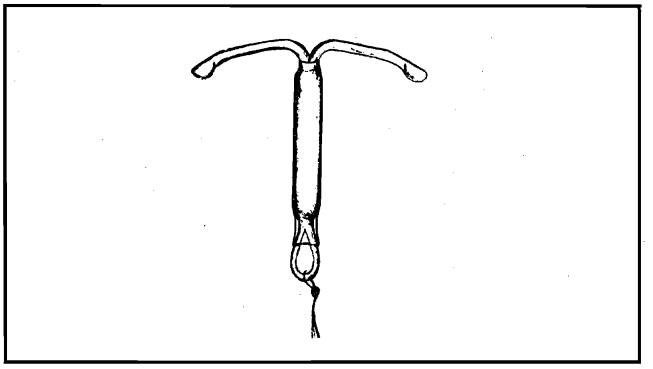

Fig. 1. Levonorgestrel-releasing IUD carries about 65 mg of the synthetic progestin. The Population Council device is manufactured by Leiras in Turku, Finland.

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Cervical osmotic dilator under development at IFRP

The IFRP's Medical Associate, Dr. Pouru Bhiwandiwala, and Bioengineer Robert G. Wheeler are primarily responsible for what many physicians have called "a significant advance in gynecologic technology."

The subject of such acknowledgments is a new cervical osmotic dilator. This is a simple device consisting of a polyvinyl alcohol sponge that is saturated with magnesium sulfate (approximately 0.7 gm) and compressed to form a thin cylindrical tent (Fig. 1). When inserted into the cervix, it can bring about significant dilation of the cervical canal within two hours.

Dilation of the cervix is one of the most common gynecologic procedures and is the initial step in a number of diagnostic and therapeutic indications. However, despite its frequent use, cervical dilation can sometimes be difficult to perform and can result in immediate and long-term complications.

Currently, the most atraumatic method of dilating the cervix is the use of laminaria (a type of kelp), a method particularly popular in Japan and parts of Europe. Use of laminaria is safe but often impractical in developing countries because of its high cost and irregular availability. Also, because cervical dilation with laminaria takes up to 24 hours, the woman must be hospitalized overnight or must make an additional trip to the clinic or hospital the next day for completion of the intended procedure.

In the United States, the use of graduated metal dilators is the most common method of cervical dilation. Metal dilators are also popular in many developing countries. Although these instruments produce rapid cervical dilation and can easily be sterilized, and thus reused, they do present some drawbacks. Because the dilators are manually manipulated, their safety and success vary with the experience and skill of each physician. If too much force is applied, cervical lacerations and tears and uterine perforations can occur. Long-term effects such as cervical stenosis or incompetence have also been reported. Prostaglandins have also been used for cervical dilation, but they are associated with side effects.

The IFRP's cervical dilator acts basically as a pump. Magnesium sulfate is an osmotic substance that displaces and draws out fluid from the cervical tissue. This displacement of fluid makes the cervix soft and produces a gradual and atraumatic dilation of the cervical canal.

Currently, the IFRP is conducting small preliminary studies to test the safety and efficacy of the cervical osmotic dilators. In one study, Dr. Filshie of the University of Nottingham in England conducted a comparative study of three types of dilators to measure the force of cervical resistance. The pressure recordings showed that compared to metal dilators (Hegar) and to natural laminaria, the osmotic dilator caused the least amount of force on the cervix (*see* graph).

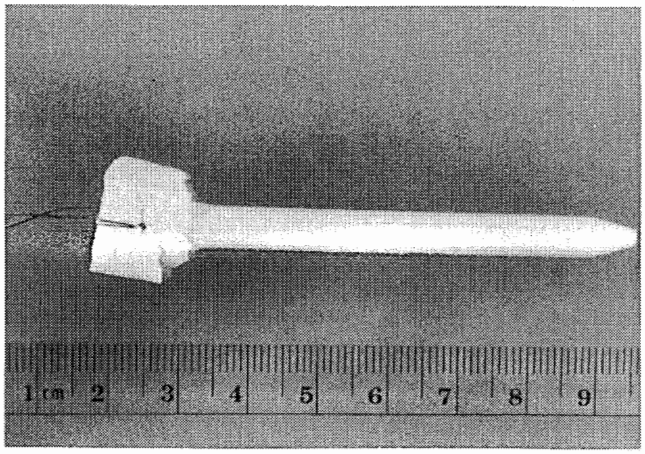
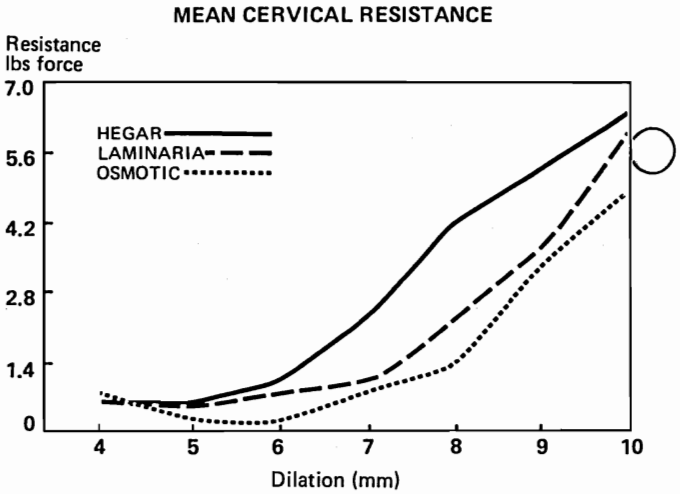


Fig. 1. The cervical osmotic dilator is a polyvinyl alcohol sponge saturated with magnesium sulfate and compressed to form a thin cylindrical tent.



Findings from preliminary studies have also shown that there is no uterine activity when the osmotic dilator is used, as the device acts exclusively on the cervix. Furthermore, samples of blood that were analyzed before and after cervical dilation with the osmotic dilator showed that the levels of magnesium remained within the normal range.

If the results of these studies continue to prove the dilators to be safe and effective, additional studies will be conducted to compare them further with other traditional methods of cervical dilation.

Because the cost of laminaria is high and the supply irregular, the development of an inexpensive and effective synthetic dilator meets a definite need.

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Experts discuss percutaneous male sterilization

There is a growing concern that the demand for sterilization in the developing world cannot be met by the use of surgical methods alone. Early this year, scientists attending a meeting at the IFRP to discuss the current status of chemical approaches to sterilization of women concluded that quinacrine was the most promising of these methods. To evaluate nonsurgical methods of male sterilization, the IFRP brought together on June 19 a number of investigators from industrialized and developing countries for exchange of experiences in designing related techniques.

The vas deferens is a difficult tube to block. The epithelium regenerates rapidly, and it is filled with fluid and sperm that tend to follow any tracks that exist. The aim of any occlusive procedure is to kill the epithelium, expose the subepithelial layers and allow fibrosis to take place before the epithelium can regenerate and the sperm can move forward again.

Nonsurgical male methods under study are administered percutaneously. For men who are reluctant to undergo surgery, a percutaneous procedure may be more acceptable. Its advantages are simplicity and safety, and it may be more easily performed by paramedics than vasectomy, an important consideration in rural areas where physicians are scarce.

Two types of percutaneous procedures are being evaluated. In the first, no attempt is made to locate the lumen of the vas. Instead, the vas muscle is targeted. In the second type, the lumen is located and targeted. Two different occlusion techniques of the first type have advanced to human trials.

Dr. Joseph Davis of New York has developed a chemical method using a solution of 3.6% formaldehyde in 90% ethanol. The solution (0.25-0.50 ml) is injected at ten different sites along a 1-cm segment of the vas using a specially designed clamp and a 25-gauge needle. In his most recent series, 25 volunteers participated. Seventeen became azoospermic after a single injection. There were four documented failures, and the rest were lost to follow-up. Two men with failed procedures chose to have a second injection, and both became azoospermic. This suggests that the sclerosing agent is effective when the agent is properly delivered to the vas muscle.

The IFRP is assisting in the development of a modified clamp that would ensure appropriate delivery of the agent to the vas. The panel decided that a single study should be performed to duplicate Dr. Davis' work using the modified clamp. If results are favorable, the IFRP will undertake an expanded field trial.

The second method was developed by Dr. Edwin Adair of Denver, Colorado who uses electrocoagulation to occlude the vas. A bipolar needle electrode is inserted a few mm into the vas muscle, current applied for a few seconds and the electrode withdrawn. Adair had a 100% success rate in his small series in Denver. However, when this method was applied by two investigators in Brazil, results were poor. The panel decided that the electrode and equipment should be redesigned to permit continuous monitoring of electrical energy delivered to the vas and that modifications be retested in animals before further human trials are initiated.

The percutaneous procedure where the lumen is targeted was developed in China. A chemical sclerosing agent is injected directly into the vas. According to the literature, 50,000 procedures have been performed. The IFRP will explore this technology.

Dr. Ronald Lewis of the Delta Primate Center raised the possibility of chemical occlusion, or electrocoagulation, of the tail of the epididymis, where, it is surmised, damage might be easier to achieve than blockage of the lumen of the vas. The tail of the epididymis is palpable and free of major blood vessels. Calcium chloride injected into the epididymi of rams to produce sterile males for veterinary purposes is known to be successful. Methylcyanoacrylate (MCA) is among the possibilities for use in humans.

The Nylon T vs the TCu-200 IUD

Findings from a recently completed study comparing the nylon-wound T and TCu-200 IUDs suggest that the Nylon T device is not as effective as first thought.

The Nylon T was designed to test the hypothesis that the effectiveness of a copper IUD is attributable to the increase in surface area of the device rather than to the copper itself. The experimental T device's vertical stem is wrapped with 200 sq mm of nylon.

An earlier study of the Nylon T in 98 women yielded favorable pregnancy and continuation rates (*see* Vol. 2, No. 2, January 1981). However, findings from two comparative studies of the Nylon T and the TCu-200 in which the devices were randomly assigned to a total of 400 not-recently-pregnant women suggest that the copper itself may have a more important role in preventing pregnancy than the increase in surface area, as shown in the table below.

Six-month event rates for the Nylon T and TCu-200 IUDs.

	Nylon T *(N = 108)*	**TCu-200** *(N = 113)*
Pregnancy rate ($p < 0.05$)	8.5 ± 2.9	0.0 ± 0.0
Expulsion rate ($p > 0.10$)	1.1 ± 1.1	1.0 ± 1.0
Discontinuation rate	2.2 ± 1.6	0.0 ± 0.0

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IFRP adopts system for reporting rare adverse events

The IFRP has devised for its collaborating investigators a system for reporting rare adverse events associated with contraceptive methods. The adoption of the new system was prompted by the IFRP's experience with different methods of contraception, which has indicated the importance of following up rare adverse events such as cardiovascular disease among pill users or pelvic inflammatory disease requiring hospitalization among IUD users. "Some of the major decisions that have been made about the management of contraceptive users have been made on the basis of data coming from the recording of these rare events," asserts Malcolm Potts, IFRP's Executive Director. "A system of reporting rare events in Great Britain has worked well."

Each IFRP investigator has been supplied with preaddressed envelopes with cards (Fig.1) designed to collect basic information on contraceptive side effects. The IFRP is asking that a completed card be returned if contact is made with any person who has a major side effect that might be related to a contraceptive method. Investigators are also requested to report an event if it is believed to be related to previous contraceptive use, regardless of duration of use or length of time since last use. Any information sent to the IFRP will be considered confidential.

"Our intention is not to measure the rates at which rare events occur or even to prove hypotheses. We realize that our reporting system cannot be comprehensive, but if investigators from two or three different parts of the world alert us to similar unusual events, we might recognize certain trends in unforeseen side effects and could then devise a special follow-up study," Potts explains. Although investigators have had to cover mailing costs, "the response to date to the reporting system has been gratifying," he says. "This is a major new initiative that the IFRP is undertaking in response to requests from collaborating investigators and health officials around the world. We think a worldwide reporting system for rare adverse effects of contraception will improve the quality of care the investigators provide and increase the safety of contraceptive care."

Contributor's Name _____

Center Number _____

Clinic Chart Number _____

Age _____ Parity _____

Method of contraception believed to be associated with event _____

Length of Use _____

Description of Event _____

_____

_____

_____

_____

_____

_____

_____

If patient was previously in an IFRP study:

Study No. _____

Patient Order No. _____

Fig. 1. Card supplied to all IFRP investigators for reporting rare adverse events associated with contraceptive methods.

Dr. Bhiwandiwala appointed to new position

The IFRP is pleased to announce the joint appointment of Dr. Pouru P. Bhiwandiwala to the positions of Medical Associate and Deputy Associate Director for International Projects.

Dr. Bhiwandiwala has been with the IFRP since 1974 and was a member of its Research Scientists group before assuming her new responsibilities. As Medical Associate, Bhiwandiwala works closely with Medical Director Dr. Leonard E. Laufe to develop, implement and evaluate research on the safety, effectiveness, acceptability, cost and demographic impact of various contraceptive methods, as well as systems for delivering health and family planning services. In addition, Bhiwandiwala will assess regional clinical research needs, provide guidance on the medical aspects of the IFRP's research and represent the IFRP within the international medical community.

As Deputy Associate Director for International Projects, Bhiwandiwala is responsible for the day-to-day administration of a professional staff that monitors the IFRP's worldwide research and programmatic activities and serves as a liaison between the IFRP and collaborating investigators. Bhiwandiwala is an obstetrician and gynecologist and has a Fellowship in Surgery from the College of Physicians and Surgeons in Bombay. She also holds degrees in family planning and population, maternal and child health care, and infant diseases from the University of Bombay, the College of Physicians and Surgeons in Bombay, and the University of North Carolina.

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In memorium: Rosa Cisneros

Sooner or later most of the people in family planning attend conferences. In 1976 The Pathfinder Fund of Boston held a meeting on New Developments in Fertility Regulation. I heard a vivacious and intelligent woman lawyer from El Salvador talk about the legal status of menstrual regulation, or very early abortion, in her country. Over coffee, I heard a little of her work helping the poor slum dwellers secure their rights to the land on which they had built the shacks they called home.

We now know that at about the same time private diplomatic messages were going from the US Embassy in El Salvador pointing out how the many problems of the country were being aggravated by rampant population growth.

I met the lawyer several times subsequently, most recently at the 1981 Conference on Family Planning in the 1980s, held in Jakarta, Indonesia. We had a drink beside the hotel pool in the brief, humid, tropical twilight. Suddenly, there was a clap of thunder and Rosa jumped out of her chair; then she relaxed, smiled and said, "Oh, I thought I was in San Salvador!" She told me how her life had been threatened, but how the Demographic Association, of which she was the Executive Director, had never been busier: the voluntary sterilization clinic had many requests, contraceptive sales were going well and the Association was even finding time to send research data to my organization in North Carolina.

People who work in development tell themselves that family planning brings health to families, implements a basic human right and helps unlock some of the tangled problems of social and economic progress. But for most, ideals do not translate into the stark choices that faced Rosa Cisneros. She was an internationally known professional and, unlike most people in El Salvador, could have sought asylum in one of several countries instead of going back in May.

On August 18, 1981, as she left her home to go to the family planning office, she was halted by a carload of gunmen, who dragged her to their car and hit her with submachine-gun fire. Wounded, she struggled to rise, and one assailant turned back and fired three shots in her face. Rosa was 42.

It is not known if the right wing killed her because of the help she extended to the poor, or the left wing because they disliked her family planning activities.

Rosa Cisneros was by no means the first person to die seeking justice for others, but she was the first person in history to die because of leadership in family planning. What would she wish us to learn from her death?

Perhaps it would be the need to face the reality of the need for family planning and the-ever present problem of abortion, to which she so often drew attention. Perhaps it would be the general theme that is tragically characteristic of all development efforts and especially of family planning—that too little is done too late and too timidly. Will other countries become El Salvadors, as brittle political situations crack apart under the continuous chafing of population growth, gross unemployment and apparently incurable gaps between rich and poor?

Perhaps, above all else, it should be the essential simplicity of the need for family planning that Rosa typified: to respect other people's choices and to provide an honest service that is culturally and economically accessible. Perhaps she would not have died if more people had stood up for the same cause at an earlier stage in the history of her country. Perhaps, if we do not learn a lesson from El Salvador, the tragedy of this type of death will become more common.

Malcolm Potts
Executive Director

Williamson joins IFRP staff

The IFRP has recently added a new Senior Program Development Associate to its International Projects Department staff. Dr. Nancy E. Williamson comes to her new post after a year as a postdoctoral fellow at the International Laboratories for Population Statistics at the University of North Carolina's School of Public Health. Earlier, she attended Harvard University, where she earned a Master's degree in Demography and Human Ecology and a PhD in Sociology. She has worked on behalf of the Population Council in the Philippines, where she was Research Advisor to the Bohol Province Maternal and Child Health/Family Planning Project for four of its five years; in India and Taiwan; and at Brown University and the East-West Population Institute.

During August and September, Dr. Williamson and a consultant to IFRP, Mr. Shyam Thapa, spent a month in Nepal, conducting a course in research methods for staff on the National Commission on Population and the Family Planning Association on Nepal. The emphasis was on giving participants practical knowledge that would assist them in their work as research officers.

Dr. Williamson is particularly interested in increasing the program relevance of population research and developing simple and inexpensive ways of evaluating programs in order to improve their functioning and impact. At the IFRP, she will be concerned with program development, evaluating subgrants, writing grant proposals and staff development.

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Program management skills enhanced at training seminar

The IFRP has initiated a comprehensive three-week training program for managers of various national fertility research programs (NFRPs) to teach a broad range of administrative skills. The first Program Manager Seminar, which was held at IFRP headquarters August 10-28, had eight participants. The managers attended lectures, demonstrations and workshops, participated in group and panel discussions, and made field visits to local health services agencies.

All the activities, which were led by IFRP staff members, were designed to teach skills used in managing research organizations, field studies and information dissemination. Specific skills emphasized included the ability to use computerized data processing techniques; to interpret computer outputs; to maintain and prepare financial and narrative reports; to organize meetings and conferences; to disseminate findings; and to prepare and submit grant applications.

The primary purpose of the IFRP's overall training strategy is to enhance NFRP effectiveness by upgrading the professional, managerial and clinical/research skills of NFRP staff and other investigators. IFRP's goal is to train researchers who can actively work with IFRP staff members as equal partners in the development and conduct of well-designed research projects. The national programs are expected to benefit from the training through more cost-effective operations, better implementation of research studies, and improved and diversified dissemination of information.

Participants in the seminar included: Dr. Dedeh Sudjana, Bandung, Indonesia (Coordinating Board of Indonesian Fertility Research—BKS PENFIN); Ms. Chitra Pasuk, Bangkok, Thailand (Thailand Fertility Research Association); Dr. Mohammad Gaffar, Bandung, Indonesia (International Federation for Family Health); Mrs. Saadia Mohamed Idris, Khartoum, Sudan (Sudan Fertility Control Association); Dr. Liliane Toumi, Paris, France; Ms. Hyacinth Robinson, Sudan (Sudan Fertility Control Association); Dr. Igusti N. Agung, Indonesia; and Dr. Carlos Augusto Laudari, Brazil.

Recent publications by IFRP staff

I-c Chi, SD Mumford and SD Gardner. Pregnancy Risk Following Laparoscopic Sterilization in Nongravid and Gravid Women. J Reprod Med *26(6)*:289, 1981. (FS-122)

I-c Chi, LE Laufe and R Atwood. Ectopic Pregnancies Following Female Sterilization. Adv Plann Parent *16(2)*:52, 1981. (FS-137)

B Janowitz, JH Lewis, A Parnell, F Hefnawi, MN Younis and GA Serour. Breast-feeding and Child Survival in Egypt. J Biosoc Sci *13(3)*:287, 1981. (Eval-61)

M Potts. Childbirth in Fortaleza. World Medicine, p. 75, 1980. Reprinted in Profiles *4(2)*:11, 1981. (SP-33)

Book on vasectomy counseling is published in Spanish

Vasectomy Counseling, written by IFRP staff member Stephen D. Mumford, and published by San Francisco Press, has been translated into Spanish for distribution to family planners throughout Latin America. The author has had considerable experience advising on vasectomy and has done substantial research in both the biomedical and social aspects of this surgery.

Although vasectomy is a family planning method encouraged in the United States, it is not widely used in Latin America. "This is primarily a result of the lack of services and information available to men seeking a permanent method of limiting the number of their children," Mumford asserts. "My book frankly discusses all aspects of the male sterilization procedure. It answers most of the questions raised by prospective candidates for this minor surgical procedure, which is usually performed on an outpatient basis, under local anesthesia."

The book, which is in its second printing in English, has been recommended for the professional involved in delivery of this method of contraception. The new translation will be distributed by the Asociación Pro-Salud Maternal, a privately funded agency operating in Mexico for the last ten years. The Asociación provides family planning services for middle- and lower-income people and training programs for paramedical personnel.

Orientación Sobre Vasectomía will be available without charge in November 1981. Address requests to: Genoveva Mora de Hamilton, Directora; Asociación Pro-Salud Maternal, San Luis Potosí 101, 1er Piso, Apartado Postal 7-1050, México 7 D.F., México.

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Can breech babies be safely delivered vaginally?

Whether or not breech babies can be safely delivered vaginally will be the subject of a one-year IFRP study of more than 10,000 breech deliveries. The research will be supported by a grant from the National Institute of Child Health and Human Development (NICHD). Based on the hypothesis that safe vaginal delivery of these infants depends to a large extent on the birth weight and gestational age of the fetus, the study will compare survival rates of infants delivered vaginally and abdominally for several weight categories. Morbidity, defined as a 5-minute Apgar score of less than 7, will also be evaluated. The information obtained through these comparisons will determine the relative risks and benefits to the mother and child of cesarean section vs. vaginal delivery as the birth weight and gestational age of the breech fetus change.

Previous research to determine the most beneficial method of delivering breech babies has produced mixed results. Reports of no significant differences in survival rates for vaginal and abdominal deliveries of breech babies exist alongside reports citing one or the other as preferable methods. In 1981, the National Institutes of Health Cesarean Birth Task Force concluded that existing data were insufficient to make a firm recommendation on delivery of the low-birth-weight breech baby.

Earlier, in a symposium on management of breech presentations sponsored by the journal *Contemporary Ob/Gyn*, the participants concluded that the physician's experience was a crucial factor: inexperienced physicians should always deliver abdominally, while more experienced ones could successfully deliver breech babies vaginally.

A problem with much of the research/literature is that the improved mortality of breeches has occurred concomitantly with rising cesarean section rates, leading many to conclude that they are related. However, in many hospitals, neonatal intensive care has also improved dramatically over the same period of time, and this is more likely to be the important factor.

Other studies have taken care of the small sample size problem by considering many years of data. This technique exaggerates the association between cesarean section and improved mortality.

The data to be used in the IFRP study will be obtained from the Maternity Record. The Maternity Record has been used by many institutions around the world and has been endorsed by the International Federation of Gynaecology and Obstetrics. The complete data set consists of approximately 17,000 breech births selected from some 415,000 delivery records from 75 contributing hospitals. All cases of multiple gestations, life-threatening congenital anomalies and antepartum deaths will be excluded from the 17,000 cases ,as will data of suspect quality. The resulting number of cases to be studied will approximate somewhat more than 10,000.

According to the Principal Investigator, Dr. Judith Fortney, "The overriding problem with previous research on breech births has been that of sample size. All the studies published to date have suffered from the small number of cases available for analysis. The large size of the Maternity Record data set improves the chances of finding a large number of breech presentation infants, which allows us to cross-classify by type of breech presentation, type of delivery, gestational age, and type of hospital. The large data set also significantly improves our chances of discovering rare effects associated with breech presentation and delivery techniques."

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Demand for sterilization in the 1980s to exceed supply, say IFRP researchers

Voluntary sterilization is the world's most prevalent method of fertility regulation, but in the developing world, the demand for sterilization will far exceed the supply of services in the 1980s. Writing in the June issue of *Fertility and Sterility* (Potential demand for voluntary sterilization in the 1980s: the compelling need for a nonsurgical method), IFRP's Drs. Elton Kessel and Stephen D. Mumford estimate that the need for voluntary sterilization in developing countries during the 1980s will approximate 180 million procedures.

The authors contend that current female sterilization technology, coupled with inadequate health care delivery systems in the developing world and the predominance of rural residents among the population make it unlikely that the projected surgical sterilization needs can be met. Hope may exist, however, in the development of new sterilization technology, such as the intrauterine administration of quinacrine pellets for nonsurgical sterilization (*see* Vol. 2, No. 3, April 1981).

In estimating the potential need for sterilization in the developing world, Kessel and Mumford cite the high levels of prevalence in all countries where sterilization is readily available (*see* Fig. 1). According to *Population Reports*, Series E, No. 6, 1981, Panama has already achieved a prevalence of 30%; Puerto Rico has maintained a prevalence of about 33% for more than 20 years. Singapore has achieved a prevalence of 22%; India and Korea, 20%; and Sri Lanka and El Salvador, 18%.

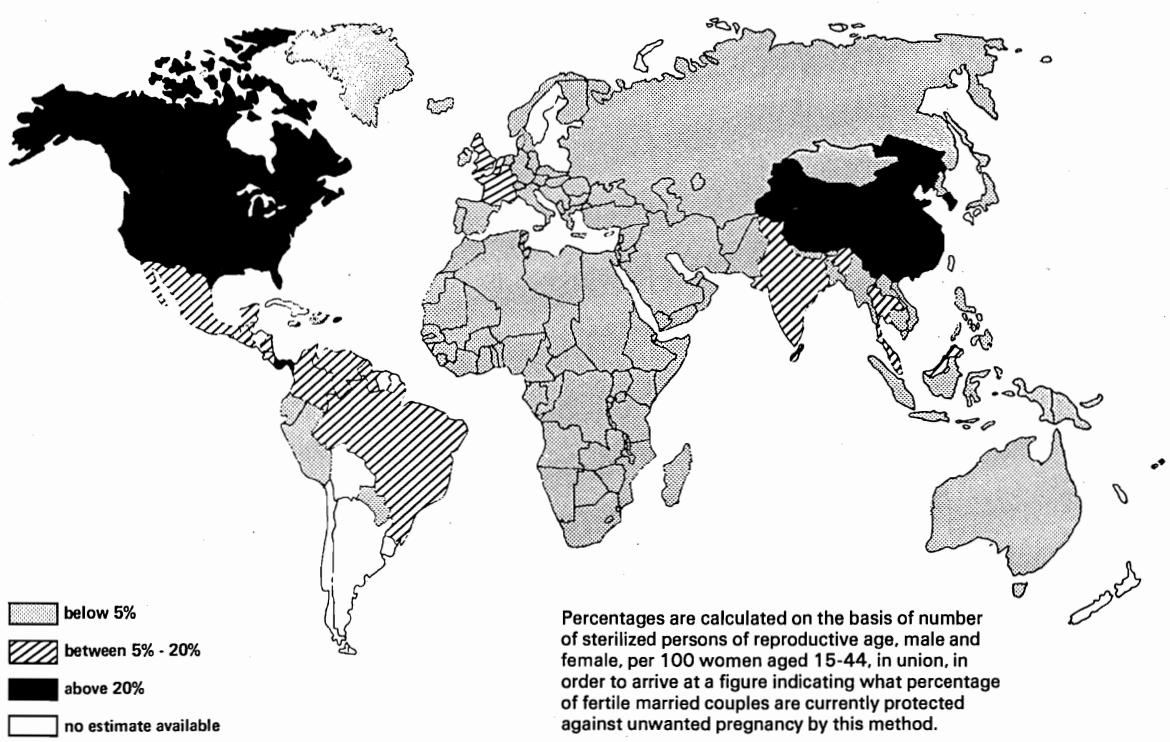
Mexico experienced the largest increase in voluntary sterilization reported by any large country in the world, from 13,000 in 1974 to 130,000 in 1977, a tenfold increase. Given these rates, the authors base their projection of demand in the 1980s on the assumption that if sterilization were made fully available, the US rate of 31.3% would prevail worldwide.

The estimated 180 million procedures they project for the developing world (excluding China) represent a fivefold increase over the number of procedures currently performed. Against this potential demand, the article reviews the existing sterilization technologies and delivery systems for accommodating large numbers of procedures, such as the camp sterilizations popular in India.

In one noteworthy example, 5000 voluntary sterilizations were completed in a rural setting in three months by one team of Indian gynecologists. Despite this kind of achievement and the wide range of female sterilization methods currently practiced, Kessel and Mumford state that it is "not possible to meet the demand with the sterilization technologies currently used even with an increase in resources several times the level that can be reasonably expected."

Their article also reviews promising new, nonsurgical sterilization techniques. A technique using liquid silicone rubber delivered through a hysteroscope t

Fig. 1. ESTIMATED WORLD PREVALENCE OF VOLUNTARY STERILIZATION 1980



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form a tubal plug is predicted to have limited use in the developing world because it requires considerable surgical skill.

Immunologic approaches—vaccines —are thought to "ultimately offer the near-perfect methods of both temporary and permanent contraception," but "they are many years away."

Finally, two chemical approaches are described: methylcyanoacrylate (MCA) and quinacrine. MCA is a tissue adhesive that is instilled into the fallopian tubes transcervically. The MCA causes tubal occlusion over a period of three months; animal studies have shown no ill effects from spillage of MCA into the peritoneal cavity. Further research to document MCA's safety, particularly its relationship to ectopic pregnancy, is recommended by the authors.

Kessel and Mumford are most hopeful about the potentiality of quinacrine pellets for nonsurgical female sterilization. Quinacrine, long approved for use as an antimalarial agent, is now being instilled as pellets inserted transcervically into the uterine cavity to cause permanent tubal occlusion. Results have been promising: pregnancy rates are higher than for conventional sterilization, but no ectopic pregnancies have been reported and other complication rates are low. "It appears that the quinacrine method of female sterilization offers the best hope for meeting the full demand" in the 1980s, say the authors.

Menstrual changes not caused by laparoscopic sterilization

Findings from a recent study by three IFRP researchers suggest that sterilization does not cause changes in menstrual patterns. The work by Dr. Pouru P. Bhiwandiwala, Associate Medical Director and Associate Director for International Projects, and Dr. Stephen D. Mumford and Paul J. Feldblum, both of the IFRP research staff, is reported in the May issue of the *Journal of Reproductive Medicine* (Bhiwandiwala et al: Menstrual pattern changes following laparoscopic sterilization: a comparative study of electrocoagulation and the tubal ring in 1025 cases.)

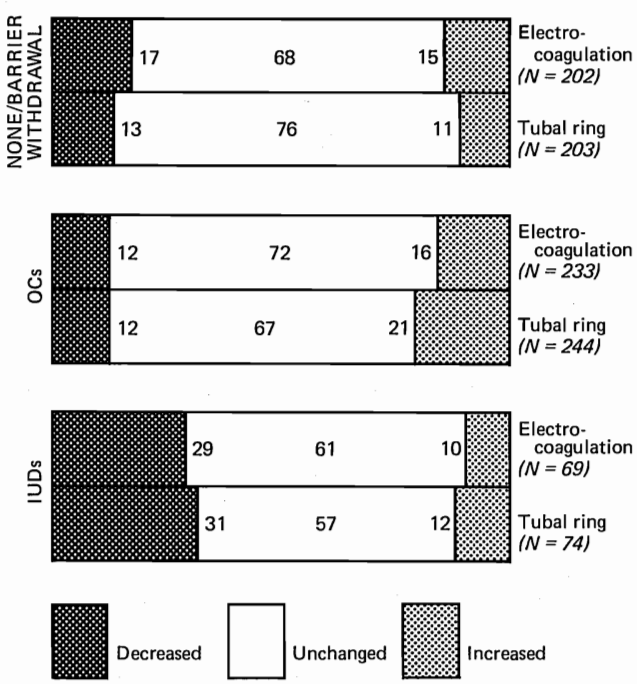
Their investigation compared the female sterilization techniques of monopolar electrocoagulation and the tubal ring to detect any differences in subsequent menstrual patterns. Data on 1025 cases were collected prospectively at five institutions in five countries. Menstrual pattern changes were determined by comparison of menstrual data collected at admission and follow-up visits. Six menstrual parameters were examined: cycle regularity, cycle length, menstrual flow duration, amount of flow, dysmenorrhea, and intermenstrual bleeding. Both occlusion groups were divided into three subsets according to contraceptive use immediately prior to sterilization: (1) no method/barrier method/withdrawal method, (2) oral pill, or (3) intrauterine device.

The majority of women in the study reported no change following sterilization. Approximately 10% (for dysmenorrhea) to 50% (for intermenstrual bleeding) of the menstrual pattern changes seen within six months following sterilization were attributed to the discontinuation of oral contraceptives or an IUD at the time of sterilization.

Using amount of flow as an example, Fig. 2 shows the effect of the discontinuation of the pill and IUD. As expected, more women discontinuing the use of the pill experienced an increased amount of flow and more women discontinuing the use of the IUD experienced a decreased amount of flow. Among women who were using no method or who were discontinuing a barrier method or withdrawal, the proportion of women experiencing a decrease approximately equaled the proportion experiencing an increase.

The study showed no statistically significant differences between electrocoagulation and the tubal ring techniques in the proportion of women who reported changes in their menstrual parameters. Other researchers have theorized that menstrual pattern changes are caused by sterilization as a result of interference with the blood supply of the tube and ovary. Electrocoagulation is much more destructive than the tubal ring, yet it caused no greater menstrual pattern disturbances. According to Bhiwandiwala, "The findings of this study definitely call into question the theory that sterilization causes menstrual changes."

Fig. 2.
Comparative Studies of Electrocoagulation and the Tubal Ring
Percent of Women with Change in Amount of Menstrual Flow from Admission to 6-month Follow-up *(N = 1025)*



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IFRP provides assistance to Senegalese association

Through a small subgrant, the IFRP recently provided technical assistance to the Association Senegalaise pour le Bien-Etre Familial (ASBEF). Ms. Nadine Burton, IFRP's Regional Coordinator for Africa, spent four weeks in Senegal in March and April as a short-term consultant; she helped ASBEF officials develop a program and budget for a grant proposal in family health to be submitted for USAID funding.

Senegal, with a 1980 population of 5,661,000, has one of the world's highest birth rates: for 1975-80, there were 47.8 live births per 1000 population (*see* Fig. 3).

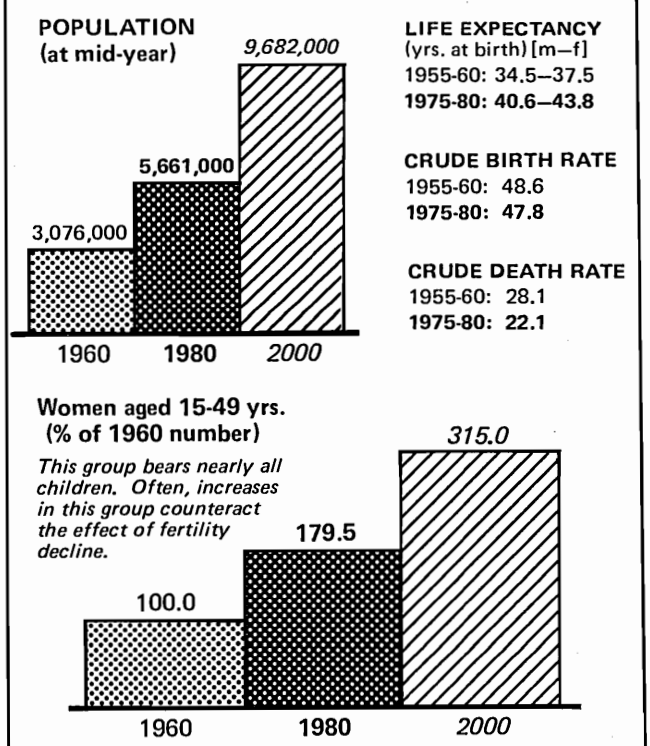
The Government of Senegal is currently in the process of implementing a large-scale Family Health Project, originally instituted by a 1979 agreement with USAID. The project was modified in 1982 to allow partial funding of ASBEF programs. This private, nongovernment agency is affiliated with International Planned Parenthood Federation-London and is also closely but unofficially linked with Senegal's Le Secretariat d'Etat à la Promotion Humaine (Secretariat for Social Affairs). Promotion Humaine is the government ministry responsible for defining and coordinating Senegal's national plan for family planning. Since 1980, ASBEF has conducted a family planning training course for nurse-midwives; surveyed the attitudes of the *marabouts* (Islamic religious leaders) toward family planning; conducted radio educational programs that promote the benefits of child spacing; and opened a small Model Family Planning Clinic in the Association's headquarters.

Under ASBEF's proposed expanded program, activities will include development of a clinical service program and an Information, Education and Communication program. The latter will emphasize to the Senegalese the positive impact of child spacing on the health of mothers and children and the direct relationship among child spacing, good nutritional practices, obstetric care, and well-baby care.

High-quality services and training and research programs are the major goals of the association, whose dynamic executive director, Mr. Khouraichi Thiam, visited the IFRP recently. The ambitious yet realistic program will place the ASBEF in a leading role in the development of Senegal's family health programs in the next five years.

The emphasis on family planning activities in Senegal comes at a time when fertility is being recognized by the government as a significant problem. According to the World Fertility Survey report on Senegal, the low use of contraception, the universality of marriage and the tendency to reduce the length of breast-feeding are combining to expose Senegalese women to a maximum risk of pregnancy. The report (The Senegal Fertility Survey 1978—A summary of findings, September 1981, World Fertility Survey) showed that only 4% of currently married women used a contraceptive method at the time of the survey.

Fig. 3. SENEGAL DEMOGRAPHIC DATA



Sources: United Nations Population Division & UNFPA

RAMOS progress to be reviewed

The IFRP has invited 11 experts to review the progress of its RAMOS studies currently underway in Bali, Indonesia, and Menoufia, Egypt.

RAMOS—the Reproductive Age Mortality Survey—is assessing the risks and benefits of contraceptive use by women in the developing world. Study data will be used to compare the mortality of women who do and do not use contraceptives, as well as to establish rates for all causes of death.

The RAMOS expert meeting will be held June 14 at the IFRP's Research Triangle Park, North Carolina, headquarters.

Participants in the meeting will include: Saad Gadalla, American University in Cairo, Egypt; Inne Susanti, BKKBN of Bali Province, Indonesia; Khairia Omran, East Tennessee State University; Herbert Peterson, Carolina Population Center, North Carolina; Diana Petitti, Kaiser Research Foundation, California; Roger Rochat and Allan Rosenfield, Columbia University, New York; James Shelton, US Agency for International Development, Washington, DC; Alan Spanos, University of North Carolina; Jeremiah Sullivan and Steve Wilson, Population Laboratories, North Carolina; Bradley Wells, Bowman Gray School of Medicine, North Carolina; and Nicholas Wright, Rutgers Medical School, New York.

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Project in Mexico compares types of community-based contraceptive distribution

A new research project initiated by the Centro de Orientacion Familiar (COF) in Mexico should yield important information on the implementation of community-based distribution of contraceptives. COF, a nonprofit organization founded in 1981 to provide family planning services to people not covered by Mexican Ministry of Health Services or insurance institutions, began the project in November 1981, with core support from the IFRP.

The project addresses two basic research issues. First, which system of contraceptive distribution at the community level produces the greatest levels of contraceptive use? One controlled primarily by community leaders, or a system in which a central office has direct control and supervision of distribution activities?

Second, is there any group of women in the project area who are put at greater risk of developing serious medical problems because they receive oral contraceptives (OCs) through a community-based distribution rather than directly from medical practitioners? And if so, how should the program be modified to provide adequate protection for these women?

The study will be carried out in two poor communities in Matamoros, Tamaulipas.

The community-controlled distribution system is being tested in Trevino Zapata (population: 8300). The organization, control and provision of supplies are in the hands of two volunteer women (coordinators) from the community who recruit, train and supply the four distributors. Physicians set policies and can receive referrals but are not directly involved in pill distribution.

The COF has served as a catalyst for organizing the group and is a resource for guidance, supplies and medical support. Particular attention is given to training in contraceptive methods, with special emphasis on the safe and effective use of OCs, and training in the maintenance of financial and service records. However, the coordinators are given essential day-to-day control over their program operations.

The design of the locally controlled system assumes that the combination of sales proceeds, interest in community service and opportunities for involvement in outside activities reward participants sufficiently to make the program work as a truly community-based program. COF also hopes to demonstrate that such programs can operate near self-sufficiency.

The COF-controlled distribution program is based in Colonia La Popular (population: 8000). COF hired, trained and pays the two coordinators, who meet once a week with a COF social worker who monitors their work. The distributors' work is spot-checked by the coordinators.

The second component of the Matamoros project—charting the prevalence of known reproductive risk factors—should help answer some of the issues surrounding community-based distribution systems. In this program, as in many others, women are offered OCs without physical examinations to screen for possible contraindications. Many of the women in the project area are already using OCs under these conditions, while others have physicians' prescriptions. There is international debate over whether it is appropriate to widen the distribution of contraceptives by reducing the level of medical support required. The study results will directly affect how the COF program is conducted because they will identify contraceptive and reproductive risk levels in the population for which screening may be particularly important.

Current and past OC users who receive their supply either by prescription or from nonprescription sources will be interviewed, along with a control group of never-users. Women will be interviewed by nursing students at their homes to obtain past history, current practice and future plans regarding contraception and childbearing. They will be examined for predisposing risk factors (eg, smoking, alcohol use, hypertension, diabetes, anemia). Diagnosis will be made from interview responses, a partial physical examination and simple clinical measurements done on the spot.

To test the validity of diagnosis, the project physician will give physical examinations, with appropriate laboratory testing, to a sample of the women. The experience gained in determining which methods of diagnosis are most appropriate will be a valuable result of the project.

The Miami-based Latin American office of Family Planning International Assistance is providing contraceptives and services of community-based distribution systems in the neighborhoods of Matamoros not covered by the COF-IFRP research project.

IFRP staff notes

• IFRP has announced the promotion of Dr. Pouru P. Bhiwandiwala to Associate Director for International Projects; she is responsible for overall supervision of a professional staff who develop and monitor IFRP's worldwide research and programmatic activities. Bhiwandiwala, also IFRP's Associate Medical Director, is the principal liaison between IFRP and its collaborating investigators.

• IFRP Executive Director Dr. Malcolm Potts has announced the establishment of an Office of Development and Government Relations, headed by Associate Director Peter J. Donaldson. His responsibilities include the development of new sources of funding, long-range planning, new business efforts, and liaison with government agencies.

• Dr. Stephen Mumford, a member of IFRP's research staff, has been named the recipient of the 1982 Humanist Distinguished Service Award that will be presented by the American Humanist Association at its annual meeting in June at the Massachusetts Institute of Technology, Cambridge, Massachusetts.

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IFRP moving ahead with plans to study natural family planning

Plans are underway to study the largest natural family planning (NFP) program in the world. IFRP is working with MOBRAL, the Brazilian Literacy Movement, to evaluate MOBRAL's recently initiated NFP program, which has begun to teach and encourage use of the ovulation (Billings) method of NFP throughout Brazil.

During the 1950s, new ways were developed to identify a woman's fertile period using cervical mucus and sympto-thermal methods. These methods are now known as NFP. With the ovulation method, women are taught to recognize estrogen-induced changes in the quality of cervical mucus, which indicate fertile and infertile days during the month. Sexual intercourse is then timed appropriately.

IFRP and MOBRAL, with US/AID support, are pursuing a plan to evaluate the NFP program for the dual purpose of improving the availability of family planning in Brazil and of making a critically important body of NFP experience accessible internationally. The evaluation will assess the teaching component of the program, its success in attracting users and retention rates of these acceptors, the community's knowledge, interest and use of the program, and the costs of making services available.

MOBRAL, which is run under the auspices of the Brazilian Ministry of Education and Culture, has signed an agreement with the National Conference of Bishops of Brazil that assures backing of the Bishops for MOBRAL's efforts to teach NFP.

Since January 1981, MOBRAL has trained 1254 of their staff at the state level and 4374 representatives from the Catholic Church. These then trained approximately 32,000 local monitors of MOBRAL and Church leaders. These will, in turn, train couples throughout Brazil in the use of the ovulation method.

Three MOBRAL staff members—Dr. Gerson Noronha, Dr. Helena Lewin and Ms. Rosana Sordi—recently spent two weeks working with IFRP staff to draft a detailed plan to evaluate the MOBRAL NFP program.

Recent publications by IFRP staff

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JD Shelton and JE Higgins. Contraception and Toxic Shock Syndrome: A Reanalysis. Contraception *24(6)*:631, 1981. (EVAL-77)

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Yugoslavian colleague visits IFRP

Dr. Mateja Kožuh-Novak, a staff member of the Gynecological Clinic of Ljubljana, Yugoslavia, recently visited the IFRP following seven months of study at the School of Hygiene and Public Health at Johns Hopkins University in Baltimore, Maryland. She spent one week at IFRP headquarters working on data from an IFRP-supported study involving 10,000 IUD insertions. The study was conducted at the Gynecological Clinic (formerly the Family Planning Institute) in Ljubljana and was directed by Professor Lidija Andolsek and Dr. Kožuh-Novak.

The IUD study covers a ten-year period and the data are being analyzed to determine rates of ectopic pregnancy, cervical dysplasia and pelvic inflammatory disease. Further, the data include women with multiple IUD insertions, which allows the incidence of side effects and events such as expulsion, termination, and pregnancy to be related to a woman who has a number of IUDs inserted over a ten-year period.

The Gynecological Clinic is a part of the Department of Obstetrics and Gynecology of Ljubljana's Medical University. The Department has over 7000 births per year. Ljubljana, in northern Yugoslavia, is the capital of the constituent republic of Slovenia. At an informal presentation during her visit, Dr. Kožuh-Novak estimated a birthrate of 16 per 1000 from a population of 2 million in Slovenia. The clinic, which has also been named a Human Reproductive Centre by the World Health Organization, has concentrated its research work in IUDs and oral contraceptives. Currently, however, it is doing an IFRP-related comparative study of two barrier contraceptive methods, in addition to its other research studies.

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IFRP becomes program of Family Health International

IFRP has become a program of the larger, newly named Family Health International organization, Executive Director Dr. Malcolm Potts, has announced. "Family health more accurately describes what we are doing and have been doing for some time. While we began as a small field trial agency studying various new contraceptives, over the years we have evolved into a broad-based research and institutional development organization. In addition to contraceptive research, our programs now include evaluations of maternity care, breast-feeding practices, and training and considerable efforts in the transfer of skills and equipment. The happy thing about our work the world over is that the well-being of mothers and children and the demographic needs of countries are complimentary to one another. There is never any conflict between working to save women from dying in childbirth and helping families to make fertility choices that will assist in development, education and economic progress. The new name better reflects the purposes and spirit of the work we conduct," said Potts in making the announcement on behalf of his Board of Directors.

IFRP will continue to operate as the major program of Family Health International, and "no change in corporate officers will occur," according to Potts.

Limited contraceptive use in Lagos

Results of a recent survey of the use of traditional and modern child-spacing practices in Lagos, Nigeria, indicate that the current level of fertility is at least as high, if not higher, than in the recent past. The IFRP-supported survey of reproductive-age women (*see* Vol. 3, No. 1, October 1981) determined that the use of effective modern methods of contraception is limited to a small minority of the population and that the demand expressed by these women for family planning services is clearly for spacing purposes. The survey also found that, on average, full breast-feeding (without supplements) lasts less than one month. As the intensity of breast-feeding is thought to significantly affect return to ovulation, this finding suggests that previous estimates of the demographic impact of breast-feeding in Nigeria may be seriously misleading.

The survey was directed and coordinated by Dr. Paulina K. Makinwa-Adebusoye, Associate Professor of Population Science at the Centre for Social, Cultural and Environmental Research, University of Benin, Benin City, Nigeria, and was monitored by IFRP Research Department staff members Douglas Nichols and S. Elizabeth Kelly.

It was undertaken to study the changing patterns of breast-feeding, postpartum sexual abstinence and use of modern contraceptive methods in a sample of Lagos women aged 15-49 years. Household interviewing was conducted for three months beginning in August 1980. Interviewers were recruited from the nursing staffs of three hospitals and were given a week-long training course in interviewing techniques.

According to the project's final report, a Total Fertility Rate of 6.57 may be calculated for the 2352 currently married respondents interviewed in the Lagos Survey. (Total Fertility Rate is a summary index that represents the hypothetical completed family size of a woman passing through her child-bearing years at age-specific fertility rates currently prevailing.) Compared with a mean cumulative fertility of 6.46 live births among all woman aged 45 to 49, it does not appear that fertility in Lagos is declining. Although the analysis shows that women with higher ed-

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ucation exhibit lower fertility, the difference is only appreciable among the comparatively few with schooling through the secondary level and beyond.

The women's low level of awareness and practice of family planning methods could be seen in the fact that even among fecund women who stated that they were neither pregnant nor trying to become pregnant, fewer than one woman in six practices modern family planning. "Indeed," the report continues, "were it not for the relatively widespread knowledge and practice of breast-feeding and postpartum abstinence from sexual activity, these levels of awareness would be substantially lower—and fertility commensurately higher."

The demand uncovered by the survey for family planning services shows a clear preference for spacing methods; of nonusers who wish to practice modern contraception and indicate a preference, fewer than one percent are interested in a permanent method. Nearly one half, however, are anxious to use "any method," a reflection of the noticeably limited knowledge of family planning.

The practice of breast-feeding continues to be virtually universal among women in Lagos. Of the 1813 respondents whose last pregnancy resulted in a live birth, 99% said they breast-fed their last-born child. However, data resulting from a question on the current status of breast-feeding show that the practice of breast-feeding declines precipitously six months after birth. The report concludes that "almost all mothers do breast-feed a newborn child, but the use of supplements starts at a very early age. Full breast-feeding is practiced by a very small minority of women." More research on lactation amenorrhea and the use and demand for modern family planning services among Nigerian women is currently being planned by the study's co-investigators.

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Maternity care project in Thailand addresses high death rates

In 1978, Thailand's maternal and infant death rates per 1000 live births were 0.4 and 55, respectively —considerably higher than rates in developed countries and even exceeding the rates of other countries in the region at a similar level of development. Faced with this significant national health problem, Thailand has begun a project to monitor one probable cause: inadequate maternal and child health services. Thailand's Ministry of Public Health and the Thailand Fertility Research Association have recently instituted a Maternity Care Monitoring project. It is designed to evaluate problems in maternity care, identify unknown factors affecting maternal and child health, and improve and strengthen maternal and child health care by incorporating a standardized monitoring system. Joint financial assistance for the project is being provided by IFRP and the Association of Southeast Asian Nations (ASEAN). The Thailand Fertility Research Association is under the direction of Dr. Somsak, Deputy Director-General, Department of Health, and Dr. Kanchana, Program Officer.

The data collected through the monitoring system is computer analyzed to return information to the service providers themselves. The feedback includes information on sociodemographic and reproductive profiles of maternity cases; clinical management and outcome of deliveries, including antenatal and postnatal events; morbidity and mortality patterns of mothers and newborns; and desired family size and prevalent contraceptive intentions/practices.

The project is unique in that it involves the entire health care structure of one province. Sukhothai Province's two provincial hospitals, 5 district hospitals, 70 health centers, 11 midwifery centers and 105 traditional birth attendants (TBAs) are all participating.

The central unit for the project, located at the Family Health Division of Thailand's Ministry of Health, is responsible for data collection, processing, and analysis and also for the supervision of all project activities. Another unit has been set up in the province to train and supervise key staff of the participating institutions and to receive and transmit all completed data collection forms to the central unit.

To record data on individual patients, the district hospitals, health centers and midwifery centers are using a standard Maternity Record Form developed by the IFRP and its collaborating investigators. The provincial hospitals are using a summary of that form, and the TBAs are using a pictorial form designed to overcome the literacy barrier.

Feedback and additional training are built into this all-levels system of health care in Sukhothai: if, for example, the TBAs are found to need instruction in a certain procedure, the auxiliary nurse-midwife at the next level of health care—the midwifery center—will instruct them personally. The midwifery center nurse-midwife, in turn, can be instructed by the higher-level medical personnel at the health centers. Health care in

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the province will benefit from this continual process of improvement through feedback.

Based on the feedback of the monitoring system, local priorities will be defined and high-risk groups identified. Mid-year and end-of-project meetings are scheduled for staff at participating institutions to discuss findings and recommendations.

After three months, data collected in the project has shown the unexpected: only 7% of births are actually being attended by TBAs. This percentage had been estimated as high as 50% before the project began. Thai midwives have informed the Thailand Fertility Research Association staff that only a small number of births are still attended by TBAs, as more mothers are inclined to be attended by qualified health personnel.

The project was recently visited by IFRP's Associate Medical Director and Associate Director for International Projects, Dr. Pouru Bhiwandiwala, and by Dr. Patrick Friel, Regional Coordinator. "The project promises something unique: it reverses the usual 'top down' planning process by creating initiative and increasing responsibility among service providers and by generating reliable local data that will result in appropriate service strategies and efficient supervision and management," commented Bhiwandiwala upon her return. "The new monitoring system for various service levels will help improve the quality of care provided to vulnerable population groups in Thailand."

Pregnancy and childbirth lead causes of death in RAMOS studies

Two IFRP RAMOS studies have begun to yield early information on the relative risks and benefits of contraception when used by reproductive-age women who live in developing countries. RAMOS—the Reproductive Age Mortality Survey—will identify the causes of death among these women to determine age-specific death rates for contraceptive users and nonusers.

Preliminary analysis of RAMOS data from studies in Menoufia, Egypt, and Bali, Indonesia, shows that the leading cause of death to women of reproductive age in both places is complications of pregnancy and childbirth, accounting for 27% of deaths in Bali and 21% in Menoufia. The second leading cause of death in Bali is infectious diseases (24%) and trauma (accident, suicide, homicide) in Menoufia (12%).

It is clear that pregnancy is the chief danger facing women in these societies and that contraceptive use is likely to bring considerable health benefits. Pregnancy-related deaths did occur following contraceptive failure, but the number was negligible.

It is noteworthy that the proportion of contraceptors among the women who died was lower than the prevalence of contraceptors in the population. In Bali, where 55% of women of reproductive age practice family planning, only 28% of the women of reproductive age were contracepting at the time of death. In Menoufia, where between 20% and 25% of women practice family planning, only 9% of the deceased women were contracepting at the time of death. This implies that when death rates to all women of reproductive age are examined, noncontracepting women can be expected to have a somewhat higher death rate than contracepting women. Future analysis will focus on this issue.

Further analysis will also examine those women who previously practiced contraception but stopped at some point before they died.

Causes of death could be assigned with reasonable confidence in most cases in both Bali and Menoufia. The cause of death was unknown in 13% of cases in Bali and 4% in Menoufia. It should be remembered that some causes of death are relatively easy to diagnose (eg, trauma, maternal deaths), whereas others are more difficult.

New aids to recruitment, follow-up

IFRP's International Projects Department is developing a new initiative to ensure the quality and follow-up of clinical trial studies. Still in the preliminary planning stages, the initiative is aimed at helping study investigators improve recruitment and follow-up efforts. The Department is investigating available informational material that might prove useful, such as brochures and pamphlets explaining various methods of contraception. The use of posters to interest the public and inform volunteers is also being considered. One such poster is shown in Fig. 1. It has been prepared to aid recruitment into barrier method studies being done in Latin America. The text cites the simplicity and ease of use of vaginal suppositories. The name and address of the collaborating clinic will appear in the poster's blank space.

Any collaborating investigator who has ideas or suggestions that might aid in study recruitment or follow-up should write the Executive Director.

Fig. 1.

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One-child Chinese family price for previous unchecked fertility

In 1957, a Chinese economist, Ma Yinchu, published an article entitled "A new theory of population." At the time he was roundly criticized, but when he died in May 1982 the *China Daily* of Beijing quoted people as saying, "If we had listened to Ma 30 years ago, we might have only 600 or 700 million today and live much better lives."

"The unforgiving nature of demographic change is the primary lesson the rest of the world must learn from the Chinese experience," says IFRP's Executive Director Dr. Malcolm Potts. He and Dr. I-cheng Chi, an epidemiologist on IFRP's research staff, recently spent three weeks in the People's Republic of China on an invitation extended by the Chinese Academy of Medical Sciences and Ministry of Health. "China is now vigorously promoting the policy of the one-child family (Fig. 2). The majority of women in urban areas now have only one child. It's for real, it works and it must be a somber example for the rest of the world," says Potts. "Most of the Westerners who have visited China remark on the policy without understanding its full implication for the rest of the world. No one enjoys implementing this policy, and many Chinese couples would certainly prefer to have larger families. There are now 5.5 million legal abortions a year in China, and some of these women would probably wish to bear the babies. But the reason Chinese women in 1982 are having abortions they do not want is because their parents and grandparents had children they did not want—China, like nearly every other country in the world, was too late in waking up to its population problem."

According to Potts, China is trying to impose a one-child family policy because population growth got out of control a generation ago. As recently as 1961, there were 30 million births a year and in 20 years from 1959 to 1979, the population probably grew from slightly over 600 million to only slightly less than 1000 million. Like most of the developing world, the population is predominantly young with millions still below the age of marriage.

It is apparent to the Chinese leadership that the physical resources of the country and the need for economic progress cannot accommodate much more than one billion people. To reach zero population growth

Fig. 2. One of the many posters seen throughout China promoting the virtues of the one-child family and, more subtly, a daughter.

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in a society where the generation now in their 50s had large families, their children cannot have more than one child. If half or more of those couples now in the fertile group adopt the one-child policy in the next few years, then the population of the country will still grow between 12 and 20% by the year 2000. "It must be understood that the one-child policy in China is not an aberration of a centrally planned communist society that is foreign to much of the rest of the world, but is the outcome of simple arithmetic that anyone can calculate with a ten dollar calculator," Potts says.

He further sees as the only difference in China and the rest of the developing countries the fact that the Chinese have to face the problem now the other nations will have to face a little later. In Brazil, 41% of the population is under the age of 15, in Mexico 42% and in Nigeria 46%. If all the young people now born in these and other countries have only two children when they become parents, the population will continue to grow. "Nations may not necessarily want or need zero population growth immediately, but they may well want to lower birth rates and this takes time to achieve. They must not repeat China's experience and fail to make family planning available now," says Potts.

Potts and Chi, who visited Beijing, Chengdu, Changsha and Guangzhou, found that contraceptives are provided free of charge and that a variety of family planning methods is easily available, including pills, condoms and both male and female sterilization. There is wide use of IUDs. The Chinese have also worked for eight years with the once-a-month pill made with steroids approved by the US Food and Drug Administration and used in the USA, although not in the combined formula developed in China. There is also a "visiting pill" for when the husband comes home only so often, and a postcoital pill.

IFRP hopes to work with its colleagues in China, assisting in the analysis of innovative studies the Chinese are already conducting. "China is becoming a center," comments Potts, "of innovation in the surgical and medical aspects of family planning. The ultimate paradox is that many women must now avoid having children they would like to have because their parents had inadequate access to family planning and were unable to control their fertility. In some other developing countries today, governments still do not endorse, promote or provide realistic family planning choices and as a result, their children are likely to be placed in the position of today's Chinese women."

Fimbrial hood for reversible sterilization ready for trials in humans

Final results from monkey trials of the fimbrial prosthesis for temporary or reversible female sterilization show that the device is completely biocompatible. No morphologic alterations of the fimbrial epitheleum and cilia were seen in scanning electron microscopies (SEMs). Earlier problems with the fixation technique were solved: the retention rate in the last group of experimental animals was 100%, according to IFRP Medical Director Dr. Leonard Laufe. "Further, researchers did not have to repair any ligaments, which is significant because monkeys have two ligaments where humans have only one that might be affected by the technique. All results now indicate an experimental technique ready for human trial."

The prototype fimbrial hood for use in humans has been designed (Fig. 3), and Laufe anticipates that the delivery system will be modified. "We hope to come up with a preloaded applicator," he says. A surgical technique for device placement and fixation is being developed. The delivery system of the device and specific suture material will be provided with every pair of hoods to be used in the clinical trials. It is also anticipated that the technique will be macroscopic, performed through a minilaparotomy incision, which suggests that the technique will not require the high-precision skill necessary for a microsurgical procedure. "However," Laufe cautions, "it will be imperative that proper tissue handling and surgical technique with specified instruments and sutures be used."

An application for an IDE (Investigational Device Exemption) from the US Food and Drug Administration is being made. This will allow trials of the device in humans. The current plan calls for US trials to be conducted at selected university medical centers.

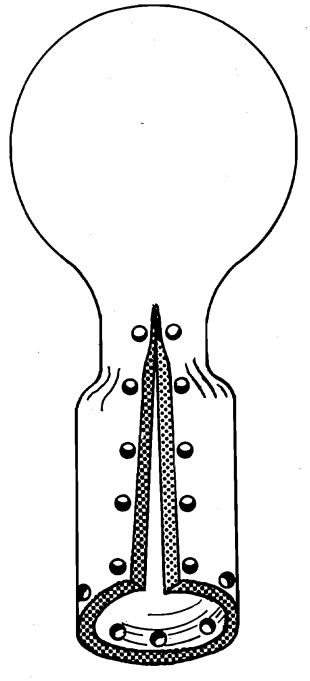

Fig. 3. Prototype fimbrial hood designed for use in human trials.

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Jessie Smith Noyes Foundation to support research workshop

Ten medical doctors from developing countries will participate in a two-week clinical research skills workshop at IFRP headquarters in September. The participants were nominated on the basis of their interest in conducting biomedical clinical trials of new contraceptive techniques. IFRP staff members will conduct the training specifically on ways to evaluate new techniques in contraceptive technology.

"The program is designed to sharpen the physicians' clinical research skills," says IFRP Regional Coordinator Dr. Patrick Friel, who is organizing the workshop. "The ten clinicians should emerge from the workshop ready to undertake a variety of research projects in cooperation with the IFRP. Their research skills will have been enhanced, and they will have been introduced to a number of important contraceptive innovations. The physicians will be able to select those methods they deem most appropriate for their own cultures and circumstances, and the IFRP will most likely then assist with projects to help them evaluate the methods selected."

Countries to be represented by the participants include Mexico, Brazil, Ecuador, Peru, Egypt, Ghana, Indonesia, Thailand, Pakistan and the People's Republic of China.

The workshop is being supported by USAID and a grant from the Jessie Smith Noyes Foundation, Inc., of New York, New York. "This grant was made in recognition of the very special contribution being made by the International Fertility Research Program to the urgent need for developing effective forms of contraception acceptable to varying cultures," stated Mrs. Edith N. Muma, President of the Foundation, in making the award.

Incorporated in 1947, the Foundation awards grants as student aid for educational purposes. Grants are made to institutions or organizations rather than to individuals and in the health field are concentrated in short-term training programs and graduate or postgraduate level research fellowships designed to provide specialized or advanced training in the field of population control.

Nigerian researcher cites need for modern contraception

Nigeria, says a recent visitor to IFRP, "has a crying need for modern contraceptive methods. Although the government knows it is important, the attitude toward family planning is only lukewarm. Traditional breast-feeding practices are being abandoned, yet are being replaced with nothing. Nigeria needs help with materials from large agencies." These comments were made by Dr. Paulina Makinwa-Adebusoye of Benin City, Nigeria, Associate Professor of Population Science at the Centre for Social, Cultural and Environmental Research, University of Benin.

During her two-week stay at IFRP headquarters, she worked with IFRP Research Associate Douglas Nichols on the analysis of data collected in a recently conducted survey of women of reproductive age in metropolitan Lagos, the capital of and largest city in Nigeria (*see* page 1). Commenting on the study, which she directed, Dr. Makinwa-Adebusoye said the results "show that women are not totally abandoning breast-feeding as one might have thought, but that very few women are today *fully* breast-feeding. They all tend to add supplements after only one month. Only 5% of the women surveyed fully breast-feed for any appreciable length of time."

The cooperative survey project with the IFRP, she emphasized, is an example of a venture that needs repeating. "Research arrangements in which a local investigator is able to conduct the field work while backed by the capabilities of an organization such as IFRP are excellent. The arrangement speeds up the time element involved in research and promotes a learning experience on both sides. It affords better research than one national could have done in her own country by herself. And the survey received tremendous publicity in Lagos—the whole project is of great benefit to Nigeria."

Dr. Makinwa-Adebusoye teaches demographic techniques in several departments, including the School of Medicine, at the University of Benin, tailoring her courses to individual needs in the various disciplines. A native Nigerian and a 1963 graduate of Vassar College in New York, she received an MA in economics from New York University and an MS and DSci in population sciences from Harvard University in 1976. Her latest book, *Internal Migration and Rural Development in Nigeria: Lessons from Bendel State*, was published in 1981.

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Training projects in Egypt aimed at range of health care workers

Can Egyptian traditional birth attendants be taught to recognize high-risk pregnancies? Can training materials for pharmacists, physicians, nurses and midwives in Egypt help them deliver better family planning services in their own communities and correct any misconceptions they might have? These questions are being studied in two new projects, part of FHI's expanding activities in Egypt. The projects are being supported under a bilateral funding arrangement between the Egyptian Ministry of Health and USAID/Egypt.

Dr. Sayed Etman, Director of Obstetrics and Gynecology at the MISR Spinning and Weaving Hospital in Mehalla El-Kubra, has worked for a number of years on a project to train Egypt's dayas (traditional birth attendants). The new project with FHI will evaluate the success of the training. The study will identify the sociodemographic characteristics of the women cared for by the dayas and discover whether or not women with obstetric problems are being referred to doctors and/or hospitals when appropriate.

Daya training is a priority for Egypt's Ministry of Health. President Mubarah signed legislation in August 1981 amending restrictive 1954 laws governing dayas' activities in attending births. Dr. Etman thinks that "the evaluation of the daya training program will demonstrate that dayas can do a good job of delivering babies and referring patients with complications to doctors or hospitals." If so, the dayas may move toward becoming integrated into the overall health care system in Egypt.

The daya project, scheduled to begin in January 1983, will use a pictorial form (*see* Fig. 1) to collect information for each birth attended, as most dayas cannot read. The multiple-choice pictures will give the daya a means to indicate the type of presentation, whether the placenta was completely or only partially delivered, the status of the baby immediately after delivery, the amount of bleeding after delivery, a subjective estimate of the baby's weight, and whether or not

Fig. 1. Similar multiple-choice columns—these refer to the well-being of the mother following delivery and whether or not she was referred to the hospital for delivery—will be used on the pictorial form for the daya training project.

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referral to a hospital occurred. The form also collects information on the well-being of the mother following delivery and whether or not she was referred to receive family planning information. An additional form will be used to collect information on the mother's and baby's health status one and six weeks after delivery.

The dayas, who are being taught to recognize pregnant women who are most likely to develop problems during pregnancy or labor, will make two or three antenatal visits to the women they attend. A simple form is being developed for the daya's use at these visits to indicate age, height and weight of patient and the number of previous pregnancies, births, and living children. They can also indicate on the form the month of the pregnancy when the visits were made, whether or not the patient has had problems such as edema or antepartum hemorrhage, and if the daya refers the patient to a doctor or hospital for problems seen at the antenatal visit.

The second project will continue FHI's support of Egyptian efforts to train physicians, pharmacists, nurses and nurse-midwives to deliver better family planning services in their own communities. The Egyptian government thinks these professionals can be far more influential in delivering family planning services than at present. Pharmacists in Egypt, in particular, have direct and personal relationships with clients in this traditional society that put them in a strong position to influence community attitudes toward family planning.

Training materials were developed last year to upgrade the family planning knowledge of all three groups of professionals and to correct any misconceptions. The materials are intended to provide information on currently promoted contraceptive products and methods, contraindications, side effects and ways to manage them, and promotional ideas.

Materials published in Arabic were distributed to 5000 Egyptian pharmacists and faculty and students of pharmacy schools. Approximately 4000 physicians received similar material published in English.

The new FHI-supported project, which will be managed by the Egyptian Fertility Care Society, will continue the distribution to pharmacists and physicians and extend it to nurses and nurse-midwives, who will receive materials in Arabic. The project will also include evaluations of the materials' usefulness for the pharmacists and physicians. A sample of physicians will be asked for their opinions and recommendations. The pharmacists' survey will obtain their opinions on whether or not they have been better able to advise customers about contraception because of the information received, as well as determine their knowledge, attitudes and practices concerning family planning. A questionnaire will be filled out for each pharmacist, who will also take an objective test on contraceptive knowledge. The results will be compared to a similar survey conducted prior to the initiation of the training materials project.

The previous survey was conducted in October 1980 in four governorates: Cairo, Giza, Assiut and Daquahliya. Four hundred fifty pharmacists were interviewed. A questionnaire was completed for each pharmacist and a contraceptive knowledge test was given. Results of the survey showed the pharmacists, who were predominantly male, to be deficient in knowledge about IUDs, injectables, surgical contraception and rhythm. It appeared that 30%-50% knew almost nothing about injectables, implants, diaphragms, cervical caps and surgical contraception. The majority, however, practiced family planning themselves (83%). Furthermore, 90% indicated that they counsel customers on family planning. They cited literature from pharmaceutical companies and formal school instruction as the most common sources for their information on family planning.

Results from both pre- and post-training surveys will be disseminated to Egyptian health practitioners and policymakers through pharmacists' conferences and newsletters sponsored by the Egyptian Fertility Care Society. The Society has already received requests for the training materials from other Arab countries in the Middle East and Africa.

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Childbearing after age 35

Although maternal age does influence infant survival, generally healthy mothers 35 and older who receive adequate antenatal care do not appear to be at greater risk for infant mortality because of their age, at least in the developed world. In developing countries, however, babies born to older mothers have lower rates of survival until hospital discharge and are more likely to have lower Apgar scores. Contrary to the reports of other researchers, however, these babies are not more likely to be of low birth weight.

These are the major findings of an FHI study of 24,012 births in three hospitals, one each in Mexi

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Egypt and Hungary. The findings are reported in "Childbearing After Age 35: Its Effect on Early Perinatal Outcomes" by J. A. Fortney, J. E. Higgins, A. Diaz-Infante, F. Hefnawi, L. G. Lampe and I. Batar, *Journal of Biosocial Science*, Vol. 14, 69-80, 1982. The study compared births to women 35 and older with those to women aged 20-34. (Mexican hospital: 5,379 births from 7 March 1977 to 6 April 1980; Egyptian hospital: 7,355 from 1 March 1977 to 1 April 1979; Hungarian hospital: 11,278 from 1 January 1977 to 5 August 1980.)

Older women tend to have other characteristics that may contribute to their risk status (see table). Although late childbearing in developed countries often involves low parity women, in developing countries it is more likely to involve women with four or more previous births. In the Mexican hospital, the oldest mothers (≥40) tended to be of high parity (9.2 live births), while in the Hungarian hospital the mean parity of women 40 and over was only 2.8. Older obstetric patients are also less likely to seek antenatal care and are likely to have less education than younger ones, both factors that are associated with increased obstetric risk. The association between age and/or Apgar score of <7 at five minutes (defined as neonatal morbidity) was significant in both the Mexican and Egyptian women. In the Mexican hospital, 2.6% of the live-born babies of the younger mothers had a depressed score at five minutes, compared with 5.2% of the babies of older mothers. In the Egyptian setting, the comparable percentages were 2.4 and 3.8. In the Hungarian hospital, however, no difference was found: 0.6% of the infants of both groups of mothers had a low Apgar score.

In each of the three hospitals, a higher percentage of older mothers had low-birth-weight babies, but the difference was small in Mexico and Egypt. In Hungary, age had a significant influence on the weight of the infant, even taking into account levels of parity, residence, number of antenatal visits, and whether or not the mother smoked during pregnancy. In an attempt to explain this significance, the relative importance of age, parity, antenatal visits, education, residence and smoking status was established for the Hungarian data. Smoking status was by far the most explanatory factor in case of low birth weight.

Survival was defined in this study as the percentage of infants surviving until the mother's discharge from the hospital. In Mexico, 96.1% of the infants of the younger mothers survived, compared with 90.7% of those of the older mothers. In Egypt, the comparable percentages were 94.9 and 87.7. But in Hungary virtually no difference was seen in the survival percentages of the two groups (98.9% for younger group, 98.4% for the older). Further, among the low-birth-weight babies, the survival percentages are significantly less among the older mothers in Mexico and Egypt, but not in Hungary. Although birth weight is an indicator of infant survival, advanced maternal age does not appear to be related to low birth weight. In two of three hospitals, there was a strong relationship between maternal age and infant survival, but none between maternal age and low birth weight.

It seems clear that among women otherwise considered low risk and when the pregnancy is well managed, the influence of age can be greatly reduced. The data from the Hungarian hospital suggest that the technology exists today to reduce the risks substantially among socioeconomically low-risk patients. The majority of the Hungarian mothers were relatively well-educated, received good antenatal care and were of low parity. For them, age appeared to be relatively unimportant. In the other two hospitals, the difference between older and younger mothers was also at its smallest in the low-risk groups with maximum antenatal care, maximum education and medium parity.

The impact of childbearing is great, both in health and demographic terms. In Mexico, more than one fifth and in Egypt almost one fourth of all births are to older mothers, compared with less than 5% in Hungary. Thus, by eliminating births to women over 35, Egypt could reduce its birth rate by 25%. In developed countries, however, as delayed childbearing becomes more common, obstetricians are anticipating an increase in the number of women over 35 having first babies. For these women, it appears that generally good health coupled with good antenatal care may neutralize attendant risks of advanced maternal age.

Table 1
Selected maternal characteristics by age of mother: Mexico, Egypt and Hungary

Characteristic/ age group	Mexico	Egypt	Hungary
Mean parity			
20-34	2.2	1.6	0.7
35-39	7.4	5.2	1.8
40+	9.2	6.7	2.8
Mean no. of antenatal visits			
20-34	1.2	1.0	7.4
35-39	1.1	1.0	7.1
40+	1.0	1.1	6.4
% with Apgar < 7 at 5 minutes			
20-34	2.6	2.4	0.6
35+	5.1	3.8	0.6
% infants < 2500 g			
20-34	11.9	7.2	11.2
35+	12.3	7.4	16.0
% infants ≥ 2500 g surviving			
20-34	96.1	94.9	98.9
35+	90.7	87.8	98.4
% infants < 2500 g surviving			
20-34	76.3	64.9	82.0
35+	58.0	44.2	84.9

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Commercially available OCs being compared in large trial

Acceptability as measured by rates of continuation of commercially available, daily combined oral contraceptives (OCs) is being studied by FHI in a clinical trial with 4500 patients. Parts of the trial got underway in October. Patient satisfaction with a specific OC usually depends upon associated side effects, a factor directly influencing the patient's decision to continue taking the drug as prescribed. While it has been proven that daily combined OCs are an effective method of contraception, FHI wants to determine the most acceptable brand of OC in terms of patient continuation and side effect rates.

Investigators have reported that the incidence and/or the prevalence of vomiting, nausea, spotting and breakthrough bleeding varies for different OCs and for the same OC when evaluated in different geographic areas. Variations in discontinuation and side effect rates have been attributed to (1) differences in dose and type of progestogen and estrogen contained in the tablet, (2) ethnic and socioeconomic differences in the populations studied, (3) differences in methods of obtaining information from patients under study, (4) the investigator's interpretation of patient complaints and (5) different expectations among users.

Side effects are thought to be minimized with OCs containing lower doses of estrogen, but it is not known whether these preparations increase overall continuation rates. Some low-dose OCs have been associated with an increased incidence of breakthrough bleeding and, again, it is not certain what effect this has on continuation rates. The FHI study is aimed at gaining information on these issues.

Specifically, FHI's trial will evaluate Norinyl 1/35, a low-dose combined OC that provides 1.0 mg norethindrone with 35 mcg ethinyl estradiol daily for 21 days. This OC will be compared to Norinyl 1/50 (1.0 mg norethindrone with 50 mcg mestranol), which is the OC currently provided by USAID to family planning programs worldwide; to Brevicon (.5 mg norethindrone with 35 mcg ethinyl estradiol), another low-dose OC; and to Lo-ovral (.3 mg norgestrel with 30 mcg ethinyl estradiol), a widely used low-dose OC.

All of these commercially available OCs differ in dosage and package design. Selected side effects including nausea, vomiting, headaches and menstrual problems as reported by the women will be recorded at admission and at follow-up, which will occur at 1, 4, 8 and 12 months after the start of OC use. Women will be asked about complaints and the assessment of the frequency of each complaint will be based on the subjective report of each woman. Side effects will not, however, be recorded on a daily basis. The trial will take place in 15 centers around the world. Women in good physical health who want to use OCs for contraception and who can be followed for at least 12 months will be recruited as study participants. Each participant will sign an informed consent form, give a medical history and receive a physical examination prior to entry into the trial.

Preliminary results of the trial are expected in 1984.

Turkey to continue study of Delta Loop IUD

A year's study of FHI's Delta Loop postpartum IUD in Turkey has led to that government's decision to continue study of the device in its national family planning program for another year. Evidence on safety and effectiveness from 1405 insertions of the Delta Loop at ten maternity hospitals convinced the Turkish family planning authorities that use of the device on a wider scale is justified, after development of appropriate training and educational materials. Turkey's General Directorate for Family Planning/Maternal-Child Health has requested FHI's assistance in developing these materials and in developing national training centers in Turkey for postpartum IUD insertion.

At a June meeting of the participants in Turkey's first year's study of the Delta Loop, data from Del IUD studies worldwide were presented. The data indicated that insertion of a Delta IUD immediately postpartum, if properly placed, is safe and associated with acceptably low expulsion rates. The relative effects of careful training and of the sutures placed on the device (*see* Vol. 1, No. 4, July 1980) are still being studied. The participants will continue study of the Delta Loop for another year, to standardize personnel training and to expand use of the device into the national program.

Under the proposed project with FHI, the Hacettepe University School of Public Health will develop and produce the training and educational materials. The training materials will instruct physicians, nurses and midwives in standardized antepartum care, insertion techniques and postpartum follow-up. The educational materials will be prepared for patients and hospital personnel to explain the contraceptive method and to improve public acceptance of a national postpartum IUD program in Turkey.

In the new study, Turkish centers will evaluate use of the postpartum Delta Loop in up to 2000 patients. Near the end of the project, representatives from participating hospitals, the Hacettepe University School of Public Health and the General Directorate for Family Planning/Maternal-Child Health will review the achievements of the project and initiate broade use of the device in the country as a whole.

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The pill and sickle cell anemia

FHI is planning to study the use of oral contraceptives by women suffering from sickle cell anemia. Three studies are being developed to be carried out in Ghana, a West African nation with a high incidence of sickle cell anemia and widespread use of oral contraceptives. The studies will be conducted in the Korle Bu Teaching Hospital in the capital city of Accra. Physicians at the hospital treat 4000 women with sickle cell disease.

In people with sickle cell disease, the red blood cells become misshapen—showing the characteristic sickle shape. A variety of factors can induce sickling. The sickling has an adverse effect on virtually every organ of the body, causing patients a variety of physical problems. In addition, patients experience recurring bouts of severe joint pain known as crises, which often require hospitalization.

The disease is inherited and pregnancy itself usually increases the number of crises for a woman with sickle cell disease, so finding the safest contraceptive method is of great importance. Some physicians prescribe the pill for sickle cell patients, believing that the risks of pregnancy are greater than those of pill use, but since the likelihood of blood clot formation increases in women with sickle cell disease, other physicians hesitate to prescribe oral contraceptives, which usually contain estrogen. Estrogen is thought to increase the formation of blood clots that can clog vital blood vessels.

Observation in Ghana, however, suggests that women with sickle cell disease do well on the pill. New studies are planned to confirm and extend this work. A recent article in the *Lancet* reports that in Jamaican women Depo-Provera, a controversial injectable contraceptive, helps women with sickle cell anemia not only as a contraceptive but because it appears to reduce the incidence of crises (*Lancet*, 31 July 1982, II, p 229).

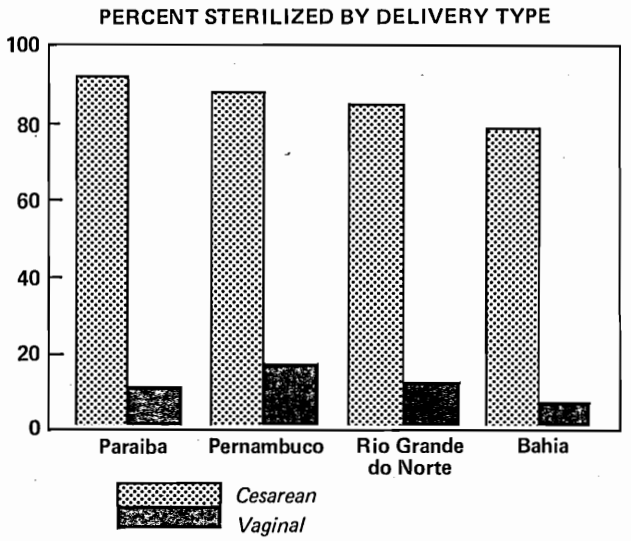
On September 8, a number of medical experts in the treatment of sickle cell anemia met with FHI staff to discuss plans for the studies. Dr. Alexander A. Bruce-Tagoe, a hemotologist from Ghana and his wife, Dr. Elizabeth Bruce-Tagoe, a public health physician, were joined by Dr. Cecil Klufio, a Ghanaian obstetrician-gynecologist who was attending a workshop at FHI headquarters (*see* page 6). Dr. Bruce-Tagoe, widely known for his expertise in sickle cell anemia, recently completed a year's sabbatical at The Medical College of Georgia in Augusta, Georgia. The College is one of 10 US centers for the study and treatment of sickle cell disease. Dr. Klufio is an expert in sickle cell disease and pregnancy. On October 14, Dr. Henry Foster from the Department of Obstetrics and Gynecology at Meharry University in Nashville, Tennessee, also visited FHI to discuss the planned studies. Dr. Foster has considerable experience in the management of the disease in obstetric patients in the US and has published articles on contraception for women with sickle cell disease. Following these discussions, FHI has developed tentative plans for studying the use of oral contraceptives in women with sickle cell anemia.

FHI hopes to survey the sickle cell patients from the Accra hospital to determine the type of contraceptive they use. Additional studies could then be planned to compare the health status of sickle cell patients using the pill with that of those who do not. Centers in the Caribbean, the US and West Africa have expressed interest in working with FHI.

Sterilization in Brazil

Bar graph shows percent of women sterilized by delivery type among all women who want no more children in four states in the northeast of Brazil, 1980. The graph was part of a poster session (Population Section) of the American Public Health Association's annual meeting, November 15, 1982. The poster session was prepared by FHI's Research Department staff members Barbara Janowitz, James Higgins and Jason Smith, along with Dr. Walter Rodrigues and Jose Maria Aruda of BENFAM, Rio de Janeiro, Brazil and Dr. Leo Morris, Center for Disease Control, Atlanta, Georgia.

Even though sterilization is difficult to obtain under most circumstances in the northeast of Brazil, surveys show that for women who want no more children, it is the most prevalent contraceptive method.



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Researchers reinforce clinical research skills in September workshop

"A good chance to share experiences from different countries . . . 90% of what I've learned is directly applicable to my own work . . . very useful . . . detailed, thorough . . . ." These were typical comments of some of the ten participants from developing countries who attended a workshop in clinical research skills at FHI headquarters in September. The two-week workshop featured 15 training sessions conducted by FHI staff on effective ways to evaluate new techniques in contraceptive technology.

In addition to sharpening the participants' clinical research skills, the workshop was intended to prepare them to undertake a variety of research projects in cooperation with FHI. The nine medical doctors and one computer analyst were selected on the basis of their interest in initiating biomedical trials of new contraceptives. Support for the workshop was provided by the Jessie Smith Noyes Foundation, Inc., of New York, New York.

Topics covered in the training sessions included "Fundamentals of Clinical Trials," "Contraceptive Technologies: Past, Present and Future," "Conducting Clinical Trials from Idea to Publication of Results," and "An Introduction to Contraceptive Safety, Rare Events, Special Problems and Tailor-Made Studies."

Significant periods of time were also set aside during the workshop for participants to meet individually with FHI staff to discuss their research interests and clinical study prospects.

Dr. Cecil Klufio of Accra, Ghana, Associate Professor at the University of Ghana Medical School, Department of Obstetrics/Gynecology and Head of the Department's Family Planning Clinic, discussed with FHI staff his interest in sickle cell disease (*see* page 5). He became interested in the disease in 1972, a year after he joined the Medical School. "After a year, I had seen many, many deaths of maternity patients with the disease. So I got together with the staff hematologist and an internist who had worked with the disease and together we worked out a protocol for management of maternity patients with sickle cell anemia. Over time, we improved the protocol and after a few years saw a decrease in mortality," he said. Klufio helped establish a once-a-week clinic for those patients who needed long periods of rest following delivery. "They needed a reliable contraceptive. I rejected IUDs because these women were already anemic and could not tolerate an increased menstrual flow, nor the risk of pelvic infection. So we selected oral contraceptives, and I have always wanted to research the use of the pill in sickle cell anemia patients."

Dr. Jose David Ortiz Mariscal of Nuevo Leon, Mexico, is the State Supervisor for Family Planning, Mexican State Health Insurance (IMSS), and the Executive Director of ESPLANIFAM, a nonprofit family planning clinic in Nuevo Leon. He hopes to influence the attitudes of health professionals by providing educational seminars on family planning for physicians and nurses from rural areas. "I would also like to be able to offer male sterilization procedures in the clinic, as well as female sterilization, pills and IUDs," he said.

Infertility was a subject of individual interest for several of the participants. Dr. Afroze Kazi of Karachi, Pakistan, Deputy Director for Medical Research at Pakistan's National Research Institute of Fertility Control, thinks the problem occurs in about 7% of Pakistani women of reproductive age. Dr. Ismail Fouad El Essaily of Cairo, Egypt, cited a high incidence of infertility among patients in his clinical practice who had previously had illegal abortions. He is a member of the Faculty of Medicine of Cairo University. He told FHI, "We need nonsurgical methods of contraception, as the women I see are afraid of operations. In rural areas, there is even a problem with the pill because women mistakenly take it only on days they have sexual intercourse. IUDs have gotten a bad reputation in some areas, too, because lesser experienced doctors often do the insertions and I was seeing one to two uterine perforations a week as a result." His hospital is a referral center for the city of Cairo.

FHI hopes to be able to do collaborative research projects with these and the other clinicians who attended the workshop: Dr. Carlos Eduardo Czeresnia, Supervisor, Department of Gynecology and Chief, Family Planning Clinic, Hospital Das Clínicas, São Paulo, Brazil; Dr. Nalo Martinez, Ministry of Education Dirección, Provincial de Educación del Guayas, Ambato, Ecuador; Dr. Herman Susanto, Department of Obstetrics and Gynecology, Medical School of Padjadjaran University, Hasan Sadikin Hospital, Bandung, Indonesia; Mr. Lin Shing Toa, Guangdong Provincial Research Institute on Family Planning, Guangzhou, China; Dr. John W. Nagahata, Area Hospitalaria No. 6, Callao Hospital "San Juan de Dios," Lima, Peru; and Dr. Sopon Chalapati, Director, Family Health Division, Health Department, Bangkok, Thailand.

According to FHI staff member Dr. Patrick Friel, who organized the workshop, "the training was successful from the perspective of both the participants and FHI. They returned home with concrete ideas for proposed research, and we developed relationships with ten dedicated and articulate ambassadors from countries where FHI works. Their comments and recommendations will also help immeasurably when FHI undertakes training projects in the future."

Men in Khartoum surveyed for attitudes on family planning

The involvement of men is known to increase the effectiveness of family planning programs, particularly so in societies with strong male influence such as in the Sudan. A recent survey of attitudes among 250 Sudanese men revealed that 50% wanted to use family planning services, but only 20% were currently using an effective contraceptive method; 80% of the men expressed a desire for additional family planning information.

Although most of the men expressed desires for large families, most indicated they might have to be satisfied with fewer children for economic reasons. Almost 60% of the men were interested in learning more about female sterilization and about 50% were interested in learning more about male sterilization. Although vasectomy is not practiced in the Sudan, almost a third of the men said they knew where to get a vasectomy. This suggests that the procedure may be acceptable to Sudanese men, for others if not for themselves. Only 2.8% had obtained any services from a special family planning clinic.

The survey was conducted by the Sudan Fertility Control Association (SFCA) and partially supported by FHI. It was carried out in Khartoum in February-March 1982. A sample of 250 men were surveyed in four locations: market places, mosques, a government office building and a large textile factory. No attempt was made to obtain a random sample of the Khartoum population. Interviews were conducted by five experienced male interviewers recruited from the Sudan's Department of Social Welfare of the Ministry of Interior Affairs.

Results of the survey showed that most (91.6%) of the men believed Khartoum to be overpopulated, with the majority citing "immigration from rural areas" as the principal cause. There was a strong belief in links between overpopulation and the following problems: "inflation" (84.8%), "shortages of food" (88.0%), "unemployment" (92.4%), "transportation problems" (93.2%), "increasing crime" (93.2%), and "housing shortages" (94.8%).

Most thought a large family ideal. Almost three fourths wanted five or more children. One hundred seventy-two men (68.8%) wanted more children, while 55 (22%) said they wanted no more children. Among those who wanted no additional children, "economic reasons" were cited by 70.9% as the primary decision factor. Table 1 shows selected sociodemographic characteristics of those interviewed. The total number of children born to ever-married men in the survey equaled 872 (mean, 4.0). The total number of children who had died was 110 (12.6%) of total children ever born. Seventy-four (33.6%) of the ever-married men had had one or more children who died.

When asked if they believed in limiting family size, 29.2% said "yes" and 67.2% said "no." Attitudes toward child spacing were much more favorable: 80.8% said they believed in child spacing, citing benefits for

Table 1

Selected sociodemographic characteristics of the 250 Sudanese men interviewed February-March 1982

Age of respondents	No.	%
≤20	2	0.8
21 - 30	73	29.2
31 - 40	111	44.4
41 - 50	41	16.4
>50	23	9.2

Years of school completed by respondents	No.	%
0	45	18.0
1 - 6	75	30.0
7 - 12	79	31.6
≥13	51	20.4

Marital status	No.	%
Married	213	85.2
Never married	30	12.0
Divorced	7	2.8

Current number of wives	No.	%
One	205	82.0
Two	8	3.2
None (never married/divorced)	37	14.8

Total number of children ever born to ever-married men

No. of children	No.	%	Cumulative %
0	18	8.2	8.2
1	31	14.0	22.2
2	31	14.0	36.2
3	37	16.8	53.0
4	25	11.4	64.4
5	14	6.4	70.8
6	17	7.7	78.5
7	15	6.8	85.3
8	11	5.0	90.3
9	11	5.0	95.3
10+	10	4.5	100.0

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the baby's health and development, the wife's health and economic conditions of the family. Of those opposed to child spacing, 36 (78.3%) said it was against the rules of Islam.

When asked to name the contraceptive methods of which they were aware, 86.4% mentioned the oral pill. In general, aside from rhythm and breast-feeding, little more than half were vaguely familiar with the remaining methods. Discussion of contraception between husbands and wives was apparently poor. Even among pill and rhythm users, the most widely used methods, only about a third of the men reported discussing the method with their wives.

Dr. Stephen D. Mumford, FHI's technical advisor to the survey, cited one encouraging finding. "Men under age 40 had more favorable attitudes toward family planning than their older counterparts. This suggests that a positive change in attitudes toward family planning is already well underway in the Sudan."

Data analysis technology transferred to Thailand

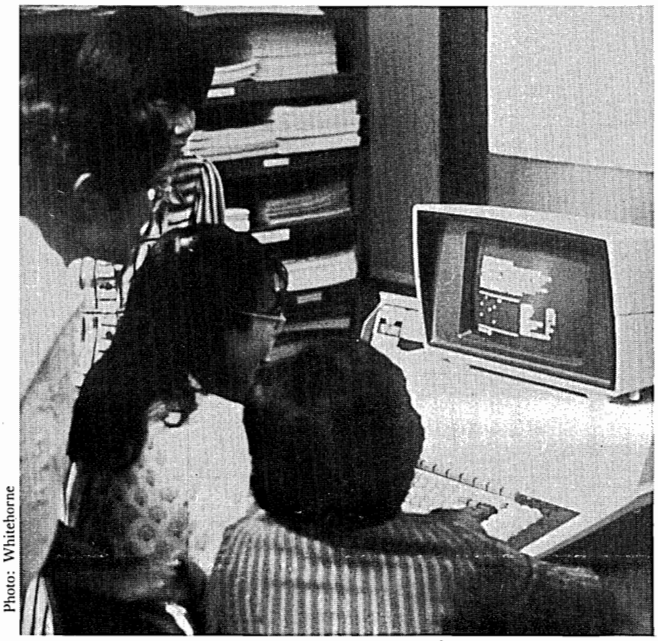

Photo: Whitehorne

Through an FHI grant, installation of a Texas Instruments microcomputer took place at the Thailand Fertility Research Association in Bangkok in July. An FHI staff member conducted a two-week training session in conjunction with the installation. Much of the data collected by FHI is analyzed through the use of standardized computer programs, and FHI has received numerous requests to transfer these programs to local facilities. The advent of inexpensive microcomputers, which are compatible from site to site and require little space or environmental control, makes possible this transfer. FHI's present plans call for the purchase of a very limited number of microcomputers, already allocated to carefully selected sites.

Report on urban poor available again

Meeting the Family Planning Needs of the Urban Poor, a report that summarizes discussion from a 1980 workshop in Juarez, Mexico, has been reprinted. Fourteen professionals attended the FHI-sponsored meeting to evaluate the most appropriate ways to deliver family planning services to the people of the rapidly expanding cities of the developing world. Coauthors of the report are FHI's President Dr. Malcolm Potts and Dr. Pouru Bhiwandiwala, Associate Medical Director. Copies are available upon written request.

Recent publications by FHI staff

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P Donaldson, D Nichols and EH Choe. Abortion and Contraception in the Korean Fertility Transition. Pop Studies *36(2)*:227, 1982. (EVAL-80)

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JA Fortney and EW Whitehorne. The Development of an Index of High Risk Pregnancy. Am J Obstet Gynecol *143:(5)*:501, 1982. (MAT-58)

B Janowitz, DC Clopton, JE Higgins, JA Nunez, MS Nakamura, LF Moreno and M Medel. Cesarean Delivery in Selected Latin American Hospitals. Public Health *96*:191,1982. (MAT-47)

B Janowitz, JE Higgins, DC Clopton, MS Nakamura and ML Brown. Access to Postpartum Sterilization in Southeast Brazil. Med Care *20(5)*:526, 1982. (FS-149)

E Kessel and SD Mumford. Potential Demand for Voluntary Female Sterilization in the 1980s: The Compelling Need for a Nonsurgical Method. Fertil Steril *37(6)*:725, 1982. Sterilization: New Techniques to Meet Demand. Summary in People *9(3)*:36, 1982. (FS-159)

AR Khan, HH Akhtar, HA Ali and B Dixon. Female Sterilization: A Comparison of Minilaparotomy and Culdoscopy. Sing J Obstet Gynecol *13(1)*: 31, 1982. (FS-145)

MM Shaaban, WA Hammad, MF Fathalla, SA Ghaneimah, MM El-Sharkawy, TH Salim, MY Ali, WC Liao and SC Smith. Effects of Oral Contraception on Liver Function Tests and Plasma Proteins in Women with Past Viral Hepatitis. Contraception *26(1)*:65, 1982. (SYS-30)

MM Shaaban, WA Hammad, MF Fathalla, SA Ghaneimah, TH Salim, WC Liao and SC Smith. Effects of Oral Contraception on Liver Function Tests and Serum Proteins in Women with Active Schistosomiasis. Contraception *26(1)*:75, 1982. (SYS-31)

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New contraceptive sponge approved for US market

A new, nonprescription contraceptive sponge (Fig. 1) will appear on the US market later this year, following approval in April by the US Food and Drug Administration. The introduction of the sponge attracted a great deal of media attention, as it is the first new contraceptive method to be approved by the FDA for many years. FHI administered the clinical testing in the United States of the sponge under a contract with the National Institutes of Health, part of the US Public Health Service. Thirteen US clinics participated in the clinical trials. Results of the FHI clinical trials were reported to the Food and Drug Administration in October 1982. The data indicated that the sponge's effectiveness is in the same range as the diaphragm and other vaginal contraceptives.

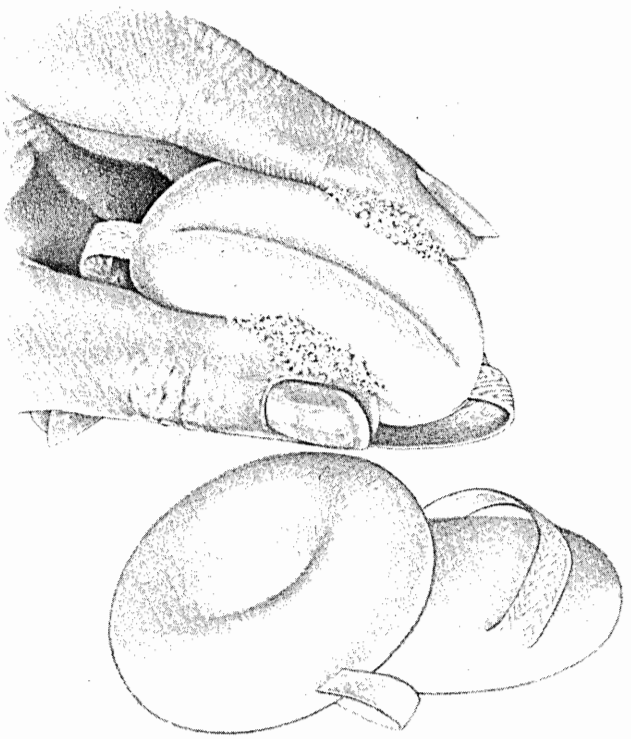

Fig. 1. VLI Corporation's vaginal contraceptive sponge is moistened with clean water before insertion. The sponge may be inserted anytime up to 24 hours before intercourse.

The sponge is manufactured by the VLI Corporation, Costa Mesa, California. Made of soft polyurethane, it is permeated with a spermicide nonoxynol-9. Unlike a diaphragm, the sponge does not have to be fitted by a physican; one size fits all. US physicians think it will be a successful addition to existing contraceptives because it allows for spontaneous sexual activity and requires little preparation. The sponge is effective for at least 24 hours and so can be inserted in advance. It also lacks the messiness associated with contraceptive creams, foams and gels.

The sponge is about 5.5 cm in diameter, 2 cm thick and is slightly concave. A polyester loop attached to the bottom facilitates removal from the vagina. The contraceptive works in three ways. During intercourse, the nonoxynol-9 is released from the sponge. The sponge also blocks the cervix so sperm cannot enter. And it is thought to trap and absorb semen, resulting in fewer sperm entering the cervical canal.

The new contraceptive will be marketed under the brand name, "Today," and will be sold for approximately US $1.00. The sponge was earlier approved for use in Britain, Norway, the Netherlands and Switzerland.

Natural family planning being studied for large-scale feasibility

FHI, in one of the early steps of its strategy to study natural family planning (NFP) methods, is planning to evaluate an NFP project in Lima, Peru. Several hundred couples will participate in the study. FHI will provide technical and financial assistance to the Lay Association for Family Work (ATLF) to train staff, improve services by adding a new NFP method (cervical mucus) to the one already available (calendar rhythm), recruit NFP users, and increase ATLF's capacity to evaluate its program. "There is a lack of information on NFP in actual use situations, although in a number of countries there are substantial numbers of people using methods involving periodic abstinence," says Dr. Nancy Williamson, head of FHI's Task Force on Natural Family Planning. "The evaluation project is a starting place for us. Peru is a good setting for an NFP project because rhythm is the most

popular family planning method in both urban and rural areas. It accounts for 41% of the family planning in use."

Techniques involving periodic abstinence from sexual relations were once known as "rhythm," but nowadays are usually referred to as natural family planning. These techniques, which include a variety of approaches to identifying the fertile period, are used by a significant proportion of the population in developing countries such as Peru, the Philippines, Sri Lanka, Haiti and Mauritius. Worldwide, NFP programs have developed alongside of, but have rarely been integrated with, older and more established family planning programs.

While the techniques have established their legitimacy as family planning methods, major family planning donors have been slow to provide large-scale support to NFP at this time. There are unanswered questions about NFP effectiveness, especially in field settings, and little or no information on the costs of NFP projects, or on the amount of follow-up required. Moreover, insufficient information has been obtained on the perspectives of users, including both women and men. It must also be shown that NFP proponents and those of established family planning programs can work harmoniously toward helping couples attain the number of children they desire.

One or more NFP methods will be evaluated for acceptability, perspectives of the users, characteristics of the users, continuation rates, cost and effectiveness in preventing unwanted pregnancies. Additionally, the training component of the project will be evaluated—the knowledge and effectiveness of the instructors, the training materials, and the clients' knowledge of NFP at follow-up. ATLF will also record the costs of NFP services, including those incurred in training, counseling, promotion, supplies, management and follow-up of users. According to Dr. Williamson, "an important part of the evaluation in Peru is that we will gain information on costs and cost-effectiveness of NFP. This is essential if we are to determine whether it is feasible to provide NFP on a large scale."

ATLF was organized in 1970 and currently runs seven clinics in the Lima area. All ATLF clinics encourage the calendar rhythm method in addition to offering pills to supplement the natural effect once played by breast-feeding in spacing pregnancies. The evaluation project will involve only one clinic, but it may be possible in the future to expand NFP services in other clinics. ATLF might also develop the capacity to serve as an NFP training center for Peru. In the long run, FHI hopes that ATLF may develop into a center for research and training in NFP.

FHI is developing several other NFP projects in Egypt, Sri Lanka and Haiti. In Haiti, two projects are being reviewed. One study would compare users of NFP, condoms and pills in the capital city, a provincial city and one rural area. Nine hundred couples would be followed over a twelve-month period. "This is a desirable research design because it would result in comparative data for the three most popular contraceptive methods in Haiti: NFP, pills and condoms," says Dr. Williamson. The second proposed study would follow up all acceptors of NFP (the sympto-thermal method is used in Haiti) taught by L'Action Familiale D'Haiti in 1982 to evaluate effectiveness, continuation rates and couple satisfaction.

FHI also plans to support basic research at the University of Chicago on a new self-aspiration method for improving prediction of ovulation through quantitative measurement of the volume of cervical mucus.

The NFP Task Force is also responsible for FHI projects on breast-feeding. These include three studies on breast-feeding and the return to ovulation in Mexico, Thailand and Egypt, as well as several planned seminars in breast-feeding research.

IUD insertions appropriate throughout menstrual cycle

"Women can be provided with IUDs upon request at any time during the menstrual cycle," according to an FHI report in a recent issue of the *IPPF Medical Bulletin* (17(1):2, February 1983). In "Wider Opportunities for IUD Insertion," Lynda Cole and Malcolm Potts maintain that while a high percentage of obstetricians worldwide limit IUD insertion to the time of menstruation, this practice means many women must make more than one visit to a clinic. In between visits, a woman can conceive an unintended pregnancy. Furthermore, in developing countries women may depend on mobile clinics or infrequent visits by trained personnel and many seek help without an appointment.

Pooled FHI data on 11,951 insertions of Lippes Loop D, TCu 200, TCu 220, Cu-7, Multiload Cu 250 and Multiload Cu 375 IUDs show no consistent relationship between the time during the menstrual cycle that the IUD is inserted and its later performance. "In no case," the authors state, "is there a distinct advantage for the first five days of the menstrual cycle."

FHI

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Trials to compare Secuclip and Filshie clip

Two mechanical tubal occlusion devices will be compared by FHI in a controlled clinical trial of 1500 female sterilization procedures, with two-year follow-up. The Secuclip (originally known as the Bleier clip after its inventor) will be compared to the Filshie clip (Fig. 2) to evaluate safety, ease of application and efficacy. The clips will be applied via minilaparotomy.

The Secuclip, made in one piece of polyacetyl plastic, is hinged so that firm pressure locks the upper flap beneath a flange on the lower flap. Complementary ridges and grooves run longitudinally along both flaps. It is 11 mm long, 4 mm wide and has a 0.1 mm gap between the opposing flaps at closure.

Recently, a disposable Secuclip applicator for minilaparotomy sterilization has been developed. The plastic scissorlike device contains a small beveled platform that holds the Secuclip firmly in place while the upper arm is brought down to lock the clip securely. The disposable applicator equipment is completely new, so that in addition to collecting data on the clip itself, the FHI study will evaluate innovative technology the manufacturer believes may capture a significant share of the market in the developed world.

Data on the Secuclip are somewhat scarce. A few European studies have been published, including some by the inventor, Dr. Bleier. These preliminary data indicate a low pregnancy rate.

The newly marketed Filshie clip is 12.7 mm long and 4 mm wide and consists of two hinged titanium arms lined with silicone rubber. As the clip is closed around the fallopian tube, the upper curved arm is locked under a flange on the lower arm and then flattened by further pressure on the applicator, providing a secure hold on the tube. A force of at least 1500 gm is required to pull the clip off the tube. As tubal necrosis occurs, the rubber lining of the clip expands to keep the lumen blocked. The tube eventually divides and the stumps heal closed. The Filshie clip may be applied via minilaparotomy, double-puncture laparoscopy, or single-puncture laparoscopy.

The Filshie clip has undergone at least five design phases and has been used in thousands of sterilization procedures in several countries, including the People's Republic of China. Preliminary data claim few surgical difficulties and injuries and a low pregnancy rate; two national family planning programs have recently contracted to use it. A possible advantage of the Filshie clip relates to its curved upper arm. This feature may facilitate occlusion of thick fallopian tubes, making the Filshie clip more suitable than other clips for postpartum or postabortion procedures.

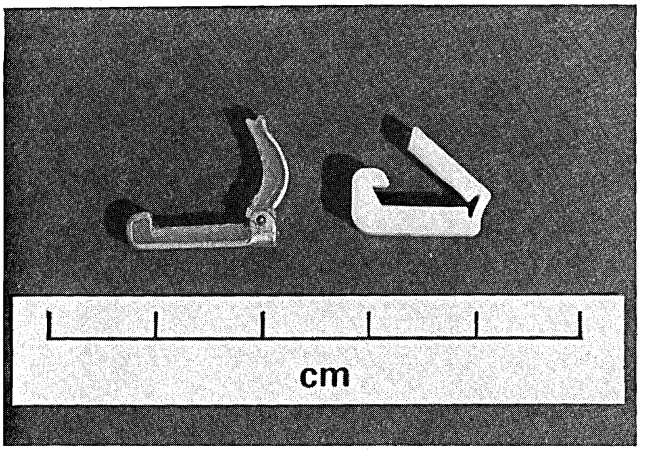

Fig. 2. The Filshie clip (left) and Secuclip.

Hospital policy and breast-feeding under study in five countries

Interviews are to be conducted in hospitals in five countries as part of an FHI study of hospital practices and policies concerning infant feeding. Selected staff in five hospitals each in Sri Lanka, Jamaica, Egypt, Bangladesh and Liberia are being surveyed to determine practices involving breast-feeding, especially postpartum, and to learn more about the attitudes of those administering hospital policies. The study is being supported by the International Nutrition Communication Service of Boston, Massachusetts. "Although there may not be a problem in, for instance, Bangladesh, hospitals in other countries sometimes make it very difficult for women to breast-feed. Milk substitutes are often given as free samples in the hospitals," says Dr. Barbara Janowitz, who is directing the study at FHI.

In each country, five hospitals are being selected as follows: a university hospital in the capital or largest city; another government hospital (Ministry of Health or Social Security) in the same city; a government hospital in another large city; a government hospital in a provincial town; and a government hospital serving a rural population.

In each of the hospitals, the same questionnaire is being administered to each of six staff members: head of the obstetrics/gynecology department, head nurse in the obstetrics/gynecology department, head of the pediatrics department, head nurse in pediatrics, head midwife, and a nurse or midwife providing direct patient care.

The questionnaire poses more than 80 questions concerning hospital policy regarding mothers and infants, including, "After cesarean delivery or other surgical intervention, when is the baby usually given to the mother for feeding?", "Is there a separate nursery at this hospital?", "Which babies stay in the nursery?", "Do you think mothers should receive free samples of formula or bottles in the hospital?", and "Who do you think should have primary responsibility for advising mothers on method of feeding?". The results will identify whether hospital staff need training in the area of breast-feeding.

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IUD performance in breast-feeding women comparable to that in nonbreast-feeding women

An FHI analysis of the experience of 2271 women wearing IUDs while breast-feeding shows that breast-feeding does not increase the risk of expulsion or other events. The finding applies both to devices inserted immediately (within ten minutes) postpartum or more than 42 days after delivery. The analysis is reported in the article "Effects of Breast-feeding on IUD Performance," published in the *American Journal of Public Health* (37(4):384, April 1983), written by Lynda P. Cole, Margaret F. McCann, James E. Higgins and Cynthia S. Waszak.

While previous studies have looked at breast-feeding and IUD use, most have examined the biologically somewhat implausible possibility that IUDs might affect lactation. These studies have found no effect of IUD use on quantity of breast milk, duration of breast-feeding, composition of breast milk or infant weight gain.

Because breast-feeding women experience stronger and more frequent uterine contractions, they may run an increased risk of IUD expulsion. The FHI analysis was undertaken to determine the effect, if any, that breast-feeding has on IUD performance.

Included in the analysis of multicenter data were four IUDs: the Lippes Loop D, the Copper T, and the postpartum modifications of both these devices (Delta Loop and Delta T, respectively). Data were analyzed separately for IUDs inserted in the interval period (42 days to six months after the last live birth) and immediately postpartum (within 10 minutes of placental expulsion). Only nonbreast-feeding and fully breast-feeding women were compared. Life-table methods were used to compare these women in terms of IUD expulsion, accidental pregnancy, IUD removal for various reasons, and overall continuation of IUD use.

For women who had a Lippes Loop D or Copper T IUD inserted in the interval period, there were no statistically significant differences in IUD performance over the first six months postpartum between women fully breast-feeding and those who were not. Similarly, when an IUD was inserted within 10 minutes of placental expulsion, there were no statistical differences in IUD performance over the first six months postinsertion between breast-feeding and nonbreast-feeding women.

The results indicate that IUD insertion for breast-feeding women is appropriate whether done immediately after delivery or at a later time. And because other studies have found that IUDs do not adversely affect lactation, IUDs may be a particularly suitable contraceptive for breast-feeding women.

In an editorial in the same issue of the *American Journal of Public Health*, the FHI study was commended for adding significantly to the literature on breast-feeding and contraception. Because the duration of postpartum amenorrhea and infertility during breast-feeding cannot be predicted easily, "the contribution made by Cole and her colleagues in this issue of the *Journal* is an important one," writes Dr. Carl W. Tyler, Jr., Director, Epidemiology Program Office, Centers for Disease Control, Atlanta, Georgia. "The distribution and promotion of contraceptives that do not inhibit lactation would permit women and their infants to receive the benefits of breast-feeding. The data reviewed by Cole et al suggest that the IUD might be such a device."

Safe vaginal deliveries after cesarean birth described by FHI researchers

In many Western hospitals women who have had one cesarean section are advised to have all subsequent pregnancies delivered by the same procedure. But in some parts of Asia a vaginal delivery is advised if the first cesarean section was for fetal distress or some indication that will not necessarily recur. Which guidelines are best?

Answers to questions like this are very much a part of FHI's work, comparing experiences from different parts of the world.

Recent findings from an FHI study of 257 women support the recommendation of the National Institutes of Health in the US to substitute repeat elective cesarean delivery with a trial of labor and subsequent vaginal delivery in selected cases. The study is reported in "Deliveries After Cesarean Birth in Two Asian University Hospitals," which appeared in the February issue of the *International Journal of Gynaecology & Obstetrics* (21:11, 1983). The article was written by I-cheng Chi, Abdul Bari Saifuddin, D.E. Gunatilake and Sylvia Wallace. Dr. Chi and Ms. Wallace are members of FHI's research staff.

Dr. Saifuddin is affiliated with the Department of Obstetrics and Gynecology, School of Medicine, University of Indonesia, Jakarta, and Dr. Gunatilake with the De Soysa Hospital for Women, Colombo, Sri Lanka. Data from their two teaching hospitals were used to assess the risks and benefits of the trial of labor recommendation. The two hospitals were selected because the medical care differed in each country: in general, fee for services in Indonesia and socialized health care in Sri Lanka.

The table gives a statistical profile of the study results. For the Jakarta hospital, the authors reported that a considerable proportion of patients who had had a previous cesarean had been subjected to a kind

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natural experiment for trial of labor before their admission to the hospital. Of the 106 women studied, 63 were delivered vaginally and the remaining 43 had a repeat cesarean. More than half of the Jakarta women were delivered on the day of admission, suggesting that most were admitted after labor started. As only one fifth of the repeat cesarean group were delivered with no labor and more than 90% had some complications of labor or delivery, the authors observe that most repeat cesareans in the Jakarta hospital were performed for some medical indication rather than the "once a cesarean, always a cesarean" doctrine.

In the Jakarta hospital, the vaginal delivery group had one stillbirth, a case of polyhydramnios. The repeat cesarean group had one maternal death, one stillbirth and three neonatal deaths. The maternal death was a 22-year-old, para 2 woman who arrived at the hospital in the first stage of labor with a diagnosis of cephalopelvic disproportion. The cesarean was performed under general anesthesia; she died of aspiration pneumonia soon after delivery. The infant survived.

Uterine rupture occurred in five patients (4.7%) in the Jakarta study. Three of these resulted in repeat cesarean delivery. The fourth baby was delivered vaginally, assisted by outlet forceps. All four mothers and three babies survived. One stillbirth occurred in a fetus because of neglected transverse lie. The mother underwent laparotomy upon admission.

In the Colombo hospital, 30 of 121 women studied were delivered vaginally. The remainder had a repeat cesarean. Over 90% of the women in the repeat cesarean group did not experience labor, suggesting that the repeat sections were elective, primarily because of the previous cesarean delivery. The low blood transfusion rate in the group supports this conclusion.

Two stillbirths and two neonatal deaths occurred in the Colombo vaginal delivery group, and one stillbirth and four neonatal deaths occurred in the repeat cesarean group. There were no maternal deaths in the study in this hospital, and no uterine ruptures were reported for either group.

The most apparent and consistent finding for both hospitals was in length of hospitalization following delivery. Over 80% of the women who delivered vaginally in both hospitals were discharged within five days, but rarely was a women in the repeat cesarean group discharged in less than eight days after delivery. The authors contend that the experience of the women in their study and the considerable savings in medical costs for the vaginal deliveries after previous cesareans support the recommendation for trial of labor in adequately selected cases.

Selected information regarding index delivery subsequent to previous cesarean delivery by method of delivery for the General Hospital, University of Indonesia, Jarkarta, Indonesia, and De Soysa Hospital for Women, Colombo, Sri Lanka, 1977-1978.

	Jakarta Hospital		Colombo Hospital	
	Vaginal delivery	Repeat cesarean	Vaginal delivery	Repeat cesarean
Number of women	63	43	30	121
Number of infants delivered	63	43	32	122
Mean age in years	27.6	28.0	31.6	31.3
% Primipara (prior to this delivery)	34.9	44.2	76.7	66.9
% With one or more antenatal visits	85.7	65.1	100.0	98.3
% Delivered same day as admission	55.7	62.8	20.0	9.2
% Delivered with no labor	0.0	23.3	0.0	92.5
% With some complications during labor/delivery	18.0	90.7	10.0	6.6
% Maternal deaths	0.0	2.3	0.0	0.0
% Stillbirths	1.6	2.3	6.7	0.8
% Neonatal deaths	0.0	7.1	6.7	3.3
% Blood transfusion	1.6	46.5	3.3	4.1
% Premature infants (< 2500 gm)	9.8	9.3	39.3*	20.8*
% Sterilization performed before discharge	23.8	45.2	6.7	43.0
% Hospitalized eight or more nights after delivery	1.6	95.3	16.7	99.2

**Singleton deliveries only. If prematurity is defined as <2250 g, the proportions of premature infants will be 21.4% for the vaginal delivery group and 6.7% for the repeat cesarean group.*

From a table in *Int J Gynaecol Obstet* 21(1):11, 1983, used with permission of the Editor.

Ford Foundation makes grant to FHI for study of possible cardiovascular disease link to vasectomy

The Ford Foundation recently has approved a two-year grant of $63,000 to Family Health International for support of epidemiologic research on cardiovascular disease and vasectomy. FHI will work with the Korean Institute for Population and Health (KIPH) on two case-control studies in Seoul to determine if an association between vasectomy and coronary heart disease and stroke exists. "FHI is delighted that the Ford Foundation has agreed to support our work in this important area. We are equally pleased to be collaborating with the KIPH, which has been one of Asia's leading family planning research institutes. We think the research will clarify the controversies surrounding vasectomy and make a significant contribution to national population programs," said FHI President Malcolm Potts in making the announcement.

The research in Korea will be supported by the International Development Research Centre of Canada.

Worldwide, nearly 35 million men have had vasectomies. In the US each year, about one half million men obtain a sterilization. Approximately 470,000 vasectomies were performed in Korea from 1962 to 1980 under a government program, and a substantial number of vasectomies were done by the private sector.

Studies of monkeys have suggested that vasectomy increases the risk of atherosclerosis. Since publication of the animal data, four epidemiologic studies on vasectomized men have found no association between vasectomy and arterosclerosis. However, most men in these studies had been vasectomized for less than eight years, while the latent period for atherosclerotic disease may be much longer. Furthermore, each study used data from either the US or Great Britain. Results in other settings may differ.

The Korean vasectomy program is one of the world's oldest, and the country's prevalence of vasectomy is the highest in East Asia. It is estimated that about 12% of all Korean ever-married men, aged 35-64, have had a vasectomy. Almost 5% had their vasectomies at least ten years ago. Moreover, acceptance of vasectomy appears to be growing: more vasectomies were performed in 1981 (31,320) than in 1980 (28,036), and more vasectomies were performed in the first four months of 1982 (20,861) than during the same period in 1981 (11,756).

FHI and KIPH studies will answer the following questions: is vasectomy associated with an increased risk of coronary heart disease and stroke? What is the relative importance of vasectomy compared with other known risk factors? What subgroups of men are at special risk of developing arteriosclerotic disease following vasectomy?

One case-control study will enroll 400 men with a first episode of an arterisclerotic disorder newly admitted to four university hospitals in metropolitan Seoul and an equal number of comparable men admitted for conditions unrelated to either arteriosclerosis and vasectomy. Diagnostic criteria will be standardized by Korean cardiologists and neurologists. Cases and controls will be individually matched by hospital, age and hospital pay status.

The second case-control study will study fatal cases of the same circulatory diseases as the hospital study, as well as cases of sudden deaths from unknown causes. A list of newly deceased men aged 35-65 whose cause of death is registered as ischemic heart disease, cerebrovascular disease or sudden death from unknown cause will be obtained periodically from the Korean Bureau of Statistics. Cases, to equal about 400, will be limited to men with at least one surviving child who were residing with their spouse in metropolitan Seoul at the time of death. Controls will be living men in the same neighborhood selected to match by age. The wives of these cases and controls will be interviewed to determine the husband's vasectomy status and presence of other risk factors for arteriosclerotic disease. Diagnoses for the cases will be taken from the death certificates, fully 80% of which in metropolitan Seoul are filled in by qualified medical doctors. A large number of men die before hospitalization, a drawback of hospital-based studies, and the second study is designed to compensate for this bias.

Recent publications by FHI staff

E Kessel, I Chi and PJ Feldblum. Postmarketing Surveillance of Intrauterine Contraceptive Devices. Contr Deliv Sys *4*:15,1983. (IUD-86)

P Lavin, C Waszak and C Bravo. Preliminary Report on a Postpartum CuT 200 Study, Santiago, Chile. Int J Gynaecol Obstet *21(1)*:71, 1983. (IUD-84)

I Chi, AB Saifuddin, DE Gunatilake and S Wallace. Deliveries after Cesarean Birth in Two Asian University Hospitals. Int J Gynaecol Obstet *21(1)*:11, 1983. (MAT-57)

NE Williamson. An Attempt to Reduce Infant and Child Mortality in Bohol, Philippines. Stud Fam Plann *113(4)*:106, 1982. (MAT-61)

JW Burns, JC Goodpasture, P Friel, R Wheeler and L Zanewald. Development and Evaluation of an Inhibitor-Releasing Matrix for Intrauterine Devices. Contraception *26(5)*:521, 1982. (METH-54).

S Mumford, JE Davis and M Freund. Consideration in Selecting a Postvasectomy Semen Examination Regimen. Nephrology *14(3)*:293, 1982. (MS-5)

NE Williamson. Sex Preference and Its Effect on Family Size and Child Welfare. Draper Fund Report *11*:22, 1982. (SP-67)

M Potts. Contraceptives Save Lives. *In* Proceedings of Second Asian Regional Workshop on Injectable Contraceptives. (Oklahoma City, Oklahoma: World Neighbors, 1982), p 8. (SP-71)

A free copy of any of these articles, or a complete catalog of FHI publications is available upon request.

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Mellon Foundation award to FHI to be used for contraceptive development

The Andrew W. Mellon Foundation of New York City has awarded Family Health International $375,000 for the development of new contraceptives. The money will be used over three years to work on three contraceptive technologies: nonsurgical female sterilization, spermicides and once-a-month contraceptives. "FHI is delighted to receive this award and appreciates the confidence the Mellon Foundation has placed in us. We have been in the early stages of research on these three promising contraceptive innovations, and the Mellon Foundation's generous support will allow us to make significant progress. We think all three have a genuine potential for contributing new and valuable contraceptive choices for couples in the developing world," says Dr. Malcolm Potts, FHI President.

Nonsurgical female sterilization now involves surgical incision of the abdominal wall to reach the fallopian tubes. A nonsurgical, vaginal route using drugs or chemicals to achieve the same result would meet one of the most important needs of national family planning programs. In several countries the demand for voluntary sterilization is greater than the ability of health services to provide current surgical techniques of female sterilization. In addition, current techniques present greater risks than the comparable operation does in more developed countries. FHI has accumulated considerable experience studying nonsurgical sterilization by means of quinacrine. An alternative agent under study that also causes tubal occlusion is the antibiotic tetracycline. Research has reached a point where studies of the toxicology of these and other substances in animals are nearing possible large trials among women. Effective delivery systems for the drug must be developed that will not only lead to tubal occlusion but will be safe even if the method is accidentally misapplied. "Any method that involves the insertion of material into the uterine cavity runs the risk of uterine perforation, just as sometimes occurs with IUDs," says Potts.

A new generation of spermicides would improve their effectiveness. "Existing spermicides," says Potts, "are crude products that act as detergents and have nonspecific effects." A new generation of spermicides is possible, with more specific effects and a lower failure rate. New compounds have been tested against sperm in the laboratory and early results in human use are encouraging. It may be possible to develop a method that will be convenient to use, perhaps with an action lasting many hours, and more effective than current spermicides. Such a method might be used alone or in combination with barrier methods, as are current spermicides. "A better spermicide would have an impact in developed as well as developing countries, and there are reasons to believe that drug licensing might well be more rapid than in the case of some other possible developments in contraceptive technology," says Potts.

Monthly steroidal contraceptives are a neglected contraceptive technology that FHI will use the Mellon funds to study. Pharmacologically, it could be simpler to use lower doses of drugs to achieve fertility control for short intervals than long ones. Western manufacturers developed and tested a monthly oral contraceptive in the early seventies but did not take it to full-scale marketing. The Chinese, however, continued work on once-a-month pills, which are now used by tens of thousands of women. A once-a-month contraceptive is likely to be viewed as an attractive option by some women in the developing world. The development of a monthly steroidal contraceptive may be an area where technical cooperation between developing countries will occur.

Study planned to determine contraception for women with rheumatic heart disease

FHI is planning a study to help Egyptian policymakers determine the most appropriate contraceptive for Egyptian women with rheumatic heart disease. Interest in this disease and its consequences in young women grew out of FHI's ongoing Reproductive Age Mortality Survey (RAMOS) in Egypt, which has shown that 12% of all deaths to women of reproductive age are attributed to rheumatic heart disease. These deaths include a number of pregnant women.

Rheumatic heart disease is known as a young person's disease; death often occurs in the 20s and 30s. Since many victims are in their reproductive years and since pregnancy places severe and sometimes lethal strain on the damaged heart, an acceptable contraceptive is needed. However, many Egyptian physicians are reluctant to prescribe oral contraceptives or IUDs for women with rheumatic heart disease. Female sterilization is not widely available in Egypt, and barrier methods, which would be recommended for such women in the West, are little used, according to Dr. Judith Fortney, who heads FHI's Task Force on Contraceptive Safety.

A meeting was held at FHI headquarters in early April to design a study to look at the effects and safety of hormonal contraception. Attending the meeting with Dr. Fortney were Egyptian cardiologist Dr. Nadia Saleem, Dr. Nicholas Wright, Rutgers University, and Dr. Ronald Gray of Johns Hopkins University. Dr. Saleem's clinic in Assiut is slated to be the site of the study.

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Research methodolgy workshop scheduled for July in Gambia

FHI plans to support a workshop on applied research methodology in family health to take place in Gambia August 8-29, 1983. The workshop will be cohosted by the Gambian Family Planning Association. It will be attended by 12 participants from Gambia, Ghana, Liberia, Nigeria, Sierra Leone and Tanzania. Four FHI staff members will attend: Dr. Peter Lamptey, Senior Program Development Associate for Africa (course coordinator/facilitator); Ms. Nadine Burton, Regional Coordinator (course administrator/facilitator); Mr. Paul Feldblum, Research Analyst (facilitator); and Ms. Rose DeBuysscher (administrative staff). There will be two local facilitators, as well.

The workshop course will cover proposal writing, research methodology, and analysis and interpretation of research data. The course will emphasize applied research methodology but will also cover selected aspects in primary health care. Each participant will be required to prepare and submit a proposal during the workshop for funding by FHI or another agency.

The workshop's major goal is to provide the requisite skills to a group of interested and dedicated researchers in the conduct of applied research in family health. To this end, the participants selected for this workshop are health professionals already collaborating with FHI in research. Their ongoing work with FHI has demonstrated an interest and desire to conduct research and, more importantly, their willingness to make time for it.

Lectures, group discussions and individual exercises will be used to present the course content. A case study approach using examples and results of research conducted by FHI in Africa will be used to illustrate the research methodologies. Each participant will go through a practical session involving the analysis and interpretation of computerized data output from these research activities. FHI intends to follow up and collaborate with each participant in the conduct of family health research in his or her country.

Workshop in Egypt to look at maternity care monitoring

A three-day workshop will be held in Cairo April 29-May 1 to introduce FHI's Maternity Care Monitoring (MCM) system to Egyptian obstetric care providers and health planners. Egyptian investigators who have used the MCM system will review their experiences for the 40 participants, and the computerized system's potential for improving maternal and child health and family planning services will be examined. The group will then develop a strategy for introducing MCM into maternity services in Egypt.

The Egyptian Fertility Care Society, under the direction of Dr. Ezzeldin Osman Hassan, will conduct the workshop and produce the proceedings, which will be printed and distributed within several months of the meeting.

The participants will include representatives from the obstetric and gynecology departments of various Egyptian universities, senior maternal and child health officials of Egypt's Ministry of Health, public health specialists, data analyses experts and senior nurse/midwives. FHI staff members Drs. Judith Fortney and Patrick Friel will help conduct the workshop, along with consultants Dr. Michael Rosenberg of the US Centers for Disease Control, National Institute of Occupational Safety and Health, Cincinatti, Ohio, and Dr. John S. Tomkinson, Secretary-General of the International Federation of Gynaecology and Obstetrics. Dr. Tomkinson will report on the establishment of a system of confidential inquiries into maternal deaths in Egypt. FHI President Malcolm Potts will also attend.

Obstetric care in Africa subject of forthcoming report

FHI staff are preparing a major report on obstetric care in Africa, using data collected from hospitals in ten sub-Saharan countries. Although many of the findings resulting from the analysis are well accepted in the West, little has been published to demonstrate that the same conclusions can be drawn about maternity care in African settings. In some countries, FHI maternity record studies have produced the only data available on obstetric management and use of family planning. The results of these studies will be useful to ministeries of health, health administrators and providers of obstetric care services. Preliminary findings indicate that:

- Conservative use of surgical intervention is indicated where women are unlikely to return to the hospital for subsequent deliveries.
- Where physicians are in short supply, other health care providers are able to recognize women with high-risk pregnancies and to make timely referrals of those requiring the care of physicians.
- Only very high parity women, those with six to eight surviving children, are interested in limiting their fertility.
- Although abortion is illegal in most of sub-Saharan Africa, induced abortion is apparently being used, especially by young women, to delay the first birth.
- While previous use of contraception is almost nonexistent, many women are interested in using modern contraceptives for birth spacing following delivery.

The report, written by Dr. Barbara Janowitz, Dr. Judith Fortney, Dr. Douglas Nichols, Sylvia Wallace, Jason Smith, JoAnn Lewis and Nadine Burton, will cover obstetric practices, allocation of resources and obstetric care, maternal mortality, birth spacing, breast-feeding, contraception, and policy implications.

Publication of the report is expected in July, and it will be produced in both French and English.

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Successful TBA project in Brazil improves health care inexpensively

A review of a project aimed at improving obstetric care in northeast Brazil has shown that better health service in seriously disadvantaged areas is possible at low cost and with the full support of the community.

A pilot project to train traditional birth attendants (TBAs) and to set up maternity units in rural areas surrounding the city of Fortaleza began in 1975. The program was developed to improve maternal and infant health care using previously untrained local people and limited resources. The TBAs not only received basic training in obstetrics, but also began to deliver women in small maternity units contributed by their communities instead of in the women's homes.

The northeast of Brazil is the country's poorest region, with a per capita income of less than half that of Brazil as a whole. The region's infant mortality rate (142 per 1000) is higher than that for any other in Brazil and typical of countries at low levels of development. Health resources were extremely limited, with a population-to-physician ratio of about 3000:1, compared with 1500:1 for Brazil as a whole.

The traditional birth attendant in the region is typically a middle-aged woman who in the past has been asked to help neighbors or friends at the time of delivery. After numerous such experiences she is recognized as a midwife in her community. She acquires knowledge from experience and observation or, possibly, from information handed down by her mother or colleagues. Most are illiterate, but have a keen sense of the practical and the obvious.

At delivery, the TBA almost always maintains her patient in a sitting or squatting position during the expulsion period, using low benches or birthing stools. She knows to put the baby to the breast immediately after delivery, even before the cord is cut.

The Assis Chateaubriand Teaching Maternity Hospital (MEAC) is one of only two free maternity hospitals in Fortaleza and provides the most sophisticated obstetric care in the area. Approximately 30,000 women are seen each year as outpatients in the antenatal, postpartum, family planning and gynecological cancer prevention clinics of the hospital. MEAC delivers about 8000 women a year.

Dr. Galba Araujo, a senior member of the faculty of MEAC, observed in the seventies that each year seven or eight women referred from the rural areas surrounding the village of Guaiuba were dying in childbirth at MEAC. He and others thought if maternity care in the outlying area could be improved, there would be fewer maternal deaths. After discussions with community leaders, support was enlisted in recruiting local TBAs to participate in a program to upgrade their skills. In addition, the community leaders offered the use of a vacant building to serve as a small obstetric unit.

A three-month course was given at MEAC for the TBAs. Initial experience showed that future training was better done in the small, freestanding obstetric units. After each course, the best TBAs were put to work in the local unit. The others went back to the community with general instructions to refer patients with high-risk pregnancies. After the success of the initial project, communities all over the area requested assistance in setting up similar programs. There are now 15 freestanding obstetric units.

Of 1881 women presenting at the obstetric units from October 1980 to July 1981, no maternal deaths occurred. The TBAs referred 235 of these patients to a Fortaleza hospital for delivery. Over 95% of women with antepartum hemorrhage or hypertensive disorders were referred by the TBAs, as were all women with premature rupture of the membranes (Table 1). The stillbirth rate was 18 per 1000 deliveries; five babies per 1000 born alive died before discharge.

As a result of the TBAs successfully identifying those at high risk, the stillbirth rate and rate of infant death before discharge were much higher for the patients the TBAs referred to the hospital. While almost

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Table 1. Labor characteristics of women presenting at obstetric units and percent referred.

	Total Cases		% Referred for delivery
Presentation during labor			
Vertex, occiput anterior posterior or transverse	95.6	(1816)	10.9
Brow/face	1.1	(21)	28.6
Breech	1.8	(34)	61.8
Transverse	0.5	(9)	100.0
Compound	0.0	(1)	100.0
TOTAL	100.0	(1881)	
Complications of labor/delivery			
None	96.5	(1815)	9.7
Prolonged/obstructed labor	2.3	(44)	97.7
Placenta previa	0.4	(7)	100.0
Placenta abruptio	0.4	(7)	85.7
Other	0.4	(8)	37.5
TOTAL	100.0	(1881)	
Condition of fetus/neonate			
Normal	96.3	(1811)	9.9
Fetal distress	3.1	(59)	83.1
Other	0.5	(10)	60.0
TOTAL	100.0	(1880)	

13% of infants born to women referred to the hospital were not discharged alive, less than 1% of those born to women at the obstetric units died before discharge.

This evaluation has shown that the project's goal of safer deliveries for rural women was achieved. Unschooled TBAs can be trained to refer high-risk patients for hospital deliveries, while conducting safe deliveries in their own communities. Equally important, this kind of training project can greatly extend the coverage provided by a hospital at a small cost.

Each unit has an outpatient clinic, a delivery room and a room with two to seven beds for postpartum recovery. They are furnished with simple equipment, including weighing scales and stethoscopes.

The units are open 24 hours a day with at least one trained TBA always on duty. A central ambulance and driver, provided by the rural security insurance program, are available to transport women to MEAC when necessary. An obstetrician and a nurse from MEAC visit each unit twice a week to supervise the TBA's activities and deal with any clinical problems.

Funding for the project is primarily provided by the Brazilian social security system. Costs for operating the units range from $200 to $2000 per month.

The success of the program has led to its expansion to include facilities for delivery at the homes of the trained TBAs. Currently there are five one-bed units and 20 more are planned for 1983. Each is attached to the home of a TBA, and women from the most remote areas can come to have their babies.

FHI plans further study of TBA project

FHI plans support for a second study of TBAs in northeast Brazil, this one a study of the one-bed obstetric units attached to homes of TBAs and of home deliveries in the more remote rural areas surrounding the town of Triari. In these more sparsely populated areas, larger units of five to seven beds are not feasible. While TBAs have been shown to perform well in the larger units, there is no information on TBAs who manage the one-bed units or on those who continue to do home deliveries.

The proposed study is to be directed by Dr. Galba Araujo of the Faculty of Assis Chauteaubriand Teaching Maternity Hospital (MEAC). He carried out the previous evaluation of the TBA training program in northeast Brazil.

The study will collect data on deliveries and referrals of approximately 50 TBAs for one year. The deliveries will include those attended by the TBAs and those at the hospital in Triari, including referrals by TBAs and referrals to MEAC.

All women will be interviewed six weeks to two months postpartum to determine if the baby is still living. The interviewers will try to get the cause of infant death at a second follow-up visit.

FHI's Maternity Record is being simplified so that it can be completed by a literate TBA or by a local resident if the TBA is illiterate. A pictorial form to record follow-up information on infant feeding, contraceptive use and infant survival status is also being designed to collect data in this study.

Monthly group meetings are planned for all TBAs in a community at which they can get help in completing the forms, exchange ideas and discuss problems, and receive continuing encouragement for the program.

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Breast-feeding topic of research seminar

Breast-feeding is nature's contraceptive. Not only is it important because of the nutritional value and emotional relationship between the mother and her baby, but because of the natural rhythm of infertility associated with lactation. On August 8-11 the Institute of Public Health of the University of the Philippines and Family Health International are co-sponsoring a meeting on *Breast-feeding: the Return of Ovulation and Contraception.* It will be attended by 50 Filipino and 15 international specialists engaged in breast-feeding research or with a serious interest in the promotion of breast-feeding.

"One of the special aspects of this meeting will be its multidisciplinary nature: biomedical scientists, clinicians, social scientists and policymakers will all take part," says Dr. Nancy E. Williamson, Senior Program Development Associate at FHI and coordinator for the seminar. "I think we will all learn a great deal from each other." The Chairperson of the FHI Board and one of the world's specialists in lactation research, Professor Roger Short, will be attending along with Dr. Pouru Bhiwandiwala, Director of International Projects at FHI.

FHI is currently supporting a study on breast-feeding patterns and the return to fertility in Mexico, Egypt and Thailand. The researchers working in these countries on this project will attend the seminar and will discuss the purpose and preliminary results.

Other presentations during the seminar will include an overview of breast-feeding patterns and trends and one of breast-feeding research. The results of the recent World Health Organization multi-country study on breast-feeding will be summarized. Dr. James Brown from Melbourne, Australia, will speak on the mucus method and identifying ovulation in lactating women.

Other sessions will deal with research on breast-feeding in the Philippines, lactation and contraception, and research on how to identify the onset of ovulation. One day of the seminar will be devoted to an examination of policies and programs aimed at promoting breast-feeding.

Former acceptors of injectable contraceptive are surveyed in Honduras

Former acceptors of the injectable contraceptive Depo Provera are being surveyed in Tegucigalpa, Honduras, to determine current interest in the product. The Asociación Hondureña de Planificación de Familia (ASHONPLAFA) provided Depo Provera from 1967 to 1978. Then in 1978, as a result of adverse publicity in the US, the use of Depo Provera was banned at all ASHONPLAFA clinics by the Honduran Ministry of Health. At that point, approximately 3500 women had accepted the method through the ASHONPLAFA program in Tegucigalpa. As is often the case, the ban did not extend to those women who could afford to make over-the-counter purchases at Honduran pharmacies, where Depo Provera is available for about the same price as oral contraceptives. An unknown number of women still use the product.

ASHONPLAFA is interested in providing objective information to the government concerning the need and acceptability of its injectable contraceptives. ASHONPLAFA requested FHI's assistance in surveying the 515 women who were actually receiving the injections through the ASHONPLAFA program in 1978 at the time its use was terminated.

The survey, which will begin in August, will attempt to contact the 515 women still using Depo Provera in 1978. The survey will determine the reasons for discontinuation, and whether the woman is interested in resuming use of the method.

The women in the survey are also being asked about their current contraceptive practice. ASHONPLAFA hopes to determine the percentage of acceptors who are continuing use of Depo Provera by over-the-counter purchase.

Additionally, women who express interest but who are not currently using Depo Provera are being asked why they do not purchase it at a local pharmacy. Their responses should determine the influence of cost and accessibility on Depo Provera use.

Finally, information is being collected on the contraceptive and reproductive histories of these women since they stopped using Depo Provera. ASHONPLAFA needs to know the contraceptive choices of previous users and their pregnancy experience.

Vaginal tablet to be tested

FHI will be initiating testing of another foaming vaginal tablet shortly. The tablet is manufactured by Ortho Pharmaceutical Corporation, Raritan, New Jersey, USA. It contains menfegol, the same spermicidal ingredient contained in Neo Sampoon foaming tablets (Eisai Co, Ltd, Tokyo, Japan). The studies will compare the new tablet (100 mg menfegol) with another Ortho tablet, this one containing the spermicide nonoxynol-9. The study should determine the safety, efficacy and acceptability of the new tablet.

The safety record and high acceptability of Neo Sampoon tablets have been amply demonstrated. In FHI comparative studies, the 12-month life-table rates for pregnancy (11.1) and medical discontinuation (3.0) compare favorably with the diaphragm and contraceptive sponge. Allergic reactions were experienced by only 1.8% of the women in the studies who used Neo Sampoon.

FHI anticipates testing the new Ortho product in three to four international studies with a total of approximately 600 women and in one or two US studies with 300 women.

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FHI research challenges female sterilization contraindication

FHI researchers have examined the tenet that previous abdominal surgery contraindicates interval laparoscopic sterilization and found some reassurance. Such patients do have more surgical difficulties at laparoscopic sterilization, but most of these are overcome without resorting to another technique or approach. This is the major finding of a report recently published in the *American Journal of Obstetrics and Gynecology* by FHI staff members I-cheng Chi, Paul J. Feldblum and Sandor A. Balogh ("Previous abdominal surgery as a risk factor in interval laparoscopic sterilization," Vol. 145, No. 7, p 841, 1983).

The authors determined that previous abdominal surgery increases the risk of surgical difficulties during interval laparoscopic sterilization, irrespective of the tubal occlusion technique used. Most difficulties, however are manageable without changing the planned procedure.

"The rates of immediate complications or early follow-up complications/complaints were not significantly different between women with previous abdominal surgery and those without," the authors state. They also note that medical costs, as reflected in operation time and duration of poststerilization hospitalization, are not increased significantly for women with previous abdominal surgery.

The report was based on a multicenter study of 261 women with previous abdominal surgery and 2256 women with none who underwent single-puncture interval laparoscopic sterilization. Six FHI data sets were included for the study. Previous abdominal surgery was defined as any surgical procedure performed through the peritoneum, including cesarean section, at any time prior to admission for sterilization. Tubal occlusion techniques used included spring-loaded clips, electrocoagulation and tubal rings.

Table 1 shows the immediate and early follow-up outcomes in women with previous abdominal surgery and those without any. Adhesions and difficulties in visualizing the tubes were the most frequently reported difficulties.

Major immediate complications such as shock, bowel/bladder injury and the need for transfusions were also examined. Differences between the two groups were small and inconsistent.

The authors note that even though a higher rate of surgical difficulties were found among the previous

Table 1. Outcomes of sterilization among women with and without previous abdominal surgery (PAS).

Tubal occlusion technique	Data set	Group	No.	Surgical difficulties (%)	Immediate complications[1] (%)	Mean operation time (min)
Spring-loaded clip	A	PAS	81	29.6[2]	6.2[3]	14.9
		None	352	15.9	1.7	15.0
	B	PAS	61	16.4[2]	8.2	9.3
		None	121	6.6	4.1	10.2
Electrocoagulation	C	PAS	32	9.4[3]	0.0	13.3
		None	696	1.7	2.0	12.2
	D	PAS	42	14.3	19.0	15.8
		None	200	9.5	14.0	15.7
Tubal ring	E	PAS	29	0.0	0.0	10.0
		None	698	0.9	2.9	10.7
	F	PAS	16	25.0	0.0	18.8
		None	189	12.2	4.8	14.7
TOTAL	—	PAS	261	18.0	6.9	13.2
		None	2 256	5.5	3.6	12.6

[1]*Includes bowel/bladder damage, shock, laparotomy required, excessive bleeding, and transfusion required.*
[2]*Pearson χ^2 test for differences between PAS and None groups with a data set significant at 0.05 level.*
[3]*Fisher's exact test between PAS and None groups within a data set significant at 0.05 level.*

(Adapted from Table III, Am J Obstet Gynecol, Vol. 145, No.7., p 843.)

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surgery women, operation time and duration of hospitalization after sterilization were similar for both groups. Further, the proportions of women discharged on the day of surgery were the same for both groups.

In summarizing their investigation, the authors point out that they were aware of possible bias in operator experience. If all the patients with previous abdominal surgery were more likely to be operated on by senior or more experienced staff members, that might obscure real differences between the outcomes of the groups. Through personal review of individual records, the authors were able to determine that no operator bias existed in any of the data sets.

Comparison of two vaginal tablets: FHI findings mixed

Nine FHI comparative studies of two vaginal contraceptive tablets are yielding mixed results. The studies have shown generally poor acceptance of the method and no clear preference for either product. FHI has encountered various difficulties with recruitment and follow-up in these studies that appear specific to the method itself.

Since late 1981, FHI has conducted a multicenter evaluation of two foaming contraceptive tablets. OVT manufactured by Ortho Pharmaceutical Corporation, Raritan, NJ, USA, and EVT by Schering Corporation, Kenilworth, NJ, USA. Each product contains 100 mg of the spermicide nonoxynol-9. *In vitro* tests of the two products revealed no significant differences in effervescence time or nonoxynol concentration.

Of the nine FHI studies, six include Neo Sampoon foaming vaginal tablets (Eisai Co, Ltd, Tokyo, Japan) as a standard of comparison. Neo Sampoon contains 60 mg of the spermicide menfegol, and is a well-established product in many countries.

With each product, the tablet must be removed from the packaging and inserted by hand high in the vagina approximately 10 minutes before intercourse. This timing allows the tablet to dissolve and suffuse the vagina with spermicidal foam. One tablet must be used for each intercourse.

Four of the nine comparative studies involve a direct comparison of OVT and EVT; three of the four are US studies and one is an OVT-EVT-Neo Sampoon study in Ghana. There is a single OVT-Neo Sampoon study, and the remainder are EVT-Neo Sampoon comparisons.

At the three-month follow-up, a significantly greater proportion of EVT than OVT users complained of burning associated with use. This difference was evident in the US studies and the three-way study in Ghana. However, the difference in the proportion of the same complaint at six months was slight. And at both three-month and six-month follow-up, there were frequent complaints of burning from both study groups in the EVT-Neo Sampoon comparison.

There is a higher discontinuation rate for discomfort among EVT users compared to OVT users in the direct EVT-OVT studies and in the three-way Ghanaian study. The total termination rate was also higher for EVT than for OVT in the three-way study.

On the other hand, in the US studies the total termination rate is higher for OVT than for EVT. The total termination rate for Neo Sampoon in the international studies is lower than that for either EVT or OVT. In straight EVT-Neo Sampoon trials in Egypt and Guatemala, there is a higher rate of discontinuation for discomfort among Neo Sampoon users. The numbers are small, however.

Some of the variance in trial results is explainable. The high discontinuation rate in the Ghanaian study is largely attributable to emigration. As the economy in Ghana worsened, more and more men left the country to find work, including many husbands of women enrolled in the FHI study. The women discontinued use when contraception was no longer needed.

To get additional information, FHI also sent questionnaires to the principal investigators of the nine studies. These clinicians were asked for comments, including suggestions for improving the tablets and possible reasons for the tablets' poor acceptance. Each investigator returned the questionnaire, and their reactions were as mixed as the study results.

The three US investigators expressed no preference for one product. Two thought the tablets were not acceptable among their patients. The third thought the tablets would be purchased and used, if marketed.

The Ghanaian investigator found OVT and Neo Sampoon of equal value and each superior to EVT. He was enthusiastic about OVT. Foaming tablets (Neo Sampoon) have won high acceptability in Ghana, where economic difficulties render some other contraceptives unavailable.

Three investigators described EVT as unacceptable because of the complaints of burning and messiness. The Egyptian investigator, however, cited EVT's ease of application, lack of effects on lactation and minimal side effects as important strengths of the product.

The investigator conducting the OVT-Neo Sampoon study reported that no vaginal method is popular with his patients and further described OVT as cumbersome and ineffective.

Recruitment and follow-up have been difficult throughout these studies. Spermicides are easily accessible as over-the-counter products. Consequently, it has sometimes been difficult to recruit users among clients of family planning clinics. To overcome this, FHI plans to explore the possibility of community-based studies of vaginal contraceptives that might reach beyond the women who attend the clinics.

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Book on FHI's maternity record experience is published in England

A book of collected research studies on FHI's seven years of experience with a system of maternity care monitoring (MCM) has been produced by three FHI staff members. Published by MTP Press Limited of England, *Childbirth in Developing Countries* was edited by FHI President Dr. Malcolm Potts and research staff members Drs. Barbara Janowitz and Judith Fortney.

The book is a compilation of research papers written by collaborating investigators and FHI staff. Topics examined include high-risk pregnancies; aspects of cesarean delivery, including breech presentation and trial of labor in women with previous cesarean deliveries; the pregnancy interval; and postpartum contraceptive plans.

"We are especially pleased to see the book in print," says Potts. "FHI's chief aim is to spread the essential information about its research as far and as thoroughly as possible. Our goal is a world community fully knowledgable about maternal and child health. We produced *Childbirth in Developing Countries* to give health planners, students and policymakers an idea of what broad implications can result from simple record keeping, appropriately analyzed. I certainly hope the book will have a Third World audience."

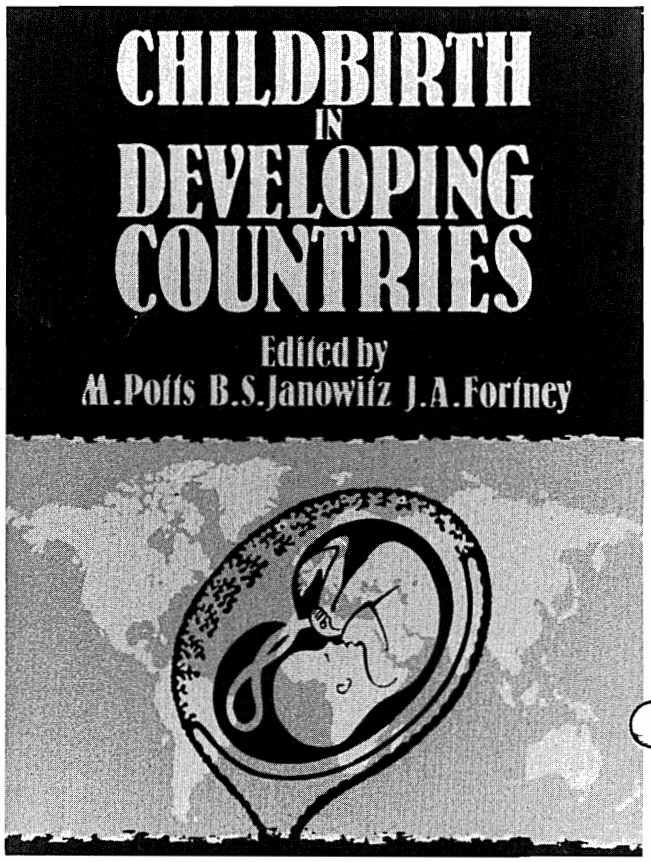
"FHI is proud of the MCM system. For years, many maternity hospitals and centers had no resources to systematically evaluate their services. Without evaluation, these facilities could not determine the most effective means to improve their maternity care services to reduce the number of maternal deaths, stillbirths and neonatal deaths."

"The MCM system was developed to survey broad aspects of maternity care through the completion of a simple patient record. The information from the records of all patients in one facility can be analyzed, and unmet needs in patient care can be identified."

All the data referred to in the book were collected on the single-sheet Maternity Record. The Record is completed for each woman who is admitted to and who subsequently delivers at the hospital, regardless of outcome. The completed records are returned to FHI for analysis. The participating institutions receive computerized standard analysis tables at specified intervals.

By October 1982, when the book was put together, the MCM system had accumulated histories of over 450,000 deliveries occurring at more than 150 maternity centers in 39 developing and developed countries. Using this large data set, staff and collaborating investigators examined the topics presented in the book.

Potts is emphatic about the value of the data. "The vast majority of births occur in developing countries, where maternity care is often rudimentary. An effective solution to these obstetric care problems can only be developed if the details of the problems are accurately understood. What is the most effective use of limited resources? What are the major causes of death? What are the priorities for preventative and curative services? Are realistic and effective family planning services available? The MCM system goes a long way toward answering those questions. The research results contained in *Childbirth in Developing Countries* are a vivid and real example of what can be accomplished—what must be accomplished."



Childbirth in Developing Countries, a collection of research papers on FHI's maternity record data was published this summer. The 162-page book is available from MTP Press, Lancaster, England.

TCu 380 Ag versus Multiload Cu 375 trial

Preliminary findings of a multicenter clinical trial comparing the TCu 380 Ag and the Multiload Cu 375 show similar results for the two IUDs. Devices were randomly allocated to 1499 not recently pregnant women at five sites. Results show that the performance of the two devices is similar with respect to pregnancy and other IUD event rates over a one-year period.

Both devices look good; pregnancy rates for the IUDs were less than one per 100 women at one year. A final report will be written by the end of the summer, after one-year follow-up has been completed at all sites.

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Vasectomy decision-making process outlined in recent report

Through a study of 235 couples and single men, an FHI researcher has found that the decision-making process leading to a vasectomy takes two to ten years (*see* Fig. 1). Program planners, though, can intervene to speed up the process. FHI research staff member Dr. Stephen D. Mumford has published a report in *Studies in Family Planning* (Vol. 14, No. 3, March 1983) entitled, "The Vasectomy Decision-Making Process." In his report, Mumford emphatically says that the key to a successful vasectomy program is satisfied customers. "Thorough counseling is essential if patient satisfaction is to be maximized. Well-informed vasectomized men invariably serve as the most influential sources of information in the community, and program administrators should use them; most are eager to discuss their experience in favorable terms."

Nine out of ten men sought and got information from vasectomized men. One third reported discussing the subject with at least seven such men. Unquestionably, says Mumford, vasectomized men are the key component in the vasectomy information network.

Mumford breaks down the vasectomy decision-making process into seven steps the man and his partner go through:

- becoming aware of vasectomy
- first talking to a vasectomized man
- deciding to have no more children
- starting seriously to consider vasectomy
- deciding temporary contraceptives no longer acceptable
- deciding vasectomy is best contraceptive method
- having a "scare" (missed period or severe side effects with pill)

The author also reports a number of reasons for delay in obtaining the procedure once the decision is made. Almost one fourth delayed because of "fear of pain." "Cost" and "inconvenience" were each cited by one fifth of the men in the sample.

The report includes concrete advice for counselors in vasectomy programs. A list of 23 questions many men ask before seeking a vasectomy is provided, the result of the author's experience in counseling more than 4000 couples making this decision.

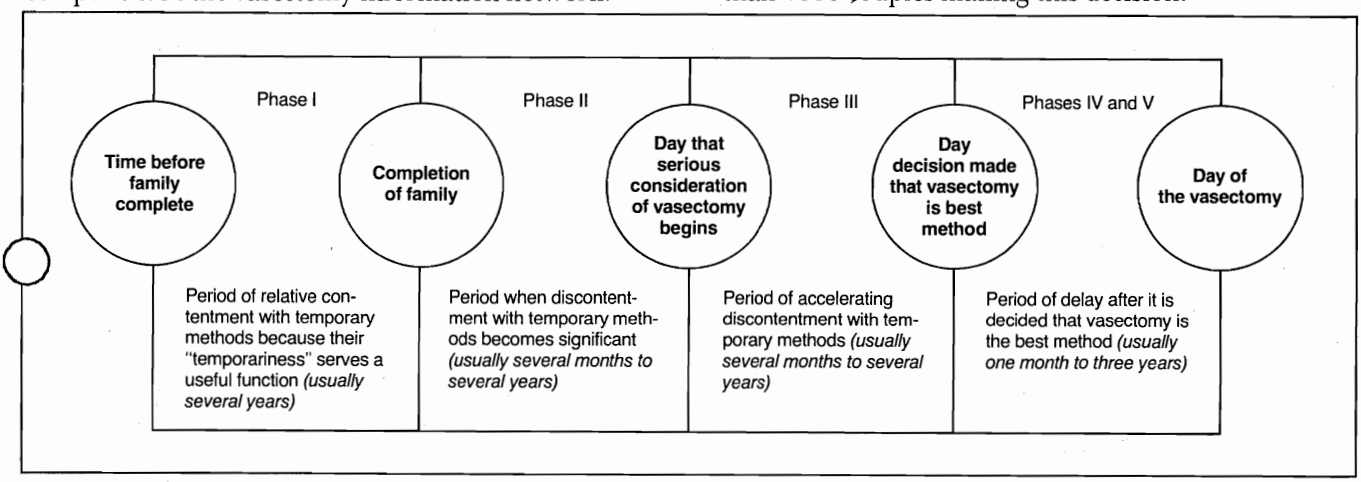

Fig. 1. Five phases through which most men pass before getting a vasectomy.
Reprinted from Stud Fam Plann 14 (3): 1983, p 87. Used with permission of the Editor.

Contraceptive technology, clinical research skills workshop set for September

Twelve medical doctors from developing countries will take part in FHI's second Contraceptive Technology and Clinical Research Skills Workshop, September 24-October 8, 1983. The two-week workshop will emphasize current contraceptive technologies and the clinical research methodologies necessary to evaluate them. Part of the workshop will involve participants designing a clinical trial study strategy for possible implementation upon their return home.

"The course is designed to strengthen the physician's clinical research skills," says FHI Regional Coordinator Mark Robbins, workshop coordinator. "The workshop is again being supported by USAID and a grant from the Jessie Smith Noyes Foundation of New York City. We are grateful for their initial support of the workshop last year, and we are encouraged by their continued support. This workshop is an important part of FHI's efforts to allow local assessment and decision-making on the range of contraceptive options to be used in developing countries."

Workshop participants are selected on the basis of their interest in conducting clinical trials of new contraceptive technology. Countries represented by this year's participants include Bangladesh, Brazil, Egypt, Indonesia, Sri Lanka, Thailand and Yugoslavia.

FHI staff members will conduct the training at FHI headquarters in Research Triangle Park, NC. Last year's postworkshop evaluation by participants, their recommendations and those of the workshop's instructors were used to help develop the study outline and textbooks for the 1983 workshop.

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FHI names Director of Contraceptive Safety Research

Dr. Michael J. Rosenberg has joined FHI as Director of Contraceptive Safety Research, effective July 1. Dr. Rosenberg was previously Chief of Reproductive Health Activity, US Centers for Disease Control, National Institute of Occupational Safety and Health.

In announcing his appointment, FHI President Dr. Malcolm Potts called attention to Rosenberg's international professional experience in Bangladesh, Brazil and Morocco. "Dr. Rosenberg is a valuable addition to our research staff. We think his background in both occupational health safety and research in family planning will bring particularly rigorous scrutiny to his study of contraceptive safety."

Rosenberg holds an MD from the University of California, Davis, and an MPH in Epidemiology and Biostatistics from the Harvard School of Public Health. He has published numerous articles on reproductive health and the methodological approaches to its study.

In 1979, Rosenberg was a member of the Visiting Faculty, Institute for Statistical Research and Training, Dhaka University, Dhaka, Bangladesh. He also served as a USAID consultant in population and epidemiology in Bangladesh and Brazil, 1979-1980.

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A free copy of any of these articles or a complete catalog of FHI publications is available upon request.

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network

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FHI supporting introduction and evaluation of NFP in Peru

Natural family planning (NFP) methods are growing in popularity alongside older, more established contraceptive methods. NFP's consistency with the teachings of the Roman Catholic Church and widespread uneasiness over the side effects, inconvenience and cost of certain modern methods of contraception have contributed to its growing popularity. FHI has recently provided support for a natural family planning project in Lima, Peru, that will help determine the methods' effectiveness, training requirements and cost.

Because of the limited documentation of NFP's record in the rural areas and in working class and slum areas of the big cities of the developing world, some family planning program managers are reluctant to provide NFP on a large scale. Questions remain about the method's effectiveness, about whether the stringent requirements of NFP methods can be maintained in a wide variety of settings, and about whether the cost of training and follow-up is prohibitive.

FHI will work with the Asociacion de Trabajo Laico Familiar (ATLF) in evaluating a natural family planning project aimed at serving couples in a working class section of Lima. At present, no clinics in Peru serving a broad population make available modern NFP methods. ATLF staff will be trained in the cervical mucus and sympto-thermal methods. In the latter method, changes in the cervical mucus are used to indicate the onset of the fertile period, and further changes in the mucus and a basal body temperature plateau estimate the end of the fertile period.

Although the ATLF runs seven clinics in the Lima area and others outside the city, it will concentrate its new NFP services in one clinic. Courses will be conducted until several hundred couples begin to use the NFP method of their choice. Participation in structured classroom sessions will be required of couples, but individual training interviews will also be available. A follow-up period of one year for participating couples is anticipated.

FHI has agreed to assist in setting up and evaluating the project. Training, the NFP methods themselves, the effect of using NFP on marriage and family, and the economic costs and benefits will all be evaluated. Because promoters of NFP emphasize that the quality of teaching is the key to a successful program, FHI and ATLF have made special arrangements with outside experts to assure high quality teaching. During the evaluation FHI and ATLF will look at the knowledge and effectiveness of the instructors, the training materials, and measure the clients' knowledge of NFP at the follow-up interviews.

Since NFP is also considered by many as an approach to strengthening family relationships, rather than just a method of family planning, FHI and ATLF will explore whether clients in the project feel the method has any effect on their marital or family relationships. Whenever possible, husbands will be included in follow-up interviews.

The costs of offering NFP services in a developing country like Peru will be carefully determined. A cost survey will review training, counseling, promotion, supplies, management and follow-up of clients. This part of the evaluation will obtain information on the feasibility of offering NFP on a larger scale.

ATLF is currently in a pilot phase of this project. Staff are being trained and educational and research materials are being pretested. Services are scheduled to begin in early 1984.

ATLF was incorporated in 1970, "to inform, guide and educate in order to provide integrated education for families in Peru—especially those of lesser means—to achieve responsible parenthood by regulating the number of their children using natural means, according to the teachings of the Catholic Church."

The ATLF clinic selected for the project is located in the San Vicente de Paul parish, a working-class neighborhood. The clinic is supervised by a Colombian nun, and the parish priest is acting as coordinator of the project. The clinic staff is committed to NFP, which gives it a good potential to recruit a large number of clients. The project's Director is Dr. Guillermo Tagliabue.

Issue highlights:

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Propranolol set for study 7

Study of maternal mortality in Senegal planned

Like many developing countries, Senegal has a high rate of maternal mortality, but the precise level and causes of death are unknown. Moreover, the main factors affecting the health of rural Senegalese women are not well understood. Given the limits of the maternal and child health infrastructure, it is important to understand the pattern of sickness and death as a first step in maximizing the use of existing resources.

Hospital-based studies in Senegal have shown the rate of maternal mortality to vary between five and ten maternal deaths per thousand deliveries depending on the type of institution studied. A longitudinal study begun two decades ago in a small rural area of the Sine-Saloum region shows a rate of seven deaths per thousand live births.

According to FHI's Nadine Burton, Senegal is on the threshold of developing an effective, national family planning program, in part as a means of improving the health of women and of lowering the maternal mortality rate. Policymakers are becoming more aware of the importance of birth spacing to protect the health of children and their mothers. Maternal and infant mortality is common, but the relationship between closely spaced births and infant survival is not well understood by many Senegalese who have traditionally equated numerous pregnancies with greater chances of having surviving children.

FHI is planning to study maternal mortality in Senegal in collaboration with the Bureau National de Rencensement (BNR). To evaluate the methodology of the proposed study, the BNR conducted a pretest in conjunction with an investigation of mortality of children under five in the region of Thies. Interviewers visited 13 villages and asked how many children had died since a given date. Information on maternal deaths in these villages was also collected during the childhood mortality study. Results of the pretest indicate that it is feasible to conduct a maternal mortality study in rural areas.

Current plans call for a three-part study designed to estimate mortality rates of women of reproductive age in the Fatik, Kafrine and Kaolack regions of the Sine-Saloum, to obtain information about obstetric care throughout the region, and to improve the reporting and analysis of maternal and child health statistics in the participating hospitals and maternities. Study sites include an area with a rural health project currently in progress (Kaolack), an area in which there was a health project before 1982 (Fatik), and an area where there has never been any large-scale health intervention (Kafrine).

The proposed study will monitor all pregnancies occurring in the study areas for which institutional care is provided. The regional hospital in Kaolack and three subordinate health centers, the two highest levels of obstetric care in the region, will collect a variety of obstetric data; lower level village health posts and health huts will use a registry which includes about 30 questions to gather information. When deaths to women of reproductive age are reported, detailed information will be collected from institutional records and attending staff.

A key element of the planned study is identifying deaths that occur outside health institutions. Visits will be made to a random sample of households to determine the number of deaths that occurred over a particular time period. Interviewers will also obtain the name, age, and marital status of each woman of reproductive age in the household.

After twelve months the sampled households will be revisited. The head of each household will again be asked about the deaths that have occurred. The members of each household will also be enumerated to determine population changes due to births, migration, marriage and death. The focus will be on recording deaths to women of reproductive age.

The third part of the study will concentrate on determining causes of death. All deaths to women of reproductive age identified during the study will be investigated. Families reporting such deaths will be interviewed about the symptoms at the time of death. Completed case histories containing the details of each death will be examined by a panel of physicians to determine the cause of death. Reports on deaths occurring in the hospitals will be compared to questionnaires answered by the family. The comparison will help evaluate the questionnaire's usefulness in collecting information on causes of death. Comparing the causes of hospital and home maternal deaths will help identify areas, improvement of which could lower death rates.

If approved, the study will begin early in 1984.

FHI

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FHI study shows no menstrual changes caused by sterilization

After reviewing over 10,000 cases, FHI researchers have cast doubt on the theory that sterilization causes menstrual changes. The majority of women studied did not experience any change in their menstrual patterns. When changes did occur, equal proportions of women reported changes in opposite directions.

These findings have been reported in the American Journal of Obstetrics and Gynecology (vol. 145, no. 6, March 15, 1983) in an article entitled "Menstrual Pattern Changes Following Laparoscopic Sterilization With Different Occlusion Techniques: A Review of 10,004 Cases" by Pouru P. Bhiwandiwala, Stephen D. Mumford and Paul J. Feldblum.

The research compared menstrual pattern changes reported by women undergoing interval and postabortion sterilization by the laparoscopic occlusive techniques of unipolar electrocoagulation, the tubal ring, the prototype spring-loaded clip and the Rocket clip. Controlling for prior contraceptive use, the researchers compared the women's menstrual cycles in terms of regularity, length, duration, amount of flow, dysmenorrhea, and intermenstrual bleeding.

Among women using oral contraceptives or IUDs at the time of sterilization, from 15% to 79% of the menstrual pattern changes seen after six months could be attributed to those methods of contraception. No significant differences were found in the occlusion technique groups with respect to the proportion of women who reported changes in menstrual patterns.

The study ranked the five groups of sterilized women according to reported menstrual change: the proportion of women who experienced change was least with the tubal ring, followed by electrocoagulation, the US and European group with the prototype spring-loaded clip, the developing world women with this clip, and the Rocket clip group.

The authors note that this ranking indicates that, contrary to the theory that the greater the tissue destruction the greater the menstrual disturbances, the most destructive occlusion technique, electrocoagulation, did not result in the greatest reported change in menstrual patterns. Their data also show that, among women using no contraception, a barrier method or withdrawal before sterilization, the proportion reporting change during the first six months poststerilization was no greater than the proportion who reported change after that time. This evidence is contrary to the notion that if sterilization disturbs menstrual patterns, it will be most apparent in the first few months after sterilization.

Ultrasound stethoscopes distributed in Zaire

Eight battery-operated fetal pulse detectors have been provided to physicians in maternity hospitals and health centers in the Republic of Zaire. As many as three dozen additional units may be distributed in coming months as part of an FHI-supported study of pregnancy wastage in this central African nation.

The two-year study, designed to document the incidence and complications of pregnancy wastage requiring hospitalization, is currently underway at ten centers in Kinshasa, Matadi and Bukavu. The study will also investigate whether the deliberate interruption of pregnancy is particularly prevalent among young, unmarried women who have little or no access to family planning services.

About 40 physicians are collaborating in this study, using both the standard FHI Pregnancy Wastage form and a supplementary questionnaire concerning individual behavior and attitudes relating to fertility regulation. At their request, FHI is supplying the fetal pulse detectors, known as "Dopplers" (Fig. 1), to compensate staffs at participating hospitals for their work in the project. This equipment is able to detect a fetal heartbeat in pregnancies as early as 12 weeks. The units are acclaimed by those associated with the project as being extremely valuable in the management of pregnancy and the early provision of proper prenatal care for mothers-to-be.

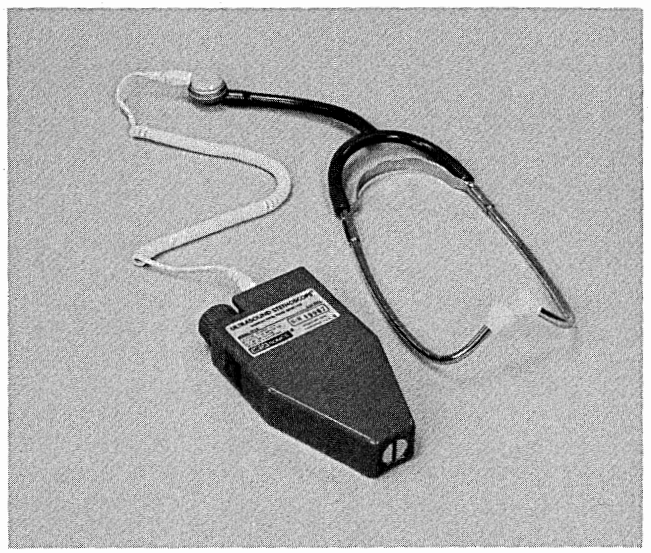

Fig. 1. The fetal pulse detector (MedaSonics, Mountain View, California, USA) shown is being distributed to doctors in Zaire.

Side effects of OCs unchanged by lower doses or vitamin supplements

Findings from a large-scale clinical trial in Sri Lanka indicate that neither vitamin supplementation nor lower-dose pills (50 mcg of estrogen) produce significant differences in side effects or continuation of oral contraceptives. The study of pill users in one urban setting, Colombo, and two rural areas, the districts of Puttalam and Matara, was conducted jointly by the Family Planning Association of Sri Lanka and Family Health International.

Results of the study were reported recently in Contraception (vol. 27, no. 5, 1983) in two articles entitled "A Comparison of Norinyl and Brevicon in Three Sites in Sri Lanka" and "A Trial of Daily Vitamin Supplementation as a Means of Reducing Oral Contraceptive Side Effects and Discontinuation in Sri Lanka" by Sriani Basnayake and S. Victor de Silva of the Family Planning Association of Sri Lanka and Peter C. Miller and Susan Rogers of the FHI staff.

Four treatments were compared: Norinyl, the standard oral contraceptive used in Sri Lanka, with a daily multi-vitamin supplement; Norinyl with placebo; Brevicon, a low-dose pill, with the vitamin supplement, and Brevicon with placebo. (Norinyl and Brevicon are both manufactured by Syntex Laboratories, Inc., Palo Alto, California.) Follow-up rates on the 2651 women were high throughout the study: over 90% of the rural women and 75% of the urban women.

In comparing vitamin and placebo usage, Table 1 shows the proportion of follow-up forms on which each of the ten most common side effects were reported, for the first follow-up and for all follow-up visits combined. Placebo users showed a slightly higher incidence of most side effects, but the differences were not significant.

In comparing termination rates, the researchers found that differences by site in both overall continuation and in reasons for discontinuation were much more striking than differences by treatment within site. As for side effects, differences between the standard-dose and low-dose pills were predictable: breakthrough bleeding was more common among Brevicon users, whereas most other side effects were more frequent among Norinyl users. The differences were often small, however, and exceptions occurred.

Interestingly, breakthrough bleeding did not appear to be strongly associated with discontinuation among the women. The data showed that (a) menstrual side effects were not commonly cited as a reason for discontinuation, (b) women who reported this symptom at first follow-up were only moderately more likely to discontinue use, and (c) rural women rarely cited bleeding/spotting as a "most disturbing side effect." On the other hand, initial reporting of a cluster of four highly correlated symptoms—headaches, dizziness, nausea, and vomiting—were found to be highly predictive of discontinuation. As in similar studies, reported side effects declined over the duration of the study.

Table 1.
Proportion of Follow-up Visits on Which Selected Side Effects Were Reported, for First Follow-up Visit and for All Visits, by Symptom and Treatment

	First Follow-up Visit		All Visits*	
Symptom	**Vitamin**	**Placebo**	**Vitamin**	**Placebo**
Spotting/ bleeding	.20	.23	.12	.10
Nausea	.26	.32	.10	.13
Vomiting	.16	.18	.05	.07
Dizziness	.26	.28	.11	.12
Headache	.50	.46	.35	.36
Hair loss	.17	.16	.10	.08
Backache	.17	.18	.12	.11
Abdominal pain	.16	.18	.11	.13
Tiredness	.23	.24	.18	.20
Irritability	.24	.30	.19	.20
Number of forms	*200*	*186*	*719*	*720*

**Tests of significance not done.*

Adolescent pregnancy high in Nigeria

A recent study on the contraceptive and reproductive practices of unmarried adolescents in Ibadan, Nigeria, one of sub-Saharan Africa's largest cities, reveals an alarming incidence of unplanned and unwanted pregnancies. Increased sexual activity and limited access to and use of modern contraception contribute to this problem, which in turn causes widespread elective termination of pregnancy among young women.

The study of "Sexual Behavior, Contraceptive Practice and Reproductive Health Among the Young Unmarried Population in Ibadan, Nigeria" was carried out from November 1981 to March 1982 as a collaborative effort of FHI, The Pathfinder Fund, and the Family Planning Clinic of the University College Hospital in Ibadan.

Interviews were conducted with 959 unmarried men and 841 unmarried women between the ages of 14 and 25. These 1800 men and women came from four settings: (1) the University of Ibadan and University College Hospital, (2) the Ibadan Polytechnic Institute, (3) secondary schools, and (4) work places in the city. Working adolescents were, in general, of lower socioeconomic status than those in the other groups. Sites were selected to obtain a representative sample of adolescents of different ages and education in Ibadan.

Only a very small proportion of respondents had formulated definite marriage plans. The number of children wanted was highest among secondary students (5.8 children) and least among university students (4.3 children), with little difference between males and females in each group.

The great majority of both men and women knew about reproductive health. Smaller proportions, but still a majority, were familiar with contraceptive methods. However, responses to a question on the time during the menstrual cycle when a woman is most likely to become pregnant showed that the level of knowledge of human reproduction among many adolescents is low.

The majority of respondents were sexually active. Among 18 year olds, 51% of the women and 78% of the men had engaged in sexual intercourse. Many respondents initiated sexual activity at age 15 or younger, when access to contraceptive services or counseling is virtually nonexistent.

Of the sexually active adolescents, the better educated tended to report more contraceptive use. Roughly a quarter of the working men and 63% of the working women reported ever having used contraception. For sexually active university men and women, these figures were 76% and 82%, respectively. Nonusers overwhelmingly cited lack of knowledge about contraception as the reason they were not using any method. Those who used contraception preferred oral contraceptives and condoms.

A surprisingly high proportion of respondents had been pregnant. Among university women, 24% (37% of those who had had sexual relations) reported at least one pregnancy. Roughly 30% of all polytechnic women and 55% of those who were sexually active had been pregnant. Among secondary school students, 16% had been pregnant, a figure that equals nearly half (44%) of all those who had had sexual intercourse. Finally, 62% of the working respondents had been pregnant at least once (see Table 2).

The study found that virtually all university and polytechnic students terminated their pregnancies by abortion, as did roughly four out of five secondary school students and working women. "This is perhaps the most important finding of the study," says the report. "It has long been acknowledged that abortion was indeed available to pregnant adolescents, but not previously documented that it is, in practical terms, the only alternative chosen by unmarried individuals included in the present sample: 183 out of 203 first pregnancies were terminated by means of induced abortion." The in-school samples tend to be self-selected to exclude women who became pregnant and elected to carry the pregnancy to term. Such women would typically drop out of school and be unlikely to return; therefore, they would not be part of the study population.

The report recommends:

- More reproductive health education and information, especially for secondary school students.
- A system of health and family planning care and advice for adolescents. Contraceptive options are especially important, because abortion is illegal. Illegally obtained abortions are often dangerous, both immediately and to long-term reproductive health.
- Further research into adolescent sexuality in Nigeria, particularly in rural areas where 75% of Nigerians live.

Authors of the report are: O.A. Ladipo, Grace Delano and E.O. Otolorin of Ibadan's University College Hospital; Douglas J. Nichols and Elizabeth Kelly of Family Health International; and John M. Paxman of The Pathfinder Fund.

Table 2.
Sexual and Pregnancy Experience Ibadan Women (1982)

	Ever Had Sexual Relations %	Ever Pregnant %	Ever Terminated Pregnancy %
University *(N = 285)*	66	24	23
Polytechnic *(N = 128)*	52	28	26
Secondary *(N = 346)*	38	16	13
Working *(N = 82)*	91	62	51

Experts discuss methods of nonsurgical female sterilization

The prospect of a safe, effective, nonsurgical method of female sterilization is both tantalizing and frustrating—tantalizing because a number of methods have been used with some success and frustrating because no one method has performed consistently well.

On September 16, seventeen experts met at FHI to discuss transcervical methods of female sterilization. The goal of the meeting was to review progress in the development of a safe, effective, nonsurgical method of sterilization that could be completed in one treatment and, if necessary, carried out by nonspecialized personnel outside a fully equipped hospital. The experts agreed, however, that the demand for sterilization is so strong in some localities that more than one administration of a drug might be accepted in order to secure a high rate of tubal occlusion.

FHI's staff reported that a follow-up study of 150 women who had 250 mg quinacrine pellets placed in the uterus on three different occasions one month apart showed a cumulative pregnancy rate of 4.3 per hundred woman-years of exposure and no ectopic pregnancies. FHI plans to implement a study of the insertion of pellets prior to scheduled hysterectomy.

Work conducted at Johns Hopkins Medical School has shown that tetracycline appears to behave like quinacrine in its ability to cause sclerosis of the reproductive tract in animals. The group recommended the initiation of human trials comparing the effect of quinacrine and tetracycline on the human fallopian tubes when inserted prior to scheduled hysterectomy.

Professor Ralph Richart of the Division of Obstetric/Gynecologic Pathology, Sloane Hospital for Women, New York; Dr. Robert Neuwirth of the Department of Obstetrics/Gynecology, St. Luke's Hospital for Women, New York; and Dr. Douglas Huber of the Association for Voluntary Sterilization, New York, on a recent visit to the People's Republic of China, both saw and performed a small number of transcervical occlusions using the Chinese technique. After the passage of a metal cannula, a 0.5-ml diameter plastic catheter is passed into the cornu of the uterus, and 0.1 ml of the sclerosing mixture of phenol, x-ray opaque material and viscous tragacanth is injected through the catheter. In some centers, every woman is x-rayed immediately after the procedure and told whether to expect a complete occlusion. In the opinion of Western observers, this method is worthy of additional study outside China.

The BioNexus Corporation is continuing development of the FEMCEPT device with which methylcyanoacrylate can be applied to the tubes. Mr. B.J. Amdahl and Mr. Lee Bolduc represented BioNexus at the meeting. With the need of some Third World countries in mind, BioNexus has developed a reusable apparatus.

Nonsurgical female sterilization has been shown to be possible, but improvements in the available techniques are urgently needed. The group considered a number of adjunctive therapies and novel delivery systems that might be used at the time of chemical sterilization to improve tubal occlusion rates. The meeting encouraged the maximum cooperation among the researchers working in this field.

FHI particularly welcomed the participation of the World Health Organization, through its representative, Dr. Earl W. Wilson. Other participants included: Dr. Linda E. Atkinson, formerly of The Ford Foundation; Dr. William Droegemueller, Department of Obstetrics/Gynecology, University of North Carolina School of Medicine, Chapel Hill; Dr. Norman Dubin, Department of Obstetrics/Gynecology, Johns Hopkins University, Baltimore, Maryland; Dr. Alfredo Goldsmith, Program for Applied Research on Fertility Regulation (PARFR), Chicago, Illinois; Dr. Theodore King, Johns Hopkins Hospital, Baltimore, Maryland; Dr. Thomas Moulding, formerly of the National Jewish Hospital, Denver, Colorado; Dr. Tim H. Parmley, Department of Obstetrics/Gynecology, Johns Hopkins Hospital; Dr. Lourens Zaneveld, Department of Physiology and Biophysics, University of Illinois at the Medical Center, Chicago; Dr. James D. Shelton and Dr. Russel J. Thomsen, US Agency for International Development, Office of Population, Washington, D.C., and Dr. Michel Vernier, consultant to FHI.

Natural family planning federation to meet in Hong Kong

About 200 participants from over 50 countries are expected to attend the Third International Congress of the International Federation for Family Life Promotion (IFFLP) in Hong Kong November 20-30, 1983. A special seminar on the development and evaluation of natural family planning programs will be held in conjuction with the Congress.

Seminar sessions will review some of the world's two dozen national NFP programs. Sessions will also cover development issues, education and training components, program accountability, evaluation and future directions. FHI is providing support for travel of some of the Congress participants and for a monograph based on the Congress papers and discussions.

The Congress will offer a general update on the scientific aspects of natural family planning and on various initiatives and experiences in family life promotional and education activities. Training workshops in three languages are also scheduled.

Exchange sessions are planned for IFFLP members from Africa, the Americas, Asia/Oceania and Europe to foster mutual planning and collaboration among members of the Federation's network. The Congress will explore collaboration between IFFLP members and private and public sector organizations.

Dr. Nancy Williamson, FHI's Director of Natural Family Planning Research, will attend the Congress and seminar.

Propranolol set for study

FHI is planning a study of the intravaginal administration of propranolol as a contraceptive. In vitro tests have shown propranolol, the most frequently prescribed drug in office practice in the United States, to be a highly effective inhibitor of sperm motility. Propranolol's effect depends on membrane activity similar to that seen with quinacrine and lignocaine and is different from that of detergent spermicides such as nonoxynol-9. The FHI study will evaluate various propranolol doses to identify one that is contraceptively effective without any clinically significant systemic effects.

The proposed study would evaluate commercially available tablets of 40 mg and 80 mg of D-propranolol in comparison with tablets of 100 mg of nonoxynol-9 and a placebo. Safety will be determined by measuring systemic absorption, adverse tissue reaction, and change in pulse and blood pressure. Contraceptive effectiveness will be measured by the standard postcoital determination of sperm motility in cervical mucus. The period of potency will be ascertained by varying the interval between insertion of the tablets and coitus.

Ten sexually active women, aged 21-40, in good physical health will be asked to volunteer for the study. All ten will have undergone female sterilization. A semen analysis of the women's partners will be performed to establish sperm counts and motility. The women will not take any other medication during the study. Cardiac, liver, renal or respiratory disease or diabetes will exclude women from becoming volunteers, as will poor cervical mucus.

Each woman will use each of four vaginal tablets —a placebo, 40 mg of propranolol, 80 mg of propranolol and 100 mg of nonoxynol-9. Women will return to the clinic from days 11 to 15 of their menstrual cycles to receive the vaginal tablet to be used at next intercourse; the order in which the products are used will be randomly assigned for each woman.

The tablets are to be inserted into the vagina one-half hour before intercourse. Readings of standard laboratory values, including blood measurements, will be taken at admission to the study and again when the woman returns to the clinic at three hours postcoitus. A cervical smear will be done at admission and again after the fourth treatment in each woman.

Six of the women wili be asked to repeat the treatments for 80 mg of propranolol and for 100 mg of nonoxynol-9. These insertions will occur at nine hours and 18 hours before intercourse, respectively.

The study is expected to take 12 months.

Bolivia evaluates individual and societal costs of pregnancy wastage

The Bolivian Society of Gynecology and Obstetrics has requested FHI's help in studying the problem of pregnancy wastage in Bolivia. Deliberate termination of pregnancy, although illegal in that country, is acknowledged to be widespread and increasing. Not only does the practice have adverse effects on the health of the women involved, but it also drains scarce medical resources that could otherwise be directed to raising general health conditions.

Bolivia presently has no national family planning program. Contraceptive methods are not widely available and often do not reach the poor. As a result, many unwanted pregnancies are known to be terminated by traditional practitioners, often under septic conditions. A recent survey of women in the nation's capital and largest city, La Paz, showed that over one out of every four women between the ages of 15 and 45 had had at least one induced abortion.

FHI is assisting in the design and implementation of a study of pregnancy wastage in five provinces. The study has several goals: to estimate the extent of early fetal loss requiring medical treatment at hospitals in each province; to estimate the proportion of pregnancy wastage that is spontaneous and the proportion that is deliberate; to determine the sociodemographic characteristics of women hospitalized for treatment of pregnancy wastage; to describe the nature and extent of medical complications associated with pregnancy wastage; to estimate the extent of contraceptive practice among women who seek treatment for pregnancy wastage, and to provide Bolivian policymakers with data that will assist them in designing adequate family planning programs at a national level.

Information will be collected on all women admitted to a sample of hospitals for treatment of complications associated with pregnancy during a one-year period. Large public hospitals that treat the majority of abortion-related cases in five of Bolivia's major cities—La Paz, Santa Cruz, Cochabamba, Sucre and Oruro—will provide the study population.

The Bolivian Society of Gynecology and Obstetrics, a nonprofit organization with branches in all Bolivian provinces, has arranged for a team of specialized staff in La Paz and in each of the five provinces to collect the data. The results of this one-year study are expected to be available in the latter part of 1984.

FHI staff notes

Dr. Pouru P. Bhiwandiwala has been elected to a section council of the American Public Health Association. The Association has a membership of 28,000 in the US and throughout the world. Bhiwandiwala is Medical Director at FHI, where she has worked since 1974.

Dr. Nancy E. Williamson has been elected to the Population Association of America's Board of Directors. Her two-year term of office begins January 1, 1984. Williamson is FHI's Director of Natural Family Planning Research. She joined the staff in 1981.

Corrected table available for book

In the book *Childbirth in Developing Countries* by Malcolm Potts, Barbara Janowitz, and Judith A. Fortney of FHI, Table 4 in Chapter 9 (page 122) is incorrect. A new table with corrected figures for the number of deliveries to women over 30 years of age has been printed and may be affixed to the proper page in the book. A copy of the correct table may be obtained by writing to Publications Unit, Family Health International, Research Triangle Park, North Carolina 27709, USA.

Recent publications

E Kessel. Maternity Care Monitoring: A New Information System. In: *Primary, Maternal and Neonatal Health: A Global Concern.* F del Mundo, E Ines-Cuyegkeng and DM Aviado, eds. (New York: Plenum Publishing Corp., 1983) p 253. (83-29)

S Basnayake, S Victor de Silva, PC Miller and S Rogers. A Comparison of Norinyl and Brevicon in Three Sites in Sri Lanka. Contraception *27(5):*453, 1983. (83-30)

S Basnayake, S Victor de Silva, PC Miller and S Rogers. A Trial of Daily Vitamin Supplementation as a Means of Reducing Oral Contraceptive Side Effects and Discontinuation in Sri Lanka. Contraception *27(5):*465, 1983. (83-31)

P Lavin, C Bravo and C Waszak. Comparison of the TCu 200 and the Progestasert IUDs. Contracept Deliv Syst *4:*143, 1983. (83-32)

E Kessel, LE Laufe and J Zipper. Future Female Sterilization Technology: What to Expect. In: *New Trends in Female Sterilization.* DAF van Lith, LG Keith and EV van Hall, eds. (Chicago, Illinois: Year Book Medical Publishers, Inc., 1983), p 205. (83-35)

P Bhiwandiwala and K Minor. Common Sense and Technology. People *10(2):*24, 1983. (83-38)

M Potts. The Chinese Problem. World Med June 11, 1983, p 33. (83-40)

I-c Chi and S Rogers. Failure to Insert an Intrauterine Device. Contracept Deliv Sys *4:*207, 1983. (83-41)

Four to receive computer training at FHI headquarters

As part of its program to improve the research skills of professionals at health institutions in developing countries, FHI has invited four computer programmers to spend five weeks at FHI headquarters for training in data processing and analysis.

The participants will study independently in areas of particular interest to their countries. Several will bring their own data and receive assistance from FHI staff in data analysis on the microcomputer. As part of this program, FHI is providing microcomputers to the participants' institutions, which will allow them to become self-sufficient in analyzing their data.

Participating in the training program October 10 through November 11 will be Arif Sentosa, Indonesian Fertility Research Coordinating Board, Bandung; Pornsinee Amornwichet, Thailand Fertility Research Association, Bangkok, Thailand; Champa Balasuriya, Family Planning Association of Sri Lanka; and Rosario Ruiz, Institute of Scientific Investigation, Durango, Mexico.

Developing world physicians attend workshop at FHI

Pictured are the twelve physicians who attended FHI's second Contraceptive Technology and Clinical Research Skills Workshop, September 24-October 8, 1983. Back row: Dr. Paulo Canella, Brazil; Dr. Radovan Breznik, Yugoslavia; Dr. Suryono S.I. Santoso, Indonesia; Dr. Sriani Basnayake, Sri Lanka; Mrs. Bernadete Martin de Castro, Brazil; Dr. Gamal Sayed, Egypt; Dr. Mongkol Na Songkhla, Thailand. Front row: Dr. Wanida Sinchai, Thailand; Dr. Latifa Shamsuddin, Bangladesh; Dr. Mohammed El-Shafei, Egypt; Dr. Iffatara Islam, Bangladesh; Dr. Hermini Sutedi, Indonesia.

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FHI continues studies monitoring vasectomy

Does vasectomy alter the risk of cancer? At first glance, that may seem an implausible question, yet some speculation has arisen recently. The work by Nancy Alexander and her colleagues showing that mice with vasectomies have more malignant tumors of various kinds than mice without vasectomies has raised the question of whether vasectomy may cause tumors in men. On the other hand, it has been suggested that because vasectomy virtually eliminates androgens (male hormones) from seminal fluid, prostatic cancer and benign prostatic hypertrophy (BPH) could be reduced in vasectomized men.

FHI and the Permanente Medical Group, a division of Kaiser-Permanente Advisory Services, will conduct a case-control study to determine the association between vasectomy and the risk of prostatic cancer and the risk of hospitalization for benign prostatic hypertrophy in men 65 years of age or younger.

After 250 cases with a first diagnosis of prostatic cancer and the same number with BPH have been identified, their medical records will be checked to determine the race of each man, whether he has had a vasectomy, and the year of surgery.

For each case, four possible controls with the same birth year as the case will be identified from among current members of the Kaiser-Permanente Medical Care Program hospitalized in the same year for any nonurological reason. The records of possible controls will be reviewed until a control is found who matches the case by race and marital status (factors related both to vasectomy and to the two diseases). When a matched control is found, the record will be examined to see whether the control had a prior vasectomy and the year of its performance. The prevalence of vasectomy in the study population is 10%.

An earlier joint FHI-Kaiser study examined the incidence of all hospitalized illnesses in groups of vasectomized and non-vasectomized men. The results of the study showed no link between vasectomy and cardiovascular disease. However, FHI recognized that long-term safety issues are of great significance, and even reassuring results may need replicating in a different culture with different ethnic groups. Therefore, FHI has launched a second study, funded by the Ford Foundation and the International Development Research Centre of Canada, of the relationship of vasectomy to heart attack and stroke among Korean men. If this research verifies the earlier Kaiser study of American men, it should allay many concerns about the long-term effects of vasectomy.

Reproductive risk factors surveyed in Matamoros

Governments around the world have supported programs in which contraceptives are sold or given to consumers with minimal medical supervision. One type of program is the community-based distribution (CBD) program, in which fieldworkers with only a few days of training distribute pills and other contraceptives to households in a specified setting. In Matamaros, Mexico, where oral contraceptives were distributed through a CBD program under the auspices of the Centro pro Orientacion Familiar (COFAC), FHI has provided technical assistance enabling COFAC to carry out a Reproductive Risk Factors Survey to answer the following questions:

Is any substantial group of women put at a greater risk of death or serious health damage as a result of this program than if the program had not existed? If so, how might such women be protected?

The health of CBD acceptors was compared with that of women accepting pills from other sources and women who had never taken pills, using parameters ranging from anemia to cardiovascular disorders. The intent was to investigate the behavior of women who may have serious contraindications to oral contraception and/or pregnancy. About 500 women were interviewed in their homes by specially trained nurses with a questionnaire supplemented by some simple, objective measurements. For validation, a complete medical history was taken and physical examination given for a subsample in the COFAC clinic. From these data,

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Responses to health indicators for which current users and never users differ significantly

Indicator	Percent of Positive Responses Current users	Never users	Degree of Significance[1]
Previous spontaneous abortion	26	37	$p < .01$
Prenatal care last pregnancy	82	70	$p < .01$
Severe foot swelling last pregnancy	29	39	$.01 \leq p < .05$
Calf swelling last pregnancy	22	30	$.05 \leq p < .01$
R. believes she has diabetes	3	7	$0.5 \leq p < .10$
R. reports diagnosis of diabetes	2	5	$.05 \leq p < .10$
Systolic pressure ≥ 131 mm.	3	7	$.01 \leq p < .05$
Diastolic pressure ≥ 81 mm.	7	13	$.01 \leq p < .05$
Ankle edema	5	15	$p < .01$
Blood glucose > 120 mg/dl	5	15	$p < .01$
Recent irregular cycle	9	15	$.05 \leq p < .10$
Recent menstrual clotting	3	12	$p < .01$
Treated for menstrual problems	3	8	$.01 \leq p < .05$
Yellowness in eyes	4	9	$.01 \leq p < .05$

[1] *Chi square, corrected for discontinuity*

some 40 separate reproductive health indicators were developed.

Findings indicated that the COFAC CBD program in Matamoros did not introduce any new source of danger to women of reproductive age. As a generality across the 40 indicators, CBD acceptors were just as healthy as acceptors from other sources and were somewhat more likely to have consulted a physician. Current pill users were healthier than never users, after controlling for age and parity. (The table shows the indicators for which the relationship is statistically significant.) This was true regardless of source of supply and did not appear to be related to socioeconomic status. One possible interpretation is that even in a poor community women are capable of some self-screening. By this interpretation, healthy women take the pill; less healthy women perceive the pill to be dangerous and avoid it. Indeed, the self-selection that takes place may well leave those women who have the most health problems choosing, by default, the greater danger of pregnancy. It is unlikely that pill users are healthier as a result of taking the pill.

The fact of regular contact with neighborhood *promotoras* (promoters), backed up by the COFAC medical center, represented an additional source of safety not previously available. *Promotoras* were responsible for promotion of family planning, including sale at a subsidized price of pills and contraceptive foam, and were trained in the use of a checklist for possible contraindications to the pill.

The CBD program introduced an important public health benefit by reducing unwanted pregnancy with its attendant dangers. Results of the survey did not support the view that physician prescription as a requirement for pill use would be a useful public health measure in that setting.

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Progestogen-only pills studied in breast-feeding mothers

The estrogen component of combined oral contraceptives has been associated with suppression of lactation. However, most progestogen-only pills have no significant adverse effects on breast-feeding, whether lactation performance is evaluated based on infant weight, milk volume and quality, or duration of lactation. The progestogen-only pills may even augment milk production. Breast milk is considered the healthiest food for infants because it not only meets their nutritional needs but also conveys protection against infection.

FHI plans to study the acceptability of progestogen-only oral contraceptives among breast-feeding women. Acceptability will be evaluated by one-year continuation rates and reasons for discontinuation or switching to other methods. The study will also meet a need by introducing a progestogen-only pill into areas where such pills are not currently provided.

The study will involve up to 4000 women in 20 clinics. Clinics selected must have a high proportion of women who breast-feed in the area and the ability to follow subjects through 12 months of contraceptive use.

Policy decisions by AID and other international donors and increased commitment from the pharmaceutical industry are making progestogen-only pills increasingly available in national family planning programs. The studies coordinated by FHI will enable national policy makers and clinicians to make optimum use of this contraceptive alternative.

Vaginal ring studies begin

A large-scale clinical trial of contraceptive vaginal rings is set to begin at two centers in Peru and one each in the United States and Yugoslavia. FHI will test a vaginal ring initially developed by the Population Council, New York to determine its initial acceptability, side effects, use-related problems, and contraceptive effectiveness. Overall method performance, as defined by continuation rates and reasons for termination, will be compared to that of Lo-Femenal, a low-dose combination oral contraceptive.

The vaginal ring is a flexible, doughnut-shaped device that fits in the vagina, where it releases a steady dose of hormone, which is absorbed through the vaginal wall and passes into the bloodstream. The effect is similar to taking the pill, but release rates are lower and more regular. It is intended to be used for three weeks and removed for one week, during which the woman will experience uterine bleeding. Each ring is designed to be used for twelve cycles (one year).

Each center is recruiting 300 volunteers for the studies; half will receive vaginal rings and half Lo-Femenal. They must be accessible for regular follow-up, which will occur at 1, 3, 6 and 12 months.

In addition to the studies comparing rings and oral contraceptives, two smaller studies will evaluate the use of vaginal rings in conjunction with educational materials that are being developed.

Vaginal rings may offer advantages over oral contraceptives for women seeking hormonal contraception. Pills require daily motivation, whereas rings are inserted only once each month; this type of delivery system may, therefore, be preferred by many women. One potential metabolic advantage is that vaginal administration bypasses the liver. Finally, there may be a decrease in side effects, ranging from circulatory disorders to nausea, that are associated with the synthetic estrogen component of combined oral contraceptives.

Figure 1.

The vaginal ring, developed by the Population Council, will be tested by FHI.

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Sterilization interest, access examined in Honduran study

Why don't women get sterilized? In 1980, FHI and the Family Planning Association of Honduras initiated a study to determine interest in and access to female sterilization at two Ministry of Health hospitals in Honduras. Four months following delivery, 344 out of 829 women planning sterilization at Materno Infantil in Tegucigalpa and 137 out of 655 planning the surgery at Leonardo Martinez in San Pedro Sula had had a tubal ligation. The percentage of sterilized women was much lower than expected. Therefore, a follow-up study two years later sought to determine what percentage of women eventually were sterilized and to obtain more information on reasons for not having a tubal ligation. This information is important to providers, who need to know the impact of factors, such as cost of surgery and travel time, that can be changed to encourage tubal ligation.

Women who remained unsterilized at the conclusion of the first study but who said they still desired sterilization were included in the 1982 follow-up study. Of these women, 32.7% were sterilized from the Tegucigalpa group and 14.7% from the San Pedro Sula group.

Both personal and situational factors have kept a high percentage of women from obtaining a tubal ligation. Of the personal reasons, the most important were "separated from spouse" and "fear of surgery." Unfortunately, no specific question on marital status was included on the survey, because investigators were unaware of the high level of instability of unions and the importance of this instability in affecting whether a woman gets a tubal ligation.

Concerning fear of surgery, it is unclear whether women were afraid all along but were reluctant to say so, or whether they had found out something about the surgery since the first study that made them become afraid. Information on the reasons for the fear is needed if the Honduran Family Planning Association is to be more effective in promoting voluntary sterilization.

The most important situational factors limiting tubal ligation are financial and time constraints. The fees for sterilization range from $10 to $17.50, but they may be waived. However, not all women have information regarding the fee waiver, or, if they do, many may be reluctant to admit that they cannot afford the fee. Efforts need to be made to ensure that women know that they can request the waiver in a way that will not prove embarrassing. A new program has recently gone into effect in Tegucigalpa and San Pedro Sula that will cover the costs of performing interval sterilizations at the Social Security hospital for women whose husbands have social security coverage.

Time constraints may apply to both the surgery itself and to the completion of requirements for surgery. The Honduran Family Planning Association clinic in Tegucigalpa began in January, 1983 to offer medical tests required for sterilization, which should reduce the time required and increase the accessibility of the procedure.

The percentage of women who experienced a pregnancy between the two studies was unexpectedly high (40%). About half of these women reported that the pregnancy was wanted, even though two years earlier on two occasions these same women said that they wanted to be sterilized. Some of these women are in new unions and want one or two additional children with the new partner. Also, a high percentage of the children born to women in 1980 were no longer alive (14% in Tegucigalpa and 12% in San Pedro Sula). Women who had lost their last child were much more likely to have become pregnant again than women whose last child was still alive. In Tegucigalpa, 70% of the women whose last child died, but only 38% of women whose last child was still alive, got pregnant again. The corresponding figures for San Pedro Sula are similar: 61% in the former group and 39% in the latter.

The high rate of pregnancy and low rate of contraceptive use among the women in the study indicates not only a need for improved access to sterilization but also to family planning in general.

IUD insertions following cesarean deliveries examined

How the IUD behaves in women who have had a cesarean section is not well known, but obstetricians in locations as diverse as China, Chile and Hungary have been looking at this problem. A paper presented at the 111th annual meeting of the American Public Health Association in November, 1983, "Cesarean and IUD Use" by I-cheng Chi, Sandor Balogh, and Katherine Ng of Family Health International, examined the performance of IUDs inserted immediately after cesarean deliveries as well as those inserted in interval women with previous cesarean sections.

Doctors at Xuan Wu Hospital in Beijing, China participating in FHI's postpartum IUD studies manually inserted IUDs through the incisions of 52 cesarean-sectioned women immediately after delivery of the placenta. In 147 women, IUDs were inserted vaginally immediately after normal vaginal delivery. Delta T and Delta Loop IUDs were inserted in equal proportions in both groups of women. These IUDs are FHI's modifications of the standard Lippes Loop D and Copper T 220C. Biodegradable No. 2 chromic sutures are added to the upper crossarm to enhance the retention of the IUD when inserted in the puerperium, thereby reducing the risk of expulsion as uterine involution occurs.

Expulsion and continuation rates per 100 women for post-cesarean section (PCS) and post-vaginal delivery (PVD) women, Xuan Wu Hospital, Beijing, China

	PCS (N = 51)	PVD (by MD only) (N = 84)	PVD (total) (N = 147)
Expulsion Rates			
1 Month*	0.0	10.9	13.8
3 Month**	4.0	12.9	16.6
6 Month*	4.0	17.6	20.5
Continuation Rates			
1 Month*	100.0	89.1	85.6
3 Month	92.1	82.9	79.3
6 Month**	85.9	74.1	70.6
Follow-up Rates			
1 Month	100.0	100.0	100.0
3 Month	100.0	95.9	97.5
6 Month	95.7	95.4	96.3

*$p<.05$ between PCS and either of the two PVD groups.
**$p<.05$ between PCS and PVD, total.

The 199 women in the study, regardless of delivery method, were homogeneous in many aspects. All were currently married; most were aged 25 to 29 years and were admitted for delivery of their first birth. None reported a history of pelvic inflammatory disease or sexually transmitted diseases. The only remarkable difference between the two groups was that all but one woman in the cesarean group, but only 57% of the vaginal delivery group, had their IUDs inserted by obstetricians/gynecologists. The follow-up rate at six months postinsertion was greater than 95% for both groups.

Expulsion rates at 1, 3, and 6 months postinsertion were significantly lower and thus continuation rates significantly higher for the cesarean group than for the vaginal group. The difference in rates did not change substantially even when the two groups were compared considering only those women whose device was inserted by the obstetricians/gynecologists. No serious adverse effects, such as uterine perforation or infection, were detected with immediate post-cesarean insertions. The two groups showed no statistically significant differences in pregnancy rates or in bleeding, pain, or other causes of removal. Two additional studies, one from another maternity hospital in China and the other from Mexico, support this finding, although neither has provided a comparison group.

Two datasets were used to examine the effect of interval insertions in women with previous cesareans. In a Hungarian center where women received locally designed Szontagh IUDs, 288 of the women had had one or more previous cesareans. Each was matched by age, parity and date of insertion with two controls who each had at least one birth but did not have a cesarean. The cumulative expulsion rates were higher among the cesarean-sectioned women than among the non-sectioned women at 1, 3, 6, and 12 months postinsertion. The other dataset used was a pooled file of over 32,000 IUD users from which 318 interval women reported one or more previous cesarean deliveries. They were inserted with one of the three common IUD types: Lippes Loop, Copper T, and Multiload device. Of these women, 299 were matched with two, and the remaining 19 with one, controls from the same dataset by center, IUD type, and the other matching criteria of the Hungarian study. No significant differences in expulsion rates were detected between the two groups overall.

These findings suggest that, as far as expulsion rates are concerned, interval insertions of IUDs in women with one or more previous cesareans perform no better, or even worse, than those in non-sectioned women. Although based on a small sample, the finding from the Chinese study suggests that for cesarean-sectioned women, if the IUD is inserted immediately after the section, the expulsion rate will be significantly lower than that in women with immediate vaginal insertion of IUDs after vaginal delivery. This is probably due to two factors: (1) The cervix is not dilated at all, or not fully dilated as it is in vaginal deliveries. (2) The IUD can be placed properly at the fundus.

This finding points the way to further understanding of the dynamics between IUDs and the uterine surroundings and in time may contribute to improved IUD performance in general and postpartum insertions in particular.

Haiti seminar discusses voluntary sterilization

Devising strategies to meet the growing demand for voluntary sterilization in Haiti was a major topic of discussion during a week-long seminar Nov. 28 - Dec. 2 organized by the Division of Family Hygiene (DHF) of the Haitian Department of Public Health and Population. More than 30 physicians trained in laparoscopy and minilap who provide services through the DHF program met to summarize progress and discuss problems of the program to date, review technical aspects of female sterilization, introduce technical aspects of vasectomy, and set goals for 1984.

FHI provided two consultant-speakers for the seminar, Dr. Lise Fortier, medical director of Planned Parenthood of Los Angeles, and Dr. Liliane Toumi, consultant for training in male and female sterilization.

The DHF has given high priority to its voluntary sterilization program, which has recorded a slow but steady increase in the number of individuals sterilized since its beginning in 1979. Postpartum minilaps account for the highest percentage of procedures (69% of cases reported to the DHF in the first half of 1983), with most of the remainder consisting of laparoscopy. In 1983, there was also an increasing emphasis on vasectomy, accounting for 5% of all cases reported in the first six months. Three physicians attending the seminar had just returned from Sao Paulo, Brazil, where they were trained in vasectomy by Dr. Marcos de Castro. An additional three are scheduled for training in Sao Paulo early this year. These six physicians will form the basis of an in-country vasectomy training program for their colleagues.

Data from an ongoing FHI Maternity Care Monitoring pilot project at Hopital Universitaire de l'Etat d'Haiti support the observation of physicians at that center that 65% to 70% of potential candidates for sterilization there are not sterilized. Discussion at the seminar identified the following possible reasons for the unmet need for sterilization: requirements for laboratory tests, lack of space for procedures and recovery, irregular supplies, and need for better patient education and motivation during the prenatal period. One suggestion to increase the access of rural populations outside of Port-au-Prince was to offer sterilization services through mobile clinics operating out of health centers around the country.

FHI is continuing its assistance to the DHF program by helping to establish reporting and to maintain data on sterilizations performed throughout Haiti. Initially, the Division will use FHI female sterilization and male sterilization patient summary forms for monitoring cases in the six centers doing a large proportion of the procedures.

The consensus of those attending the seminar was that a strong voluntary sterilization program is of the utmost importance in meeting Haiti's family planning needs.

Effect of IUD placement on expulsion examined

Previous FHI studies have demonstrated that immediate (within 10 minutes of placental expulsion) postpartum insertion of an IUD is not associated with any increased risk of infection or perforation. It is a safe choice to offer a woman, although the explusion rate is higher than for interval insertions in menstruating women.

In the past, FHI has looked at variations in IUD design and expulsion rates. Now it is looking at the influence of placement within the uterus. To test the theory that expulsions of IUDs are reduced if the IUD is placed high in the uterine fundus, Family Health International is studying IUD insertions at a hospital in Monterrey, Mexico with the aid of echosonography.

Approximately 100 obstetrical patients who have received postpartum IUDs will be monitored with ultrasound at 2 hours and 24 hours postpartum and again after the uterus has returned to its initial size. After follow-up of expulsions, analysis will test for any link between placement and expulsion.

Columbia establishes program in development law and policy

The Development Law and Policy Program of the Center for Population and Family Health, Columbia University has been established to provide assistance on legal and policy matters regarding family planning, sex discrimination, and population. Doctors and health care personnel with questions, problems, or suggestions on laws and policies on contraceptive distribution, voluntary surgical contraception (including informed consent), health and allied health personnel should contact the program. In cooperation with lawyers from the countries, the program can provide information, technical assistance, and training on such issues. For additional information, contact: Stephen L. Isaacs, JD, Director, Development Law and Policy Program, Center for Population and Family Health, Columbia University, New York, NY 10032, USA (telephone 212-694-6980).

Non-surgical sterilization clinical studies continuing

FHI has coordinated clinical studies in the USA, Latin America and Asia to develop a non-surgical method of female sterilization. An ongoing FHI study at the University of Texas at San Antonio with Dr. Leonard Laufe is testing the anti-malarial drug quinacrine as an agent for nonsurgical, chemical sterilization of women. Quinacrine is capable of causing limited damage to the surface epithelium of the fallopian tubes, leading to scarring and permanent obstruction without causing irreversible damage to the uterine endometrium or underlying tissues of the reproductive system. Quinacrine has been used previously in the USA to obtain scarring in the pleural cavity in the treatment of such diseases as tuberculosis. Studies overseas have shown quinacrine has the potential to be offered on a wide scale as a non-surgical method of voluntary sterilization in women.

The San Antonio study uses as subjects women who are scheduled for hysterectomy. Twenty-four hours prior to surgery, they receive an intrauterine application of quinacrine. Blood drawn during the 24 hours after insertion will be analyzed to determine the systemic effect of the drug.

In the world as a whole, an estimated 33% of contraceptive users have chosen voluntary sterilization to limit their family size. By contrast, 16% use oral contraceptives and 18% use IUDs. A non-surgical method of tubal occlusion that could be safely performed in a primary health center would extend this popular choice to millions of individuals who are currently denied it in the poorest countries due to lack of adequate surgical services.

Filshie clip to be compared to modified Pomeroy technique

The Filshie clip, a newly-marketed mechanical device for female surgical sterilization, has undergone at least five design phases and has been used in thousands of sterilization procedures in several countries. At least one national family planning program has contracted to use the new clip. Family Health International has, therefore, planned and received approval for a trial of the Filshie clip, comparing it to the modified Pomeroy technique of female sterilization.

In use since early in this century, the Pomeroy technique for tubal ligation is the standard against which all postpartum female sterilization procedures should be measured. Pomeroy procedures, in which the tube is looped and tied and a portion of the loop surgically removed, account for the majority of sterilizations performed in the postpartum period. The reversibility of these ligations is regarded as from poor to fair due to the length of tubal destruction.

The Filshie clip may be applied via minilaparotomy or by single or double puncture laparoscopy. Preliminary data claim few surgical difficulties or injuries and a low pregnancy rate. A possible advantage of the Filshie clip relates to its curved upper arm. This feature may facilitate occlusion of thick fallopian tubes, making the Filshie clip more suitable than other clips for postpartum and postabortion procedures. In addition, since a smaller section of the tube is destroyed, the chance of reversibility of clip sterilization is probably greater than with other mechanical methods.

Selection of study sites in Latin America and Asia is complete, and training of investigators is now underway.

Child survival, TBAs in Brazil subjects of study

FHI is supporting a two-year study in Brazil with a dual purpose: to obtain information on the referrals and deliveries of all traditional birth attendants (TBAs) working in a rural area of the State of Ceara, and to determine infant mortality and causes of death. It is hoped that the services now established in Brazil could become a model for other parts of the world.

In an earlier project, information on deliveries at four obstetric units in the rural and semiurban areas surrounding Fortaleza was obtained. These data showed that TBAs at the units referred all but a very few of the more difficult cases. Recently, the TBA training program of the Maternidade Escola Assis Chateaubriand (MEAC), directed by Dr. Galba Araujo, has been expanded to more remote rural areas. In these more sparsely populated areas, large obstetric units of five to seven beds are not feasible; therefore, the program has emphasized setting up one-room units attached to the homes of TBAs and training TBAs who will continue to attend deliveries at the homes of patients.

While the best of the trained TBAs working in the larger obstetric units have been shown to do a good job in making appropriate referrals and reducing maternal and infant mortality, no information is available for the TBAs managing one-bed units or doing home deliveries. To determine whether these TBAs make adequate referrals and what factors they take into consideration in making referrals, the FHI-funded study will obtain information on all deliveries and referrals of the approximately 80 TBAs who work in the rural areas surrounding the town of Trairi.

The second phase of the study will follow up women who have delivered to determine an infant mortality rate and causes of death for infants dying within one year of delivery. Questions are also designed to determine what proportion of infants are fully or partially breast-fed at two, six, and twelve months. The results of this study may be especially important due to the fact that the Northeast of Brazil is known to have a low prevalence of breast-feeding, which may account for the high incidence of diarrheal diseases. Diarrheal diseases are suspected of causing a significant proportion of infant mortality.

Natural family planning advisory committee formed

During 1983, Family Health International increased its support of research in the field of natural family planning (NFP) and established a separate research department, headed by Dr. Nancy E. Williamson, to focus exclusively on NFP and breast-feeding research.

The new department is supporting both basic research on indicators of ovulation and programmatic research on the effectiveness of various approaches to NFP teaching and service delivery. This includes research on the natural rhythm of infertility associated with breast-feeding. An important aim is to increase the capacity of developing country institutions to conduct their own research on NFP methods and programs.

A Natural Family Planning Advisory Committee has been formed to review FHI's NFP and breast-feeding projects. The committee will also provide guidance and suggestions on future research directions for FHI's NFP work.

Members of the NFP Advisory Committee are William A. Campbell, LLB, Institute of Government, University of North Carolina at Chapel Hill; Armando Cifuentes, MD, Director of Family Action Program, Fundacion Carvajal, Cali, Colombia; Dr. Julia J. Henderson, former Secretary-General of IPPF/London, and member of Board of Directors of Planned Parenthood of Orange County, Chapel Hill, NC; Barbara Kass-Annesse, RNNP, Project Coordinator, Natural Family Planning & Fertility Awareness Methods Instructors Training Program, Los Angeles, CA; Sister Francesca Kearns, Executive Director of World Organization of Ovulation Method Billings (WOOMB/Guatemala) and National Director of Centre Pastoral Familiar America Latina (CENPAFAL), Guatemala City, Guatemala; Claude A. Lanctot, MD, Executive Director, International Federation for Family Life Promotion, Washington, DC; Suzanne Parenteau-Carreau, MD, Medical Director, SERENA Canada, Montreal, Canada; Gebhard FB Schumacher, MD, (Technical Advisory Committee representative), Professor/Chief, Section of Reproductive Biology, Dept. of Obstetrics/Gynecology, University of Chicago, Chicago, IL.

The first meeting of the NFP Advisory Committee is scheduled for March 12 and 13 at FHI headquarters, Research Triangle Park, NC.

Recent publications

RG Wheeler and K Schneider. Properties and Safety of Cervical Dilators. Am J Obstet Gynecol 146(6):597, 1983. (83-30)

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L Andolsek, M Kozuh-Novak and C Waszak. A Comparative Study of the Nylon T and Copper T 200. Contracept Deliv Syst 4:297, 1983. (83-37)

L Randic and SA Balogh. The Effect of Hydrogel on the Reduction of Bleeding Associated with IUD Use: A Comparative Study of the Plain and Hydron-coated Spring Coil. Contracept Deliv Syst 4:301, 1983. (83-38)

AS Gerais, S Alwahab, KF Omran and WC Liao. A Comparative Study of Two Estrogen Dosages in Combined Oral Contraceptives Among Sudanese Women. Int J Gynaecol Obstet 21(6):459, 1983. (83-39)

P Bhiwandiwala and K Minor. First World Standards versus Third World Settings. Draper Fund Report 12:27, 1983. (83-40)

J Zipper, RG Wheeler, DM Potts and M Rivera. Propranolol as a Novel, Effective Spermicide: Preliminary Findings. Brit Med J 287:1245, 1983. (83-41)

A free copy of any of these articles is available upon request.

—In Memoriam—

Members of the Board of Directors and staff of FHI were saddened to learn of the death of a former member of FHI's Board of Directors, Professor Hubert deWatteville, MD of Geneva, Switzerland.

Professor deWatteville was elected to FHI's board in 1976 and served until his resignation in December 1982 for health reasons. He was a distinguished international scholar and committed obstetrician and gynecologist. He served as Secretary-General of the International Federation of Gynecology and Obstetrics (FIGO) and of the International Association for Maternal and Neonatal Health (IAMANEH); as Professor and Chairman, Department of Obstetrics and Gyneclogy, University of Geneva, and as a clinical practitioner in obstetrics and gynecology. His sound counsel will be missed.

Professor deWatteville is survived by his wife, Elisa.

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Oral contraceptives and cancer risk

Two studies reported in the October, 1983 issue of The Lancet received worldwide attention and caused considerable concern among family planning organizations. "Breast Cancer in Young Women and Use of Oral Contraceptives: Possible Modifying Effect of Formulation and Age of Use," by M.C. Pike et al., suggested that women who used pills with a high progestogen potency for at least four years before age 25 doubled their risk of breast cancer. M.P. Vessey et al. reported in "Neoplasia of the Cervix Uteri and Contraception: A Possible Adverse Effect of the Pill" that the incidence of cervical cancer in pill users rose with duration of pill use; no such trend with duration of use was noted among IUD users.

Since, in most countries, cervical and breast cancer are the most common cancers in women and many women take pills, any increase that could be attributed to the pill would have important public health consequences. However, a review of these two articles and of related literature indicates that the findings published in The Lancet should be viewed with great caution.

Breast Cancer The research by Professor Pike and his colleagues has methodological weaknesses, among them the fact that study participants were asked in telephone interviews to describe the packages of pills they had used. Since women were asked about pill use that in some cases was more than ten years earlier, the possibility of recall bias exists. Further, in the 1960s, pills were often prescribed for noncontraceptive reasons (such as dysmenorrhea, irregularity, or acne); the analysis did not account for this. In Pike's study, the controls were slightly older than the cases. Since the pill was not so widely prescribed in the early 1960s as later, this may mean that the controls had more limited access to oral contraception when they were under 25. Finally, Pike's use of progestogen potency has been questioned because, although the effect of progestogen potency on the endometrium has been measured, its effect on the breast has not.

Perhaps more important than these problems is the fact that other, major epidemiological studies have found no association between oral contraceptives and breast cancer. None of the "big three" cohort studies (the Royal College of General Practitioners' study, the Oxford Family Planning Association study, the Walnut Creek study) found an association, nor did any of the large (more than 500 cases) case-control studies. None of the smaller case-control studies found an overall association, although several did find a relationship between breast cancer and the pill in some subgroups of women—women with benign breast disease, and women who took pills before their first full-term pregnancy. Research on breast cancer does not usually report the age at which oral contraceptives were taken; however, when data collected for some of the studies cited above were reanalyzed as Pike and his colleagues had analyzed their data, no relationship was found between early pill use and development of breast cancer.

The methodological flaws in the research conducted by Pike et al., together with findings from other studies (both prospective and retrospective), have led researchers in FHI's Contraceptive Safety Division to concur with the April, 1984 statement of the U.S. Food and Drug Administration that "there appears to be no increased risk of breast cancer in oral contraceptive users or any subgroup of users."

Cervical Cancer The questions raised by Vessey regarding cervical cancer are more difficult to evaluate. The research questions were asked well, but several factors that influence a woman's likelihood of developing cervical cancer were not measured. If these risk factors were not equally distributed in the case and control groups, Vessey's conclusions may be in error. Since the factors were not measured, there is no way of determining their contribution to the observed results. Among these factors are: (1) Cervical cancer is associated with sexual behavior; risk increases with early age at first intercourse and number of sexual partners. Young women are more likely than older women to choose oral contraception over other methods, as are women who are more sexually active. (2) Smoking

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is an important risk factor for cervical cancer and in some studies has also been found to be more common among pill users. (3) Sexually transmitted diseases, especially herpes virus and papilloma viruses, are also a risk factor for cervical cancer. Some contraceptive methods (ie, condom and diaphragm) protect their users against sexually transmitted diseases; pills do not.

In addition to these three factors, women using oral contraception are more likely than other women to receive regular Pap smears and thus to have cancer diagnosed if it occurs. No study taking these difficulties into account has found a positive relationship between oral contraceptive use and cervical cancer. Among the cohort studies, the Oxford FPA study found an increased risk of cervical cancer among oral contraceptive users and a reduced risk among diaphragm users, but the factors of smoking and sexual behavior were not controlled. In two different analyses of data from the family planning clinic at Grady Hospital in Atlanta, Georgia, Ory and his colleagues found an increased risk, but neither took smoking or sexual behavior into account. An early report found an increased risk among oral contraceptive users in the Walnut Creek cohort but did not control the confounding factors; later analysis of data from the same group, which did control for sexual behavior (but not smoking), found no increased risk. Although some case-control studies have found an association with cervical dysplasias that persists when sexual behavior (but not smoking) is controlled, many others have not.

FHI's Contraceptive Safety Division concludes that there probably is an association between oral contraceptive use and cervical cancer but that it is not as strong as some analyses have shown. Women who use oral contraception for several years appear to have a risk of contracting cervical cancer that is 10% to 50% higher than for women who have never taken the pill. However, for women who smoke, who have several sexual partners, or who have been exposed to various venereal diseases, the risk is much higher. Women who use the pill should have regular Pap smears.

Egyptian natural family planning project begins

With technical assistance from FHI, investigators in Egypt are attempting to discover how great the potential demand is for learning natural family planning (NFP) methods. Through interviews with outpatients coming to the obstetrics/gynecology, pediatric, and other departments of Ain Shams University Hospital in Cairo, information will be collected on whether the women have ever heard of any NFP methods for either preventing or facilitating conception. The researchers will also determine the local terms people use to refer to periodic abstinence. Based on this information, investigators will devise a questionnaire for structured interviews with 500 hospital outpatients.

The structured interviews will contain specific questions about knowledge of NFP and willingness to learn about NFP through classes at the hospital. From the 500 interviews, ten to twelve couples will be recruited to form a class in NFP methods. The teaching approach of this class will be determined by answers to the survey questions, including who would be the most appropriate people to teach NFP to the couples (M.D. or non-M.D., man or woman) and which specific NFP methods to teach.

If this project uncovers a significant demand for NFP, a second project will be undertaken to introduce and evaluate an NFP service at the hospital. Dr. Maher Mahran, professor and chairman of obstetrics/gynecology at Ain Shams and principal investigator for the study, believes that Egyptian women are good candidates for NFP training because they are already knowledgeable about their own bodies. As an example, he cites obstetric patients who are able to distinguish between false and real labor by self-examination to determine whether the cervix has dilated.

"In many developing countries, only a minority of couples uses family planning methods," says Nancy Williamson, FHI's director of natural family planning research. "There may well be a demand for methods requiring no supplies or medical procedures. Formal teaching of NFP might be built on this base and could increase the effectiveness of periodic abstinence."

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Volumetric vaginal aspirator may aid in natural family planning

All natural family planning (NFP) methods are based on the determination of a woman's fertile period so that a couple may abstain from sexual relations or use mechanical means of birth control during that time. Researchers are seeking more accurate methods of predicting the onset of ovulation in order to increase the effectiveness of natural family planning. A new device developed by Dr. Gebhard F.B. Schumacher, a fertility specialist at the University of Chicago who serves on FHI's Technical Advisory Committee, and Dr. Stephen J. Usala, a former medical student at the University's Pritzker School of Medicine, holds the promise of providing a new, cheap, and relatively simple way of predicting ovulation.

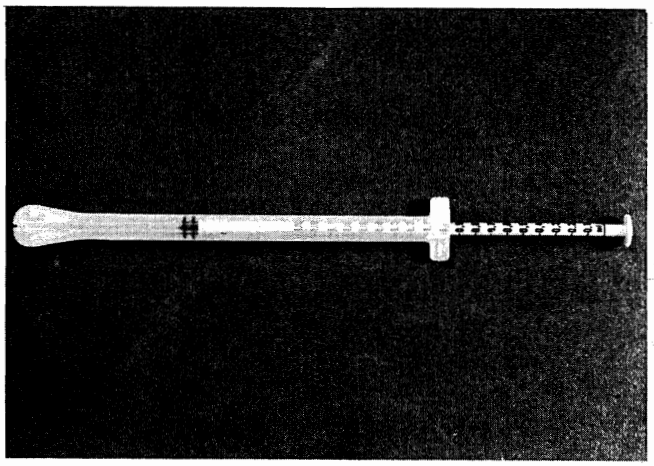
Called a volumetric vaginal aspirator, the instrument allows women to measure their own vaginal fluid on a daily basis. In early studies of seven women carefully studied over 18 menstrual cycles, a striking threefold to thirtyfold increase in the volume of vaginal fluid occurred a few days before ovulation. Results from 12 more women for a total of 26 cycles confirmed the earlier studies.

Blood samples were taken in order to measure the levels of estrogen, known to increase prior to ovulation, and luteinizing hormone, which peaks sharply on the day of ovulation, in the women studied. These confirmed that ovulation typically had occurred after the fluid volume increase. In addition, participants recorded their basal body temperature (BBT) upon waking. Although the BBT does not predict ovulation, it frequently increases by one half to one degree Fahrenheit after ovulation, thus serving as an indicator of the end of the fertile period.

The prototype of the vaginal aspirator is a disposable plastic syringe marked at .05 milliliter intervals so that fluid levels can be easily measured. After the manufacturing process for the aspirator is perfected so that the instrument can be mass produced, Dr. Schumacher hopes that large-scale clinical trials will be initiated in the US and abroad. The larger studies and an endocrine study are needed in order for effective rules to be developed for applying the method in either birth control or fertility enhancement.

The vaginal aspirator could be useful not only for preventing unplanned pregnancy but also for aiding couples experiencing infertility to pinpoint the time that conception is most likely to occur. As an aid in birth control, the aspirator should have a success rate similar to or better than that of a diaphragm, Dr. Schumacher believes. Although the women testing the vaginal aspirator were able to use it without assistance, Dr. Schumacher emphasizes that some patient education will be necessary if it becomes commercially available. Fertility awareness teachers could incorporate it into their courses.

Research on the volumetric vaginal aspirator has been supported by FHI and by Mothers' Aid Research Fund of Chicago Lying-In Hospital.



The volumetric vaginal aspirator (known in Germany as the vaginal fluid pipet) will be manufactured by Recipe, Munich, W. Germany, under the trade name R-Ovumeter.

Congressional OTA funds reproductive research

Family Health International has received a grant from the Office of Technology Assessment of the U.S. Congress to summarize current research on occupational influences on reproduction and make recommendations for improved data collection and sharing of findings. American workers are exposed to almost 70,000 chemical, biological, and physical agents in the workplace, with the number increasing by 1,000 agents each year. The proportion of women in the work force has increased steadily from 37 percent in 1970 to more than 42 percent at present, and it is expected to reach 45 percent by 1990. Thus, more and more women are being exposed to any occupationally-related reproductive hazards that may exist.

Because the relationship between occupation and reproduction is subtle, large research samples are necessary to identify hazards. Methods employed by researchers in past studies were not likely to pinpoint hazards readily. Dr. Michael Rosenberg of FHI and Dr. Carl M. Shy of the University of North Carolina will review existing research on the relationship between occupation and reproductive impairments (infertility, fetal loss, birth and developmental defects) and will summarize current surveillance efforts. They will offer proposals for a systematic approach to the collection and analysis of data, coordination between institutions involved in assessing reproductive hazards, and dissemination of research results. Large data sets and coordination of information should make it possible to identify reproductive hazards in the workplace quickly if they occur.

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INTRAUTERINE DE

The intrauterine device is the contraceptive choice of 60 million women in the world today. In several respects, it is an ideal contraceptive: it is highly effective, and it needs little further attention after insertion. On the minus side, an IUD requires trained personnel and a medical facility for insertion. It may become displaced or expelled, sometimes leading to uterine perforation or pregnancy. In addition, some users have side effects ranging from pain and bleeding to pelvic inflammatory disease.

Family Health International has sought to improve IUD performance through several approaches. These have ranged from attempts to design IUDs with enhanced effectiveness and reduced shortcomings to studies pinpointing optimal insertion times and techniques. This issue of Network focuses on the results of recent IUD research.

Postpartum IUD insertion

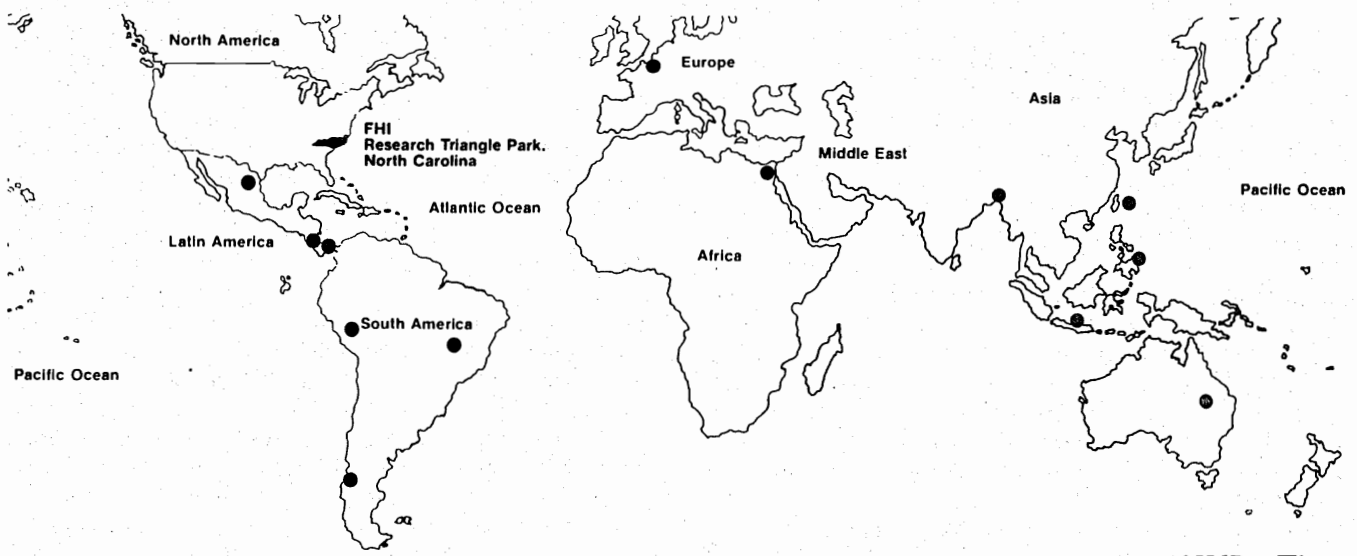
The largest study of postpartum IUD insertion to date has shown that the practice is not only safe but also effective if the IUD is correctly placed. Modifications in design of the device are unnecessary to reduce expulsions if proper insertion techniques are used. These findings from a major multicenter trial conducted in 13 countries by Family Health International have broad programmatic implications.

Some medical practitioners have been slow to introduce postpartum IUD insertions because of concern about the possibility of higher expulsion, infection, and perforation rates. In addition, the stress of labor and delivery can make it a difficult time for making a well-considered decision about contraception. On other hand, postpartum insertion of IUDs, especia in institutional deliveries, has a number of advantages: ease of insertion, high motivation of the mother at that time, availability of skilled personnel and appropriate facilities, and convenience for the mother.

In 1977, FHI began developing IUDS that would have clinically acceptable expulsion rates (ie, similar to interval rates) when inserted in the postpartum period. By adding chromic catgut suture material to the upper arms of the TCu and Lippes Loop, FHI developed the Delta T and Delta Loop. A preliminary evaluation of the modified T and Loop indicated acceptable expulsion rates. Expanded clinical trials of the Delta T and Delta Loop were undertaken to evaluate the following: optimal timing of postpartum IUD insertion, the safety of postpartum IUD insertion, expulsion rates of the Delta T and Delta Loop compared to the TCu 220 C and Lippes Loop D, expulsion rates of IUDs with different insertion techniques.

A multicenter, comparative trial involving 3791 women at 15 sites in 13 countries evaluated the safety and effectiveness of the devices. In addition, 19 centers evaluated the timing of postpartum IUD insertion. Many of the centers in the study were large, urban maternity hospitals of the developing world with heavy caseloads of between 10,000 and 30,000 deliveries a year. Because urbanization is increasing in developed countries, increasing numbers of women likely to receive their obstetric care in such facilities in the future. These women will be candidates for postpartum IUD insertion.

In an upcoming article in The Journal of Reproductive Medicine, "Postpartum Insertion of Modified Intrauterine Devices," L.P. Cole, D.A. Edelman, D.M.



Sites in thirteen countries participated in FHI's comparative trial of the safety and effectiveness of IUDs. The countries (indicated on the map) are Mexico, Costa Rica, Panama, Peru, Brazil, Chile, Belgium, Egypt, Bangladesh, Indonesia, Philippines, Taiwan, and Australia.

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otts, R.W. Wheeler, and L.E. Laufe report the results of the trials. They reach a number of important conclusions about postpartum IUDs.

Insertion should take place within 10 minutes of placental expulsion. Data were collected on 2595 Delta Loop and Delta T insertions from 19 sites in which insertions were performed either immediately or from 10 minutes to 36 hours after delivery of the placenta. The expulsion rate of IUDs that were inserted in the 10-minute- to-36 hour period was significantly higher than the rate of expulsion for immediate (within 10 minutes) insertions.

Furthermore, if insertion is done within 10 minutes of delivery, there is no increased risk of infection or uterine perforation. In the comparative evaluations of different IUD types and insertion techniques, the perforation rate was 1 per 3800 insertions and the rate of pelvic inflammatory disease ranged from 1.4 to 2.0 per 100 women, similar to rates reported for interval IUD insertions.

The type of device inserted is less important than the method of insertion. Differences in IUD expulsion rates among centers participating in the trials were generally greater than differences among expulsion rates for different IUDs; the expulsion rates at different clinics ranged from six to 37 per 100 women at six months. The fundal placement of the device should be emphasized, and at insertion the operator should be able to sense through the abdominal and uterine walls the impact of the device reaching the fundus (the large upper end of the uterus).

Expulsions are higher for postpartum than interval insertions but not so high as to make the offer of an IUD immediately postpartum unacceptable. Also, delaying insertions has several drawbacks: It is impossible to predict for individual women (especially those who are breast-feeding) when ovulation will return, and it may be inconvenient or impossible for a woman to return to a medical facility for insertion. For example, Latin American observers a decade ago found that of those women who planned to return for contraceptive advice six weeks postpartum, half failed to do so. Postpartum insertion of IUDs could have a demographic impact in countries where women do not return for contraception after giving birth.

Several recommendations emerge from the study. First, in countries where women are unlikely to return to the medical facility for interval insertion, immediate postpartum IUD insertion should be promoted. Second, it is important to ensure that those performing insertion understand and use the proper insertion technique.

Finally, since many women in developing countries have their babies at outlying hospitals or clinics attended by midwives, and since earlier studies have shown that suitably trained midwives are as successful as physicians in performing interval insertions of IUDs, the authors recommend that countries undertake the training of midwives in postpartum IUD insertion. Such a program should significantly increase the number of women receiving contraceptive services immediately postpartum.

Insight from failure

Since the incidence of pain or bleeding associated with IUD use is related to the size of the IUD, attempts to decrease these unpleasant side effects have centered on the development of smaller, copper devices such as the Copper T (TCu) and the Copper 7 (Cu 7).

Dr. Jaime Zipper of Santiago, Chile was the first to show that the addition of copper to intrauterine devices increases their effectiveness, thereby allowing a reduction in the size IUDs must be to prevent pregnancy. In 1979, he designed another copper IUD, the Copper I, to reduce further the size of the plastic vector carrying the copper. The Copper I consists of a straight stem with small crossarms in an 'X' configuration designed to anchor the IUD in place. A copper wire is wound around the stem of the device, exposing 200 square millimeters of copper.

In an article entitled "Evaluation of the Copper I Intrauterine Device," scheduled for publication in Contraceptive Delivery Systems, Dr. Zipper, Mirtha Rivera, and Cynthia Waszak report on a study of 98 women inserted with the Copper I at the Hospital Barros Luco in Santiago. One third of the women suffered mild to moderate pelvic pain at insertion, but no perforations occurred.

The women were asked to return for one-, three-, six-, and twelve-month follow-up examinations. Eighty-eight women (90%) returned for at least one follow-up. Of these, 42 women reported some type of primary bleeding or pain complaint during the follow-up period. Complaints included intermenstrual spotting (13.6%), intermenstrual pain (11.4%), intermenstrual bleeding (11.4%), and dysmenorrhea (10.2%). Prior to insertion, 22 women had reported problems with pain or bleeding, primarily intermenstrual pain (10.3%) and intermenstrual spotting (5.2%). Four women (4.5%) were diagnosed with pelvic inflammatory disease (PID) confined to the uterus and two women (2.3%) with PID confined to the adnexa. One woman with adnexitis and one woman with endometritis had their IUDs removed at the time of diagnosis.

The accidental pregnancy rate was 3.2 at six months and 9.0 at 12 months. The expulsion rate was also high: 15.8 at 12 months. There were no reports of bleeding or pain at 12 months; however, there was one removal for pain or bleeding at 15 months postinsertion. Three removals occurred for other medical reasons (two for PID and one for painful intercourse) and one

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for an unspecified personal reason. The overall continuation rate was 72.6 at 12 months.

Medical research aims to sort out good and bad ideas. The Copper I was a good idea that didn't work in practice, but it provided added insight into IUD action. Although the data and clinical impressions indicate that the goal of reducing menstrual side effects was achieved, both the pregnancy and expulsion rates were unacceptably high. The high pregnancy rate may have been due to the reduced size of the IUD or to increased displacement or expulsion, some of it unnoticed. The high expulsion rate indicates that the Copper I's anchoring against the anterior-posterior surfaces of the uterus is less effective than the anchoring of the Copper T against the lateral edges of the uterus. Even though the crossarms on the Copper I had an 'X' configuration to assure good contact and were sloped to allow motion in the fundal direction while resisting motion in the cervical direction, anchoring was not adequate.

Unlike some IUD research, the Copper I was designed according to specific biological hypotheses, not blind guesswork. In the long run, success is built on failure almost as often as on previous success. Data from the Copper I is likely to further efforts to decrease IUD side effects with future devices.

Inventions look promising

Like the Copper I IUD, an IUD with inverted strings recently developed at FHI is an effort to improve upon a popular design by eliminating an undesirable side effect. To aid in removal of the new IUD, a string retriever has also been devised. The two inventions show promise of solving several problems encountered by some IUD users: uterine infections, and removal of IUDs with retracted strings.

Clinical evidence from cultures taken directly from the uterus suggests that IUDs with strings are associated with a higher probability of bacterial invasion of the uterus than those without strings. While the uterine cavity is normally sterile, the vagina is not. The cervix, which connects the uterine cavity with the vagina, normally protects against ascending pathogens, and the presence of an IUD marker string may

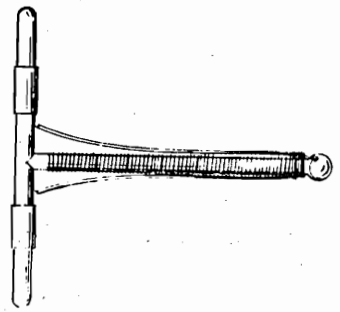

Fig. 1. IUD with inverted strings.

diminish this protection, providing a pathway for bacteria. It is well established that IUD users have a higher incidence of pelvic inflammatory disease (PID) than matched samples of nonusers. However, epidemiological evidence relating rates of PID to whether strings pass through the cervix is equivocal and requires additional data collection.

A new IUD designed by bioengineer Robert G. Wheeler and President Malcolm Potts of Family Health International eliminates extrauterine marker strings. A modification of the Copper T IUD, it features threads attached to the lower cervix end of the IUD but directed toward the uterine fundus or crossarm of the IUD. The free ends of the threads are held loosely under a collar to prevent them from being expelled into the cervix (Figure 1). Future availability of this IUD depends on results of clinical trials.

A second invention by Wheeler and Potts makes possible the removal of IUDs without marker strings as well as IUDs whose strings have retracted spontaneously into the uterine cavity. The new IUD retriever (Figure 2) consists of a flexible plastic handle, twisted stainless wire core of the brush, nylon filament bristles, and a sheath. The nylon bristles are bent into a hook on each end so that the retriever will engage intrauterine strings when the brush is rotated either clockwise or counterclockwise.

Preliminary tests of the retriever in Mexico and England have shown it to be effective in removing IUDs with retracted strings. FHI is seeking a manufacturer to make enough retrievers for the expanded studies necessary before wide-scale distribution.

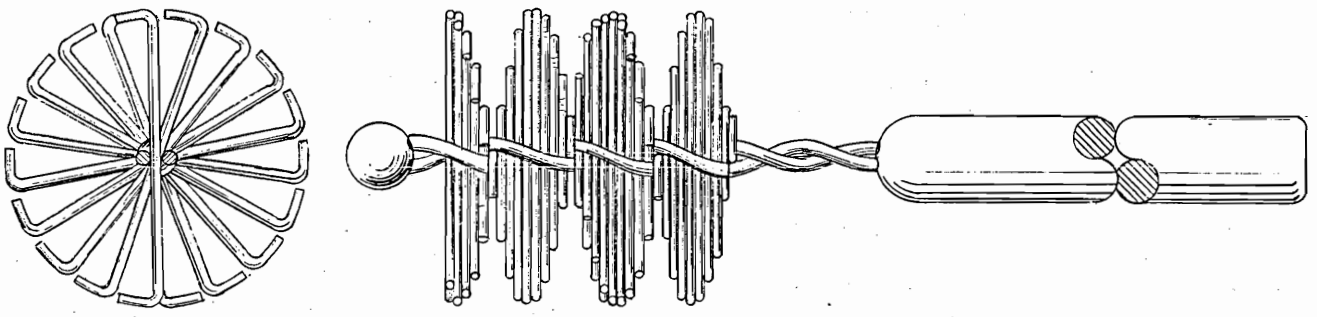

Fig. 2. IUD retriever.

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Study looks at effect of oral contraceptive on sickle cell disease

Despite of the special need of women with sickle cell disease to limit their pregnancies, no clinical trials have investigated available contraceptive methods to see which would be best for sickle cell patients. Although some scientists believe oral contraceptives ameliorate the symptoms of the disease, data to support the hypothesis are lacking.

Sickle cell disease, an inherited disorder occurring mainly in people of African descent, carries an increased risk of maternal morbidity and mortality. During a "crisis," the red blood cells become misshapen, cutting off the blood supply to living tissue. Sickling can affect virtually every organ of the body, and patients may experience recurring bouts of severe joint pain, often requiring hospitalization. Pregnancy itself usually increases the frequency of crises and other complications. Although women with the disease, after appropriate genetic counseling, may want children, they commonly choose to have a small family. Thus, defining the safest contraceptives for women with the disease is important.

In 1983, FHI conducted a survey of contraceptive prevalence among women with sickle cell disease. Four hundred women who attended the Institute for Clinical Genetics at Korle-Bu Teaching Hospital in Accra, Ghana were interviewed regarding their reproductive history and contraceptive use. The most striking finding was that 75% of women in this high-risk group were not using reliable contraception.

Although many physicians believe that women with sickle cell disease should not use oral contraceptives, the reasons for this belief are unclear. The scientific literature, for example, provides no support for it, and suggests that progesterone, similar to one of the two steroids contained in oral contraceptives, has a beneficial effect in sickle cell disease. Progesterone inhibits the sickling of red blood cells, thereby reducing the frequency of painful crises and the number of irreversibly sickled cells, and it significantly increases total hemoglobin and red blood cell mass, count, and survival.

Family Health International will conduct an 18-month study in Jamaica to evaluate the effects of an oral contraceptive on sickle cell disease. Thirty women between the ages of 20 and 40 who are attending the adult sickle cell clinic at the University Hospital of the West Indies are being recruited for the study. Volunteers will be selected who have been sterilized or are using an intrauterine device or barrier method of contraception. Participants will take either an oral contraceptive or placebo for the first 24 weeks of the trial, take no medication for the following 12 weeks, and then take the alternate medication for the final 24 weeks.

At clinic visits throughout the trial, each patient's physical condition will be assessed and a sample of her blood drawn for analysis. The effects of the oral contraceptive will be evaluated by monitoring such parameters as red blood cell survival (a direct measure of red blood cell turnover) and percent of irreversibly sickled cells, and by recording the frequency of painful crises, infections associated with sickle cell disease, and other physical complaints.

Dr. Boonsri recipient of Sharon Camp Fellowship

Dr. Boonsri Chuntrasri has been named the first Sharon Camp Fellow at Family Health International. FHI established the Sharon Camp Fellowship Program in honor of the former Chairperson of the Board of Directors, Dr. Sharon Camp, who is vice president of the Population Crisis Committee in Washington, D.C. Each year, one or two fellows will be selected from among applicants to spend 6 to 12 months at FHI headquarters in Research Triangle Park, North Carolina working on a research project of their choice. Fellowships are available to experienced researchers, including clinicians, epidemiologists, and social scientists, in the area of family planning and reproductive health. FHI provides travel to and from North Carolina and a stipend for fellows and their families.

Dr. Boonsri is a member of the staff of the Department of Obstetrics and Gynecology, Pramongkutklao Army Hospital, Bangkok, Thailand. During her stay at FHI, she will analyze data from a longitudinal study of breast-feeding and return to fertility conducted as part of FHI's four-country breast-feeding study. She will bring data from the Thai portion of that study for analysis.

Dr. Boonsri was chosen from a field of applicants from seven different countries. She will begin her fellowship this summer. Dr. Malcolm Potts, President of FHI, commented, "We were in the happy predicament of having an outstanding group of candidates, which made the choice of a fellow difficult."

Professor Maher Mahran (left) of Ains Sham University and Dr. Malcolm Potts (right) of Family Health International at March 20 meeting with President Hosni Mubarak (center) of Egypt. Discussion centered on the experience of countries with active family planning service programs, with emphasis on the opportunity to use existing structures in society.

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FHI funding Mexican survey of contraceptive practices

FHI is asking two questions about programs of community-based distribution (CBD) of contraceptives: are they safe, and do they work? The first question has been partially answered from studies in Matamoros, Mexico (see Network, vol. 5, no. 2) showing community-based distribution of oral contraceptives did not introduce any additional risk to women of reproductive age.

A new study, also in Mexico, will be conducted by the Federacion Mexicana de Associaciones Privadas de Planificacion Familiar (FEMAP) to assess the impact of a model CBD program on contraceptive prevalence. In Juarez, where the model program originated, over 30,000 couples have accepted contraceptives through the CBD program since 1980. However, some of these acceptors may already have been obtaining contraceptives from pharmacies, clinics, or other sources prior to the initiation of the FEMAP program in their community. The question remains: has the FEMAP intervention increased contraceptive prevalence or merely substituted an alternative source of family planning services?

FHI is providing technical and financial assistance to FEMAP to collect information to be used in the design and implementation of family planning programs, with a special emphasis on community-based distribution. Household surveys in selected areas of Leon and Saltillo—cities with low availability of contraceptive services—will obtain information on selected demographic characteristics of the target populations, past contraceptive use patterns, reported side effects, and the satisfaction of women with their current method. In the case of women who are not using contraception, their interest in family planning and the percentage of women in need of contraceptive services will be ascertained.

Data from the study will be useful in determining to what extent the CBD model has succeeded in informing women about contraception and the services provided through FEMAP. A special question to be addressed relates to the availability of sterilization. Do women know of the operation, and if so, is FEMAP providing them with an opportunity to obtain it? Similarly, the role of the program in providing information about and referral for other clinic methods, such as IUDs, will be assessed. Finally, the role of program personnel in counseling women concerning choice of method, possible side effects, and actions to take in the event of problems is unknown. Although such information on distributors will not be collected until follow-up surveys are done, the initial surveys will provide data to serve as guidelines in training distributors.

The data collected and analyzed in this investigation will be directly applicable to the family planning programs FEMAP is establishing for the urban poor in Leon and Saltillo. Other FEMAP CBD programs may also be refined as a result of the survey findings. The information will be used to determine what efforts distributors can make to improve overall prevalence.

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network

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Experts meet to discuss predictors of ovulation

New tests allow doctors to predict almost the exact moment of ovulation, but such tests require sophisticated drugs and equipment found only in high technology settings. Predicting ovulation for couples who want to practice natural family planning but do not have access to such technology is less accurate. Experts from around the world met in North Carolina in December with FHI researchers to discuss current and proposed methods of detecting ovulation and ways to make prediction easier and more reliable for couples to use on their own. Researchers with extensive field experience discussed the logistics of implementing the techniques developed by laboratory researchers. Methods were evaluated in terms of accuracy, invasiveness, practicality, laboratory requirements, and cost.

Trying to predict ovulation is a relatively new field of endeavor. For most of history, people believed that the risk of pregnancy was highest during menstruation. In the 1930s, scientists discovered that ovulation occurred approximately two weeks before menstruation. This led to the rhythm method (calendar method) of fertility control. Although NFP programs today rarely recommend this method alone, use of the calendar for calculation of the postmenstrual (preovulatory) phase of the cycle is often incorporated into the teaching of the symptothermal method.

Ms. Barbara Gross of Australia spoke to the conference on indicators of ovulation used as the basis of natural methods of family planning, including the basal body temperature method, the cervical mucus method, and the symptothermal method. "The only positive evidence of ovulation is the occurrence of pregnancy or visualization of follicular rupture and pick up of the ovum following rupture," she pointed out. The methods she described are imperfect indicators of ovulation.

A new technology created in the 1970s—radioimmunoassay—led to the discovery that hormone surges occur at a woman's midcycle and thus are linked to ovulation. Hormone measurements now serve as more reliable predictors of ovulation than previously used indicators such as basal body temperature, which is more appropriate for determining retroactively that ovulation has occurred. Methods for determining hormone levels in blood, urine, saliva, and breast milk were discussed during the conference.

Radioimmunoassays of hormones in serum are widely used in the treatment of infertility. Serum hormone determinations are useful tools in monitoring ovarian function, including ovulation. However, in a paper prepared by Dr. Gebhard Schumacher of Chicago, it was pointed out that relatively frequent blood sampling is necessary to establish a serum hormone profile. The radioimmunoassays to determine the hormone levels require special laboratory facilities, skilled personnel, and the disposal of radioactive waste.

Recent development of new technologies based on antigen/antibody reactions using antibodies linked to enzymes (phosphatase or peroxidase) have already replaced some radioimmunoassays. The advantages of the enzyme-linked-antibody methods are that a color reaction can be measured by photometric techniques or in a semiquantitative way by comparison with color standards. In contrast to the short half-lives of the radioisotope-labeled antibodies, commonly used enzyme-labeled antibodies are relatively stable and can therefore be stored over longer periods of time. The instrumentation is more economical, the problems of radioactive waste disposal are eliminated, and the demands for training are reduced. Application of this method to other body fluids may open the way to home tests.

Ms. Barbara Gross described a new technique for patient self-sampling of serum prolactin levels. This simple, less invasive technique uses a finger prick whole blood sample spotted onto filter paper. Prolactin measurement has been shown to be a sensitive index of returning menstruation and fertility during lactational amenorrhea. The filter paper blood spot technique could potentially be used in large field studies of breast-feeding women to validate the measurement of serum prolactin as an index of returning fertility.

Issue Highlights

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Gonadotropins and steriod hormone metabolites are excreted in urine. Dr. James Brown reported on the efforts of his research group in Australia to develop simple assays and do-it-yourself kits. One kit for measuring the hormone pregnanediol-3-glucuronide (PdG) in urine was tested with volunteers who were practicing natural family planning and were proficient at recognizing their mucus symptoms. The women had no difficulty with the urine collections or dilutions, but other problems arose. In the original version of the kit, the volume of urine was measured by drops, and most women could not resist adding several extra drops "to make sure." Thus, urine volumes could differ by more than 100%. The problem was solved by the use of a cheap, automatic pipette that delivered precisely 125 ul of urine.

Some women, knowing what the result should be from their mucus symptoms, misread the result even though it was obvious to laboratory personnel checking later that an opposite result had been obtained. But for women with inadequate or confusing symptoms of ovulation (for example, breast-feeding women or women who have recently discontinued the contraceptive pill), hormone assays transform a situation of uncertainty and desperation to one of knowledge and confidence. They become enthusiastic users who have provided excellent results. The kit evolved during the trials to a simpler, more acceptable version.

Assessment of ovarian activity based on samples of saliva is an interesting new approach that is attracting considerable attention. Samples can be easily collected by spitting directly into wide-necked plastic tubes. Samples are stable on storage at low temperatures, and in temperate climates may be mailed to a central laboratory for assay. This noninvasive, cost-effective sampling procedure is often more socially acceptable than giving blood or urine samples, a factor that has proved particularly useful for studies of ovarian activity in women of low socioeconomic status in Third World countries.

Dr. Diana Riad-Fahmy from Wales told the conference that because salivary concentrations of hormonally active steroids are low, precise determination of hormone levels therefore requires development of sensitive immunoassay techniques. Simple, direct assays for salivary progesterone have been established, but those for estradiol require considerably more research before they will be useful in routine practice. Computerized processing of salivary progesterone data allows accurate assessment of luteal function and retrospective dating of the cycle. Predicting ovulation must, however, await development of more suitable assays for salivary estradiol.

In a discussion of indicators of ovulation from breast milk, Dr. Peter Hartmann of Australia noted that changes in glucose in breast milk correspond to phases of the ovulatory menstrual cycle; these same changes are found in saliva. There is also an increase in sodium in breast milk just prior to ovulation, with another rise in the mid-luteal phase of the cycle. However, much more research is needed on whether breast milk constituents can be measured that would allow prediction or detection of ovulation.

In addition to describing the state of the art of hormone determination and outlining directions for future research, the conference helped Family Health International plot a strategy for research on the appropriateness of natural family planning research for breast-feeding women. FHI is planning several studies to determine the validity of NFP methods for breast-feeding women, in part by determining the proportion of postpartum ovulations that are predicted by NFP symptoms (cervical mucus, basal body temperature, and characteristics of the cervix). An independent confirmation of ovulation can be made through ultrasound or measuring ovarian hormones to validate the NFP symptoms.

Several areas for future research were identified by the experts. Cervical mucus patterns, which vary so among lactating women, need to be more precisely described as an aid to the practice of NFP among breast-feeders. Another step is to study the mucus patterns before the first menses postpartum. One researcher presented evidence that the mucus pattern during that period did not always correlate with the estrogen surge. Thus, two periods of mucus secretion need to be studied: before and after the first postpartum bleeding episode. By measuring ovulation, and not simply pregnancy and menses, FHI will be better able to contribute to the general body of knowledge about the return of fertility (ovulation) in breast-feeding women.

A summary of the meeting will appear in Research Frontiers in Fertility Regulation, published by the Program for Applied Reseach on Fertility Regulation. An edited collection of papers is also planned.

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Contraceptive technology and reproductive health subject of workshop in the Philippines

Family Health International, in cooperation with the Philippine Commission on Population and the U.S. Agency for International Development, sponsored a workshop on "Reproductive Health for the '80's" in Manila Nov. 12 and 13. The workshop provided sixty Philippine physicians representing all the regions of the country an update on recent developments in contraceptive technology and selected issues in reproductive health.

The workshop was held in conjunction with the annual meeting of the Philippine OB/GYN Society (POGS) Nov. 8-10. Dr. Jack Lippes, inventor of the Lippes Loop who is now serving as vice president for medical research of FHI, delivered the keynote address on "Recent Advances in Contraceptive Technology" at the Population Session during the POGS meeting. He emphasized "the tremendous benefits birth control or birth spacing provides to children themselves. The spaced child weighs more at birth, is less likely to be anemic, and is more likely to survive to adulthood." Dr. Lippes reminded the obstetrician/gynecologists that "in an era of rising expectations and advancing technology, the medical profession must stress the quality of the newborn baby and educate the public to the advantages of a small family."

Dr. Lippes joined other international and local participants with expertise in various aspects of contraceptive technology to deliver lectures at the workshop. They included Dr. Alan Rosenfield, Chief of Obstetrics and Gynecology and Director of the Center for Population and Family Health, Columbia University; Dr. Andrew Kaunitz, obstetrician/gynecologist, University of Florida; Dr. Carl Gustaf Nilsson, University of Helsinki, Finland; Dr. Henry Burger, specialist in natural family planning methods, Melbourne, Australia; Ms. Arja Ojansuu of Leiras Pharmaceuticals (manufacturers of NORPLANT® subdermal implants), Finland; Dr. Albert Siemens, Director of Clinical Trials, Family Health International. Contraceptive technologies discussed included injectable and oral steroidal contraceptives, subcutaneous hormone-releasing contraceptive devices as well as hormone-releasing IUDs, and sterilization. One session dealt with fertility awareness and natural family planning.

By providing a forum for Philippine specialists in family planning to exchange ideas with their foreign colleagues, the workshop enabled the local experts to identify needs that the Philippine population program should address and mechanisms by which individual physicians can contribute to the program more effectively.

In small group discussions of the role of the obstetrician/gynecologist in the population program, each group was assigned to devise strategies to meet a particular objective. The objectives were to identify obstetrical patients at risk and to provide optimum care for such patients and their children in accordance with existing resources in the locality; to identify and clarify the role of the obstetrician/gynecologist in providing fertility management services; to establish relationships for the provision of comprehensive care (including improving prenatal care and reducing infant mortality as well as providing contraceptive and sterilization services) through existing providers in the region; to encourage contraceptive biomedical research as it relates to the Philippine situation. FHI will develop and support plans for studies in the Philippines in the research areas the workshop participants indicated are most promising.

Sharon Camp Fellowship Program accepting applications for 1985

Family Health International's second annual Sharon Camp Fellowship competition invites applications from experienced researchers in the area of family and reproductive health, including clinicians, epidemiologists, and social scientists. The recipient will spend six to twelve months at FHI headquarters in Research Triangle Park, North Carolina working on a research project. FHI's staff and facilities will be available to the fellow, who will have the opportunity to learn in a working environment.

Fellows may work in the area of reproductive or family health either using the data available at FHI or bringing their own data with them. Others may wish to focus on policy issues or historical perspectives of family planning programs in various countries. Given the relatively short duration of each fellowship, projects involving new data collection are generally not feasible.

To be considered for the fellowship, applicants should submit a letter expressing interest, a curriculum vitae, an abstract of two or three pages describing the research project to be completed during the stay at FHI, and a statement of technical and financial support the candidate would require for the project. Fluency in English is required. Applications must be received at FHI no later than April 15, 1985. The 1985 fellowship will begin on or about October 1.

Selection will be based on the relevance and potential contribution of the proposed work to the area of family and reproductive health and to FHI programs, the technical acceptability of the program, and the competence of the applicant to carry out the proposed work as demonstrated by the supporting documentation submitted as part of the application. FHI will provide travel to and from North Carolina and a stipend to cover expenses during the residency period.

The Sharon Camp Fellowship Program was established to honor the former Chairperson of the Board of Directors, Dr. Sharon Camp, who is vice president of the Population Crisis Committee in Washington, D.C. The current Fellow is Dr. Boonsri Chuntrasri of Bangkok, Thailand.

Study examines menstrual changes following female sterilization

Most women have no change in menstrual pattern following female sterilization, according to an FHI report. "The best predictor of whether a woman ... (will have) menstrual pattern change after sterilization is whether her pattern had any abnormal characteristics during the three months prior to the procedure," states an article in Studies in Family Planning entitled "Menstrual Patterns after Female Sterilization: Variables Predicting Change" by Lynda P. Cole, Judith A. Fortney, and Kathy I. Kennedy of FHI.

The authors developed a new methodologic approach that eliminated most of the problems of earlier studies to examine the question: Is tubal sterilization related to subsequent menstrual pattern disturbances, possibly leading to hysterectomy or other surgery?

Earlier studies have had contradictory findings; some have reported increased menstrual disturbance while others have found no change after sterilization or have been inconclusive. Some of these have been retrospective studies, with problems of inadequate recall of menstrual patterns prior to sterilization. Even the prospective studies have shared some weaknesses with the retrospective investigations, including failure to separate elective from medically indicated sterilizations, failures to account for the previous use of contraceptives that influence menstrual patterns (i.e., pills and IUDs), failure to account for age and parity, failure to provide appropriate controls, failure to report improvement as well as negative changes in the menstrual pattern, failure to look at changes in two or more measures simultaneously, and failure to define terms and to attempt to quantify changes (leading to the use of such vague descriptions as "menstrual disorder" or "significant abnormal bleeding").

Most of these problems were eliminated by the authors. They constructed an Index of Menstrual Pattern Change using the four menstrual pattern measures found most important by the World Health Organization: regularity, length of cycle, duration of bleeding, and dysmenorrhea. The index is a single number based on the sum of changes reported by a woman, with greater change yielding a higher number.

Using data collected during FHI's clinical trials of sterilization methods in 23 countries, the authors selected 1,555 cases for analysis. The women were between the ages of 25 and 34, had had between two and six live births, were more than six weeks postpartum or postabortion, and had not used an IUD or hormonal contraception during the three months before sterilization. At the time of sterilization, patients answered questions about their three last menstrual cycles; the questions were repeated at the 12-month follow-up visit.

In analyzing the data, women were divided into two groups according to whether their menstrual cycles were 'normal' or 'abnormal' at admission. This was done to see whether women with abnormal menstrual cycles were more or less likely to change. Table 1 summarizes the percentage distribution of scores on the Index of Menstrual Pattern Change at 12-month follow-up. Of women whose periods were normal before sterilization, 92.5% had scores of 0, 1, or 2 (out of a possible 15); none had scores as high as 8. Even among women previously classified as abnormal, 80.2% had scores of 0, 1, or 2.

Table 1.
Percentage distribution of scores on Index of Menstrual Pattern Change (IMPC) at 12-month follow-up, by normality of menstrual pattern at time of procedure.

Score on the IMPC	Normal at admission	Abnormal[1] at admission	All women
0	61.8	20.4	53.4
1	21.6	39.0	25.1
2	9.1	20.8	11.5
3	4.8	11.6	6.2
4	1.4	4.4	2.0
5	0.8	2.8	1.2
6	0.2	0.6	0.3
7	0.2	0.0	0.2
8	0.0	0.3	0.1
Total	100.0	100.0	100.0
Number	1,237	318	1,555

Note: IMPC scores have a possible range of 0 to 15. Actual scores ranged from 0 to 8, with 0 indicating no change and 8 indicating much change.

[1]Abnormal is defined as irregular cycles or cycles of <21 or >35 days, duration of bleeding <2 or >7 days, and/or moderate or severe dysmenorrhea.

Source: Published with permission from Judith A. Fortney, Lynda P. Cole, and Kathy I. Kennedy, "A new approach to measuring menstrual pattern change after sterilization," *American Journal of Obstetrics and Gynecology* 147, no 7 (1 December 1983):835.

The authors report, "abnormality was the best predictor of change when all women were considered. Abnormality alone explains 9% of the variance." Of the parameters included in the Index of Menstrual Pattern Change, irregularity was the best predictor of change. Among sterilization methods, ligation and excision was most associated with change; however, the association was not strong. For women who had normal menstrual cycles before sterilization but reported abnormal cycles at the 12-month follow-up, the method of tubal occlusion was the best predictor of change.

No change in any of the menstrual pattern variables was reported by 53.4% of all the women in the study. This leaves 46.6% who did report some change; these

included improvements as well as negative change. Over 59% of the women with abnormal patterns at admission were reporting normal cycles one year later.

"In general, women whose menstrual patterns are extreme in any way at the time of the sterilization procedure are more likely to experience change than women with more average menstrual patterns. This is not surprising and would perhaps also happen had they not been sterilized," the authors conclude. "What is of particular interest in this analysis is that no single variable stands out as being a good predictor of menstrual pattern change for all women, and that all variables in combination do not explain very much of the variation."

Vanguard contraceptive users subject of Senegal research

What influences a woman to join the vanguard of contraceptive users in a country where acceptance of family planning is just beginning? FHI gave support to the Division des Etudes Demographiques (Division of Demographic Studies) in Dakar, Senegal to conduct a study to answer that question.

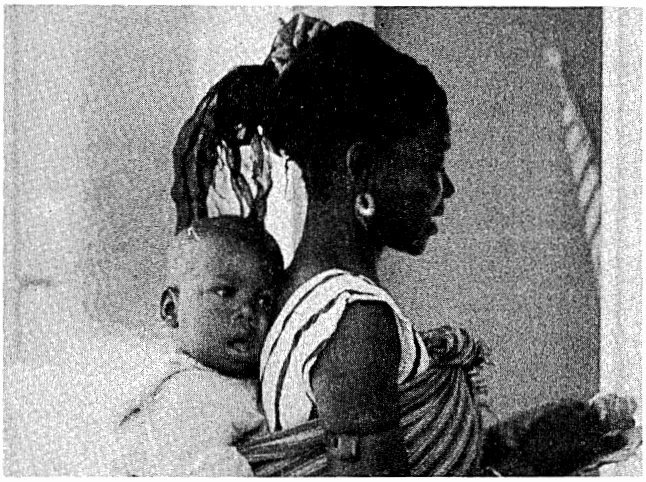
Senegal only recently repealed the pronatalist laws that were remnants of its former status as a French colony. Since 1981, family planning and maternal and child health services have slowly developed in the capital, Dakar, and other urban centers. The concept of birth spacing is still not well known by the general population, and services are not yet widely available. Contraceptive prevalence in 1983 was estimated at between five and ten percent of women of reproductive age in the Dakar-Cap Vert region. The FHI-sponsored study of the early acceptors of contraceptive services was based on the assumption that better understanding of the personal characteristics and motivations of those currently using or seeking out contraception can assist in effective planning and implementation of service delivery programs.

Three family planning clinics operated in the Dakar-Cap Vert region at the time of the study. La Croix Bleue, a private clinic, has provided fee-for-service care since 1964 to a largely middle-class clientele. A government Ministry of Health clinic, the PMI de Medina, is situated in a densely-populated market area near the city center and has offered free services since 1976. Finally, the Family Planning Association of Senegal (ASBEF), with support from the International Planned Parenthood Federation (IPPF), has operated a model clinic in a residential area since 1981. These three clinics together provided approxi-

Table 1.
Background Characteristics of Clinic Clients

	ASBEF	PMI de Medina	Croix Bleue
Number of cases	281	709	229
Percent younger than age 30	60	59	35
Percent with no education	23	37	41
Percent with secondary education	47	34	39
Percent working	37	26	36
Percent husband working[1]	95	90	96
Percent Christian	7	6	17
Percent born in Cap Vert Region	61	60	43
Percent never married	10	9	9
Percent in polygamous unions	25	23	25
Average age first marriage[2]	19.1	17.8	18.2
Average age first pregnancy[3]	19.0	18.4	18.9
Percent with live birth in last 12 months	35	24	20
Average parity	4.1	4.6	5.0
Average number living children	3.8	4.2	4.6
Average ideal family size	4.9	5.1	5.1
Percent wanted last pregnancy[3]	34	33	60
Percent wanting additional children	70	68	60
Percent first accepted FP this clinic	41	67	66
Percent coming to clinic for 1st time	13	15	10
Percent with knowledge other FP clinics	67	27	16

[1] currently-married women (79% of total)
[2] ever-married women (91% of total)
[3] women with 1 or more pregnancies (98% of total)



A mother and her child pause before entering the PMI clinic.

mately one tenth of the family planning services in the greater Dakar area in 1983. The remaining women received services from private physicians and pharmacies.

During January and February of 1983, all family planning clients seen at the three clinics were interviewed regarding their sociodemographic characteristics, reproductive histories, knowledge and attitudes about family planning, patterns of contraceptive use, and reasons for the current visit. Clients returning to a clinic for resupply of or information about a method previously accepted were included in the study population; such individuals proved to be the large majority of the clients at each of the three centers during the study.

As Table 1 shows, the clients were remarkably similar with regard to marital status, the initiation of childbearing, and fertility plans. One client in ten at each clinic had never married, and one fourth were currently in polygamous unions. Mean age at first marriage was 18 years at the PMI and Croix Bleue clinics and 19 years among ASBEF clinics, and the average age at first pregnancy was strikingly constant across the three clinics (18.4 to 19.0 years).

To understand the process by which women became interested in regulating their fertility, and the subsequent stages leading to the adoption and continued use of an effective method, clients were asked questions about their interest in family planning, past use of contraception, and current method. Most women reported that they had used either traditional child-spacing practices (rhythm, withdrawal, folk medicines, and fetishes) or no method at all before their initial clinic visit. Returning clients had since adopted or switched to effective modern methods.

Of particular interest are the methods provided to women coming for the first time to one of the three clinics (Table 2). At the PMI de Medina Family Planning Clinic, 69 percent of such clients received condoms or female barrier methods; very few received pills or an IUD. Nearly one fifth of the first-time visitors received no method at all, but only information relating to family planning. On the other hand, two thirds of the initial clients at the ASBEF clinic and all

Table 2.
Method Provided to First-Time Clinic Clients
(Percent Distribution)

	ASBEF	PMI de Medina	Croix Bleue
IUD	65	5	100
Pills	14	9	—
Barrier methods	8	69	—
None	14	18	—
Total	100	100	100
(Number of clients)	(37)	(103)	(23)

those at the Croix Bleue were given IUDs. Contraceptive dispensation at the three clinics did not take into account whether a woman wanted to limit her family to the number of children she already had or whether she wanted to use contraception to space future childbearing. Rather than tailoring the contraceptive to the particular needs of the client, clinics generally dispensed them according to the method orientation of the respective clinic personnel.

At the ASBEF and PMI clinics, seven out of ten women had learned about the clinic from a friend or relative; only one in five reported a medically-trained person as her source of information. Among clients at the Croix Bleue, on the other hand, twice the percentage (43%) had learned about the clinic from a doctor or nurse, and fewer from family or friends.

When asked how family planning information could best be made available to Senegalese couples, more than half of the women seen at the Croix Bleue clinic thought that it should be handled by medical personnel. Only ten percent of the clients at the other two clinics gave this response; most favored the broadcast media or "friends." At each of the three clinics, the percentage who stated that the husband is the best source of family planning information was less than ten percent.

To assess the principal barriers to wider acceptance and use of family planning among the general population, respondents were asked to give their own opinions why "most Senegalese women are not using family planning." Lack of knowledge about contraceptive methods and the opposition of husbands were reported to be the most important reasons for non-use, together accounting for nearly 75 percent of the responses. At the other extreme, neither cost nor availability were cited as significant factors, and the opinions of persons other than the husband were not important. Only six percent of the clients thought that the fear of side effects is the most important barrier to contraceptive use among Senegalese women.

The two principal reasons given for non-use appear to be associated with the level of education of the clinic clients. Women who have had schooling beyond the primary level are most likely to cite the lack of information as the principal reason women are not practicing family planning. Conversely, they are less likely than their less-educated counterparts to attach great importance to the husbands' opposition.

The study findings provide a variety of information on the relatively few individuals seeking to regulate the number or spacing of their pregnancies by means of modern contraception. In this period of rapid development of programs to increase the acceptability and use of safe and effective child-spacing methods throughout Senegal, it is important to understand the needs and preferences of those who seek out family planning services.

Service providers in the Cap Vert region have traditionally favored IUDs over methods requiring frequent resupply or daily compliance, such as condoms and oral contraceptives. As a broadened service delivery program attempts to motivate large numbers of reproductive-age women to become acceptors, it may become necessary to increase the variety of services offered in what have traditionally been single-method programs and to offer methods according to the needs of individual acceptors.

There is substantial potential demand for permanent methods of birth control among existing family planning acceptors—a demand that is likely to grow as ideal family size norms decrease and outreach programs acquaint Senegalese women with the various options available to limit their family size. The study found that at least 30 percent of the clients at each clinic wanted no more children. Many of these women, most of whom are older grandmultiparas, would be interested in learning more about female sterilization; a number of "pioneer" acceptors would doubtless follow.

Responses given by clinic clients emphasize the need for improved information, education, and communication programs about family planning if the demand for and use of contraception is to increase among Senegalese women. Use of the broadcast media might prove effective in a society with a strong oral tradition (coupled with a low level of literacy) and a limited medical infrastructure. Included in these information programs must be ways to overcome the traditional opposition of men to their wives' use of modern fertility-regulating methods, educating husbands that contraception offers a couple the opportunity to space their pregnancies as they choose, thus improving the health of both mother and offspring as well as the general well-being of the family.

Pregnancy vaccine research

by G.P. Talwar

Is a vaccine against pregnancy possible? Yes, we have evidence that it is. Clinical cases of infertility in which immunological factors are the sole cause have been observed worldwide. We do not know how or why the body's own defense system interferes with the normal biological process of fertility, nor do we know how to reverse this action, but it does occur. Furthermore, it is possible to immunize fertile animals experimentally to make them infertile. In almost all of these experiments, the immunity has been reversible as the titers of circulating antibodies diminish with time.

Theoretically, it is possible to make more than one pregnancy vaccine. Each could intervene at a different point in the reproduction process. For example, sperm could be made inactive or the membrane surrounding the egg made impervious to penetration; either would block fertilization. However, most of the pregnancy vaccine work in the last decade has been concerned with developing and perfecting a vaccine directed against human chorionic gonadotropin (hCG), a hormone essential for pregnancy. An anti-hormone approach has several advantages. With hormones, we are dealing with molecules whose structures are known; they are available in pure form from natural sources and can also be obtained by gene cloning; we have accumulated information on their biological activities. Hormones relay their messages through the circulation; thus, there is more opportunity to intercept hormones by antibodies than to intercept sperm, or sperm-ovum interaction, for which adequate amounts of antibodies are required in the genital tract.

If a woman conceives in mid-cycle, hCG is formed about the 23rd day, and it sends a signal to prevent menstruation. The anti-gonadotropin vaccine-induced antibodies intercept the signal, so the corpus luteum is not sustained and menstruation will occur. Such a vaccine has been tested and confirmed in three species by four laboratories. One question that remained unanswered until lately was whether the possible cross-reaction between anti-hCG vaccine-induced antibodies and the pituitary hormone LH led to side effects. When monkeys immunized with a frankly cross-reactive antigen were autopsied, no side effects were discernible. In fact, cross-reaction with luteinizing hormone may enhance the effectiveness of anti-hCG and qualify it as a pre-implantation vaccine.

Investigators over the last few years have demonstrated the return of fertility in anti-hCG vaccine-immunized animals when antibodies declined. The progeny appear normal and are being followed up for normal reproductive capacities on maturity. Three generations of primates, if healthy, will further help confirm the safety of the vaccine.

Early human trials and toxicology studies on anti-hCG vaccine were conducted in Delhi and Bombay, India; Helsinki, Finland; Uppsala, Sweden; Santiago, Chile and Bahia, Brazil. Antibodies were produced in 61 of the 63 women vaccinated with this vaccine, and no side effects were reported. As the vaccine was linked to tetanus toxoid, the women received protection against tetanus at the same time as formation of antibodies against the pregnancy hormone.

One important limitation of the vaccine is the variation between women in the amount of antibody produced. If a woman does not develop a high enough antibody titer, she can become pregnant. Although this trait is also a feature of the vaccines against communicable disease, on immunization of an entire community, the general population is protected when a large enough percentage of the people develops an immunity, even if a minority does not develop sufficient antibodies. However, this variation in human physiological response is not desirable in a pregnancy pre-

vention program, where women of proven fertility may come up for immunization.

The problem facing developers of a pregnancy vaccine today is how to make a formulation that is safe while producing enough antibodies for efficacy. Its effectiveness should last at least a year to a year and a half, when a booster shot could be given to those desiring to prolong the interval. A polyvaccine designed to interfere at several points could have a high effectiveness.

Future plans call for the development of a polyvalent immunoprophylactic fertility control vaccine with additional carriers. For example, building in the hepatitis B surface protein antigen as a carrier would confer immunity against that disease as well. Such a combination would make the vaccine even more acceptable in many parts of the world.

(Guest columnist Dr. G.P. Talwar is director of the National Institute of Immunology in New Delhi, India.)

Reproductive health management conference in November addresses sub-Saharan Africa concerns

The Conference on Reproductive Health Management in Sub-Saharan Africa sponsored by the International Project of the Association for Voluntary Sterilization gathered nearly 200 health providers and policymakers from 42 countries in Freetown, Sierra Leone, November 5-9. FHI was represented by Dr. Peter Lamptey, associate medical director for clinical trials. He was co-author with Kathy Jesencky of a background paper for the conference, "Building National Commitment: The Role of Research and Data Collection."

The president of Sierra Leone, Dr. Siaka Stevens, opened the conference with a call for increased availability of family planning and voluntary surgical contraception. Dr. Fred Sai of Ghana, in his keynote address, urgently appealed to the sub-Saharan health leaders to be courageous and energetic in their delivery of preventive health services, such as family planning, to help lower the very high maternal morbidity and mortality rates throughout the region.

Planned by a sub-Saharan steering committee, the conference was seen by leaders as a turning point for the region. It was the first major conference on the topic of reproductive health for sub-Saharan Africa. Representatives of 34 sub-Saharan countries and 17 international organizations attended, including the following conferees sponsored by FHI: Dr. Cecil Klufio, Ghana; Dr. Alabi Ladipo and Dr. Alex Omu, Nigeria; Dr. Samba Duale and Dr. N'Landu Mangani, Zaire; Dr. Joseph Lauroy, Senegal.

The sub-Saharan leaders produced specific recommendations aimed at sub-Saharan governments and non-governmental organizations. They called for a greater emphasis on family planning and voluntary surgical contraception over the next decade. Conference participants challenged all governments and health professionals in sub-Saharan Africa to expand family planning services to 50% of their reproductive-age populations by the year 1994.

Copies of the Sierra Leone Resolution, Recommendations, and abstracts of conference presentations are available from the Secretariat of the World Federation for Voluntary Surgical Contraception, 122 East 42nd Street, New York, NY 10168, USA. A conference report will be available in 1985, as well as as special issue of the World Federation's newsletter, Communique.

Selected research briefs

Postpartum IUDs in Mexico

Dr. Ramon Aznar, head of the medical subdivision of the Mexican health insurance program (IMSS), reports that postpartum insertion of IUDs has met with great success in Mexico. In 1983, the number of postpartum IUD acceptors in the family planning program of the IMSS reached 83,763, making it the most popular method of postpartum contraception there. The program emphasizes the need for adequate training of delivery room staff and for alerting women to possible contraceptives postpartum.

FHI has conducted studies of postpartum IUD use worldwide, including Mexico before the programmatic use of the method. Mexico now has the largest experience of any country in postpartum insertion. The Mexican experience serves to validate the contention that postpartum IUD insertion, accomplished during one of the few times in many women's lives that they have contact with the health care system, can make a significant contribution to family planning in the developing world.

Recent publications

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I Chi and E Kelly. Is Lactation a Risk Factor of IUD- and Sterilization-related Uterine Perforation? A Hypothesis. Int J Gynaecol Obstet 22(4):315, 1984. (84-25)

LP Cole, JA Fortney and KI Kennedy. Menstrual Patterns after Female Sterilization: Variables Predicting Change. Stud Fam Plann 15(5):242, 1984. (84-26)

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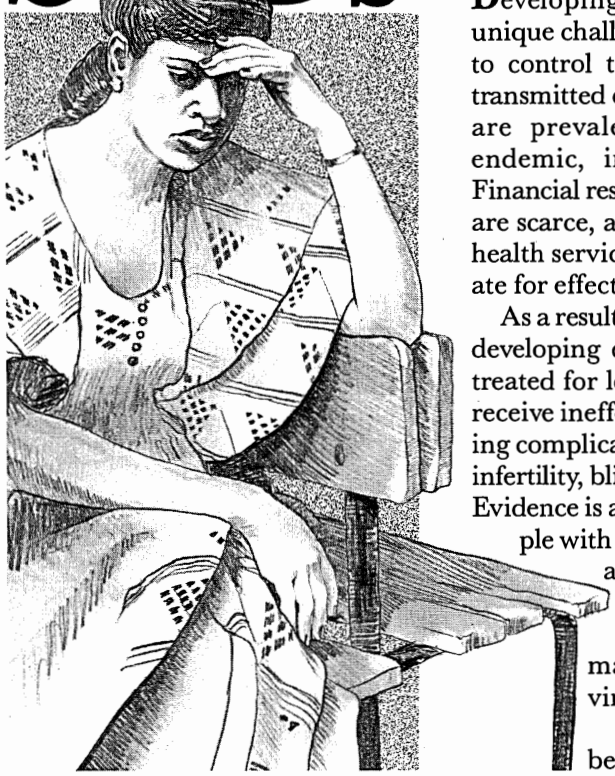
STDs



Management of sexually transmitted diseases

Developing countries confront unique challenges in their attempts to control the spread of sexually transmitted diseases (STDs), which are prevalent, and sometimes endemic, in their populations. Financial resources for STD control are scarce, and the organization of health services is often inappropriate for effective service delivery.

As a result, patients with STDs in developing countries often go untreated for long periods of time or receive ineffective treatment, causing complications that can result in infertility, blindness and even death. Evidence is also mounting that people with bacterial or viral STDs are more likely to acquire (and perhaps also transmit) the human immunodeficency virus (HIV).

"More emphasis should be placed on the STD complications," says Dr. Andre Meheus of the University of Antwerp. "Even the scarce and fragmentary data which are available point to an enormous health problem."

To attempt to reduce the incidence of STD complications, Dr. Meheus suggests, the first steps in the implementation of an STD control program in developing countries should be:

1) good management of patients with STDs and their contacts;

2) case finding for syphilis in the antenatal population;

3) screenings and case finding for gonorrhea in high-risk groups; and

4) systematic prophylaxis for ophthalmia neonatorum in the newborn.

The most crucial step, good case management, should consist of a problem-oriented approach that

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Fighting AIDS: a health care priority

By Halfdan Mahler, M.D.

Many times in recent years I have been asked why we should spend so much time, effort and money fighting AIDS when many other diseases are killing more people. Each year, for example, 14 million children under the age of five die worldwide — and nearly all of them of easily preventable conditions. Ninety-nine percent of these deaths occur in Third World countries. Each year, half a million women die from childbirth and abortion. Ninety-nine percent of these deaths are also in the Third World.

By comparison, as of September 1988 there were 111,854 acknowledged AIDS cases worldwide — and only 20 percent of these cases were in the Third World. Even though it is likely that many cases go unrecorded, the numbers are trivial. Why should the World Health Organization, Family Health International and other agencies put special effort into preventing AIDS?

First of all, no other disease is new to the medical scene and

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STDs

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is feasible for the rural health organizations where the vast majority of people obtain their health care — health centers, dispensaries and village aid posts.

Although the incidence of STDs is lower in rural areas than in urban areas, the scarcity of trained medical personnel and comprehensive laboratories in rural areas makes effective treatment of any STD difficult. Urban facilities are usually much better equipped to make definitive STD diagnoses and treatments.

Since diagnosis before treatment is seldom possible in rural areas, the World Health Organization (WHO) recommends STD management programs adopt simple treatment protocols based on the most common STD symptoms:

- urethral discharge;
- gynecologic complaint, such as vaginal discharge, low abdominal pain or dysuria;
- genital ulceration; and
- inguinal bubo, a swelling of the lymph nodes in the groin.

As outlined in these protocols, patients who exhibit urethral or vaginal discharge are initially treated for gonorrhea. Patients with genital ulcers should first be treated for both syphilis and chancroid. Patients are treated with inexpensive antibiotics such as penicillin and Bactrim and told to return in seven days. If the symptoms are still present at follow-up, patients are treated for the most likely remaining cause (refer to the diagrams below for details). Treatment varies from place to place depending on the prevalence of STDs in each area. For example, where penicillinase-producing gonnorrhea strains are common, as in Africa and Southeast Asia, cefotoxime and probenecid or spectinomycin tetracycline treatments may be necessary.

To use these health protocols, all primary health workers must learn the etiology and clinical presentations of STDs and their possible complications, how to elicit a sexual history and how to conduct a physical examination. Supervision with further in-service training is always necessary. But once training is complete, patient management based on STD symptoms can prove to be an effective approach for primary health centers without the resources to conduct thorough diagnostic procedures.

Management of Urethral Discharge

This strategy, as applied to patients with urethral discharge in rural and urban Swaziland in 1978, can be summarized as follows, according to Meheus: If 100 males are seen with urethral discharge, 100 first-line treatments, six second-line treatments and 20 contact treatments result, at a cost of less than $1 per case.

Management of Vaginal Discharge

If a woman presents with any of the common gynecological complaints of STDs, the health worker must first rule out PID by clinical examination. If PID is suspected, the patient should be referred to a well equipped clinic.

Management of Genital Ulcers

All genital ulcers should be carefully examined, as treatment can depend on the appearance of the ulcers. Painless, well-rounded lesions are treated as syphilis; painful, necrotic lesions, as chancroid; and painful, multiple vesicles, as herpes.

With all these patient-management protocols, program effectiveness can be enhanced if background data are collected before and after the treatments. Meheus suggests:

1) data on the local etiology of urethritis;

2) data on the local antibiotic susceptibility patterns of gonococci; and

3) a clinical trial with different treatment regimens.

If implemented properly, this approach to STD management based on simple treatment protocols has several advantages, including standardized treatment, contact tracing and treatment, health education directed at a high-risk group, follow-up and case referral where necessary, and the collection of simple statistics designed to enhance the treatment efficacy and advance STD epidemiology. While the approach will not eradicate STDs in developing countries, it should reduce the suffering caused by the complications of untreated genital infections and decrease the risk of AIDS.

One of the most common complications of STDs is infertility. In both men and women, untreated genital infection can cause infertility by creating inflammation or blockage in the upper reproductive tract. Untreated gonorrhea in women can result in pelvic inflammatory disease (PID), an infection often originating in the cervix that then ascends to the fallopian tubes and ovaries. PID can lead to fluid-filled cystic areas, adhesions, scarring and other permanent damage to the fallopian tubes. A woman with PID is likely to become permanently infertile if the disease is severe, if she has suffered multiple episodes, or if treatment is delayed. In Africa, more than 40 percent of acute admissions in gynecology wards are related to PID.

Tubal damage can also be caused by untreated chlamydial infections, which seem to be as prevalent as gonorrhea in many areas of the world. Both chlamydial infections and gonorrhea can also cause male infertility. STD infections in men begin in the urethra (urethritis) and can then spread to the vas deferens and epididymus (epididymitis). Scarring can result that partially or completely blocks sperm transport. When epididymitis goes untreated, as many as 50 to 80 percent of the men with this disease may become permanently infertile.

STDs can also cause disease in newborns. In one study conducted in the Central African Republic, ophthalmia neonatorum, a disease that can cause blindness in children, was traced to gonorrheal infection in 27 percent of the cases and to chlamydial infection in 19 percent of the cases. In Lusaka, Zambia, about seven percent of newborns have congenital syphilis, and in India, about five percent of stillbirths or neonatal deaths have beeen attributed to congenital syphilis.

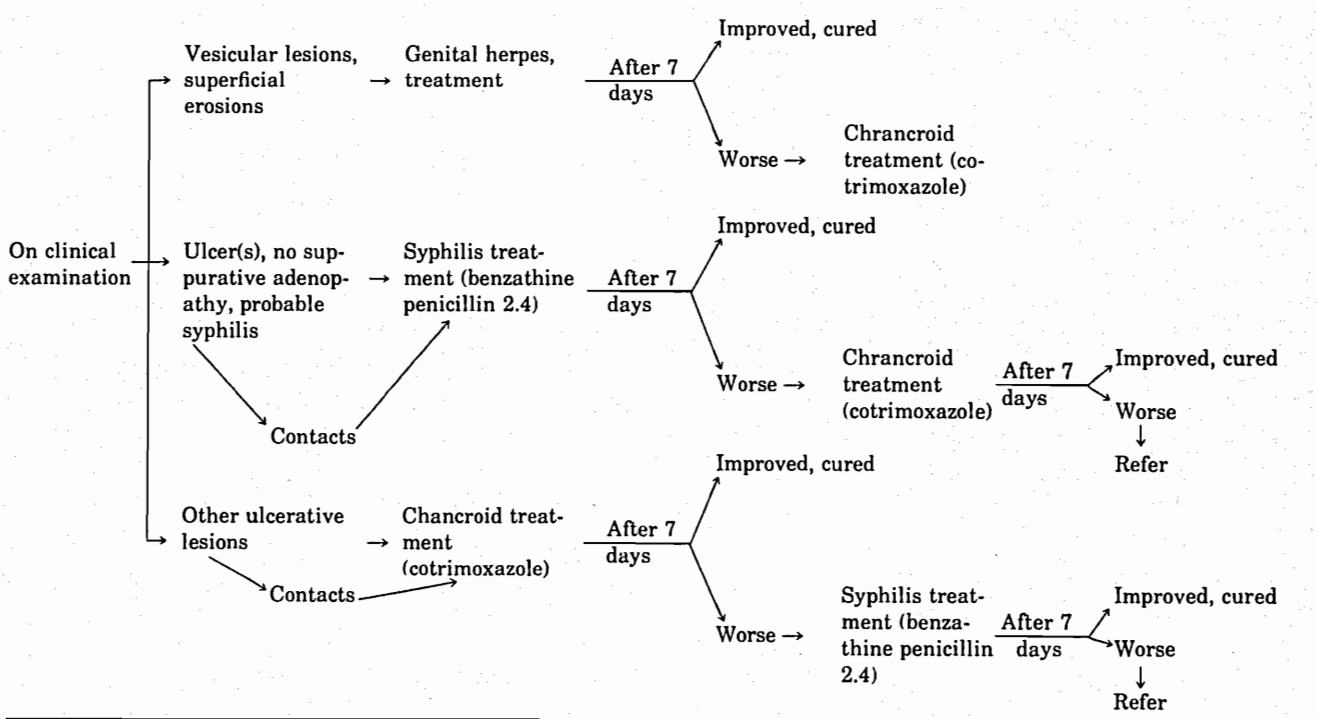
Unless changes are made in STD management, these complications will continue to harm many patients because STDs are on the rise worldwide. While syphilis rates have remained relatively stable in Canada, Denmark, Sweden, West Germany, and Great Britain, they have gone up in the United States and in several developing countries. According to data reported in Population Reports (Series L, Number 4), in Costa Rica the syphilis rate increased four-fold between 1965 and 1976, from 45 to 185 per 100,000. The South Pacific Islands (with the exception of Papau New Guinea) experienced a 13-fold increase between 1973 and 1978, from five to 65 per 100,000. It must be noted, however, that these dramatic increases could be the result of improved reporting and monitoring of syphilis.

Gonorrhea is especially common in Africa. It is estimated that in rural Uganda, three percent of the people have gonorrhea; in Nairobi, Kenya, it is seven percent and in Kampala, Uganda, ten percent of the population is infected. In the United States, by comparison, the gonorrhea rate peaked in 1975 at less than half of a percent and has declined significantly, according to the Centers for Disease Control (CDC) in Atlanta, Georgia.

The incidence of STDs in developing countries may continue to increase, notes Dr. Stuart Brown of the CDC. He emphasizes the importance of urbanization, increasing numbers of young people (those most at risk for STDs), and a tendency toward delaying marriages — all factors that are increasing STD risks.

Yet, Brown maintains, effective STD interventions can be initiated. The WHO treatment protocols, combined with advances in technological support, improvement in the health care delivery system's capacity, and changes in the public's and policy makers' understanding of the STD problem, can make a difference. "STD programs in developing countries can be improved," he says. "The time is now." □

Table 1 One strategy for the management of "genital ulcer(s)" when no laboratory facilities are available



Source: *Sexually Transmitted Diseases,* Holmes, King K, Mardh, Per-Anders, Sparling, P Frederick, Wiesner, Paul J. New York, McGraw-Hill, 1984, pp. 1001-1005.

Intravenous drug abuse speeds the spread of AIDS

The latest survey results from Thailand find over 40 percent of intravenous drug abusers tested for AIDS are infected with the human immunodeficency virus (HIV). In New York, intravenous drug abusers make up more than half of the nearly 4,000 heterosexuals known to have AIDS. Clearly, intravenous drug abusers (IVDAs) face a substantial risk of contracting the virus.

Very few Third World countries report HIV infection associated with intravenous drug abuse. This could be due to low IV drug abuse in some countries or, as Dr. Barbara Janowitz of FHI's AIDSTECH Division points out, "If you don't look for the problem, you won't find it. The important thing is to set up a surveillance system early. By the time a full-blown case of AIDS is reported, it's too late, in a sense."

Outreach is a very effective way to educate drug abusers.

Researchers know that once HIV is introduced into a drug abusing population, it can spread quickly. In the Thai study, the rate of HIV seroprevalence (the percent of the population with HIV antibodies in the blood) among IV drug abusers jumped from one percent in late 1987 to 16 percent in March 1988 to 42 percent by September 1988. Studies of blood samples from IVDAs collected over time in New York City also show seroprevalence rising to more than 40 percent within three years after the first seropositive sample was collected. In several Italian cities, seroprevalence rose to about 50 percent within four years after the first seropositive sample was collected, and in Edinburgh, Scotland, seroprevalence rose to about 50 percent within just two years.

Two key factors correlate with the virus' rapid spread among IVDAs, according to Dr. Don Des Jarlais of the New York State Division of Substance Abuse Services. The first factor is a high frequency of drug injecting. In the New York City area, for example, the period of rapid HIV spread among IVDAs in the late 1970s and early 1980s coincided with a significant increase in supplies of heroin and cocaine and, subsequently, greater frequency of injections.

The act of injecting a drug may enhance the transmission of HIV infection by stimulating immune system function. Nonsterile drug preparations, the use of nonsterile equipment, and nonsterile injection procedures could all act as immune system stimulants. *In vitro* immunologic stimulation of HIV-infected immune system cells (T cells) has been demonstrated to lead to increased viral replication and T cell death. Researchers have also observed a relation between frequency of drug injection and increased loss of T cells in IV drug abusers.

The second main factor associated with rapid virus spread is the sharing of drug injection equipment. In the United States the sharing of syringes and needles, called "works," is an integral part of drug culture. Because needles and syringes are sometimes difficult to obtain, sharing stretches the supply of a precious commodity. More importantly, sharing of works symbolizes trust and unity among fellow users.

When injecting drugs, abusers often draw blood into the syringe after injecting the drug to ensure that they have injected all the drug in the syringe. When shared, works are used repeatedly until they are occluded by dried blood and other material. In the "shooting galleries" of some U.S. cities — locations where abusers can buy drugs, rent needles and syringes, and "shoot up" — a disposable needle and syringe may be used as many as 50 times. Sharing a needle once is all it takes to transmit HIV from the blood of one person directly to the blood of another.

Des Jarlais notes that, like IVDAs' nonsterile injection procedures, IVDAs' lifestyles also expose them to many factors that may affect their immune function and thus the acquisition and outcome of HIV infection. These factors include the use of alcohol and marijuana, poor nutrition, stress, and frequent exposure to a wide variety of infectious agents.

Just like other people infected with the virus, drug abusers can also spread HIV through sexual contact. In fact, "the drug users can become the dominant source of heterosexual transmission within the area," Des Jarlais says. Studies in New York City of transmission of HIV from drug abusers with AIDS to heterosexual partners indicate that about 40 percent of the partners have been infected.

In Thailand, where little is known about the sexual behavior of IVDAs, the magnitude of transmission of infection from IVDAs to their sexual partners is unknown, according to the *National Medium Term Program for the Prevention and Contol of AIDS in Thailand* prepared by the Thai Ministry of Public Health. Yet, the report states, "given the size of the intravenous drug population, estimated to be on the order of 80,000 or more, it is inevitable that this will exacerbate the rate of sexual transmission currently found in groups with high-risk sexual behaviors."

Female prostitution also affects the heterosexual spread of HIV from infected drug abusers. Studies suggest that many prostitutes in the U.S. and Europe are also IVDAs, and that many IVDA prostitutes are seropositive. A serosurvey of street-working prostitutes in New York City, for example, found that half of those who injected drugs were infected with HIV.

Several countries in Latin America, Africa and Asia, in fact, have undertaken innovative campaigns to educate prostitutes about their potential for spreading HIV. Using a training module developed by researchers at Family Health International, officials in these countries are implementing a peer education program utilizing fellow prostitutes.

"You need someone to talk to these women, someone they're comfortable with," explains Dr. Barbara Janowitz of AIDSTECH. "The peer educators provide condoms and answer questions about how to get clients to use condoms. These are not the kind of things a prostitute would want to ask a doctor or nurse."

While several strategies exist to curb the spread of HIV among IV drug abusers who are not prostitutes, others focus directly on the drug injection procedure. One approach is to urge IVDAs to stop shooting up or to stop sharing works — drastic behavior modifications that have not met with great success. A more realistic approach is to recommend safer injection practices, as well as consistent condom use.

Educational outreach campaigns instructing IVDAs how to sterilize their works by cleaning them with household bleach and rinsing them with water is one way to accomplish this objective. Outreach is a very effective way to educate drug abusers, Janowitz explains. "These people want to be healthy," she says. "You just have to meet them in their culture and on their own terms."

In San Francisco, for instance, outreach workers with the Mid-City Consortium to Combat AIDS, explain to drug abusers how to sterilize their equipment with bleach. They distribute small bottles of bleach and also pass out condoms.

Programs designed to increase the number of sterile needles and syringes are another way to improve the sterilty of injection equipment. Some cities have handed out free or inexpensive sterile equipment and others, such as Amsterdam (Holland), Sydney (Australia), New York City, and a private group in Tacoma, Washington have instituted a sterile needle and syringe exchange program, where IVDAs can turn in their used works for new ones.

The important thing is to set up a surveillance system early. By the time a full-blown case of AIDS is reported, it's too late, in a sense.

Among developing nations, Thailand is leading the way in national efforts to prevent the spread of HIV among IVDAs. Responding to its existing epidemiological evidence, the Ministry of Public Health states the need to prevent and control HIV among intravenous drug abusers as the number one priority in their national AIDS prevention program, calling it "of paramount importance." Their current program objectives focus on assessing the trends of HIV among IVDAs; providing appropriate medical and social services, such as drug rehabilitation programs; and launching education and information campaigns aimed at IVDAs and key segments of the general population, such as adolescents. "The only reason that Thailand knows it has a problem is because they've set up a surveillance system," Janowitz notes.

Contrary to what many people believe, IV drug abusers can be educated about the transmission of HIV. According to Des Jarlais, data from studies in New York City indicate that as early as 1984, almost all IVDAs in the city had heard of AIDS and knew that it could be transmitted through shared drug injection equipment. More importantly, half of them reported that they had changed their behavior in some way to reduce the risk of developing AIDS.

In San Francisco, the seroprevalence of HIV infection has remained fairly stable or increased much less rapidly than in large Northeastern cities probably through intensive efforts to educate IVDAs and to provide them with bleach. Surveys conducted among IVDAs show that the precentage who report that they clean their needles has risen. Even in cities where IV drug abuse is currently a small problem, it is important to educate IVDAs on how to control the spread of HIV infection. □

High condom quality essential to reduce HIV spread

Although the extent to which condom use prevents disease transmission varies with different sexual practices and user consistency, condoms are an important front-line defense against the spread of AIDS. For this reason, the quality of condoms worldwide is an important public health concern. Condom storage, condom manufacturing techniques, and national condom quality standards are all factors that affect condom quality and, consequently, condoms' prophylactic capability.

The vast majority of condoms are made from latex, the sap of the rubber tree. Since latex deteriorates over time, condom quality should be periodically monitored during condom storage and after distribution to consumer outlets. Manufacturers generally estimate that under good storage conditions condoms have a three- to five-year shelf life, but temperature extremes, humidity, light, ozone, abrasions, rodents and insects can all contribute to the deterioration of stored condoms, notes Jane Hutchings, Program Officer at PATH (Program for Appropriate Technology in Health). From the time a condom is manufactured to the time it is used, Hutchings explains, it passes through three distinct storage stages, each with unique hazards.

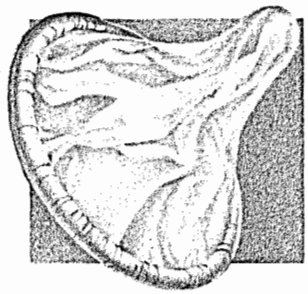
• **Transport to, and storage in, a warehouse.** Under optimal storage conditions, condoms can be expected to last about five years, but in many developing countries optimal standards are not realistic. In warehouses without air-conditioning, humidity can destroy package seals, allowing entry of insects, molds or fungi. The temperatures inside a tin-roofed warehouse in a hot climate can exceed 60 C (140 F), and while heat deteriorates condoms more slowly than humidity, storage in such extreme temperatures can damage both packaging and condoms themselves. These conditions can lead to severe condom deterioration in just one year.

• **Delivery to, and display in, a dispensing outlet.** While displayed in retail outlets, condoms can be impaired by mechanical damage from handling and exposure to ultraviolet (UV) light from sunlight or fluorescent lamps. Of these two factors, UV light is the most dangerous, able to reduce significantly the strength of condoms in transparent packages in only a few hours. Opaque packaging prevents UV-related deterioration.

• **Storage and handling by the consumer prior to and during use.** Condom deterioration can be caused by prolonged condom storage in wallets or tight pockets. Contact with petroleum-based substances during use, such as petroleum jelly, mineral oil and many hand lotions, can also result in serious deterioration of the condom. These products can degrade latex after only 15 minutes.

Several studies indicate that condom deterioration is likely to result in breakage during use. A study by Dr. Michael Free, director of PATH, divided condoms used by Indonesian male volunteers into four groups: 1) condoms purchased from the manufacturer and used as bought; 2) condoms purchased from the manufacturer and then exposed to UV light for five hours; 3) condoms purchased from the manufacturer and then exposed to UV light for ten hours; and 4) condoms stored for 42 months in a hot, humid climate before use. Volunteers were not relying on the condoms for contraception.

The researchers determined that the longer condoms were exposed to UV light, the more prone they were to breaking during use. An even more significant finding was that nearly 50 percent of the condoms used after 42 months of warehouse storage broke during use. Only seven percent of the new, untreated condoms (in the group one) broke.



Because the available data suggest that environmental factors in many developing countries may reduce the effectiveness of condoms as prophylactics against sexually transmitted diseases (STDs), the World Health Organization (WHO) is developing new guidelines for condoms specifically intended to slow the spread of AIDS in these countries. FHI President Dr. Malcolm Potts explains that because of ill treatment of con-

doms during distribution, the specifications for condoms for Third World countries to slow the spread of AIDS may have to be stricter than those for contraceptive purposes in Western countries.

To meet this challenge, FHI is conducting research to develop a more effective condom. "We're trying to develop a product that will be inherently stronger, have a better shelf life, withstand extreme storage conditions and be compatible with any kind of lubricant a person might use," explains Dr. Robin Foldesy, Associate Director of Clinical Trials at FHI. The research team is investigating several new designs and looking at different polymers to determine whether they are cost-effective and easily processed.

Initial condom quality, as opposed to factors that affect quality in the field, is determined by the condom manufacturing process. High quality latex condoms have been shown to be impermeable to the organisms that cause several STDs, including gonorrhea, chlamydia, syphilis, granuloma inguinale, lymphogranuloma venereum, trichomoniasis, candidiasis and AIDS. These organisms are too big to pass through the latex. Therefore, if the condom does not tear, is put on before sexual contact is initiated and removed afterward, users of high-quality latex condoms are protected against contracting these diseases.

Several factors can affect condom quality during production, including consistency of the latex, humidity, temperature and cleanliness. These factors are all carefully controlled in large, automated condom plants. To ensure condom quality, some condom-importing countries and nearly all major condom-producing countries have national condom quality standards. Typically, these standards require:

- visual inspection for packaging defects
- measurement of length, width, thickness, and/or mass
- a test for holes
- a test for strength.

While condoms have been used for at least 400 years to prevent the spread of STDs, the rise of AIDS has focused renewed attention on the condom's prophylactic capability. Improved condom storage conditions, higher condom quality, and strict condom quality standards will help ensure that all condom users will be better protected against HIV and other sexually transmitted diseases. □

Resources

Publications on up-to-date information about AIDS include:

AIDS and the Third World (1988/89 edition) 198 pages. US$9.50 per copy; reduced prices for quantity orders.

Blaming Others by Renee Sabatier, 168 pages. US$9.50 per copy; reduced prices for quantity orders.

WorldAIDS news magazine
6 issues for US$25.00 per year.

The Panos Institute, 1409 King Street, Alexandria, VA 22314 USA or 8 Alfred Place, London WCIE 7EB UK

AIDS newsletter
AIDS Bureau, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT UK

Confronting AIDS: Directions for Public Health, Health Care, and Research (Summary Report) National Academy Press, 2101 Constitution Ave., NW Washington DC 20418 USA (Free summary of the AIDS report of the Institute of Medicine and National Academy of Sciences. Full report also available, approximately US$25.00 per copy; reduced prices for quantity orders.)

Literature Search Program
Reference Section, National Library of Medicine, 8600 Rockville Pike, Bethesda MD 20894 USA (AIDS literature search, updated 2-3 times a year. Primarily clinical research.)

Population Reports series L, no. 6: "AIDS — A Public Health Crisis" Population Information Program, The Johns Hopkins University, 527 St. Paul Place, Baltimore MD 21202 USA (Available free to developing countries in English, Spanish and French.)

Surgeon General's Report on Acquired Immune Deficiency Syndrome U.S. Public Health Services, Public Affairs Office, Hubert Humphrey Bldg., Room 725-H, 200 Independence Ave., SW, Washington DC 20201 USA

What Science Knows about AIDS (Articles from Scientific American, October 1988.) 128 pages. W.H. Freeman and Company, 4419 West 1980 South, Salt Lake City Utah 84104 USA. US$9.95

(Price information was not available for all of the above publications. For those not offered free, some may be available at reduced prices for orders from developing countries.)

Breast-feeding and birth spacing

Breast milk is unquestionably the best food for infants, providing excellent nutrition and tailor-made protection against disease. Breast-feeding also offers nearly total fertility control for the mother during the first six months following childbirth, with protection diminishing gradually over the next 12 months or so. Therefore, policymakers in developing countries — indeed, throughout the world — should make breast-feeding an integral part of national health policies. Proper policies regarding breast-feeding and the spacing of births can prevent a myriad of infant and maternal deaths each year and help curb population growth. These are the findings of a FHI study published in a recent issue of *Nature.*

Endocrinologists are uncovering the mechanisms by which lactation inhibits reproduction. Afferent neural inputs to the hypothalamus following nipple stimulation seem to cause a local release of beta-endorphin, which inhibits hypothalmic secretion of gonadotrophin-releasing hormone. This suppresses the pituitary's secretion of gonadotrophin and hence curtails ovarian activity. Anything that significantly reduces suckling frequency will ultimately erode the natural contraceptive effect of breast-feeding.

Unfortunately, the practice of breast-feeding is eroding in many societies. Women in developing countries who are young, affluent, educated, or who live in urban areas are especially likely to forego or at least shorten the duration of breast-feeding. This trend could have serious detrimental effects on both population growth and family health. Paradoxically, it is these same young, urban, affluent trendsetters who are leading the return to breast-feeding in many developed countries.

To assess the impact of changing breast-feeding practices on fertility and infant survival, Drs. Malcolm Potts and Shyam Thapa of FHI and Dr. Roger V. Short of Australia's Monash University analyzed data gathered from approximately 150,000 women in 29 developing countries as part of the World Fertility Survey, the largest social survey ever undertaken. The data come from five African nations, 12 Asian and Pacific nations, and 12 nations in Central and South America.

In Africa and Asia, breast-feeding prevents four births during a woman's reproductive years. This means breast-feeding mothers will have one-third fewer children than they otherwise would have. In Kenya, for example, women who live through all their childbearing years and conform to age-specific fertility rates could potentially have about 12 children, but they actually average only 7.3 children because of breast-feeding. In Central and South America, on the other hand, modern contraception has largely replaced breast-feeding as a way to regulate fertility.

They also calculated what would happen to birth rates if the duration of breast-feeding declined by as much as half. In Africa, average fertility would increase by up to 27 percent. Asian and Pacific nations would see a gain of more than 22 percent, while fertility in Central and South America would increase by almost 9 percent. Offsetting the increased fertility rates would require major increases in contraceptive usage, especially in Africa and Asia. In Senegal, for example, a 50 percent decline in breast-feeding would require a 400 percent increase in contraception to hold the rate of population growth at its present level. In Pakistan and Nepal, the increase would have to be even higher.

"Of course, we do not expect the incidence of breast-feeding to drop by such large amounts, but the figures clearly indicate the importance of breast-feeding in regulating fertility," says Thapa. "This fact often gets overlooked in public health planning — but it should not be, since regulating fertility in order to space births is important in safeguarding infant and maternal health," he adds.

Infants born less than two years after a preceding birth are twice as likely to die before age five as those born after a longer interval. However, a substantial proportion of children in developing countries are still born too closely spaced: nearly 30 percent in Asia and 40 percent in the Americas. Even in sub-Saharan Africa, where traditional practices such as taboos on intercourse during lactation also help to space births, about 20 percent of babies are born within two years of a sibling. The problem is especially severe in Kenya, where 37 percent of all babies are followed by the birth of a sibling within two years. Because of changing breast-feeding practices

and the erosion of postpartum sexual abstinence, the mean duration of contraceptive protection provided by breast-feeding is now only ten months, far shorter than in other African countries. However, there has not been a corresponding increase in the use of contraceptives. The result has been an increase in fertility over the years, and today's young women are likely to end up with more children during a shorter span than their own mothers had.

Proper birth spacing can be achieved by a judicious combination of breast-feeding and modern forms of contraception. But given its undoubted health benefits, breast-feeding should always be considered when formulating public health policies for developed or developing nations. Fortunately, recent research suggests that breast-feeding behavior responds readily to education, social encouragement, activities of women's self-help groups, and changes in medical attitudes and practices. In situations where many women work, legislation protecting a woman's right to breast-feed is important.

In Africa and Asia, public policies should aim to maintain the current level and duration of breast-feeding. Women living in urban areas, where breast-feeding patterns are changing most rapidly, will need special attention. Promotion of breast-feeding in the Americas should concentrate on its health benefits for infants, since it is not used in most of these nations to regulate births. In general, mothers should nourish their babies solely with breast milk for the first four to six months. Breast-feeding should then continue for as long as possible, with supplementary feeding as necessary, and the women should consider using other methods of contraception to ensure at least a two-year interval between births.

One possibility is the "mini-pill," which contains only a low dose of progestogen. It does not suppress lactation as combined birth control pills may do, yet for breast-feeding women is believed to be just as effective. Since women in some locations tend to stop taking oral contraceptives after several months, it's best to delay pill use until six months after birth in fully breast-feeding women in order to minimize the contraceptive overlap.

Intrauterine devices (IUDs) also have no effect on lactation. Studies suggest that the best time to insert IUDs is within ten minutes or so of placental expulsion. This can be particularly important when delivery may be a woman's only opportunity for contact with a health professional capable of performing the insertion. Breast-feeding women can also choose diaphragms, spermicides, condoms, or natural family planning; while these methods have higher failure rates than the Pill or IUDs, they are good for lactating women to use before starting a more reliable method.

If mothers in the 29 nations included in our study spaced their pregnancies by an average of at least two years, the current total of 2.6 million deaths of children under one year of age would fall by at least 20 percent, resulting in a saving of about 500,000 lives each year. Roughly 33,000 infant deaths could be prevented each year in Africa, 80,000 in the Americas, and 390,000 in Asia.

"Without a doubt, breast-feeding and birth spacing save lives. To ignore this fact when formulating public health policies would betray a callous disregard for the welfare of the next generation," Thapa concludes. □

Recent publications

88-15 PJ Feldblum, E Bernardik, MJ Rosenberg. **Spermicide Use and Sexually Transmitted Disease.** JAMA 259(19):2851, 1988.

88-16 SM Rosenthal. **Recent Declines in Reproductive Mortality in England and Wales.** Brit J Fam Plann 14(2):46, 1988.

88-17 GS Grubb, JA Fortney, S Saleh, S Gadella, A El-Baz, PJ Feldblum, SM Rogers. **A Comparison of Two Cause-of-Death Classification Systems for Deaths Among Women of Reproductive Age in Menoufia, Egypt.** Int J Epidem 71(2):385, 1988.

88-18 R Snowden, KI Kennedy, F Leon, VC Orense, HW Perera, R Phillips, I Askew, A Flynn, LJ Severy. **Physicians' Views of Periodic Abstinence Methods: A Study in Four Countries.** Stud Fam Plann 19(4):215, 1988.

88-19 M Kozuh-Novak, L Andolsek, SA Balogh, C Waszak. **Long-term Use of Intrauterine Devices.** IPPF Med Bull 22(1):1, 1988.

88-20 L Andolsek, M Kozuh-Novak, SA Balogh, C. Waszak. **Long-term IUD Use in Ljubljana, Yugoslavia.** Research Triangle Park, Family Health International.

88-21 RE Roddy. **Genital Herpes.** Phy Assist 12(7):21, 1988.

88-22 K Henry. **Mopping Up a Lingering Threat.** South 94:113, 1988.

88-23 L Potter, S Wright, D Berrio, P Suarez, R Pinedo, Z Castaneda. **Oral Contraceptive Compliance in Rural Columbia: Knowledge of Users and Providers.** Intl Fam Plann Perspect 14(1):27, 1988.

88-24 B Janowitz, P Bailey, RC Dominik, L Araujo. **TBAs in Rural Northeast Brazil: Referral Patterns and Perinatal Mortality.** Health Pol Plann 3(1):48, 1988.

88-25 PJ Feldblum. **Protective Effect of the Contraceptive Sponge Against STDs in Thailand.** In: Selected Proceedings of Southern Regional Conference on International Health in the 1990's: Directions in Research and Development, Chapel Hill, North Carolina, October 29-31, 1987 (National Council for International Health, 1988), p. 73.

Mathematical models assist AIDS researchers

Mathematicians and computer scientists have joined the fight against AIDS by developing mathematical models and computer programs designed to help understand the disease. Though no one has an exact count, there are probably more than 100 models of the AIDS epidemic, ranging from very simple models designed to answer a specific clinical question, to very complex ones designed to assist in the development of global public health strategies.

No matter what the level of complexity, models can help clinicians or policy makers who have to decide the most effective course of action when confronted with an AIDS dilemma. In general, there are four types of AIDS models: simple analytic, extrapolation, convolution and computer simulation. The "simple analytic" type aims to elucidate the dynamics of the epidemic itself — how fast it will spread, for instance, and whether or not it will die out on its own.

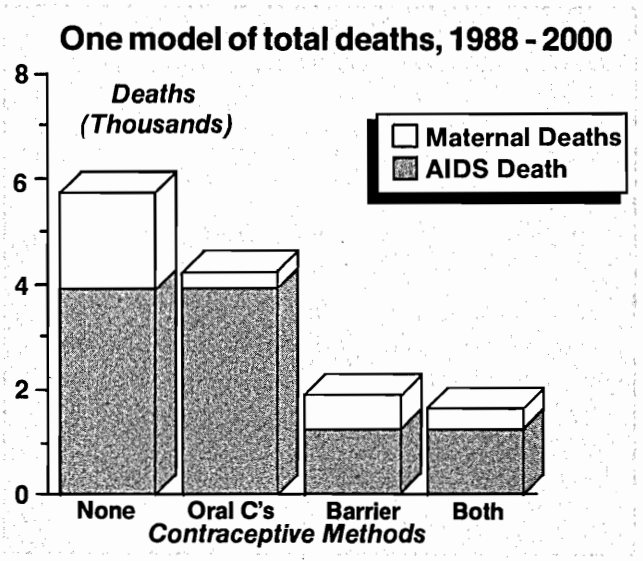
"Extrapolation" models utilize historical AIDS data to forecast future disease trends. For example, a model developed by W. Meade Morgan of the Centers for Disease Control predicts that in the year 1991, about 74,000 AIDS cases will be diagnosed in the United States, bringing the cumulative case total to 270,000. His predictions are based on the current shape of the epidemic curve.

A drawback of this type of model is that it assumes the epidemic will continue to progress in the future as it has in the past. Yet, recent data indicate that among homosexuals in the United States the epidemic is slowing down, while among intravenous drug abusers it is accelerating. Because extrapolation models can not take these complexities into account, their projections are only useful for the short-term, perhaps three to five years into the future.

The third type, "convolution" models, utilizes more complex epidemiological data to assess the impact of the epidemic. Such a model has been developed by S. K. Lwanga and J. Chin of the World Health Organization (WHO). To operate it, they use the following two estimates about a specific country (called input variables): the prevalence of HIV infections in the population, based on survey data, and the year when HIV infection probably began to spread extensively in the population.

With these data, and other estimates derived from them and other research, the model can then forecast the annual and cumulative number of AIDS cases through the next five to seven years. This forecast makes it possible to envision the consequences of the epidemic on the health care system and the whole society.

This type of model and the fourth, or "computer simulation," type are the most interesting, says Dr. David Sokal, an epidemiologist at FHI who works on



AIDSTECH projects. "They can tell you what the consequences of the epidemic are likely to be," he explains. "And they let you try out different prevention strategies before you get to the field, which can save lots of money and lives in the long run."

John Bongaarts, of the Population Council, has developed a sophisticated computer simulation model designed to be used by a developing country. It requires more input variables than the WHO model and also incorporates data about people's sexual behavior. A user of the model could, for example, hold all other factors constant and examine only the consequences of increased condom use, or of a change in the proportion of highly sexually mobile males or females before or after marriage.

Common sense is the best tool for evaluating a potential model.

By comparison, Sokal has developed a relatively simple computer simulation model that analyzes reproductive mortality among adult women. One of its possible applications is utilization by family planning managers who are grappling with a dilemma about AIDS and contraception: The Pill is better than the condom at preventing births, but it does not protect women from AIDS; condoms are less effective contraceptives, but are better at preventing the spread of AIDS. Which should the manager promote?

Sokal's model uses five fixed parameters, which the user does not alter:

- The projection period is from 1988 to 2000;
- Without contraception there is a 30% pregnancy rate each year;
- Oral contraceptives reduce the pregnancy rate by 80% and do not influence the risk of HIV transmission;

- Condoms reduce the pregnancy rate by 67% and prevent 50% of HIV transmission;
- Four contraceptive use patterns are compared: none, oral contraceptives, condoms, and both methods.

The following parameters are set by the user and for illustrative purposes have been set as indicated:

- Initial seroprevalence. Set at 1%, a low seroprevalence level.
- Rate of HIV increase. Set at 50% a year from 1988-1992 and then at 25% per year from 1993-2000, a rapid progression.
- Maternal mortality. Set at 5 per 1000 pregnancies.

Given this set of parameters, the model projects that the number of deaths from AIDS would be much higher than the number of deaths due to childbearing, especially when either the Pill or no contraception at all is used. Consequently, Sokal urges family planning programs to develop screening criteria to identify women at risk of HIV and then advise these women to use condoms.

"Obviously, however, women often do not have the power to get their partners to use condoms," Sokal notes. "AIDS control programs and family planning programs must coordinate and strengthen their efforts to get men to use condoms."

While mathematical models can give clinicians and policy makers a glimpse into the dynamics of the AIDS epidemic or, as illustrated, a chance to simulate AIDS prevention strategies, it must be stated that not one of them is perfect. Each model has its limitations and, at this point in their evolution, all models are only as good as the data entered into them. Where data is sketchy or unknown, as in many developing countries, modelers must estimate some parameters as best they can.

The Pill is better than the condom at preventing births, but it does not protect women from AIDS; condoms are less effective contraceptives, but are better at preventing the spread of AIDS. Which should a manager promote?

Unless one is a mathematician, there is no sure way to know if a proposed model is well designed, and Sokal maintains that common sense is the best tool for evaluating a potential model. Can it address the questions of concern? Is the model user friendly? Is it flexible enough to allow sufficient manipulations?

Properly designed and applied, models can be of value to health professionals and other decision makers attempting to understand AIDS and ultimately reduce its incidence. Quite simply, Sokal says, "the purpose of mathematical modeling is to help people make decisions." □

Mahler

Continued from page 1

subsequently presents such a significant increase in infection rates. If, for some tragic reason, the public health community does not deal with a disease such as measles, then children will continue to die as they have in the past — but probably not at a higher rate. With AIDS, however, there is the possibility of an exponential growth of cases. Preventing one case today, therefore, can prevent two, four, eight, or sixteen tomorrow. Immediate prevention of AIDS presents an opportunity to save lives now and further down the road and to avoid the potential strain on already overstressed health services.

Secondly, no other infectious disease is as lethal as AIDS and no other disease is as infectious for as long a time. Other bacterial and viral infections have short incubation periods, and the infected person may only be capable of passing the disease to somebody else for a matter of days. But people infected with HIV can carry that infection for ten years or much longer. During that whole time they appear to have the potential to infect other people.

Thirdly, no other disease presents as formidable a global public health challenge in the current absence of vaccines or drugs that are scientifically effective, socially applicable and economically feasible. In the face of this technological vacuum, a rapid discovery of how to promote healthy sexual behavior in widely different social, economic and cultural settings becomes imperative and urgent.

Fourthly, no other disease presents quite the complex ethical and political problems associated with AIDS. The sexual transmission of the disease commonly begins in those groups of people who have the most sexual partners and who have rarely been the focus of medical or social attention.

In summary, then, the AIDS challenge is as much a human one as it is a scientific one. Control of the disease will depend not only upon society's continued willingness to expend limited health care resources, but also its ability to extend concern and respect to individuals with a variety of lifestyles. □

Dr. Mahler, Director General Emeritus of the World Health Organization, was recently appointed to FHI's Board of Directors.

AIDSTECH UPDATE

Since the majority of people with HIV infection and AIDS become infected through sexual contact, preventing sexual transmission is widely considered the top priority among health organizations working to slow the spread of the disease.

Slowing the spread of HIV infection through sexual transmission is also AIDSTECH's first priority, according to Dr. Peter Lamptey, the program's director. AIDSTECH's second priority is preventing HIV infection through blood transfusions.

Preventing sexual transmission

AIDSTECH is providing funds and technical assistance to expand and replicate successful interventions to prevent sexual transmission of HIV among those who engage in high-risk behavior. These target groups include truck drivers, military recruits, migrant workers and people with sexually transmitted diseases (STDs).

"In a world of limited health resources, changing the behavior of those at highest risk is the most efficient way to prevent the spread of HIV infection," Dr. Lamptey explains.

Condom use among prostitutes has increased as a result of a pilot project funded by FHI in Accra, Ghana, with support from the American Foundation for AIDS Research. Working with Dr. Alfred Neequaye, chairman of the Ghana Technical Committee on AIDS, FHI staff helped establish a program to train prostitutes to educate their peers about AIDS and HIV infection and to distribute condoms.

AIDSTECH staff are developing similar projects to train peer educators and distribute condoms among soldiers in Ghana and women and men with multiple partners in the Philippines, the Dominican Republic and Zaire.

Surveillance

Tracking the spread of HIV infection is important in order to evaluate the impact of these interventions. AIDSTECH recently assisted Mexico in the analysis of blood samples from a major national serosurvey.

AIDSTECH epidemiologist Dr. David Sokal says the Mexican survey confirmed that AIDSTECH's strategy of surveillance through small serosurveys of sexually active groups, or "sentinel" groups, is more effective than large national surveys. The Mexican survey found a reassuringly low prevalence of seropositives, but these results may be misleading because a large portion of those at highest risk had refused to participate in the survey.

Sentinel surveillance, on the other hand, can provide valuable information about the pattern and distribution of HIV infection at a lower cost by anonymously testing several hundred blood samples from people who have come to a medical facility for other kinds of testing or treatment. If possible, STD clinic clients, people with multiple sex partners, military personnel and truck drivers in areas with low prevalence should be retested at regular intervals. Groups more representative of the general population, including women attending prenatal clinics, voluntary blood donors and health care workers should also be tested in high-prevalence areas.

Safe blood supply

Since transfusions of blood contaminated with the virus are another major route of HIV transmission, AIDSTECH is working with national AIDS committees throughout the world to ensure that transfused blood is free of HIV. AIDSTECH provides technical assistance in assessment of needs, program planning, cost-benefit analysis, procuring equipment, training in HIV testing and planning for the sustainability of programs.

AIDSTECH has helped plan blood screening programs in Burkina Faso, Senegal and Guatemala. In Malawi, AIDSTECH staff conducted a training workshop for 20 laboratory technicians and provided technical assistance to help establish 11 HIV testing laboratories.

PVO funding

AIDSTECH is providing grants of $25,000 to $50,000 to private voluntary organizations (PVOs) for AIDS interventions, applied research, surveillance and training in developing countries. Preliminary concept proposals will be reviewed every three months. Deadlines for submitting preliminary proposals are January 1, April 1, July 1 and October 1 of each year. □

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INSTITUTIONAL DEVELOPMENT: A SUCCESS STORY IN BANGLADESH

Last year, the Bangladesh Ministry of Health and Family Planning approved a major expansion of a program introducing the contraceptive implant Norplant.® About 1,500 women were using this contraceptive in pilot programs coordinated from three clinics in Dhaka, the capital city, and several rural clinics. Encouraged by these successful projects, Bangladesh officials decided to offer Norplant® to 24,000 women through 32 clinics throughout the country.

For such a big step, the government planners needed a highly professional and experienced family planning organization to supervise the scientific elements of the project, train field workers, and develop counseling materials. The Bangladesh Ministry turned to a local organization, the Bangladesh Fertility Research Programme (BFRP). With a four-year track record in helping to introduce Norplant® into Bangladesh, this quasi-governmental family health organization was ideally prepared to help the Ministry of Health and Family Planning begin expanding the Norplant® program nationwide. The Bangladesh Ministry could entrust the supervision of the expansion to this in-country organization thanks in part to a process called "institutional development."

The basic goal of institutional development is to assist an organization to gain the capacity to function effectively and independently. In the context of family planning research, an organizational infrastructure has to be built which is capable of conducting research studies at the field level, disseminating information within the scientific and general communities, and shaping and influencing state and national family planning policies. This process also requires strong staff leadership, a network of researchers, a diversified funding base, and long-term planning.

In 1976, Family Health International (FHI), recognizing the need for a family health research center in Bangladesh, helped establish the Bangladesh Fertility Research Programme in collaboration with Bangladesh government officials. Initially, the BFRP functioned as a data-collection center for FHI, which was then conducting clinical trial studies and other research in Bangladesh. Yet, until 1985, the BFRP lacked the capacity for a broad range of independent projects. That year, two things happened which caused FHI to shift more attention to developing the organizational capacity of the BFRP.

First, FHI made institutional

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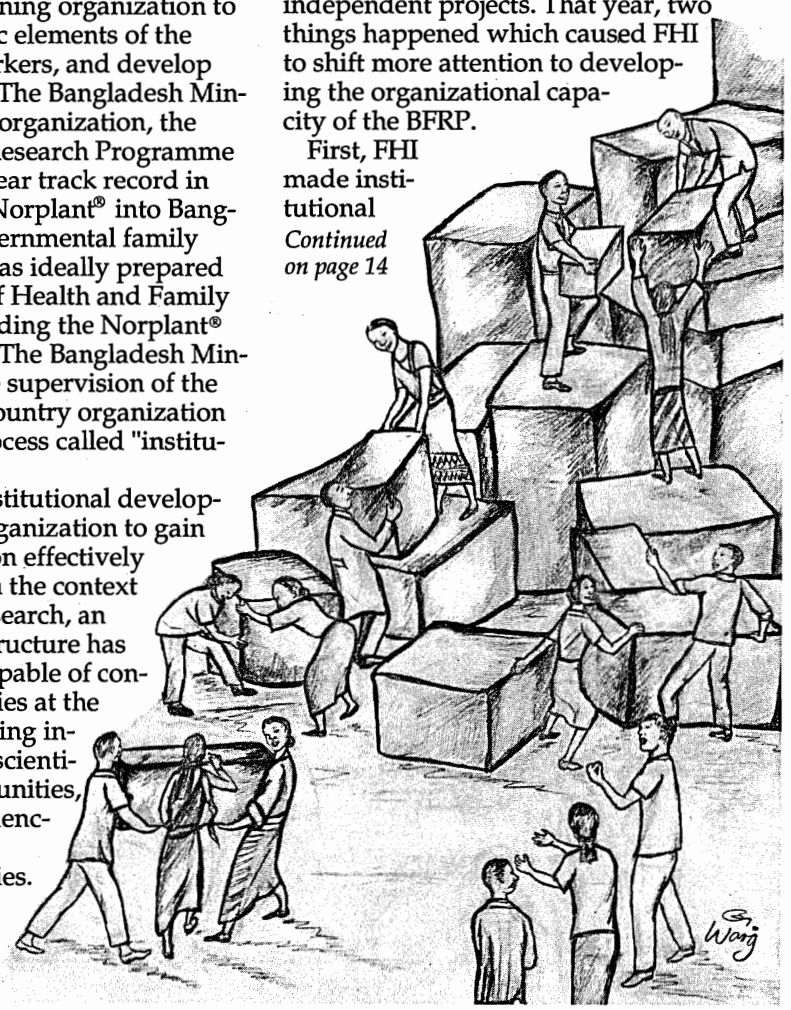

health news

INTERNATIONAL FORUM ON POPULATION IN THE 21ST CENTURY

According to the United Nations Fund for Population Activities (UNFPA), the year 2025 will see a world population of 8.5 billion and a 70% increase in the proportion of people in developing countries living in urban areas, with the results of growing poverty and extensive damage to the environment.

According to the UNFPA predictions, there will be 8.5 billion people on our planet in the year 2025.

This bleak picture, derived from the UNFPA's review of its population programs, was presented at the International Forum on Population in the 21st Century held in The Netherlands in November. At the meeting, the participants adopted the Amsterdam Declaration. "The six billionth inhabitant is now expected to be born in 1998 – one year sooner than projected only two years ago," states the Declaration. Charting a course of action for the 1990s, it identifies seven areas – including political commitment, resource mobilization, community awareness and international cooperation – which must be strengthened in order to reach the goals of slower population growth, lower maternal and infant mortality rates, longer life expectancy and better-balanced demographic distribution. The Declaration also underscores the importance of activities such as contraceptive technology research and management training which will require a two-fold increase in current national and international funding to $9 billion annually by the year 2000.

The UNFPA estimated this cost of family planning based on their goal for "medium" population growth, rather than the more ambitious projections for "low" population growth. ▣

TCU 380A IUDS EFFECTIVE FOR SIX YEARS

The Copper T 380A intrauterine device has been accepted by the U.S. Food and Drug Administration (FDA) as being an effective contraceptive method for six years after insertion, an increase from the four years' duration of effectiveness previously claimed. The FDA statement follows a study based on data from a World Health Organization study. ▣

AIDS CONFERENCE

Although the extent of the AIDS epidemic in Africa varies greatly between and within countries, the Fourth International Conference on AIDS and Associated Cancers in Africa, held in Marseilles, France in October, focused on the rapid progression of the epidemic in that continent.

Reports at the conference revealed alarming HIV (human immunodeficiency virus) prevalence rates in many areas. Some of the most dismal statistics came from Rwanda and Uganda. For instance, one study in an antenatal clinic in Kampala found that 23% of the pregnant women – and 31% of those pregnant for the first time – were infected with HIV; in some rural areas, the infection rate was found to be 12% (11% of men, 14% of women).

Statistics show that the level of HIV infection in Côte d'Ivoire is rapidly catching up with the levels found in Central and East African countries.

There was some good news at the Marseilles conference: pilot AIDS intervention programs in Zaire and Zambia showed that intensive counselling of discordant couples, community involvement and home care were successful in helping raise awareness, change community behavior patterns, and prevent transmission of the disease. ▣

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EXPANDING CONTRACEPTIVE OPTIONS

Family planning begins and ends with individual couples choosing when to have children. And it is a general rule that the wider the variety of contraceptive options available, the greater the number of couples who will take advantage of some form of contraception.

With this in mind, a long-standing FHI goal has been to help introduce a range of new contraceptive technologies in the developing world, says Dr. Malcolm Potts, president of FHI. "We also seek to ensure that people have adequate information about the advantages and disadvantages of the various methods available so they can make informed choices."

Since 1972, FHI has worked with investigators in dozens of developing countries conducting well-designed and carefully executed clinical trials of promising or established contraceptive methods. The studies have examined many of the major contraceptive methods: female sterilization, intrauterine devices (IUDs), long-acting hormonal implants, and oral contraceptives, as well as innovative approaches to the introduction and distribution of such methods. The studies help to establish a method's safety, efficacy, and acceptability under local conditions within a given country – information that is often required to gain governmental approval for use, says Dr. Roberto Rivera, director of FHI's Division of Clinical Trials. They can also hasten widespread adoption of the method by enabling physicians, nurses and other family planning providers – as well as users and potential users – to become familiar with a technology that may be new to a country or program.

Alan Dehmer

The waiting room of a family planning clinic in Senegal.

Female sterilization

FHI's early research efforts, for example, proved important in popularizing two improved procedures for female sterilization: laparoscopy and minilaparotomy. Interval sterilization – that is, sterilization performed later than six weeks postpartum – was once a major surgical procedure and hence was relatively uncommon. But the new procedures, developed in several Western countries and Japan during the 1960s, showed promise of being simpler and safer.

As laparoscopy and minilaparotomy began to attract increasing global attention, FHI undertook a series of studies, beginning in the mid-1970s, in which more than 20,000 sterilization procedures were monitored. "We determined that the new procedures, which require a much smaller incision and can often be done on an outpatient basis, were indeed easier for clinicians to perform and thus safer for women," says Lynda Cole, administrative officer of FHI's AIDSTECH Division. "Minilaparotomy in particular requires much less equipment and training, and is especially suited for use in the numerous clinics and other health-care facilities far from major urban areas."

Both laparoscopy and minilaparotomy procedures have become widely accepted. Indeed, voluntary female sterilization is now the most prevalent form of family planning worldwide – chosen by more than 130 million women. Demand is expected to grow significantly during the 1990s.

Given the importance of voluntary female sterilization, FHI continues to search for improvements in the method. Clinical trials have been completed recently in nearly 20 countries to determine the safety and efficacy of the Filshie Clip, a mechanical device for occluding the Fallopian tubes. Because it causes less damage to the tubes than do other occlusion methods, the Clip may offer a greater chance that the

Continued on page 4

Expanding options

Continued from page 3

sterilization could be reversed if desired. Preliminary data covering more than 9,000 women suggest that the Clip is just as effective as other occlusion methods and poses fewer surgical difficulties. It is considerably more expensive, however, which may prove a deciding factor in whether the Clip will be widely adopted in developing countries in the near future.

TCu 380A

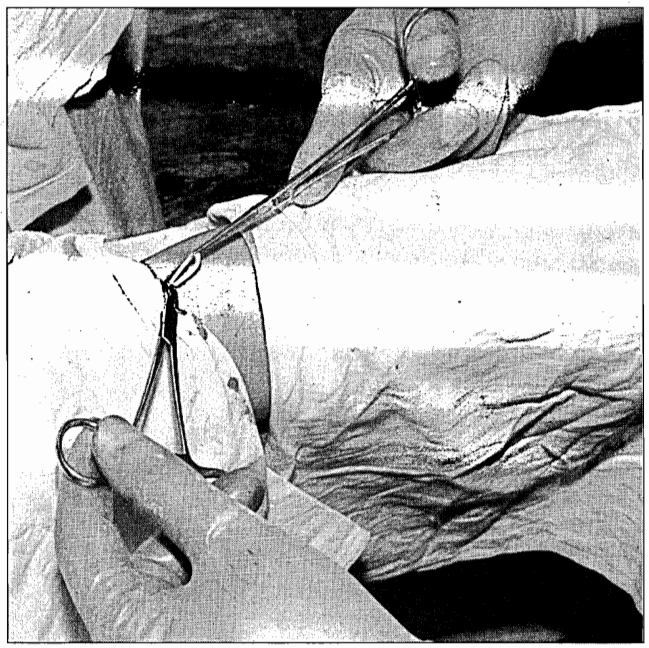
Intrauterine devices (IUDs) are second to voluntary sterilization in worldwide contraceptive prevalence, with an estimated 70 million users. One of the newest IUDs is a copper-bearing T-shaped device called the TCu 380A, which may be destined to become the predominant IUD in family planning programs around the world.

FHI is examining the TCu 380A in a series of clinical trials at approximately 25 sites in 18 countries located throughout Asia, Africa, Latin America and the Middle East. "The primary intent of these studies is to compare the device with the standard IUD most frequently used in each country," says Gaston Farr, research associate in FHI's Division of Clinical Trials. "We also tried to select countries with little or no experience with the TCu 380A, so we could introduce family planning providers, as well as users, to what seems an especially promising new technology."

Information has been collected on nearly 10,000 women fitted with IUDs – representing the world's largest IUD database in terms of number of users and variety of research sites.

Preliminary analysis of the data indicates that the TCu 380A is significantly more effective than other IUDs and about equal or better than other devices with respect to other major concerns, such as rate of expulsion, continuation of use, and incidence of bleeding or pain. Indeed, the results have been impressive enough that several countries, including Mexico and Thailand, have joined the ranks of the many countries that have approved the TCu 380A for use in national family planning programs. "In Thailand, the government now distributes TCu 380As through almost 700 hospitals across the country," says Dr. Kanchana Kanchanasinith, director of the Division of Health Statistics of the Thai Ministry of Public Health.

The TCu 380A had earlier been approved by the U.S. Food and Drug Administration (FDA). A.I.D. is a major supplier of the device to developing countries. FHI's clinical trials will therefore give participating countries an important advantage for early widespread use of the TCu 380A in family planning programs.



San Balogh/FHI

A Norplant® capsule is removed from the inside upper arm of a woman in Egypt.

Norplant®

Women who want more children, but who would like to postpone getting pregnant, often discontinue contraceptive use because they dislike the inconvenience of available methods that require high levels of individual "compliance," or accuracy of use. FHI is addressing this problem by evaluating several new long-acting systems, including Norplant® contraceptive implants. Developed by the Population Council, Norplant® consists of six hollow silastic capsules filled with levonorgestrel, a synthetic progestogen hormone. The capsules are implanted just under the skin on the inside of the upper arm, where they slowly but steadily release their contents. Pregnancy can be effectively prevented for at least five years – yet the method can be reversed at any time the woman wishes by removing the implants.

FHI is sponsoring clinical trials of Norplant® at 43 study sites in 12 countries, most of which have had no previous experience with contraceptive implants. Nearly 100 physicians participating in these trials

have been trained in the insertion and removal techniques, and clinical data have been collected on more than 8,000 women to determine the overall acceptability of the implants in different populations, according to Sandor Balogh, associate director of FHI's contraceptive introduction program in the Division of Field Development and Training. "Based on FHI studies," he says, "Norplant® has received approval for use in national family planning programs in four countries – Haiti, Sri Lanka, Nepal and Bangladesh." Norplant®'s clinical performance is being investigated by other international research groups as well, and the technology has received regulatory approval in 10 additional countries in both the developed and developing world. Bangladesh has recently announced an expanded program to insert Norplant® sets in 24,000 women, and Nepal plans to provide implants to nearly 8,000 women over the next year or so.

FHI has also coordinated the development of educational materials in selected countries to promote local knowledge and acceptance of Norplant.® These include simple pictorial booklets geared to reach potential users and their husbands, as well as more technical materials designed for physicians and other service providers. In addition, FHI has organized several national seminars on Norplant® targeted at physicians and policymakers in key government positions, which received extensive coverage by the media.

Norplant® is now awaiting U.S. regulatory approval, which could be granted during the first half of 1990 by the U.S. Food and Drug Administration (FDA). Approval by many other countries is then considered likely to follow, and tens of millions of women could begin using Norplant® during the next decade.

Progestogen-only pills

Since the estrogen component of combined oral contraceptives has been linked to suppression of lactation, breast-feeding women have been generally advised to choose a different method if contraception begins within the first six months after delivery. Progestogen-only pills do not lessen the volume of breast milk produced and may even enhance lactation. A.I.D. and other international donor organizations are therefore making progestogen-only pills increasingly available to national family planning programs.

FHI is conducting several clinical trials of progestogen-only pills at more than 40 sites in approximately 15 countries in order to evaluate their overall acceptability among breast-feeding women. In one series of trials in Latin America and Africa, for example, roughly 60% of the 4,000 women involved were found to be still taking the pills after six months – an indication that they seem to be reasonably well accepted. "These trials, as with other FHI studies, provide a controlled way of introducing this new type of contraception to physicians and other family planning providers," says Dr. Allen Rosman, associate director of FHI's Division of Clinical Trials. "And as these individuals become familiar with the approach and pass their new knowledge along to others, use can be expected to expand progressively within the national program."

Nadine Burton/FHI

Women at the family planning clinic in Cité Soleil – a suburb of Port-au-Prince, Haiti – receive oral contraceptives.

Community-based distribution

To complement the introduction of new contraceptive technologies, FHI has also focused efforts on devising creative distribution channels for reaching potential users. For example, in one project early in FHI's history – called Visites à Domicile de Motivation Systématique (VDMS) and conducted from 1977 to 1981 in Marrakech Province, Morocco – specially trained public health workers delivered contraceptives door-to-door.

They visited 150,000 households, reaching nearly 165,000 women. Their goals were to identify all women eligible for family planning services (those aged 15 to 44), to collect basic information on the reproductive background and contraceptive status of each woman, and to offer oral contraceptives (OCs) or condoms to eligible women and to refer those desiring an IUD to the appropriate health facility. This was followed by a second visit approximately five months later to assess the

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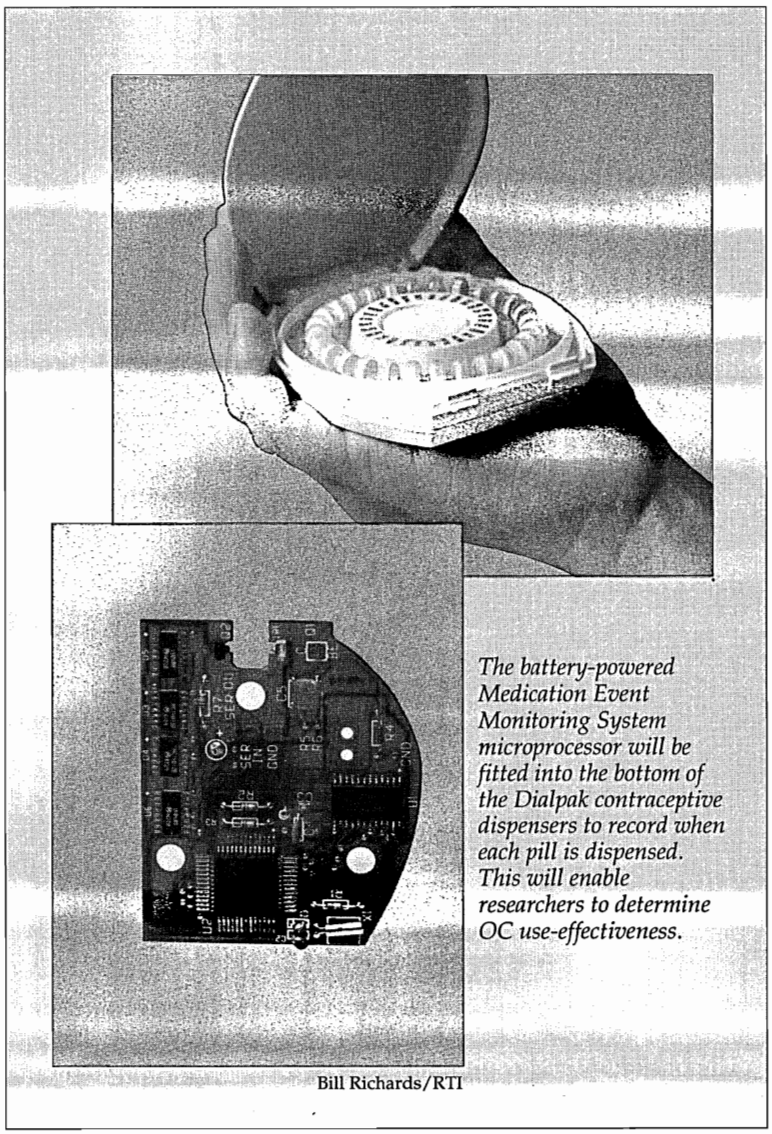
PILL COMPLIANCE: THE DETERMINANT OF PILL USE-EFFECTIVENESS

Since their introduction 30 years ago, oral contraceptives (OCs) have become the most popular modern method of family planning in the world.[1] About 8% of all married women – 63 million worldwide – use OCs to regulate their fertility.[2] Yet, despite near-universal acceptance of OCs from Australia to Zimbabwe, health researchers know very little about one crucial aspect of Pill use: How accurately do women take the Pill?

Only 12 quantitative studies of OC "compliance" – that is, accuracy of Pill use – have been found in the literature, and their criteria vary so much that their levels of compliance can't be directly compared, says Dr. Linda Potter, research associate at Family Health International. Compliance criteria in these studies range from missing one pill in three months to missing three pills in one month.



The battery-powered Medication Event Monitoring System microprocessor will be fitted into the bottom of the Dialpak contraceptive dispensers to record when each pill is dispensed. This will enable researchers to determine OC use-effectiveness.

Bill Richards/RTI

Moreover, says Dr. Potter, compliance in these studies was measured by questionnaires, daily OC compliance calendars, participation in clinical trials, urine checks for riboflavin levels in riboflavin-containing OCs, and counting the number of OCs left in packets during or at the end of a cycle. Most of this after-the-fact information came from asking women to remember not only when they took the Pill, but also why they didn't take it if they missed a day or two.

"We can't always assume that a woman didn't take the Pill because she just forgot to do it," says Dr. Potter. "There are too many other variables, such as concern about side effects, cost, or not knowing how long to wait between cycles."

For all their variance, the compliance studies agree on one point: the Pill is almost 100% effective when properly used, but less effective if there is poor user compliance. In the United States, an estimated 3% of married and 6% of unmarried users become pregnant in their first year on the Pill.[3] In some developing countries, the failure rate is as high as 20%.[4]

Unlike most other medications, OCs are unusual in that a healthy woman must follow a strict regimen of daily pill-taking for months or even years. Moreover, mod-

ern OC dosages are so low, compared to those of the 1960s, that missing even one day may result in pregnancy. The first OCs contained as much as 25 times the progestogen and three to four times as much estrogen as some of today's low-dose formulations. Although these early OCs were notorious for their side effects, says Dr. Malcolm Potts, president of FHI, "they did have the virtue that a woman could forget to take the Pill for one or two days and still not become pregnant."

Most modern OCs (including triphasic OCs) contain less than 35 micrograms of estrogen and less than one milligram of progestogen. While they are associated with fewer and less severe side effects, the changes in their formulas demand rigid compliance by the women who use them. In particular, the progestogen-only "mini-pills," which contain no estrogen, require very scrupulous user compliance for effective protection. Even a consistent time of day for taking this OC becomes important. According to a 1988 study, a mini-pill user who misses one or two tablets may face a much higher risk of pregnancy than a woman who uses a combined formulation and misses a tablet.[5]

Triphasic OCs, which are used by most American women, have fewer metabolic side effects than other combined pills (OCs combining estrogen and progestogen). Nonetheless, these formulations also require strict compliance because they are linked to the highest incidence of breakthrough bleeding. They share another problem as well. Each month's packet contains three or four colors of pills, which can be confusing to even the best-educated new user. One set of the colored pills in the 28-day dial packets are the seven placebo tablets, there to help ensure compliance by allowing uninterrupted use.

The packaging for combined OCs used in many developing countries is no better. Many of these countries use the 21-day pack of OCs. Each cycle of 21 pills is followed by a seven-day "rest" before the next cycle begins. Lacking the uninterrupted schedule afforded by the triphasics and other 28-day packets, the 21-day cycle can lead to noncompliance and potential OC failure because many women in developing countries receive confusing information about how long to wait between cycles or are less calendar-oriented than Western women.

"Taking pills accurately is not easy," says Dr. Potter. "In fact, it can be quite complicated. We now have three different kinds of pills, each with different rules. It would be better if every woman who gets a packet of pills could get a condom at the same time and be told, 'If you miss three days of the combined pill, use the condom for the rest of the cycle.' Users of the mini-pill should be told, 'If you miss one day, use a condom for the rest of the cycle."

For Dr. Potter and other family planning researchers, the central issue with OCs is user compliance. Can compliance be reliably measured? And if so, how?

Dr. Potter believes a recent development by a small medical electronics firm in California may hold the answer to finally obtaining accurate data on OC compliance. The Aprex Corporation has engineered its battery-powered MEMS (Medication Event Monitoring System) to fit in the base of Ortho Pharmaceutical's Dialpak contraceptive dispenser. Unseen and unheard, MEMS uses a microprocessor linked to an optical sensor to digitally record the date and time each pill is removed from the Dialpak. The device activates itself when a user opens the Dialpak cover. Pushing a pill out breaks a beam of light in the optical sensor, an event that causes the microprocessor to instantly record the time and date. The data can be easily transferred to a desktop computer for plotting a calendar of compliance.

The advantage of MEMS lies in its real-time recording of data. It requires no counting of number of pills used, recall of OC use or other forms of post-usage monitoring of compliance. "MEMS is unobtrusive, in no way interferring with the daily routines of OC users," says Dr. Potter, who is evaluating the device for use in a pilot study of compliance among U.S. women. If the pilot study is successful, a much more comprehensive study using MEMS in OC dispensers probably will be undertaken in a developing country.

"By learning more about women's actual pill-taking behavior and the errors they make in taking the Pill, we can provide them with better information on OC use," she says. "Improved packaging, labeling and patient instruction package inserts, and better counseling by providers, would be important outcomes of an improved understanding of actual OC use." ■

"Users of the mini-pill should be told, 'If you miss one day, use a condom for the rest of the cycle.'"

[1] Lower-Dose Pills, *Populations Series* A(7): 1, 1988.

Worldwide female sterilization and IUD use are more prevalent than use of oral contraceptives, but there are more new OC users each year than new users of other modern contraceptive methods.

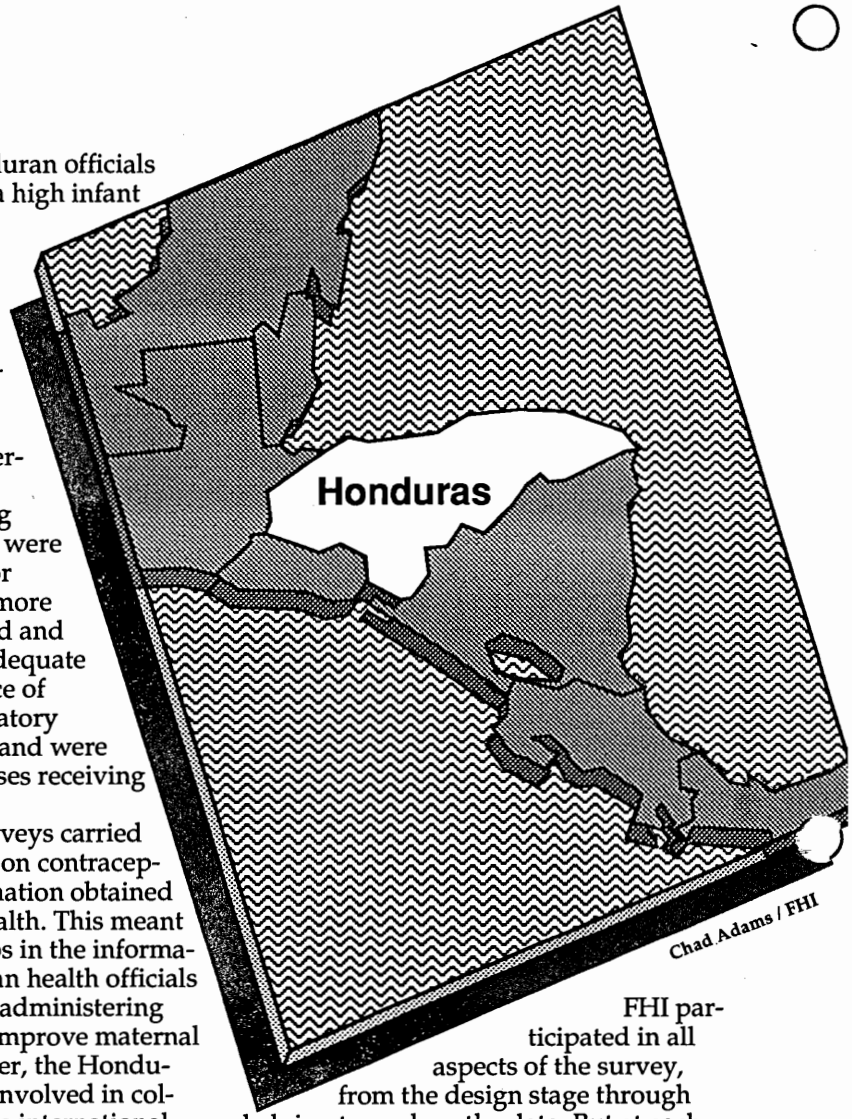
[2] Ibid.

[3] WR Grady, MD Hayward, J Yagi. Contraceptive Failures in the United States: Estimates from the 1982 National Survey of Family Growth, *Family Planning Perspectives* 18(5), 1986.

[4] Ibid.

[5] RA Hatcher et al. *Contraceptive Technology 1988-1989* (New York: Irvington, 1988), p. 25.

GOOD SURVEY DATA LEAD TO BETTER HEALTH POLICY OPTIONS



Chad Adams / FHI

In the early 1980s, Honduran officials were concerned about a high infant mortality rate. They also wanted to determine the effectiveness of various programs designed to combat early childhood illnesses. Was the proportion of women getting prenatal care expanding? Were more women delivering in hospitals? Was the proportion of babies being breast-fed increasing and were babies being breast-fed for longer durations? Were more children being immunized and were immunizations at adequate levels? Was the prevalence of diarrhea and acute respiratory infection (ARI) declining and were children with these illnesses receiving appropriate treatment?

As recently as 1981, surveys carried out in Honduras focused on contraceptive use, with little information obtained on maternal and child health. This meant there were important gaps in the information available to Honduran health officials who were designing and administering various interventions to improve maternal and child health. Moreover, the Hondurans had been primarily involved in collecting data, while outside international agencies had directed the analysis of the data. Thus, many Honduran health officials lacked the practical experience of analyzing large-scale survey data, and in using that data to develop health policies and to monitor and evaluate health intervention programs.

In 1987, the U.S. Agency for International Development Mission in Honduras (AID/Honduras) financed a project which addressed both needs – the gaps in information and the hands-on experience in analyzing and using large-scale survey data. Called the "Epidemiology and Family Health Survey," it was a collaborative process involving the Honduran Ministry of Health and ASHONPLAFA, the Honduran Family Planning Association, along with two U.S agencies, Family Health International (FHI) and Management Sciences for Health.

FHI participated in all aspects of the survey, from the design stage through helping to analyze the data. But at each point, FHI's role was to assist the Ministry of Health and ASHONPLAFA in executing the various functions themselves. Understanding the background of the 1987 Honduran survey, its results, and the collaborative process involved, shows how important a comprehensive survey can be in shaping effective health policies.

Maternal and Child Health Surveys

Since the 1970s, standardized surveys have been used around the world to measure levels of fertility, contraceptive use, breast-feeding duration, and the unmet need for contraceptives. Building on this model, more recent surveys have evolved, often referred to as Maternal and Child Health and Family Planning (MCH/FP) surveys. FHI began its work with MCH/FP surveys in Brazil in the

late 1970s.

During the early 1980s, AID/Honduras increased its funding to the Honduran Ministry of Health for a broad range of child survival efforts, including an expanded immunization program, oral rehydration salts for children with diarrhea, and the promotion of breast-feeding. In addition, it funded a 1984 MCH/FP survey, which was designed to go beyond contraceptive use, the focus of a 1981 survey in Honduras. The 1984 survey produced national and regional estimates of contraceptive use and levels of fertility, as well as information on breast-feeding – all of which could be compared with data from the 1981 survey. The 1984 survey provided other information on maternal and child health, including incidence and treatment of diarrhea, incidence and treatment of ARIs, more detailed information on immunization, activities of traditional birth attendants (TBAs), and use of institutional facilities for delivery-related care.

In order to make a more precise estimate of the infant mortality rate than then available, the 1987 survey gathered data from nearly 12,000 households, more than twice the size of the 1984 survey. Larger sample surveys are necessary for better estimating infant mortality rates because events (deaths) are relatively rare. Complete birth histories of more than 10,000 women were obtained, generating data on 28,000 live births occurring since the 1950s.

The survey attempted to determine, among other things, immunization coverage, prevalence of diarrhea and its management, and the frequency of acute respiratory infections and their management. The interviewers asked specifically about the symptoms of dehydration and whether oral rehydration salts were being used. Diarrheal disease is the primary cause of infant and child mortality in Honduras, and acute respiratory infections are second.

In preparing for the 1987 project, the Ministry of Health increased its computer facilities by adding several powerful microcomputers and by expanding its staff. The Honduran staff managed data entry and editing, using a computer software package called SURVEY developed by the U.S. Centers for Disease Control. The field work (data collection) lasted almost six months; two months later, preliminary results were available.

Survey results

What is most important in the context of this discussion is how the data on the maternal and child health issues provided valuable information to evaluate efforts to expand maternal-child health coverage and to determine what additional tasks still needed to be accomplished. These new tasks include attention to AIDS, also covered in the 1987 survey.

Breast-feeding. Comparing the 1987 data with 1981 and 1984 data provided information on how well the national breast-feeding promotion campaign called PROALMA was working. The analysis showed that breast-feeding increased steadily from 1981 to 1987; in 1981, the mean duration of breast-feeding was 15 months, whereas in 1987 it had increased to 17 months. On a less positive note, the 1987 survey shows that the duration of exclusive breast-feeding is very short. More than one-half of babies received other food or other milk during the first month of life. Many food substances are introduced at an early age. About half of the children aged five to six months have been given tea or coffee.

Maternal care. While there was little change in the percentage of mothers receiving prenatal care or in the percentage delivering in hospitals over the period 1984-1987, there were some encouraging signs that health care was improving. The percentage of mothers who received tetanus toxoid increased from about 33% to 50%; thus more infants were protected against neonatal tetanus. Also encouraging is the finding that traditional birth attendants who were trained were far more likely than were untrained TBAs to refer a woman for institutional prenatal care; clearly, though, more TBAs need training and those who are trained should refer more women to a health center or hospital.

Diarrhea and respiratory infections. The survey found that 18 percent of children under age five had diarrhea on the day of the survey or during the previous two days – only slightly lower than the 20% finding in 1984. While 74% received some treatment, only 17% received oral rehydration therapy (ORT) – about the same percentage as in 1984. While efforts have been made to encourage use of ORT, these results indicate that, at least at the national level, such efforts have not been successful.

Immunization among children. The percentage of children under age five who are adequately immunized has increased markedly. From 1981 to 1987, the percentage jumped from 46% to 73% for polio

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editorial

KEY FACTORS IN INSTITUTIONAL DEVELOPMENT

Julia Beamish/FHI

JoAnn Lewis

The mission of Family Health International is to improve contraceptive choices and reproductive health for people throughout the world. We work in partnership with researchers, government and private sector programs and institutions in more than 50 countries to implement a range of research and program strategies to carry out our mission. Our underlying philosophy in this work is to enhance the skills and capabilities of the institutions and individuals with whom we collaborate in the development, implementation and utilization of research and interventions. Our goal is also to leave behind the tools and skills that individuals and organizations need to answer other questions or carry on programs once FHI's project or study is completed.

The cornerstone of FHI's institutional development program is the long-term support that we provide to Family Health Research Centers (FHRCs) in a number of countries. For more than 10 years, FHI has worked with organizations to build local capabilities to plan, conduct, evaluate and disseminate findings of research, to address issues and answer questions of relevance to local and national family planning programs, as well as to participate as equal partners in research with a more global agenda. FHI is currently working with FHRCs in six countries (Bangladesh, Egypt, Indonesia, Kenya, Sri Lanka and Thailand), and is also providing assistance to organizations in Mali, Mexico and Niger. Each of these institutions is unique; some are private non-governmental organizations, some operate as a research arm of ministries of health or population policy bodies, and still others constitute a research unit within a family planning service delivery program. The development of each organization and the program of research implemented by each FHRC is determined by local needs, interests, priorities and resources. What these organizations share with one another and with FHI is a common goal to build local capacity to carry out research and programs that improve reproductive health and contraceptive choices.

FAMILY HEALTH RESEARCH CENTERS

Indonesian Fertility Coordinating Board (BKS PENFIN)	University of Nairobi, Department of Obstetrics and Gynecology (UON/Kenya)
Thailand Fertility Research Association (TFRA)	Malian Association for Family Planning (AMPPF)
Bangladesh Fertility Research Programme (BFRP)	National Center for Family Health of Niger (CNSF)
Egyptian Fertility Care Society (EFCS)	Mexican Interuniversity Group for Epidemiologic Research in Reproductive Health (GIMIESAR)
Family Planning Association of Sri Lanka (FPA/SL)	National Population Council of Egypt (NPC/Egypt)

The FHI approach to institutional development is comprehensive and integrated, and involves financial and technical support to strengthen the research and program skills of the staff, develop the necessary program support infrastructure, and improve management and fiscal expertise. Our strategy involves training, technical assistance, the transfer of information and computer and research management technology, and financial and technical support to implement research projects. FHI makes a long-term commitment of core funding to the FHRC which is gradually phased out as the institution matures and is able to obtain support from other sources.

A number of critical factors are essential to the success of the institutional development process. FHI strives to assure that these elements are addressed in our relationship with the FHRCs:

- the **leadership** of an individual who will devote considerable time, energy and creativity to the development of the institution;
- the **long-term support** of a donor to assure financial stability during the institution-building process;
- a **"critical mass"** of staff with the appropriate skills to manage and carry out the research agenda;
- the **vision** to see national research needs and the potential to address these needs;
- **technical assistance** and field-oriented **training** to develop the skills and provide experience for the staff;
- the development of **management skills**

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TECHNOLOGY TRANSFER: THE ROLE OF TRAINING

In the last four years, FHI has supported about 125 training conferences, seminars, meetings and workshops ranging from one-on-one training to large scientific conferences. Overall, nearly 7,000 health professionals from developing countries have attended these events, most of them held in-country. Cumulatively, these programs contribute to one of the most important aspects of a central FHI goal – institutional development.

"We have a responsibility to transfer our skills so that other people can do work related to the research priorities in their own countries," says Mark Robbins, FHI's associate director of Field Development and Training.

Training is the cornerstone of FHI's effort to transfer research skills and information to individuals and organizations in other countries. Over the years, FHI training has focused on five general needs:

- **training in research methods** related to clinical trials, epidemiology, data analysis, survey methodology, and other research needs;
- **medical training** regarding various contraceptive methods, especially the implant Norplant,® sterilization techniques for men and women, sexually transmitted diseases, and reproductive health;
- **management systems** including computer use, data management and quality control, and accounting and financial planning;
- **scientific information** through annual scientific meetings, contraceptive technology update seminars, and regional scientific congresses;
- **information dissemination** and writing skills for journalists and scientific writing for clinicians.

Many of the seminars and conferences have been part of FHI's long-term collaborative relationship with family health research centers (FHRCs). Other training has targeted countries where FHI does not have a sister relationship with an FHRC, but supports specific projects or aims to develop local skills in research.

" These people take their new skills back to various institutions," says Mr. Robbins. "Many of the people we train have in turn trained others in their own countries. This is central to the concept of institutional development."

Karen Hardee – Cleaveland / FHI

Norplant ® is explained to nurses at the family planning clinic at Mansoura University Hospital in Egypt, where FHI has conducted training of clinicians.

Over the last four years, FHI has used its self-instructional modules on clinical trials research methods in Egypt, Bangladesh, Sri Lanka, Panama, Sudan, Indonesia, Brazil, Zimbabwe and Guatemala. The teaching modules have been translated into Spanish, French and Portuguese for this training. Training to strengthen general research skills and help people write research proposals for funding by international agencies has been the centerpiece of workshops in Niger, Kenya, Cameroon, Haiti, and Egypt. Four training sessions on epidemiology methods have been conducted in Mexico. FHI has also brought persons from Thailand, Egypt, and Indonesia to the United States for data analysis training.

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AIDS PREVENTION THROUGH DRAMA IN CAMEROON

The play's characters find their power in unanimously agreeing to make their use of condoms a prerequisite to accepting clients.

Street theatre – a highly appreciated art form in Cameroon – has in recent years become a popular way of sharing messages on family planning and health in Africa. Now, a group of prostitutes who comprise the company of Les amies de Douglas et Rose (The Friends of Doug and Rose) are preparing to tour Cameroon with "Marriage to the Condom," a play about AIDS and the importance of using condoms to avoid contracting HIV and other STDs. The Friends' aim is twofold: to spread awareness of STDs – particularly AIDS – among their peers and the general public, and to encourage the use of condoms.

The scene: a bar frequented by prostitutes and interested men. Dialogues, rather than a plot, carry the play's messages. In addition to providing essential information to help prevent the spread of AIDS among persons who practice high-risk behaviors, "Marriage" paints a true picture of the working lives of prostitutes, popular perceptions of AIDS and the repercussions of STDs. The explicit dialogues and instructional use of props desensitize its condom-wary audiences, who will be targeted by a condom marketing campaign to be accompanied by the play.

Mary Bean /FHI

Two Friends rehearse "Marriage."

The play emerged from a 1987 AIDS intervention program in Yaoundé for high-risk individuals, funded by USA For Africa and conducted by Family Health International in collaboration with the Cameroon Ministry of Public Health. FHI targeted prostitutes based on the premise that a few people with many sexual partners have a greater potential of spreading the virus than do more people with few sexual partners, according to Dr. Doug Nichols, associate director of Program Evaluation at FHI and technical monitor of the program.

In addition, prostitutes in Yaoundé are geographically mobile, so they can serve as conduits of HIV infection around Cameroon. According to Dr. Marcel Monny Lobé, project manager from the National AIDS Control Services and the play's director, most of the 69 cases of AIDS that have been diagnosed in Cameroon have been found in Yaoundé and the port city of Douala. "Although the prevalence of HIV infection in Cameroon at the start of the program in late 1987 was quite low in the general population (0.3% to 0.5%) in comparison to neighboring countries in Central and East Africa, it is likely to increase rapidly if effective steps are not taken to slow its spread," says Dr. Nichols.

The intervention program called for the selection of 11 prostitutes who demonstrated leadership qualities to be trained in the capacity of Peer Health Educators (PHEs). They in turn became information providers and motivators by explaining to their fellow prostitutes the threat of AIDS to themselves, their families, partners and peers; by teaching them to adopt safer sex practices; and by showing them where to obtain condoms.

A group of 125 prostitutes – 6.6% of whom were found to be HIV seropositive – educated by the PHEs was studied to determine the impact of PHE training. One element of the training comprised role-playing to teach the PHEs techniques for motivating their peers to use condoms during all their commercial sexual encounters.

The idea to produce a play was born out of one of these role-playing sessions. "Marriage" will help convince its audiences to adopt safer sex practices by playing out the issues underlined during the motivational training. These address individuals' self-interest and concern for family, friends and partners. The play also works on an especially strong sense of solidarity, not only in the grand effort the Friends are making to be part of the troupe and produce the play around the country, but also in their promotion of a united spirit among

women in the trade. The play's characters find their power in unanimously agreeing to make the use of condoms a prerequisite to accepting clients.

While setting up the intervention program with Dr. Monny Lobé and his colleagues, Dr. Nichols and Rose De Buysscher, FHI's program coordinator for Cameroon, visited several pharmacies in Yaoundé looking for condoms and vaginal spermicidal tablets. "We found they were difficult to find and prohibitively expensive," says Ms. De Buysscher. Now, based on the positive results of the program, the United States Agency for International Development (A.I.D.) is giving the government of Cameroon approximately nine million condoms. The supply of condoms, together with an educational program funded by FHI's AIDSTECH Division and implemented by the National AIDS Control Services, will help prevent the spread of AIDS in Cameroon. And after having conducted a successful subsidized condom sales project in Zaire, Washington-based Population Services International (PSI) is jointly sponsoring with AIDSTECH a social marketing campaign for condoms in the country. The Friends will go on the road side-by-side with the PSI-AIDSTECH campaign to launch a country-wide AIDS prevention effort from health centers, STD clinics and neighborhood associations.

"Marriage to the Condom" is not the first project to provide AIDS education through drama. For instance, "One of Our Sons is Missing" – a play about a young man with AIDS and his family's and community's reaction – has been touring Trinidad and Tobago. Both plays are firsts in their regions. But the findings of the Cameroon study which spawned this play, as well as those of Caribbean actors and producers, show an immense lack of understanding of AIDS or the prophylactic role of condoms. In Yaoundé, about half the women at the start of the program did not understand how HIV is transmitted. Similar gaps in understanding were found in Trinidad and Tobago, as – in another instance – in the public's ambiguous perception of the difference between having AIDS and being infected (yet often appearing healthy) with HIV. Questionnaires at the end of the intervention project showed a significant increase in the level of awareness.

"The only way to fight AIDS is through prevention, and prevention is everybody's business," says Dr. Monny Lobé. "Everyone, at his or her own level, can do something to prevent AIDS." There is no doubt the Friends and other travelling theatrical troupes are proving to be an important innovation in the fight against AIDS. ■

Editorial

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as well as **research skills** to assure a sustainable institution;

- the **support of the country's policy leaders** to provide a favorable climate in which the work of the institution can be carried out with maximum potential to have input into informing policy decisions and the implementation of programs;
- the ability of the organization to **diversify its funding** sources.

In working with the FHRCs, FHI employs several mechanisms to assure that the critical elements are addressed as successfully as possible. The following technical assistance and training are provided to develop the staff capacity and skills in contraceptive and reproductive health research and interventions, and the ability to disseminate results effectively:

- financial planning and the use of fiscal control systems;
- assistance in developing strategies to aid national policy leaders in formulating appropriate policies based on local data;
- technical assistance in study design, execution and report generation;
- assistance in developing long-term plans and evaluation frameworks oriented toward a smooth transition from core funding support to integrated multiple-source funding;
- information dissemination and research utilization strategies and skills;
- automated data processing and analysis skills;
- staff development geared to specific needs and goals.

FHI takes a great deal of pride in the institutions with which we have been privileged to work over the past decade. Many of them have matured into strong organizations that are providing critical inputs into the development of sound family planning policies and programs in their countries. Among the lasting contributions that FHI has made during our history, perhaps the FHRCs are the most important. ■

JoAnn Lewis is FHI Vice President for Programs

Institutional development

Continued from page 1

development a priority, particularly the network of family health research centers with which it was involved. Second, the BFRP Executive Council, chaired by the Secretary of the Ministry of Health and Family Planning, hired a new, dynamic director, Dr. Halida Akhter. Originally from Bangladesh, Dr. Akhter had trained in the United States and was working with the World Bank in Washington, D.C., when she decided to return to her homeland. Dr. Akhter brought both the experience and the vision to move the BFRP into a new stage of development.

"The process of institutional development has been a critical one for us," says Dr. Akhter. "We needed backup support and training, and still do. But Bangladesh needed its own capacity for reproductive health and fertility research programs of all sorts. And we are nearing that point."

Since 1985, the BFRP has increased its staff from five to 21 professionals, has established itself as an organization capable of sophisticated field research, and now is leading the efforts to offer Norplant® to women throughout Bangladesh. The organization has carried out contraceptive research in collaboration with other international organizations, and has successfully sought funds from the World Health Organization, the Ford Foundation and others. While still working closely with FHI, the BFRP no longer depends on it for direction and support.

The evolution of the Bangladesh Fertility Research Programme – which parallels the evolution in FHI's approach to working with collaborators around the world – shows why institutional development is important and what makes it work.

The evolution of the Bangladesh Fertility Research Programme... shows why institutional development is important and what makes it work.

Focus on building skills

For FHI, the new focus on institutional development meant concentrating efforts on building skills in family health research centers such as the BFRP. In 1985, FHI decided to phase out its "core support" grant funding of the BFRP and similar centers in Egypt, Indonesia, Sri Lanka and Thailand over a five-year period. The programs would have to develop a more diversified funding base, but in order to attract funding, they needed to increase their technical and managerial capacity.

Helping the centers to expand their research capacities meant training local staffs in more advanced research methodology and concepts. The goal was for local center staff members to go beyond the day-to-day tasks in administering research projects toward understanding the scientific rationale behind the projects themselves, from designing such projects to analyzing them. To achieve this goal, FHI used many training and research tools.

FHI sponsored two workshops in Bangladesh on improving research skills, one for BFRP staff, and one for other researchers in the country. After that training, the BFRP then held two of its own workshops, to train still others in the country in the basics of research methodology.

As the BFRP research capacity expanded, the BFRP required increased sophistication in processing and analyzing data and the capacity to attract and manage various sources of funding. Responding to these needs, FHI provided BFRP with an IBM PS2 computer for data processing, and a BFRP staff member attended a programming workshop in the United States. FHI is also assisting the BFRP in setting up modern double entry accounting systems with computerized accounts.

Information dissemination

Now with the capacity to design its own studies, raise its own funds for those studies, manage those funds, and analyze the findings, the BFRP needed the ability to disseminate what they were learning. FHI provided the funds to hire the first BFRP information manager.

"One of our major objectives is to disseminate relevant and useful information on contraceptive technology and reproductive health to various target groups in the country," explains Dr. Akhter. "Rumors and bad publicity on methods often reach users sooner than positive information." In 1988, FHI held a workshop specifically for staff responsible for public information programs at the family health research centers, including the BFRP. In addition, FHI supplied reports and other materials to the local programs to serve as the basis for popular articles in the various countries. The BFRP information manager placed 15 articles in Bangla and English newspapers last year, using many FHI-supplied materials for background information.

In February 1989, FHI held its first scientific writing seminar for mid-level family health research center staff. Four persons came to the two-week seminar, including one from the BFRP. The participants analyzed their data during the workshop and by the end of the two weeks had drafted articles. Two of the articles are scheduled

for publication in international journals – in *International Family Planning Perspectives* and in *Contraception*.

Today, the BFRP reports its research through technical reports, a newsletter, conference proceedings, manuals and policy reviews. These materials are designed for many audiences – policymakers and program planners, other researchers and service providers, grassroots field workers and users, and even potentially antagonistic groups.

Expanding capabilities

From expanding its research capacity to disseminating its results to many audiences, the Bangladesh Fertility Research Programme has established itself as an important resource within Bangladesh. Handling the Norplant® trials attracted the attention of the Ministry of Health and Family Planning. But that is just one of BFRP's projects. The BFRP has moved from working strictly on clinical trials to managing survey research projects, maternal morbidity studies, research on how well various contraceptives are being accepted, and other efforts. It coordinates clinical studies conducted by hospitals, clinics and researchers, and is included on the Bangladesh National Technical Committee, composed of senior researchers in the country concerned with family planning.

The Bangladesh Fertility Research Programme has made tremendous strides as an organization. A crucial underpinning to BFRP's success, says Dr. Akhter, "has been following a staff development strategy for all of our activities." Such a strategy requires attracting capable staff and providing an opportunity and environment for staff members to learn and participate in the growth of the organization.

"Since there is a dearth of qualified persons in the area," says Dr. Akhter, "the most difficult aspect of institutional development is to find and hire talented people, train them on the job, and maintain good quality output."

The director of an organization plays a central role in the staff development process. "The chief of a research organization is simultaneously an administrator, a researcher, a teacher, and a manager," says Dr. Akhter. "What is most important is to share credibility with the staff. It is very crucial to give them the feeling of satisfaction about the job they are performing. Recognition of their work, their talent, is their best reward. It is essential to give them a sense of belonging to the organization and a sense of achievement, no matter how small the work may be." ■

Role of training

Continued from page 11

FHI sponsored training for all the investigators participating in Norplant® clinical trials at one of two regional training centers in Indonesia and the Dominican Republic. The investigators represented a total of 12 countries. In country-training for other clinicians has been provided in Haiti, Nigeria, Egypt, Sri Lanka, Nepal and Bangladesh. Medical training on IUD insertion was held in Mali and El Salvador (the latter included IUD insertion during the postpartum period), and on female and male sterilization in Mexico and Thailand.

"Success in these efforts is measured by the increasing number of individuals designing, conducting, and evaluating important research projects related to contraceptive development and reproductive health," says JoAnn Lewis, vice president for programs at FHI. ■

NEW FHI PUBLICATIONS

- 89-34 R Rivera, JR Gaitan, R Ruiz, DP Hurley, M Arenas, C Flores, AB Hernandez. Menstrual Patterns and Progesterone Circulating Levels Following Different Procedures of Tubal Occlusion. *Contraception* 40(2): 157, 1989.
- 89-35 T Khan, KI Kennedy, A Kazi, M Steiner. A Study of Breastfeeding and the Return of Menses and Pregnancy in Karachi, Pakistan. *Contraception* 40(3): 365, 1989.
- 89-36 NE Williamson. Breastfeeding Trends and Patterns. *Int J Gynecol Obstet*, Suppl. 1, p. 145, 1989.
- 89-37 G. Savina, KI Kennedy. The Effect of a Breastfeeding Education Program on Lactational Amenorrhea in the Philippines. *Stud Fam Plann* 20(4): 203, 1989.
- 89-38 HW Perera, M Steiner, KI Kennedy, R Snowden, Perspectives of Physicians in Sri Lanka on Periodic Abstinence. *Ceylon Med J* 34(2): 87, 1989.
- 89-39 GS Grubb, A Coker. Re: Condylona and the Intraepithelial Neoplasia of the Uterine Cervix: A Case-Control Study. *Am J Epidemiol* 130(2): 427, 1989.
- 89-40 V Orense, M Steiner, KI Kennedy, R Snowden. Perspectives of Physicians in the Philippines on Periodic Abstinence Methods of Family Planning. *J Philippine Med Assoc* 65(2): 216, 1989.

FHI publications are available at no cost to interested persons. For copies, please write to Ms. Debbie Wade at FHI.

Expanding options

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acceptability of the delivery system and provide more pills or condoms.

Two of every three women who were offered oral contraceptives at the initial visit accepted them, with almost 90% of the initial acceptors continuing use at the time of the second visit and with fewer than 1% reporting side effects and consequent discontinuation. Overall use of contraception increased from 49% to 65% in the city of Marrakech, and from 13% to 46% in the rural remainder of Marrakech Province. VDMS thus demonstrated conclusively that household distribution by nonmedical personnel is a highly effective means of increasing contraceptive use, even in a society in which the traditional belief in large families may be deeply rooted, says Dr. Doug Nichols, former project monitor of the VDMS project and now associate director of FHI's Division of Program Evaluation. Based on the project's success, Morocco has since expanded household distribution – without intensive data collection – to most of the country.

Jim Rugh/World Neighbors

FHI's contraceptive introduction program will enable more families in developing countries to regulate their fertility.

Contraceptive introduction

FHI is paying increasing attention to the significant challenge of moving new contraceptives from clinical research into everyday use, and has created a special contraceptive introduction program. The staff will focus first on technologies that have already demonstrated very high acceptability, such as Norplant® contraceptive implants and the TCu 380A intrauterine device, and will identify what obstacles stand in the way of widespread use. They will also coordinate development of training programs for providers, educational materials for users, and seminars to involve the mass media.

"We will be looking at the entire transfer process," says Mr. Balogh, who is heading up the contraceptive introduction program. "The goal is to coordinate FHI's efforts with other international organizations and with local ministries of health and family planning groups to most effectively foster and support the introduction of new contraceptive methods." ■

1 Levels and Trends of Contraceptive Use As Assessed in 1988. United Nations, New York, *Population Studies*, No. 110, 1989, p. 42.

Honduras

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(there was a polio epidemic in 1984); for DPT, from 42% to 71%; for measles, from 60% to 75%; and for BCG, from 50% to 73%. Even these percentages may be understated because only those children with immunization cards were evaluated.

AIDS. Honduras has the highest AIDS case-to-population ratio in Central America. It thus has a great need to increase educational campaigns and promote risk-reducing behaviors. Survey data identified specific kinds of misinformation that educational efforts will need to overcome.

Hondurans look to the future

Through the 1987 survey, the Honduran survey staff gained invaluable practical experience in designing, implementing, and analyzing large surveys. In the process, the Ministry of Health and ASHONPLAFA officials have improved their skills in evaluating their own programs. Without good data on breast-feeding, for example, there would be no way to determine how well the breast-feeding program was working.

Increasingly, the Honduran Ministry of Health and ASHONPLAFA have become more independent and capable of conducting sophisticated surveys, from design through policy analysis. Strengthening the capacities of these institutions was a central FHI goal throughout the 1987 Honduran survey.

These newly gained skills were evident at the recent Honduran National Scientific Week Conference; the Ministry of Health staff responsible for the survey submitted 20 abstracts based on the 1987 survey results. When the next survey cycle begins, the Hondurans will know which issues demand the most attention. They will also know how to acquire the data they need to make informed policy decisions. ■

FAMILY HEALTH INTERNATIONAL

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HIV AND BREASTFEEDING: RISKS AND REALITIES

By the end of 1992, mothers infected with the AIDS-causing human immunodeficiency virus (HIV) will give birth to at least 1 million babies, according to projections by the World Health Organization. At least 250,000 of these infants will be infected with HIV through their mothers.

In the face of such news, health experts are looking for ways to control the further spread of HIV from infected mothers to their newborn children. Among the questions raised in this context is, "Should HIV-infected mothers breastfeed?" While research on this issue is still in the early stages, experts agree that for now, in virtually all cases, mothers in developing countries should breastfeed.

"Those of us who work internationally believe that the potential risk, if any, of HIV transmission through breast milk is more than counterbalanced by the benefits of breastfeeding," says Neal Halsey, director of the Division of Disease Control at the Johns Hopkins University School of Hygiene and Public Health.

In November 1989, Dr. Halsey and other experts in this field met with representatives of the World Health Organization (WHO) in Paris to review the WHO position regarding HIV-infected mothers and breastfeeding. At that meeting, held in conjunction with a major international conference, "The Implications of AIDS for Mothers and Infants," Dr. Halsey and his colleagues reaffirmed WHO's position regarding breastfeeding and HIV infections, established in 1987. "Where the safe and effective use of alternatives is not possible," the WHO recommendation says, "breastfeeding by the biological mother should continue to be the feeding method of choice, irrespective of her HIV infection status."

There is still uncertainty about the nature of HIV transmission from mother to child. Thus far, researchers have found that HIV-infected mothers transmit the virus to their babies 20 to 50 percent of the time, primarily *in utero* or during delivery. Put in a positive way, 50 to 80 percent of these infants appear to be free from the HIV infection, and show no evidence of the presence of HIV antibodies. This raises the question: Should the mothers of these *uninfected* babies breastfeed or not?

When considering HIV transmission, breastfeeding or bottlefeeding is a choice between risks and benefits.

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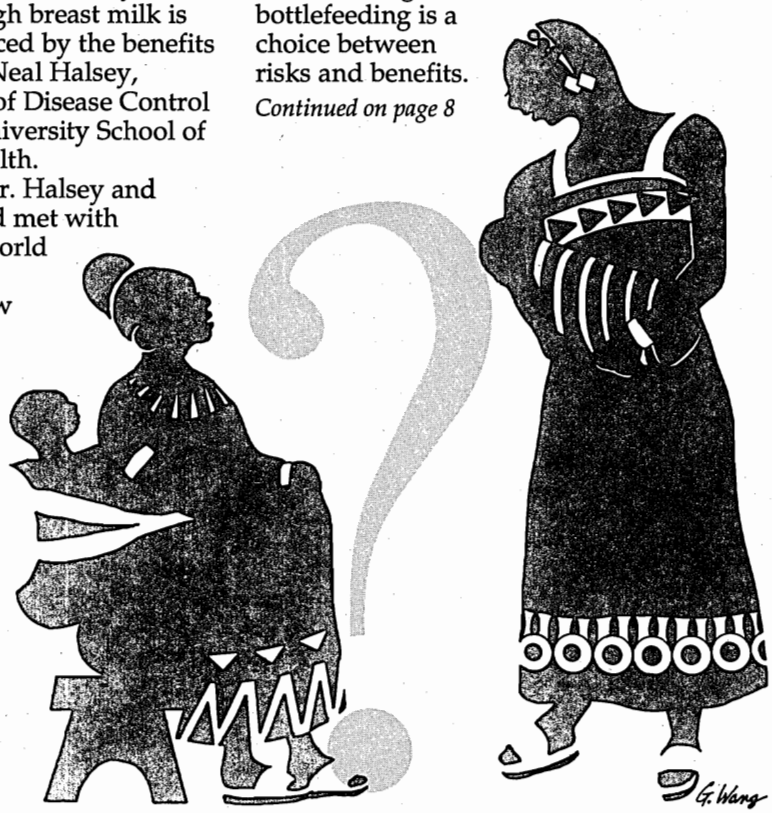


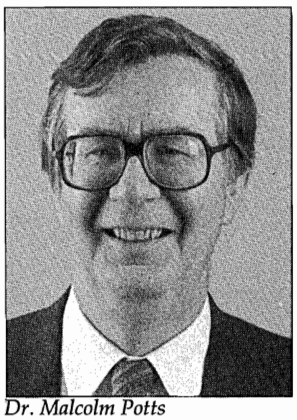
editorial

FACING THE FUTURE NOW

As I write this I am looking across the heart of London. I have noticed impressive growth in the skyline since I left here in the 1970s. It is no wonder: The whole world is changing at an alarming rate. Cities are becoming more crowded. Carbon dioxide and other "greenhouse" gases are heating up the atmosphere. And rain forests are disappearing.

As we enter the 1990s, these changes continue to be driven by excessive population growth worldwide. No matter what we do, the world's population will double to about 10 billion in the 21st century. But if we don't try to do something now to slow this growth trend, the population will triple to 15 billion. That's three times as many people competing for a dwindling supply of natural resources, and potentially three times as many pollutants being pumped into our already fragile atmosphere.

The future of our planet will be decided in large part by family planning. Expanding the availability of safe, effective contraceptive options — particularly in developing countries — is perhaps the single most important step we can take in the 1990s to improve the quality of life for all in the decades to come.


Dr. Malcolm Potts

We know that family planning works. Wherever contraceptive options have been available, fertility rates have declined. In rural areas marked by poverty and

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letter from the editor

AIDS AND THE FAMILY

Once considered by some to be a plague on "marginal" populations, AIDS has now become a family problem. By the end of 1992, at least 1 million children will be born to mothers infected with the human immunodeficiency virus (HIV) that causes AIDS, according to projections by the World Health Organization. At least one-fourth of these infants will be infected with HIV through their mothers. Indeed the AIDS pandemic threatens to reverse the progress that has been made to reduce infant mortality rates, particularly in developing countries.

This issue of **network** features a series of articles about some of the conditions that place families — particularly women and children — at risk for HIV infection.

Our cover story addresses the difficult question of whether a mother infected with HIV should breastfeed. So far, the answer is yes for women in developing countries, where the health risks associated with bottlefeeding continue to outweigh the potential risk of transmitting HIV through mothers' milk.

In other news, blood transfusions continue to pose a risk for HIV infection in some areas of the developing world. This is of particular concern to pregnant women, new mothers and infants, who receive most of the blood transfusions in developing countries. Our story in this issue discusses the urgency for maintaining safe, adequate blood supplies.

In this issue we also address the HIV risks for commercial sex workers, many of whom are wives and mothers in need of information about family planning and AIDS. One article discusses both the possibilities and problems associated with using peer education to teach prostitutes about the importance of using condoms. Another report summarizes the findings from the World Health Organization's special consultation on HIV and prostitution, held last summer in Geneva. Both articles stress the need for intervention efforts that reach beyond commercial sex workers to their clients and regular partners; once infected with HIV, clients would bring the virus home to their wives, who may in turn infect their future offspring.

We also have good news to report on expanding contraceptive options for two population groups: men and older women.

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FHI

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ORAL CONTRACEPTIVES FOR WOMEN OVER 40

Despite earlier concerns about potential health hazards for older women, oral contraceptives (OCs) now are regarded widely as an appropriate family planning option for many women over 40.

This shift follows action by two major organizations in the United States. In October 1989, the Fertility and Maternal Health Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) called for removal of age limits on the use of OCs by healthy women who do not smoke; and in 1988 the American College of Obstetricians and Gynecologists issued a policy statement asserting that "healthy, nonsmoking women aged 35-44 may continue to use oral contraceptives."

"It therefore seems appropriate for family planning providers in developing countries to make OCs available to older women who have no other risk factors for cardiovascular disease, such as smoking, obesity and high blood pressure," says Judith A. Fortney, director of FHI's Division of Reproductive Epidemiology and Sexually Transmitted Diseases. "Many older women throughout the world still need contraceptive protection, and OCs are definitely one of the most effective methods available. If women had not been able to get OCs because of their age, this should no longer be considered a negative factor."

Although the FDA had no previous official position regarding the upper age limit for OC use, most U.S. physicians followed a guideline of 35 years for women who smoked and 40 for those who did not. This prescribing pattern grew out of warnings contained in the FDA-approved patient package insert for OCs, which declared that "smokers 35 and older and nonsmokers 40 and older who use oral contraceptives have an increase in mortality higher than those using other methods of birth control." The claim was based in part on several studies during the 1970s and early 1980s, from which researchers determined that the risk of heart attack among women over 40 was four times greater for OC users than for non-users, and the risk of stroke was five times greater. Both estrogen and progestin are linked to heart disease; estrogen can cause clotting, progestin can raise cholesterol.

More recently, however, a growing number of researchers have begun to argue that OCs now contain much lower doses of both estrogen and progestin than the earlier pills did, and thus should be safer for long-term use. Whether this is indeed true has not yet been established, because the lower-dose pills have only been in widespread use for about 10 years.

Bill Richards / RTI

But even if lower-dose pills do not prove to pose fewer cardiovascular risks, the argument continues, the risks are minimal at worst. In the United States, for example, the absolute risk for heart attack and stroke among nonsmoking premenopausal women over 40 is fairly small. Indeed, Dr. Fortney says the level of risk has decreased dramatically during the past two decades. And while the risk levels for these diseases in developing countries are not known precisely, they are probably even lower.

"Even more important," she says, "is the fact that the risks of pregnancy-related mortality and morbidity increase rapidly with age." In the United States, maternal mortality is roughly 10 times higher among women 40-44 than among women in their 20s, and 50 times higher for women 45-49. In addition, complications of pregnancy, such as toxemia and postpartum hemorrhage, increase markedly with maternal age, as does the risk of some birth defects. "So overall," Dr. Fortney concludes, "the definite serious risks associated with getting pregnant greatly outweigh the other health risks linked to OC use among many older women."

Although the exact level of maternal mortality is not known for most developing countries, it is known that in some regions the rate is 100 times higher than in the developed world. This situation, says Dr. Fortney, makes expanding the choice of effective contraceptive options a pressing global issue. ■

—Tom Burroughs

"Many older women throughout the world still need contraceptive protection, and OCs are definitely one of the most effective methods available."

health news

INDONESIAN FAMILY PLANNERS PROMOTE BREASTFEEDING

Indonesian family planning officials have taken a major step to promote breastfeeding through their national family planning program. BKKBN, the National Family Planning Coordinating Board, has recently launched a program to train family planning field workers, counselors and providers on how to educate women about both the nutritional and contraceptive advantages of breastfeeding.

As part of this effort, BKKBN has developed local information materials, including a poster and training booklet, with assistance from Family Health International (FHI). The booklet, entitled "Breastfeeding and Child Spacing," is available in Bahasa Indonesia. The publication was reviewed and endorsed by a committee comprised of policy-level representatives of public and private organizations in Indonesia, including the Ministry of Health, Society for Perinatalogy, Breastfeeding Promotion Association, Working Mothers' Association and several universities.

"Family planning represents a unique opportunity, as well as a highly effective means of promotion of breastfeeding," observe Drs. Haryono Suyono, chair of BKKBN, and Shyam Thapa, a senior research associate at FHI, in the preface to the booklet.

As of 1987, about 58 percent of ever-married Indonesian women of reproductive age had received services from BKKBN. Moreover, about one-fifth of currently married women of childbearing age are visited by a family planning field worker at least twice a year, according to a 1987 national survey.

Studies have shown that breast-fed Indonesian infants have a significantly lower level of malnutrition and a lower risk of diarrhea and respiratory diseases than bottle-fed infants. In addition, breastfeeding in Indonesia has been effective in reducing the total potential fertility per woman of reproductive age by 28 percent.

However, while most women in rural Indonesia breastfeed their infants, many urban mothers have either shortened the duration of breastfeeding or abandoned the practice altogether. Breastfeeding has also been found to occur less frequently among mothers who deliver at hospitals or who have consulted or been assisted by a modern birth attendant.

"Even among women who intend to breastfeed or those who are already doing so, many lack information about optimal feeding patterns and are unaware of how to solve problems that may arise," say Drs. Suyono and Thapa.

In addition to integrating breastfeeding information into family planning programs, Indonesian health officials will promote breastfeeding through the mass media. BKKBN will also work with women's groups and government agencies to disseminate information and encourage legislation to protect the right of women to breastfeed, especially in the workplace.

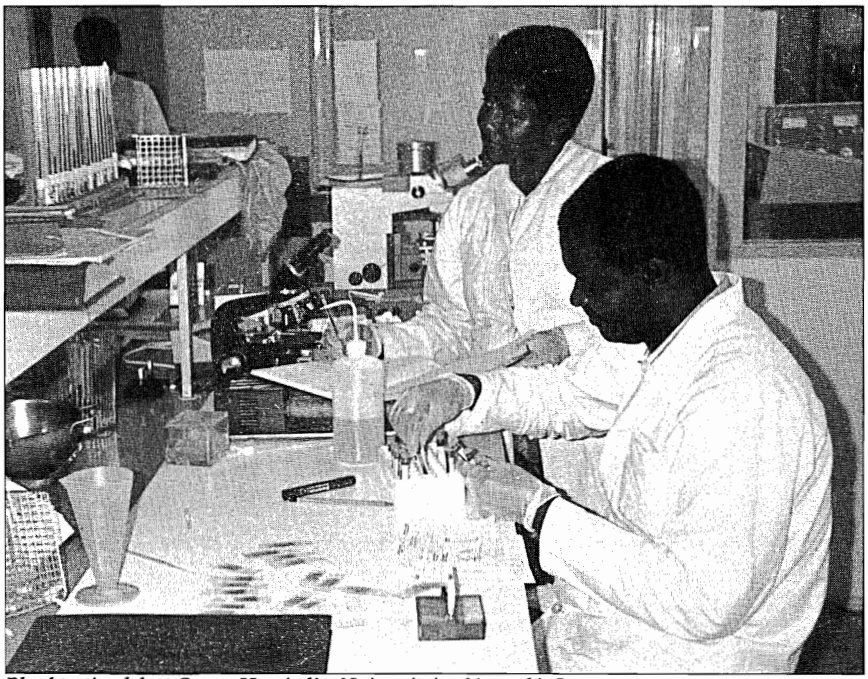
"We hope that the initiative and approach taken by BKKBN will provide encouragement and serve as a model for many other family planning programs around the world," says Drs. Suyono and Thapa.

The English-language version of the booklet "Breastfeeding and Child Spacing" is available from the World Health Organization, Programme on Maternal and Child Health and Family Planning, Division of Family Health, Avenue Appia, 1211 Geneva 27, Switzerland. ■

AIDS AND BLOOD TRANSFUSIONS: ENSURING SAFE BLOOD SUPPLIES

Blood transfusions can save lives. However, they can also result in unnecessary illnesses and deaths in areas where donated blood is not screened for the human immunodeficiency virus (HIV) that causes AIDS.

Transmission of HIV infection through blood has focused new attention on the need for safe and adequate blood supplies, especially in areas with high HIV prevalence rates. This is of particular concern to pregnant women, new mothers and children, who receive most blood transfusions in developing countries.



John Stanback

Blood testing lab at Centre Hospitalier Universitaire, Yaoundé, Cameroon.

"The neon light is on for testing [blood]," says Jean Emmanuel of the World Health Organization's (WHO) Global Programme on AIDS. "One has to test for HIV, at the same time remembering that an integrated blood transfusion system with voluntary non-remunerated blood donors is the cornerstone of safe blood. In addition, appropriate use of blood will ensure a successful program."

Just six years ago, no commercial means existed to test blood for HIV infection. Today, tests for HIV are available in most developing countries, and substantial screening for the virus is being done. Yet countries with limited resources face major barriers to establishing a safe and adequate supply of blood.

Health officials say the best way to control the transmission of HIV, hepatitis B, syphilis and other infectious agents in blood is to establish an integrated blood transfusion system. This involves proper blood collection, testing, storage and distribution, as well as trained technicians and appropriate criteria for using transfusions. However, establishing a centralized blood transfusion system is costly and requires a commitment of resources from national government officials.

"We need government commitment to sustain the blood program beyond just HIV testing," explains Dr. Emmanuel, who before joining the WHO staff in Geneva had directed the establishment in Zimbabwe of Africa's most successful blood transfusion service.

In 1988, WHO launched the Global Blood Safety Initiative (GBSI) in conjunction with the League of Red Cross and Red Crescent Societies and other groups. The objective of the Initiative is to support the development of integrated blood transfusion services in all countries.

"Prevention of HIV is of course very important, but it is part of a larger issue," says W.N. Gibbs, chief of WHO's Unit of Health Laboratory Technology and Blood Safety, which coordinates the GBSI. "We have identified eight countries as priorities

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Blood

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for development of their blood transfusion services, and we hope to be able to mobilize the funding to start these projects this year."

In addition to the eight countries, which have not been publicly identified, GBSI is working in several other countries on blood donor recruitment, training of technicians, prevention of HIV and other infections, and other programs, according to Dr. Gibbs. All of this work is designed to function within the context of national health priorities and AIDS prevention and control plans.

Health officials, the Global Blood Safety Initiative and others working with blood transfusions face a two-pronged task: to test for HIV infection and at the same time to build a safe and lasting system for transfusions. Both tasks involve obstacles regarding supply, distribution and establishing criteria for transfusions.

Health officials face a two-pronged task: to test for HIV infection and at the same time to build a safe and lasting system for transfusions.

Supply

Having adequate blood supplies is a major problem in most developing countries. According to a review of 185 countries in 1988, the supply of blood "in low-income countries is grossly insufficient to meet requirements," reported Dr. C.G. Lopez of WHO. Low-income African countries (per capita Gross National Product less than US$1000) collected less than three units of blood per 1000 population, compared to 56 units per 1000 for high-income European countries. Blood can only remain in a blood bank for 21 to 35 days, depending on the anti-coagulant solution added, so a constant supply is needed.

In rural areas, most transfusions that occur in clinics or small regional hospitals come from family members called upon during an emergency. Such blood can now be tested for HIV, using new screening methods which give results in 10 to 15 minutes.

In contrast, cities may have more opportunities for donors but also a high HIV-prevalence rate in many countries. Hence, screening systems have to be in place. Large hospitals with well-trained staff can use the ELISA HIV-testing method, which requires one day for results but can test 50-100 samples at one time. The ELISA test costs about US$1 per sample, compared to about US$1.50-$4.00 for the quicker tests. However, ELISA requires sophisticated equipment and is only cost-effective if large numbers of samples are tested.

Another problem, particularly in many Latin American countries, is the use of paid donors. Paid donors resist blood screening because they do not want to endanger a source of income. Commercial donors often practice high-risk behaviors for HIV infection and hence are often not desirable donors. To avoid this dilemma, the GBSI guidelines call for developing a volunteer donor system. "We are working on donor motivation and recruitment," says Dr. Emmanuel, who is a member of the GBSI Secretariat.

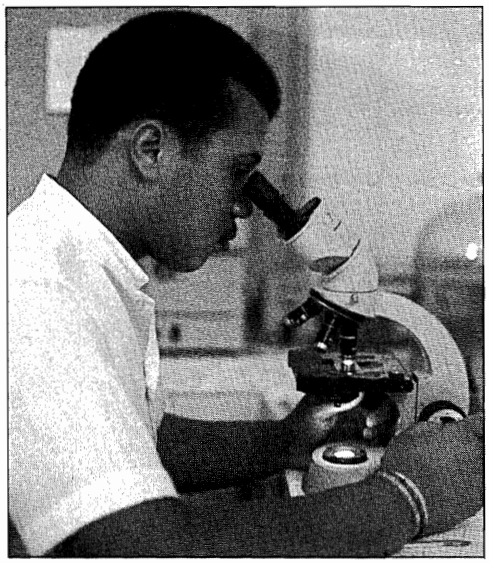
Distribution

The ideal blood distribution system would vary according to country. Generally, large countries such as Nigeria or Indonesia need to use testing facilities in different regions of the country. But smaller countries can use a centralized system, if they have good transportation systems which can quickly carry blood samples to centralized testing facilities.

In Zimbabwe, half of the blood is collected in mobile vans and half in fixed locations. "The blood is processed at decentralized blood banks and stored for use while the specimen tubes are sent overnight in refrigerated transport for testing at centralized testing sites," explains Dr. Emmanuel. "This ensures safety, quality assurance and an economically sound testing policy. The ELISA test is used where at least 50-100 units are tested [at one time], while other tests such as simple particle agglutination tests are used for lesser quantities. Where emergency blood transfusion needs testing, rapid simple tests are used, preferably using blood from previously screened, voluntary regular, non-remunerated donors." Blood samples that test negative (i.e. no HIV antibodies) are cleared by the blood bank for use and sent back out to the regional centers.

In a regional system, blood is tested in large batches in regional hospitals. This approach requires more training than centralized systems, especially if the ELISA test is used.

"The essential problem is the fragmentation of blood transfusion services," explains Dr. Anthony Britten, former head of the blood program for the League of Red Cross and Red Crescent Societies and now a consultant working closely with the GBSI. "Many countries have no organized blood transfusion


Alan Dehmer

Screening blood at STD clinic in Dakar, Senegal

systems: Each hospital is forced to take care of its own needs, often in emergency situations.... A few developing countries have been able to address their need for HIV-testing because the organizational infrastructure already exists. But where HIV testing is only possible on a hospital-by-hospital basis, it is not cost-effective and laboratory standards cannot be assured."

Dr. Emmanuel explains that in many countries the infrastructure is not in place for even a regional system. The WHO National Program Support Unit/GBSI is involved in developing transfusion systems in such countries, including Ghana, India, Indonesia, Nigeria and Sierra Leone.

Establishing criteria for transfusions

An integrated blood transfusion system includes proper blood collection, testing, storage, distribution and training of technicians. Even with all of this, however, adequate criteria are needed for using transfusions. A meeting held last fall in Cameroon and recent events from Romania illustrate the importance of such criteria.

Cameroon. In November 1989, 45 physicians and blood bank managers participated in a workshop in Yaounde, the capital of Cameroon, to establish guidelines for appropriate blood transfusions for that country. Nine of the 10 Cameroon provinces were represented at the meeting, sponsored by the U.S. Agency for International Development and Family Health International's AIDSTECH division, in cooperation with the Cameroon National AIDS Control Service. Among the 11 formal presentations was a review by the Cameroon Ministry of Health on managing blood services in the context of the current GBSI focus on integrated blood transfusion systems.

The central problem that emerged in the discussions was an inappropriate use of transfusions, especially regarding conditions of anemia. In Cameroon, four of every five transfusions are in response to anemia in women or children. Dr. J. Fosi-Mbantenkhu of the Central Hospital in Yaounde explained that understanding the cause of anemia is essential for its treatment and can prevent unnecessary transfusions.

The Cameroon conference concluded that the number of blood transfusions should be reduced, that family donation should be retained because of existing social structures, and that volunteer, unpaid donors should be encouraged so as to increase the supply of safe blood. The participants developed guidelines for appropriate blood transfusions regarding anemia, as well as acute hemorrhaging and elective surgery. Regarding chronic anemia, these guidelines recommend not using a transfusion if the hemoglobin level is greater than 6 grams per deciliter; if hemoglobin is less than 6 grams, health workers should consider transfusions if the anemia cannot be clinically tolerated.

Romania. In February 1990, reports from eastern Europe revealed that more than 700 children in Romania had been infected with HIV. That number is expected to increase; many children have already died from AIDS. Researchers suspect these pediatric HIV cases may have been caused by the routine practice in Romania of injecting adult blood into young babies who appear thin or anemic. Since news of the HIV infections spread, Romanian health officials have banned this widely discounted practice — known as microtransfusion — and begun screening blood.

Both the Cameroon conference and the developments in Romania illustrate the broad range of issues triggered by the concern over HIV transmission. Building a lasting system for safe blood transfusions will take time and commitment, addressing issues of supply, distribution, appropriate use and other related factors. But it is the urgency of testing for HIV

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An integrated blood transfusion system includes proper blood collection, testing, storage, distribution and training of technicians.

Breastfeeding

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Breastfeeding is convenient, economical and medically beneficial — the baby gets protection against various childhood diseases through the breast milk. At the same time, breastfeeding may or may not transmit HIV. By contrast, in developing countries, not breastfeeding is known to result in substantial infant mortality.

Lance Woodruff

Which risk is greater — the risk of HIV infection through breastfeeding or of an infant dying because of not breastfeeding?

"We think there's a low risk of infection from breast milk," says Margaret Stanback, an epidemiologist conducting two studies in Haiti of HIV-infected women who are breastfeeding. "At the same time, there's a substantial risk of mortality from malnutrition and associated diarrheal illness in children who are not breastfed in the developing world." Ms. Stanback and Dr. Warren Johnson, chief of the Division of International Medicine at Cornell Medical Center in New York City, work with both diarrhea and AIDS clinics in Haiti, where Dr. Jean Pape collaborates with them as clinical director of the studies.

"Until we have evidence of a substantial risk from breastfeeding," concludes Ms. Stanback, "the only responsible recommendation at this point is that women in the developing world continue to breastfeed."

Measuring the risk

What evidence is currently available on the risks of breastfeeding? What questions remain to be answered?

Since 1985, a handful of case reports have noted that HIV has been detected in human milk and that the virus may have been transmitted to infants through breastfeeding. Together, the reports involved fewer than 10 infants, however, and the transmissions came through unusual circumstances. For example, a wet nurse in the late stages of AIDS appears to have infected one infant. Other babies apparently became infected through breast milk from mothers who had received postpartum transfusions of blood infected with HIV, an increasingly rare circumstance. Even so, HIV transmission through breastfeeding was considered to be possible.

Prompted by these reports, in 1985 the U.S. Centers for Disease Control (CDC) recommended that HIV-infected mothers bottlefeed. The United Kingdom issued a similar recommendation. Under criticism for their statements, health officials in both the UK and United States eventually clarified their recommendations, explaining that they applied only to their countries — developed countries where infant formulas are readily available to virtually everyone, as is sanitary water for diluting the formula. The WHO, meanwhile, stressed the importance of breastfeeding by HIV-infected mothers in *developing* countries, where safe bottlefeeding alternatives are not readily or universally available.

Scientists have had less than a decade to investigate possible vertical transmission (i.e., from mother to child) of HIV through breastfeeding — a short time for reaching definitive answers to such a complex problem. Researchers are using various approaches to examine two basic questions, both still unanswered. First, is HIV transmitted at all through breastfeeding? If so, what is the added risk of breastfeeding?

"We are *trying* to address both questions," says Dr. Halsey of Johns Hopkins. Researchers there are looking to related issues for guidance. "This is quite similar to the story for hepatitis B," says Dr. Halsey. "It [hepatitis B] is known to be in breast milk, but the rate of vertical transmission was not different for breastfed and non-breastfed infants."[1]

There are obstacles to researching these issues. For example, a mother's antibodies to various diseases remain in a newborn for up to 15 months or longer. Tests measure the presence of *antibodies* to HIV, not the presence of the virus itself, because

this is much easier and less expensive. Hence, for general purposes, an infant must be at least 15 months old before researchers can know for certain if the antibodies present are residual from the mother or actually produced by the child.

However, the development of a new method of registering the presence of HIV in blood samples may help solve this particular research obstacle. Called the polymerase chain reaction (PCR), this test amplifies the genetic chain in the blood, so that the HIV virus might be detected within the infant's DNA. But only very small numbers of infants have been studied using this technique, and it is expensive to use, even in small, controlled studies. "We conclude that the polymerase chain reaction will be a useful technique to diagnose HIV infection in newborns and to predict the subsequent development of AIDS," a research team reported in *The New England Journal of Medicine*. "However, larger studies will be required to determine the sensitivity and specificity of the test."[2]

As mentioned earlier, researchers tend to agree that HIV-infected mothers transmit the virus 20-50 percent of the time. Given what is known about viral transmission, researchers expect that transmission of HIV would most likely occur *in utero* (where the virus in the mother's blood may meet the fetus's blood at the placenta) or during delivery — rather than during breastfeeding. Where infection occurs neither *in utero* nor at birth, the rate of transmission through breast milk, if it exists at all, is not known. But knowing the rate of transmission through mother's milk is central to knowing the relative risk of breastfeeding versus bottlefeeding for uninfected babies.

To examine directly the rate of transmission through breastfeeding, as distinguished from transmission *in utero* or at delivery, studies need to be undertaken of breastfeeding mothers who are infected during the postpartum period. Also, uninfected infants of HIV-infected mothers — those infants who did not get the virus *in utero* or during delivery — need to be identified and studied. Research on either group of mothers and infants is very difficult.

Postpartum infection. Postpartum HIV infection of the mother could occur through blood transfusions or heterosexual contact. Increasingly, countries throughout the world realize the dangers of HIV-infected blood and are attempting to put screening systems into place. In some developing countries, postpartum blood transfusions are rare due to inadequate blood supplies and other reasons. But in other areas, blood transfusions are more common and sometimes used inappropriately, including during the postpartum period.

As the epidemic changes, dangers of postpartum HIV infection could come from women who are infected sexually — and do not know it. "They could then transmit the virus to the babies through milk," says Kathy Kennedy, a research associate at Family Health International (FHI) who is focusing on breastfeeding issues. "They could transmit the virus before antibodies could even be measured." There is a time lag after HIV infection during which the antibodies cannot yet be detected in testing.

The possibility of postpartum infection raises questions that need examination. For example, many scientists think that mothers are more infectious at the time they themselves acquire the infection.

Uninfected infants. Gathering data on uninfected babies born to HIV-infected mothers is an even more difficult research task. Yet providing information on this issue is central to the dilemma health policymakers and practitioners face. How does one judge whether breastfeeding or bottlefeeding is more dangerous for *uninfected* babies born to an HIV-infected mother? Prevention of HIV transmission is possible for these infants, who are the basic target of the CDC recommendation. However, studying such a group of babies, until recently, could only be done indirectly. As explained above, the infection status cannot easily be determined at birth. Moreover, because of the low incidence of testing for the antibody, mothers usually do not know whether they are infected with the virus.

Three recent studies show how researchers are addressing these difficult questions. Two of them, from Zaire and Australia, found that breastfeeding does not present an additional risk to infants already exposed to HIV during pregnancy or delivery. The third, by FHI researchers, examines the relative risk of breastfeeding and bottlefeeding in developing countries using various assumptions of infant mortality and other risks.

"There is no additional risk from breastfeeding for a child already exposed [to HIV] during (the) pregnancy and/or at

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"Because of the potential benefits of breast milk and its crucial importance in child survival in developing countries, nearly all HIV [infected] mothers in Africa should breastfeed their children."

Breastfeeding

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delivery," reported the Zaire researchers at the 1989 Paris conference. The Zaire study was conducted in conjunction with the (CDC). "Because of the potential benefits of breast milk and its crucial importance in child survival in developing countries, nearly all HIV [infected] mothers in Africa should breastfeed their children."[3]

A group of Australian researchers also reported their findings at the Paris conference. "[W]here the mother was already infected at the time of delivery, there is no evidence of any additional risk [to infants] from breastfeeding," the study concluded.[4]

Breastfeeding is still the preferred method of infant feeding in developing countries, even for a mother known to be infected with HIV.

While research continues, policymakers and health practitioners must make judgments and choices now. An FHI research team led by Ms. Kennedy has developed a model for comparing the risk of breastfeeding and bottlefeeding for *uninfected* infants born to *HIV-infected mothers*. The question of whether to breastfeed ultimately focuses on the uninfected infants. The model compares the number of deaths that would occur under various conditions, especially the risk of infant mortality due to HIV infection, as well as diarrhea and dehydration associated with bottlefeeding. Where such risks are high, more babies would die if HIV-infected mothers bottlefed rather than breastfed, the researchers concluded.

Assuming a 10 percent infant mortality rate, which is typical of much of Africa, and assuming the most conservative relative risk of bottlefeeding, 30,000 deaths among 100,000 uninfected bottlefed babies would be expected, the FHI team reported in *Tropical Doctor*. "If all were breastfed, again assuming 10 percent infant mortality, and assuming a 5 percent [HIV] transmission rate by breast milk, there would be about 14,000 deaths."[5] In simple terms, under these conditions, about twice as many bottlefed as breastfed babies would die.

Ms. Kennedy is now using this theoretical model to analyze existing data on HIV infection. "Our new study should help policymakers know how to apply our model to their specific situation," she says.

Future policy directions

While research continues on this issue, HIV infection reaches deeper into the next generation. Meanwhile, policymakers look for guidance to the major international agencies examining the HIV transmission issue. The conflict between the WHO and the CDC recommendation has worried some researchers.

"Although the CDC recommendation that HIV [infected] mothers refrain from breastfeeding has not been directed to women in developing countries, the danger exists that this recommendation will be heeded in situations for which it was not intended," explained the FHI group in *Tropical Doctor*. "There is a clear precedent for changes in infant feeding practices — namely the decline of breastfeeding and the rise of artificial feeding — to follow the lead of industrialized nations."

Margaret Oxtoby, from the AIDS program at CDC, wrote in 1988 what many consider the most definitive overview of the HIV and breastfeeding issue yet available. "In areas where breastfeeding is preferred even for the known HIV-infected mother, statements about HIV and breastfeeding may have adverse impact far beyond their intent," she observed. "It is particularly worrisome that in developing countries where breastfeeding is most crucial to infant survival, concern about HIV transmission may have negatively affected general attitudes toward breastfeeding."[6]

Faced with many difficult choices concerning AIDS, policymakers can at least take heart that breastfeeding is still the preferred method of infant feeding in developing countries, even for a mother known to be infected with HIV. Dr. Oxtoby concluded her long examination of this issue with two sentences that still serve as the best guide in developing countries. "Careful studies may unravel the answers to these questions and assist clinicians in individual situations in which the mother is known to be infected with HIV or has been recently exposed to HIV," Dr. Oxtoby explained. "Meanwhile the strong evidence of the beneficial effects of breastfeeding should continue to provide the framework within which broad public health policies are developed." ■

— *William R. Finger*

Footnotes

[1] **network** devoted much of Vol. 10, No. 4 (1989) to the hepatitis B virus. For a free copy, please write Deborah Wade, FHI, P.O. Box 13950, Research Triangle Park, N.C. 27709, USA.

[2] MF Rogers et al. Use of the Polymerase Chain

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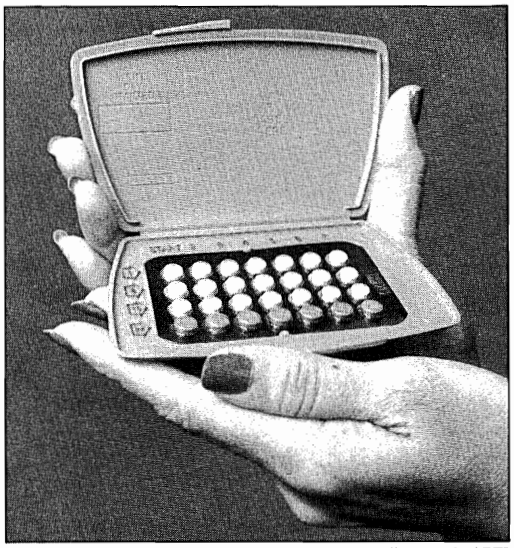
WHAT TO DO WHEN 'THE PILL' IS TAKEN INCORRECTLY



Bill Richards / RTI

Today's low-dose oral contraceptives are highly effective, but it is crucial to take the pills according to the prescribed daily schedule. With the lowest-dose formulations, forgetting to take even one tablet during a cycle can place a woman at increased risk for pregnancy.

"It would be better if every woman who gets a packet of pills could get a batch of condoms at the same time," says Dr. Linda Potter, research associate at Family Health International. "Then they could be told, 'If you miss three days of the pill, double up on your pills for three days (that is, take two pills each day for three days) and use the condoms for the rest of the cycle. Ignore any breakthrough bleeding.' Users of the mini-pill should be told, 'If you miss even one day of the mini-pill, double up on your pills for each day missed and use the condoms for the rest of the cycle.' There are other ways to safely make up for missed pills, but they are more complicated to remember and carry out, and they vary from one type of OCs to another."

Editorial

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illiteracy the change has been modest. But where women have more opportunities and economic progress has been more marked — as in Thailand, Indonesia and Colombia — the decline in birth rates has been remarkable.

In fact, fertility rates in many developing countries are declining much faster than they did in the United States. While it took 58 years for the average family size in the United States to shrink from 6 to 3.5 children (1842-1900), it took only 23 years to accomplish the same results in Indonesia (1961-1984) and only eight years in Thailand (1969-1977).

We also know that couples want help in planning the size of their families. Demographic Health Surveys show that in many countries 50 to 80 percent of couples want family planning. The women who crowd the abortion wards of so many Third World hospitals provide further testimony.

The 1990s will see a significant increase in the number of women reaching childbearing age. To lower fertility rates further, we must raise contraceptive use for this expanding population. FHI estimates that we need to increase the number of contraceptive users in developing countries (excluding China) by at least 68 percent by the year 2000. Compared to our previous work in family planning, this is indeed a formidable challenge. But compared to the dollars spent for other budget priorities, it will cost very little — actually no more than just a penny a day for each taxpayer in the developed world to help their counterparts in developing countries.

For Family Health International and our friends around the world, the 1990s will be a critical decade. We will not succeed by merely doing more of the same. We are on the front lines of a historic battle. We must do everything we can today to win a better future for all.

— *Dr. Malcolm Potts, President, FHI*

FHI research news

PEER EDUCATION: LEARNING HOW TO CHANGE HIGH-RISK BEHAVIOR

From street corners, hotels and bars, commercial sex workers in developing countries are learning about AIDS prevention, through a series of projects involving a process known as peer education. In this approach, sex workers are trained to teach their co-workers about the human immunodeficiency virus (HIV) that causes AIDS, and about the importance of using condoms.

Pilot projects to study peer education have been conducted among female sex workers in Ghana, Cameroon and Mali, with technical assistance from Family Health International. Findings have provided valuable lessons for these and other peer education programs.

For example, in each of the pilot projects, prostitutes who received health information from their peers reported increased condom use with their paying clients. However, the sex workers acknowledged that they usually don't use condoms with their regular partners. In addition, the women said they sometimes do not use condoms with clients who refuse to wear them.

Such reports of increased — but inconsistent — condom use underscore the complex nature of relationships among sex workers, their clients and their regular partners. Researchers acknowledge that they still have a lot to learn about sustaining behavior change among this population.

"These pilot projects have been very promising, a good start," says Jim Spilsbury, Francophone Africa project coordinator for AIDSTECH, the Family Health International (FHI) project working on preventing AIDS in developing countries. "But they raise questions about the next steps. For example, there was nothing in these studies directed at the clients and regular partners."

Each of the pilot projects used the same basic approach. Leaders within the prostitute community were identified, recruited and trained regarding HIV/AIDS and prevention of infection and transmission. Peer leaders then worked directly with other sex workers — educating them about HIV/AIDS, providing information about safer sexual practices and distributing condoms.

The projects varied in recruitment methods, follow-up approaches and distribution systems for the condoms. In some of the projects, the condoms provided were spermicidally treated. In several of the countries, the prostitute leaders encouraged their peers to use a spermicide suppository when a client would not use a condom.[1]

"These pilot projects have been very promising, a good start. But they raise questions about the next steps."

The pilot project in Ghana

In early 1986, no clinical case of AIDS had yet been diagnosed in Ghana; testing showed that only one of 98 prostitutes living near Accra, the capital, were infected with HIV. By the end of 1986, however, testing showed 72 Ghanaians infected with the virus, 63 of them women. Many of these women reported that they had recently come back to Accra, their home, after participating in commercial sex work in other African countries.

The strategy of this first pilot project was to test the feasibility of an approach to contain the spread of HIV infection in Accra by increasing the use of condoms and spermicides among sex workers. The Ghana Technical Committee on AIDS directed the project; FHI provided technical assistance with funding from the American Foundation for AIDS Research (AMFAR). The chair of the Ghana committee, Dr. Alfred Neequaye, directed the on-site project work.

In the spring of 1987, Dr. Neequaye and his project team organized discussions with small groups of female prostitutes at three sites where sex workers congregated and where there was an informal network of communication among them. Most of the women had heard of AIDS but did not know how it was transmitted, the project team learned. The women thought they were at elevated risk but didn't know how to protect themselves. These discussions led to the identification of six women who had senior status among their peers and the ability and motivation to counsel others.

The project staff and peer educators recruited sex workers for the program. After being trained, six peer educators talked with 72 other prostitutes about AIDS and supplied them with condoms and spermicidal foaming tablets. The educators, who were paid a monthly stipend, delivered the condoms and spermicides in informal, convenient ways

(often at homes) rather than on a prescribed schedule, such as a weekly appointment. The condoms and spermicides were given to the women free of charge.

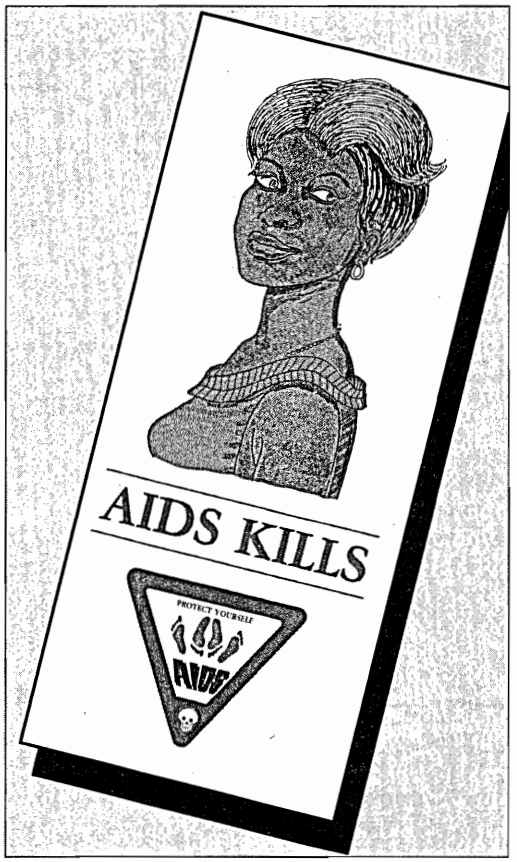
At the beginning of the project (June 1987), 72 prostitutes completed a survey on knowledge, attitudes and practices concerning AIDS/HIV and sexual practices. In January 1988, when the pilot project ended, only 45 of the original 72 women completed the follow-up interview. Before the peer education process had begun, one in three of the women (among the original 72) understood correctly that they they could contract AIDS from a man who appeared to be healthy; at the end of the study nine out of 10 women (among the final 45) understood this point.

Reported use of condoms and/or spermicides with customers increased dramatically during the six-month period. Only 9 of 72 women (13 percent) reported regular use of condoms and/or spermicides at the beginning of the project. Six months later, 40 of the 45 women completing the survey (89 percent) said they were using condoms and/or spermicides regularly.[2]

There are some problems with these results, however. The final group of 45 women was much smaller than the original 72; they might have been the ones most motivated to use condoms. Additionally, it should be noted that *reported* condom use was not validated externally to determine to what extent condoms were *actually* used. AIDSTECH is currently developing strategies to validate reported condom use, including monitoring the incidence of STDs.

The Ghana project also showed the difficulties in relating reported condom use to rates of HIV transmission. "This may be a significant enough increase in condom use to reduce the spread of HIV infection among the population, but there were not enough women enrolled in the program to assess adequately to what extent the increased use of condoms slowed the incidence of HIV infection," reported the FHI Ghana project team.

Unforeseen benefits arose during the project as well. As word spread among sex workers about the purpose of the condoms, more women wanted to



This brochure was used in FHI's first peer education project in Ghana.

participate. After the pilot study in Ghana had begun, another 144 prostitutes were enrolled in a supplementary program. This group had to purchase the condoms at wholesale prices through the Ghanaian social marketing program.

FHI is now working with the Ghana Ministry of Health to develop and implement a city-wide health education and condom distribution program for sex workers and their partners.

Peer education expands to other countries

Since the Ghana pilot project, peer education has been incorporated into many HIV intervention efforts. Projects similar to the Ghana study have been completed in Cameroon and Mali, with assistance from FHI and funding from USA for Africa. Other HIV intervention projects involving peer education are underway in Zimbabwe, Nigeria,

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As word spread among sex workers about the purpose of the condoms, more women wanted to participate.

Peer Education

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Tanzania, Kenya, Burkina Faso, India, Mexico and the Dominican Republic.

Lessons from the Ghana pilot effort have been incorporated into many of these studies. Survey questions have been refined, as have expectations regarding, for example, the number of women who are likely to continue to participate in the full project and the ability to determine if the HIV transmission rate is declining.

Projects in Cameroon and Mali have confirmed the basic findings in Ghana: Peer health education may be an effective way to provide HIV/AIDS information to commercial sex workers, and it results in reports of increased condom use. However, it is still not known whether actual condom use is increasing significantly or whether this behavior change will be sustained over a long period of time.

The Mexican project is the first FHI-assisted peer education effort conducted as part of an existing family planning program.

In Cameroon, 11 female prostitutes received a monthly stipend to work with 125 of their peers. As in Ghana, a large number of women dropped out of the study. However, this is not surprising since sex workers in Cameroon, as elsewhere, are very mobile and often change their places of employment. Among the 73 prostitutes who completed the final interview, the number reporting frequent condom use jumped eight-fold, from 6 to 48 percent.

The popularity of the Cameroon program resulted in additional prostitutes receiving educational materials and condoms, as it had in Ghana. FHI is providing technical assistance and funding to the Cameroon National AIDS Control Service to expand the program to an estimated 10,000 prostitutes and clients in three cities.

In another effort, the Mexican Federation of Private Family Planning Associations (FEMAP) in 1988 began integrating a peer education project into its existing family planning program. In the first year, the FEMAP research team conducted surveys throughout a large "red light" district frequented by Mexicans and by foreigners crossing the border from El Paso, Texas. It is a highly organized, complex business, involving an estimated 1500 commercial sex workers working out of specific establishments and on the streets. FEMAP's efforts include on-site education programs and peer education training.

The project enrolled and trained 74 prostitutes as peer educators. In December 1989, 56 were still involved in the program, reflecting a 23 percent dropout rate. These peer educators are providing information to an average of 255 commercial sex workers per month. Results of reported condom use are not yet available. The Mexican experience is the first FHI-assisted peer education effort conducted as part of an existing family planning program.

Limitations of peer education

Researchers are cautious about reaching definitive conclusions from peer education efforts. "This is a mobile population," says Mr. Spilsbury of AIDSTECH, who is working on expanded programs in Mali and Cameroon. "The women who drop out are probably the ones not using the condoms. So the study results have a bias towards those most likely to use condoms. Plus, this is *reported* use. We can't be certain of their actual behavior."

Perhaps the most striking limitation to these research projects is the degree to which they fail to influence the behavior of clients and regular partners. In the follow-up interviews in the Cameroon project, for example, 63 percent of the prostitutes reported that their clients were opposed to using condoms. When the client refused to use a condom, more than one-third of the prostitutes had sex with no protection, a third used a spermicide, and nearly one-third refused sex. Other studies show that women who rely on commercial sex work to support themselves and their families are reluctant to antagonize clients who are unwilling to use condoms and might take their business elsewhere. Moreover, these women may wish to marry and become pregnant, thereby reducing their incentive to use condoms with their regular partners.

"Peer education is a good way to reach prostitutes and to increase the use of condoms," says Dr. Peter Lamptey, director of AIDSTECH. "But to be effective, it has to be part of a larger strategy that reaches clients and regular partners, as well as other high-risk groups. And, condoms must be readily available to the target population." ■

Footnotes

[1] Virtually all spermicides produced in the United States contain the compound nonoxynol-9, also known as N-9. It is the active ingredient in spermicide products that kills the sperm as well as HIV in the seminal fluid. Laboratory tests have shown conclusively that N-9 kills HIV in vitro, even at low concentrations. Other active ingredients, including

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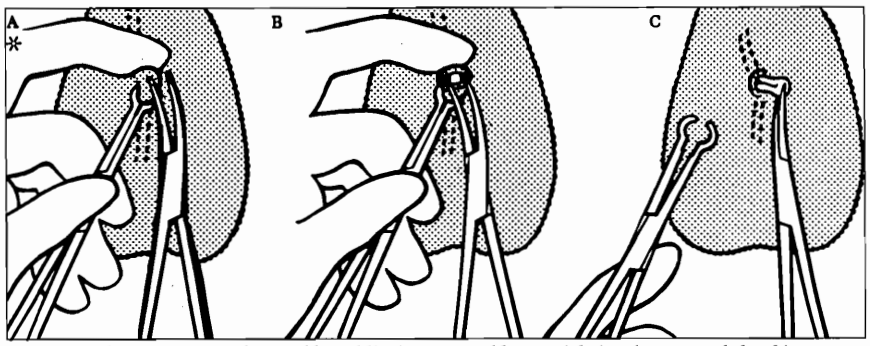
THAILAND ENCOURAGES NO-SCALPEL VASECTOMIES

Fifteen years ago, Chinese surgeon Li Shunqiang introduced a new contraceptive technique to his countrymen: the "no-scalpel" vasectomy. Ten years later, doctors from other countries went to China and observed the procedure for the first time. To date, "no-scalpel" vasectomies have been performed on more than 8 million men in China and more than 20,000 in other countries.

In December 1989, in Bangkok, Thailand, more than 50 physicians and family planners from 14 countries convened the first international symposium on no-scalpel vasectomies. They agreed that this procedure has less bleeding and fewer complications than conventional vasectomies. The meeting coincided with the vasectomy festival held annually in Thailand as part of the King's Birthday celebrations. Nearly 800 men received no-scalpel vasectomies at the 1989 festival.



Tom Yagle, Outlook, PATH 1988

*In a no-scalpel vasectomy the vas (dotted line) is grasped by special ring forceps and the skin and the vas sheath are pierced by sharp-tipped dissecting forceps (A). The forceps then stretch an opening (B) and the vas is lifted out (C). * Illustration has been altered slightly.*

A traditional vasectomy — performed under local anesthesia — requires a scalpel, incision and stitches. With the no-scalpel approach — also performed under local anesthesia — a physician makes a tiny puncture in the scrotum with a small, forceps-like instrument with two sharp points. Using the same instrument, the doctor stretches the hole, just large enough for the vas deferens to be pulled out and then ligated and tied in order to prevent sperm from reaching the seminal fluid. No sutures are required to close the puncture.

Li Shunqiang, the Chinese surgeon who originated the technique, spoke at the 1989 Bangkok conference. From 1974-1985, Dr. Li and his associates used the no-scalpel procedure exclusively in China.

In 1985, at the invitation of the State Family Planning Commission of China, the Association for Voluntary Surgical Contraception (AVSC) brought a team of experts to China from the United States, Egypt, Thailand and Singapore to observe sterilization techniques, including the no-scalpel vasectomy. A U.S. surgeon, Marc Goldstein of Cornell University, returned to China in 1986 and was trained in the technique himself.

In 1986, under the sponsorship of the AVSC, Drs. Li and Goldstein trained doctors from Thailand, Nepal, Sri Lanka and Bangladesh in the no-scalpel procedure. Among those trained was Apichart Nirapathpongporn, director of the Medical and Nursing Bureau of the Population and Community Development Association in Thailand. Dr. Apichart has become a world leader in the no-scalpel technique, training 35 surgeons in 11 countries and serving as the chair of the local organizing committee for the 1989 symposium. To date, no-scalpel vasectomies have been performed on about 8,000 men in Thailand, including about 3,000 at the last three King's Birthday celebrations in Thailand.

In 1988, AVSC and the Los Angeles Family Planning Council introduced the no-scalpel vasectomy to the U.S. medical community; so far 44 U.S. physicians have been trained in the procedure. Later that year, AVSC sponsored a training session in Bogota, Colombia, where Dr. Apichart trained physicians from Guatemala, Brazil and Colombia. ■

— For further information, contact: Dr. Roberto Rivera, Family Health International, P.O. Box 13950, Research Triangle Park, N.C. 27709 USA (919-544-7040); Dr. Douglas Huber, Medical Director, Association for Voluntary Surgical Contraception, 122 East 42nd Street, New York, N.Y., 10168 USA (212-351-2510); or Dr. Apichart Nirapathpongporn, Director of Medical and Nursing Bureau, Population and Community Development Association, 8 Sukhumvit, Soi 12, Bangkok 10110, Thailand, (66-2-2558804).

HIV AND PROSTITUTION: A REPORT ON A SPECIAL WHO MEETING

Participants emphasized the need to reach beyond commercial sex workers to their clients and regular partners.

Preventing the spread of HIV infection among prostitutes, clients and partners is both controversial and complex. In some cases, commercial sex workers feel that they are being blamed unfairly for the spread of AIDS. At the same time, some policy makers are reluctant to spend public money on such a stigmatized population. Finally, health-care providers may wonder how best to assist a special population of which they have little knowledge or understanding.

Nevertheless, efforts to control the spread of AIDS are focusing increasingly on prostitution. By definition, prostitutes engage in sex with multiple partners, placing themselves at high risk for infection with the human immunodeficiency virus (HIV) that causes AIDS. Moreover, in many settings — particularly in large Western cities — some sex workers are also intravenous drug users (or have partners who are), putting them at additional risk for HIV infection.

Projects underway around the world have had varying degrees of success in persuading prostitutes and their partners to modify high-risk behaviors. To review available information on current intervention strategies, the World Health Organization's Global Programme on AIDS (WHO-GPA) convened a special meeting last summer in Geneva. Twenty-two participants from 18 countries attended the four-day meeting, including experts in medical anthropology, prostitution, epidemiology, program evaluation, biomedical research and the social science aspects of AIDS and other sexually transmitted diseases (STDs). It marked the first time that representatives of prostitutes' advocacy groups had ever attended a WHO consultation.

Participants at the Geneva meeting reported on a variety of projects involving peer education, information dissemination, condom distribution, and HIV control and treatment programs for commercial sex workers and their clients. They also discussed alternative employment programs for prostitutes seeking to leave the sex industry. The meeting featured reports on activities in Australia, Brazil, Cameroon, Costa Rica, the Dominican Republic, Ghana, Greece, Kenya, Mexico, the Netherlands, Peru, the Philippines, Thailand, the United States and Zaire.

Because there are many types of sex workers, different approaches are necessary to gain their interest and cooperation in educational programs. Programs may be based within prostitute organizations, health clinics or communities. Education efforts may include AIDS prevention counseling, training on the correct and consistent use of condoms, and prevention and treatment of STDs. Finally, participants noted, the content of the message must be simple and understandable within the context of the local culture.

Again and again, participants at the WHO meeting emphasized the need to reach clients and regular partners, as well as prostitutes. Yet, most intervention projects have left client education to the sex workers themselves, who have a financial stake in not alienating or frightening their customers. Moreover, strategies that work with female prostitutes may not be effective with clients, because men and women may be motivated by different factors. Participants suggested that client education programs could take place at sites where sex workers meet their patrons, such as at bars and hotels; at work places, such as factories and transport companies; at clinics where clients may receive treatment for STDs; and at military camps.

The WHO meeting also focused on the need for expanded efforts to market and distribute condoms, prevent and control other STDs related to HIV transmission, and evaluate the effectiveness of programs. In addition, participants discussed the policy and legal barriers to effective intervention efforts among prostitutes and clients. For example, in areas where prostitution is illegal, mandatory registration and testing for HIV infection might drive sex workers underground and make them less likely to take advantage of prevention and treatment services. Similarly, the illegality of prostitution can make it difficult for health workers to reach sex workers and clients.

A Consensus Statement summarizing the findings of the WHO meeting recommended expanded efforts for preventing HIV infection in prostitutes and clients through program development,

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NUTRITION TRAINING MANUAL AVAILABLE

A Spanish-language nutrition training manual used by family planning workers in Latin America is now available in English. **Nutrition Education for Family Planning Workers**, produced by Development Associates, is designed for training field workers and family planning service delivery personnel.

For additional information contact: Development Associates, Population Programs Division, 2924 Columbia Pike, Arlington, VA 22204, USA. ■

TRAINING FILMS PRODUCED IN KENYA

The Family Planning Association of Kenya and the Association for Voluntary Surgical Contraception have released two training films produced entirely in clinics and hospitals in Kenya.

- Intended for use in training programs for doctors and operating room nurses, **Minilaparotomy for Voluntary Surgical Contraception** portrays both postpartum and interval minilaparotomy procedures performed under local anesthesia.
- **Counseling: Helping People Make Family Planning Choices** is useful for African policymakers, program managers and health-care providers who counsel family planning clients. Both films are available in English and French as 16-mm films and as videos (NTSC, PAL and SECAM). For further information, contact the Association for Voluntary Surgical Contraception, 122 East 42nd Street, New York, NY 10168, USA. Telephone 212-351-2507, fax 212-599-0959, telex 425604. ■

WHO meeting

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implementation and evaluation. The statement stresses the need "to engage as rapidly and forcefully as possible" in activities to reduce HIV infection of prostitutes, clients and partners. Participants also agreed that interventions "should be designed in consultation with sex workers, and should not be impeded by legal structures." Furthermore, they recommended, "Plans should be drawn up — and budgets identified —immediately."

Other recommendations from the WHO meeting include the following:

- Governments should be encouraged to acknowledge the presence of prostitution within their countries and the urgency of developing effective interventions.
- Economic analysis should be conducted regarding the cost of condoms, the availability of alternative employment and the importance of sex work to the national economy.
- Research should be conducted to increase understanding of the knowledge, attitudes, beliefs and practices associated with prostitution — including drug dependency and sex work involving adolescents and children.
- Research should investigate the nature of male resistance to using condoms.
- A forum should be established for information dissemination about existing interventions, policies, research and funding.
- Technical support and funding should be ensured for the evaluation of existing interventions and the development of new and innovative strategies.
- HIV education, support and prevention services should be provided, expanded and integrated into overall health care services. ■

—For a copy of the "Consensus Statement on HIV Epidemiology and Prostitution," write to the World Health Organization/ Global Programme on AIDS, CH-1211, Geneva, Switzerland.

HIV interventions among sex workers "should not be impeded by legal structures."

Footnotes

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benzalkonium chloride and menfegol, are used in spermicide products manufactured elsewhere and seem equally effective against HIV.

[2] The most conservative way to report these data would be to note that reported condom use went from 19 to 56 percent, rather than 19 to 89 percent. Forty of the 45 women in the follow-up interview said they used condoms and/or spermicides regularly. Under this conservative approach, the 40 would be at least 56 percent of the original 72 women. The 56 percent figure assumes none of those who dropped out of the study were using condoms.

AIDS PREVENTION HANDBOOK

Family Health International is publishing a handbook for program managers and health-care providers on approaches and methodologies for implementing AIDS prevention programs in sub-Saharan Africa. **The Handbook on AIDS Prevention in Africa**, edited by Peter Lamptey, M.D. Dr.P.H., Director of FHI's AIDSTECH Division, and Peter Piot, M.D. Ph.D. of the University of Antwerp, covers the following topics:

- Epidemiology of AIDS in Africa
- HIV testing
- Epidemiologic surveillance methods
- Reducing HIV transmission through blood
- Control and prevention of sexually transmitted diseases
- Communication strategies in AIDS prevention
- Competency-based training for AIDs prevention
- Targeting of prevention programs
- Condom programming for AIDS prevention
- Counseling in AIDS
- Community-based management of AIDS
- AIDS prevention in family planning programs
- Primary health care and AIDS control programs
- Evaluation of AIDS control programs

Copies of the handbook will be available from FHI in June. For more information, please write to: Debbie Wade, Publications Assistant, Family Health International, P.O. Box 13950, Research Triangle Park, N.C. 27709 USA.

'FACTS FOR LIFE' TRANSLATIONS AVAILABLE

Facts for Life, a 78-page booklet explaining low-cost health measures that can save millions of children's lives in the developing world, has been translated into native languages of the following countries: Afhanistan (Dari and Pashto), Bangladesh (Bangla), Burma (Burmese), Burundi (Kirundi), China (Chinese, Uygurs, Kazaks, Mongolian, Korean, Tibetan, Bai, Lisu, Lawu and Nasi), Egypt (Egyptian), Ethiopia (Amharic), Ghana (national adaptation) India (several local languages), Indonesia (national adaptation) Iran (Farsi), Kampuchea (Khmer), Malawi (Chichewa), Mali (Sonrai and Tamacheq), Mexico (national adaptation), Mozambique (Mozambican Portuguese), Nepal (Nepali), Nigeria (Ibo, Hausa, Yoruba and Pidgin English), Pakistan (Urdu), Philippines (four local languages), Rwanda (Kinyarwanda), Senegal (national adaptation), Sierra Leone (national adaptation), Sri Lanka (Sinhala and Tamil), Sudan (national adaptation), Swaziland (national adaptation and Siswati), Tanzania (Swahili), Thailand (Thai), Togo (Togolese), Viet Nam (Vietnamese), Zambia (seven major Zambian languages) and Zimbabwe (Shona and Ndebele).

For further information, contact UNICEF House, DIPA, H9F, Facts for Life Unit, 3 UN Plaza, New York, NY 10017, USA.

Facts for Life is also available at no cost in English, Spanish and Portuguese from Family Health International, P.O. Box 13950, Research Triangle Park, NC 27709 USA.

Footnotes

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Reaction for Early Detection of the Proviral Sequences of Human Immunodeficiency Virus in Infants Born to Seropositive Mothers, *The New England Journal of Medicine*, 320(25), 1989, p. 1649.

[3] T Manzila et al. Perinatally Acquired HIV Infection (PI): Absence of an Additional Risk Due to Breastfeeding in a Cohort of 108 Infants Born to HIV(+) Mothers, *Les Implications Du SIDA Pour La Mere et l'Enfant — Resumes/Abstracts*, Conference Internationale Paris, November 27-30, 1989, p. 19.

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A PENNY A DAY CAN HELP SOLVE POPULATION CRISIS

Solving the global population crisis is both achievable and affordable, according to a new report from Family Health International (FHI). The report, entitled "A Penny a Day," argues that the United States and other industrialized nations can help reduce the rate of global population growth to manageable levels by the year 2000 by spending about $1 billion annually — or less than one cent per day per taxpayer — to expand family planning options for developing countries.[1]

If current growth patterns continue, the population of the world will triple from over 5 billion today to about 15 billion. However, if family planning services are made available around the world, global population could stabilize at about 10 billion, according to the FHI report.

Family planning already has had a dramatic effect on birth rates in countries where contraception is available, according to the report. In fact, family size in many developing countries has decreased faster than it has in the United States. While it took 58 years for the average family size in the U.S. to shrink from 6 to 3.5 children (1842-1900), it took only 23 years to accomplish the same dramatic transition in Indonesia (1961-1984) and only eight years in Thailand (1969-1977).

Still, many parts of the developing world lack adequate family planning services. Moreover, the world's population has grown at an unprecedented rate in recent years. In order to reduce this growth rate, FHI estimates, the number of contraceptive users in developing countries must increase by at least 68 percent by the year 2000.

However, in recent years, industrialized nations have decreased their level of financial assistance for family planning programs in developing countries. According to FHI only 1.3 percent of total overseas development aid from industrialized nations now goes toward helping to provide family planning services in developing countries. In fact, U.S. consumers spend more money each year on Halloween costumes than industrialized nations combined spend to help developing countries with family planning.

"We are facing a critical crossroads," said Dr. Potts. "If we want to stabilize the world's population at a reasonable level, we must commit the necessary resources now, before it is to late."

Footnote

[1] The total workforce in industrialized nations is about 517 million. If you multiply this figure by $3.65 (1 cent per day for 1 year), the total is $1.9 billion per year, more than the estimated $1 billion needed in foreign technical and financial assistance to achieve the UN's "medium" world population projection of 6.25 billion by the year 2000.

U.S. consumers spend more money each year on Halloween costumes than industrialized nations combined spend to help developing countries with family planning.

FAMILY PLANNING SCHOLARSHIP

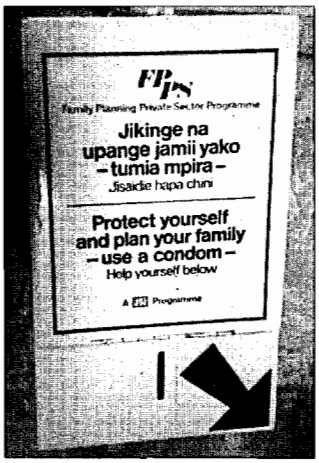
Organon, a pharmaceutical company based in the Netherlands, is offering a special scholarship for family planning providers in developing countries. The Organon Family Planning Scholarship covers the cost of post-graduate study of up to one year at a reputable institute or clinic of the recipient's choice.

The award is open to candidates (not older than 45 years of age) who are already active in family planning, but seek further training and research opportunities in this field. Previous winners have come from Nigeria, People's Republic of China, Tanzania and Zimbabwe.

Applications must be received by May 1. For information, write to: Organon International BV, Institutional Affairs and Family Planning Department, P.O. Box 20, 5340 BH OSS, The Netherlands.

CORRECTION

A recent **network** article (Vol. 11, No. 1) on pill user compliance contained an error regarding the level of progestogen in oral contraceptives (OCs). The article should have stated that the first OCs contained as much as five times the progestogen as some of today's low-dose formulations.



Peter Lamptey / FHI

This condom dispenser in Nairobi displays a dual message: Plan your family and prevent HIV transmission.

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FHI publications are available at no cost to interested persons. For copies, please write to Ms. Debbie Wade at Family Health International, P.O. Box 13950, Research Triangle Park, NC 27709 USA.

Letter from the Editor

Continued from page 2

One story notes that oral contraceptives are now considered safe for most women over 40. Another provides a brief update on an emerging contraceptive procedure for men known as the no-scalpel vasectomy.

In preparing this issue of **network**, we were reminded that family planning and AIDS prevention efforts grow more urgent — and more intertwined — every day. ■

—Dee Reid

Blood

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infection that continues to drive this attention to safe blood.

"Development of integrated blood transfusion services may take years to achieve maturity," explains the report on the Global Blood Safety Initiative formation meeting. "It is essential that the need to encourage development of integrated blood transfusion services should not inhibit active and aggressive efforts to prevent transmission of HIV and other infectious agents through blood transmission." ■

— William R. Finger

FAMILY HEALTH INTERNATIONAL

network

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POSTPARTUM CONTRACEPTION: DEVELOPING STRATEGIES FOR EXPANDED SERVICES

Every day thousands of women all over the world give birth at hospitals and maternity clinics. For many women living in developing areas, childbirth is the *only* time they receive medical care in a clinical setting. These women may not return until they are ready to deliver their next baby. Without access to family planning counseling and effective contraceptive methods, they are likely to become pregnant again within a year or two.

However, where contraceptive information and services are available to women receiving maternity care, many choose to begin using contraception in the postpartum period — generally defined as the first 42 days after delivery. Some elect to have an IUD inserted immediately after delivery, or to undergo sterilization while still in the hospital. For example, under a postpartum contraceptive program administered by the Mexican Institute of Social Security (IMSS), more than half of 650,000 women who gave birth last year began using contraception — or underwent sterilization — before they left the hospital (see related story on page 17).

This is one example of a program designed to provide contraceptive methods to postpartum women, while they are hospitalized for labor and delivery. However, for programmatic and policy reasons, a postpartum program does not have to be restricted to providing family planning information and services at the hospital – or even only during the standard 42 days postpartum.

For example, women who breastfeed fully receive a natural form of postpartum contraception for six months or more. They need information about how to breastfeed effectively and when to begin using another method before the contraceptive benefits of breastfeeding begin to wane. Moreover, many women don't deliver their babies at the hospital; they would be served most effectively by programs that can offer safe and effective postpartum contraceptive information and services in settings closer to their homes.

"The point of any family planning program is to ensure that women have the

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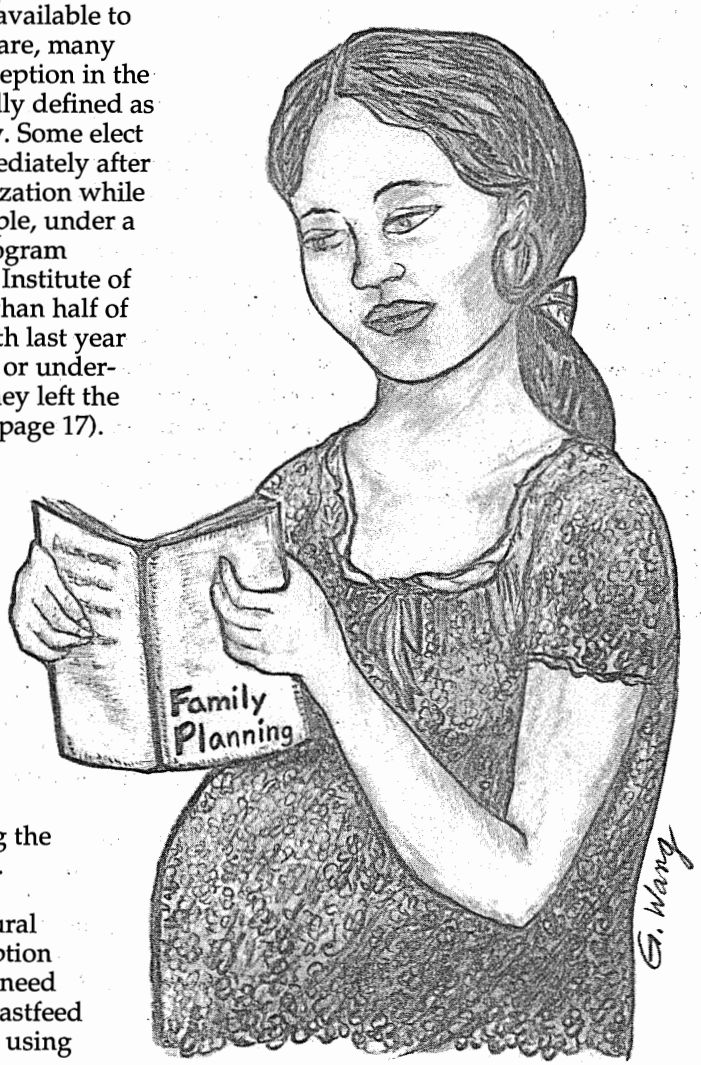


editorial

THE NEED FOR POSTPARTUM CONTRACEPTIVE SERVICES

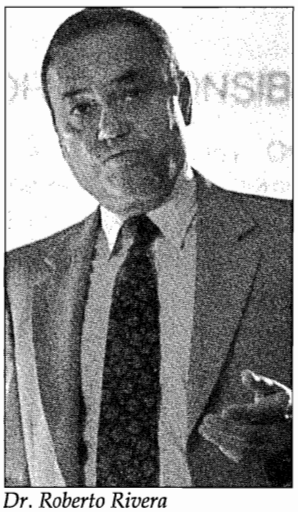
For several years, Family Health International (FHI) has been involved in the clinical evaluation of various contraceptive methods to determine their potential for use in the postpartum period, including IUDs, female sterilization procedures and progestin-only pills. At the same time, there has been a growing interest among health-care providers and policymakers in finding ways to offer family planning options to women in the postpartum period.

In response, FHI has made a special commitment to further explore this issue by co-sponsoring the International Conference on Postpartum Contraception, September 17-20, 1990 in Mexico City, in conjunction with the Mexican Institute of Social Security (IMSS) and the Mexican Ministry of Health. This conference will be the first in a series of expert meetings on this subject; subsequent regional gatherings are being planned for Africa and Asia.

Postpartum contraception has been defined in different ways, mostly reflecting particular programmatic situations. For the purpose of the Mexico City conference, postpartum contraception will include the provision of contraceptive services from the time of delivery through the sixth postpartum week, as well as the provision of such services to breastfeeding women well beyond the sixth week postpartum.

Several family planning programs have initiated postpartum contraceptive programs. In some locations, postpartum contraceptive services have been integrated successfully into existing maternity services. Hospitals and clinics that already provide maternity services have both the technology and personnel needed for postpartum contraceptive services. Providing additional training to existing personnel can be achieved without major investment. In addition, postpartum contraceptive services have been incorporated successfully into some other health services, including maternal and child care.

The primary purpose of the Mexico City conference is to promote the further integration of postpartum contraception into family planning programs, maternal and child care, and reproductive health services. To this end, FHI has invited a multidisciplinary group of experts to participate in the meeting. They represent the major health and social disciplines involved in the field of contraception, including both clinical and programmatic functions. Participants will be encouraged to share their ideas about the potential benefits, concerns and unresolved research questions associated with postpartum contraception.


Jerry Markatos

Dr. Roberto Rivera

At the initiation of the conference, presenters will discuss the determinants of postpartum fertility for breastfeeding and non-breastfeeding women. These discussions will establish the basic grounds to address two issues: 1) the appropriate time to initiate different contraceptive methods in the postpartum period and 2) duplication of contraceptive coverage in amenorrheic breastfeeding women.

Much of the conference will be devoted to discussing the clinical and programmatic requirements associated with the use of a variety of contraceptive methods in the postpartum period. It is necessary to have a choice of methods to meet the needs of different couples and to fit the resources of various programs. Moreover, although the role of breastfeeding as a fertility regulating method is accepted widely, the conditions for its programmatic use still require more precise guidelines.

We believe that the Mexico City conference will be an important step towards expanding postpartum contraceptive options to thousands of women who otherwise might not receive adequate family planning services. We will report on the outcome of the meeting in a future issue of **network**. ■

– Dr. Roberto Rivera,
Director, Clinical Trials Division, FHI

FHI

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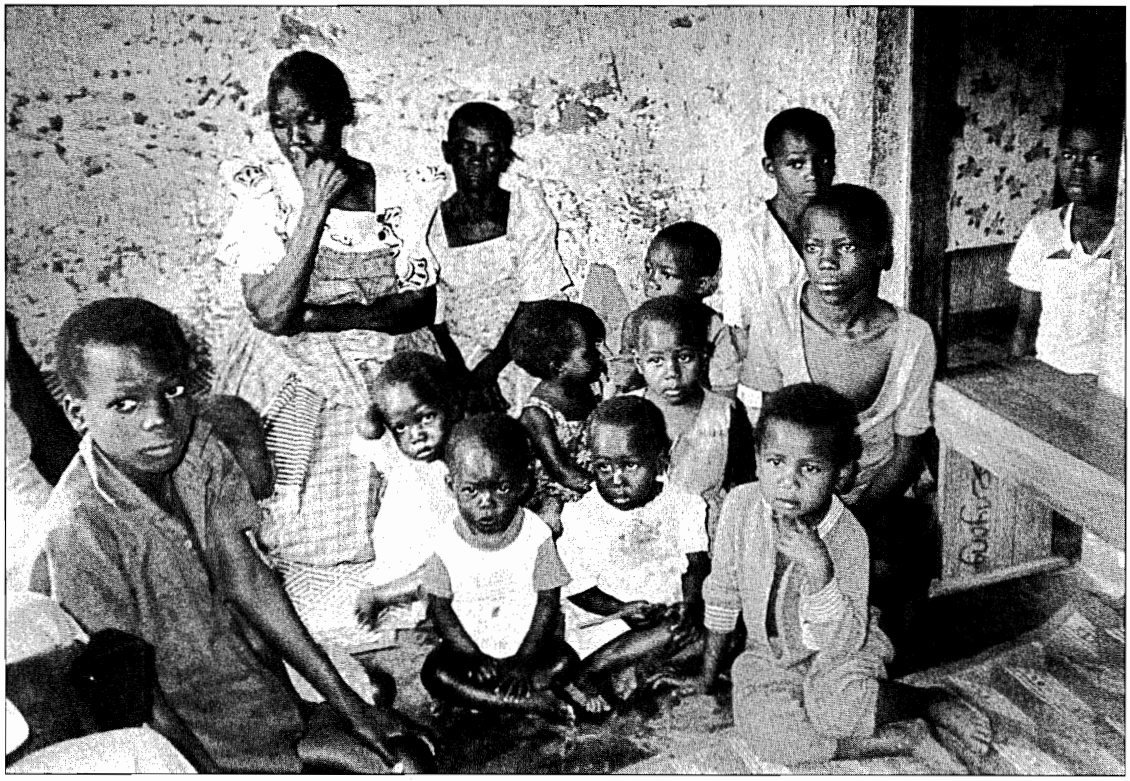
PEDIATRIC AIDS: CHILDREN DRAMATIZE THE FAR-REACHING COSTS OF THE PANDEMIC



Jane Perlez/The New York Times

A woman in Mutikula South, Uganda cares for her 12 grandchildren orphaned by AIDS.

In 1982, the mainstream medical community had not yet acknowledged that AIDS was killing children. A prestigious U.S.-based journal rejected a paper on pediatric AIDS by a New York City immunologist already treating young children dying of the disease. Journal editors said they needed more proof that children could contract AIDS.

Now the World Health Organization (WHO) estimates that by the end of 1992 — just a decade later — about 1 million babies will have been born with the human immunodeficiency virus (HIV) that causes AIDS. Moreover, epidemiologists at the U.S. Agency for International Development estimate that AIDS may well reverse gains made in reducing infant and child mortality rates in the developing world.[1]

As HIV is increasingly transmitted by heterosexual contact throughout the world, infected women are passing the virus to their newborns. Speaking before the WHO conference on the "Implications of AIDS for Mothers and Children" held in November 1989, Dr. Jonathan Mann, then Director of WHO's Global Programme on AIDS, summarized disturbing data from throughout the world: HIV had been detected in 24 percent of pregnant women tested at one site in Kampala, Uganda; in 55 percent of infants under 18 months tested in orphanages in Port-au-Prince, Haiti; and in 4.3 percent of pregnant women tested at a site in Newark, N.J. in the United States.

"Yet these rates and statistics necessarily fail to convey the impact of HIV infection in women, mothers and children — the destruction of families, the poison of discrimination and prejudice, the fear and reality of abandonment," Dr. Mann told the WHO meeting. Moreover, he noted, the impact of AIDS on women and children has highlighted the "imbalances, deficiencies and inequities in existing health and social systems."

The ways in which AIDS affects children — including infants born with the HIV infection and youngsters whose parents die of AIDS — dramatize how the pandemic is altering the fundamental social, cultural, economic and political fabric of many countries. At the same time, pediatric AIDS might also force policymakers, health officials, donor groups and potential parents to address basic issues in combating the pandemic — from managing underfunded primary health-care systems to frank talk about sex.

Pediatric AIDS has already produced three specific challenges: how to prevent further transmission of HIV from adults to children, how to provide for children who become orphans when their parents die of AIDS, and how to care for infected children.

In addition, pediatric AIDS affects overall health-care funds available for children. UNICEF estimates that each week 250,000 children die in the developing world from preventable diseases and malnutrition.[2] This figure

dwarfs WHO's projected total of about 1 million infants born with HIV by the end of 1992. But the AIDS pandemic has just begun. The real death toll will only become clear in the future. Moreover, HIV infection, by weakening the immune system, is already inviting new and more aggressive epidemics of tuberculosis and other diseases.

"The primary and most important strategy for preventing further HIV transmission to children is to keep mothers and fathers from getting the virus in the first place."

Preventing further HIV transmission

Children get infected with HIV primarily by their mothers during either pregnancy or childbirth.[3] In developing countries mothers may have received the AIDS virus through sexual contact with an infected man, through a transfusion of blood from an HIV-infected donor, or in limited cases, through intravenous (IV) drug use. Sometimes children are infected through blood transfusions and in rare cases by HIV-infected needles. Basically, infants get infected with HIV because adults get infected and transmit the virus to children.

"The primary and most important strategy for preventing further HIV transmission to children is to keep mothers and fathers from getting the virus in the first place," explains Dr. Peter Lamptey, Director of AIDSTECH, a division of Family Health International.

This strategy underlies virtually all intervention efforts in the developing world. Prevention programs and strategies vary depending on many factors, including location (urban vs. rural), the behaviors of targeted populations, knowledge and attitudes about AIDS, approaches to safe sex, research questions and political considerations .

"The second line of defense, after these primary efforts, involves preventing HIV-infected women from transmitting the virus to infants," says Dr. Lamptey.

The most obvious way to target this group involves screening and counseling women of childbearing age. But such an approach has many problems, including cost, cultural issues, emotional impact and unresolved research questions about HIV/AIDS. Costs for blood testing alone can be prohibitive. A test for the HIV antibody costs about US $1.50 per person, but many developing countries spend only $5.00 per person a year on all health care. Such cost contraints mean that HIV testing has to target small groups of women, such as those going to STD (sexually transmitted disease) clinics, those whose children have AIDS, and those whose sex partners have AIDS or may have HIV. Still, even this approach seems impractical.

"Screening is not a feasible option," explains Dr. Lamptey. "First, it is difficult to reach the right people. And, even if you did, there is little you could do to counsel them or change their minds [about having children]. What are you going to tell them?"

For many women, having babies is fundamental to their role in society. If a pregnant woman tests positive for HIV, she might not want to have an abortion (even if it were legal and available). Having a baby is especially important in countries where the infant mortality rate is as high as 15 percent (150 deaths per 1,000 infants under age one), making the odds for infant survival poor. Moreover, research has shown that HIV-infected mothers pass the virus to their newborns only 20 to 40 percent of the time, leaving 60 to 80 percent of the newborns uninfected with HIV.[4]

Research questions further cloud the issue. For example, a pregnant woman with no AIDS symptoms may be less likely to transmit the virus than one who is very ill with AIDS. Researchers do not know whether pregnancy hastens the onset of AIDS for an HIV-infected woman. Nor can tests determine the exact length of time a person has been infected. Another consideration is the hope that a drug will be developed that can keep the infection under control forever. In the meantime, should a woman be counseled to postpone pregnancy until such a drug is available? There are no easy answers.

AIDS and family planning. Family planning programs provide an opportunity for informing and counseling women of childbearing age about HIV/AIDS — especially as it relates to contraception. However, this too has problems. "Government family planning clinics are excellent vehicles to reach women and children," says Elizabeth Preble, Senior Advisor for AIDS at the United Nations Children's Fund (UNICEF). "But they haven't been eager to incorporate AIDS into their regular work."

Efforts have been made to promote AIDS education among family planning associations, primarily among nongovernmental organizations. Since late 1987, the International Planned Parenthood Federation (IPPF) has held regional workshops throughout the world, to encourage senior staff from most of the IPPF-affiliated family planning associations in about 125 countries to discuss AIDS education issues. The IPPF booklet, "Talking AIDS — A Guide for Community Work," has been

Jane Perlez / The New York Times

translated into eight languages.

"We're trying to broaden the issue to talk about sexual health, not just HIV," says Gill Gordon, Communication and Education Advisor for IPPF's AIDS Prevention Unit. "Once people have had a chance to explore the possibilities and get a more concrete sense of what it's about, we've found a lot of enthusiasm among family planning associations for including HIV and STD education both in their counseling and in their IEC [information, education, and communication] programs."

Family Health International (FHI) has also taken a strong interest in finding ways to integrate AIDS education with ongoing family planning programs. In the summer of 1989, WHO convened a meeting of experts from around the world to review draft guidelines on AIDS and family planning. FHI hosted the meeting in North Carolina. WHO is expected to publish these guidelines later this year, as well as guidelines on AIDS prevention as it relates to maternal and child health. In addition, in July 1990, FHI supported the efforts of the Thailand Ministry of Public Health and the Thailand Fertility Research Association to hold the first nationwide conference in the world on AIDS and family planning issues.

Contraception and HIV/AIDS are fundamentally related, but developing contraceptive options that also prevent AIDS presents problems. Currently, condoms are the best way to protect women and their future children from HIV transmission. However, condom use is controlled mainly by men, not women. In many settings women lack the power to negotiate with their partners about the importance of condom use. This raises issues of sexual politics. "It calls upon the woman to assert dominance in the sexual act," says Zena Stein of the Columbia University HIV Center for Clinical and Behavioral Studies.[5]

Researchers are trying to test and develop female-controlled contraceptive methods that also provide protection against HIV infection. FHI, for example, is studying the effectiveness of spermicides containing nonoxynol-9 and evaluating a female condom, which is inserted much like a diaphragm and held in place by an outer ring. Even if the female condom became commonly available, which will take many years, the long-term goal for many AIDS educators and women's advocates is to get men as well as women invested in preventing HIV transmission and in family planning in general.

Education as prevention. Ultimately, all types of efforts to reduce sexual transmission of HIV can also affect pediatric AIDS, from general health and sex education to basic training of health-care workers. "Kids in primary and secondary schools in Uganda, for example, are taught about clean water and about preventable diseases," explains Ms. Preble of UNICEF, who works extensively in East Africa. "Now they are taught in addition how to prevent AIDS."

At the University of Kinshasa, in Zaire, the School of Public Health surveyed more than 3,500 health-care workers in 1987-88 to determine what they knew about AIDS. "The school now knows what issues regarding AIDS they need to integrate into the general public health curriculum, which already includes child survival, environmental health and sanitation management," explains Dr. Susan Hassig, who spent two years on this project in Kinshasa before joining AIDSTECH in 1990 as an Operations Research Specialist.

Ensuring safe blood supplies. Prevention of HIV transmission to children also requires attention to blood screening and clear criteria for using blood transfusions. Most blood transfusions in many parts of the developing world, especially in Africa, go to women during pregnancy and childbirth, and to children with anemia, a common symptom of malaria and sickle cell disease. Hence, preventing transmission through infected blood is particularly important for children. WHO has established a Global Blood Safety Initiative, which is working to develop integrated blood transfusion systems, in conjunction with national AIDS programs and such groups as the League of Red Cross and Red Crescent Societies.[6] This is the main worldwide network of groups monitoring blood transmission issues.

Family planning programs provide an opportunity for informing and counseling women of childbearing age about HIV/AIDS – especially as it relates to contraception.

Caring for AIDS orphans

While the mission of the public health community is to prevent children from getting infected with HIV, the medical and social services communities are trying to cope with children who need care. This means competition for scarce resources, overlapping demands, and the need for innovative community efforts.

AIDS orphans — children whose parents have died from AIDS — are another tragic consequence of the pandemic. The cost of providing for these children, including many who are not infected, is beginning to stretch local social service and family support systems. For example, in a rural section of the Kagera region in Tanzania, half the population of the district are now orphans who are dependent on the elderly for food, clothing and shelter. "However hard they work, [these older people] cannot provide their basic needs," explains a report by The Panos Institute and Save the Children.[7]

The cost of providing for AIDS orphans is beginning to stretch local social service and family support systems.

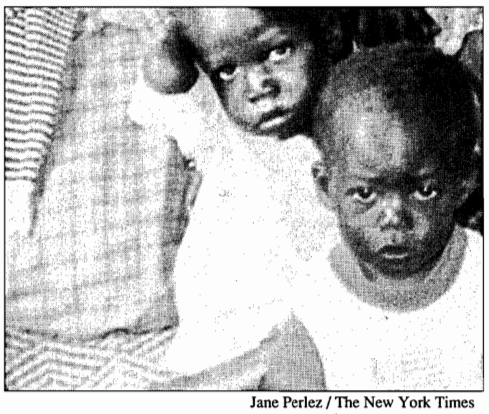
In a front-page story on Sunday, June 10, 1990, *The New York Times* described the situation of AIDS orphans in Uganda. "The AIDS epidemic here is perhaps more haunting, more depressing than Africa's hard-case wars and famines," wrote Jane Perlez from Uganda. In Rakai, a county of about 300,000, AIDS has killed the parents of an estimated 40,000 children, she reported.

Orphaned children demonstrate how the AIDS pandemic affects not only health-care issues but also social service and family support systems. UNICEF, which historically has linked health and humanitarian issues, recently convened a group to consider development of strategies for AIDS orphans. UNICEF estimates that there will be 3 to 5 million AIDS orphans in central and east Africa by the year 2000.[8]

Providing medical treatment

In developing countries, the prevalence of diarrhea, malnutrition and other diseases among children complicates AIDS diagnosis and treatment issues. Laboratory diagnostic facilities are often minimal, making the establishment of clear criteria for clinical symptoms important. Then, there are the costs involved.

"Treatment for the disease can devastate your budget," says Dr. Elizabeth Holt of the Department of International Health at The Johns Hopkins University, who has worked in Port-au-Prince, Haiti with Dr. Reginald Boulos in a two-year study of pregnant women. "The big question is what is the appropriate treatment [for AIDS] that should be used in Haiti? Even if the drug companies donated drugs, the limited resources could interfere with monitoring patients."



Jane Perlez / The New York Times

A WHO/GPA working group is now drafting a document called "Clinical Management Guidelines for HIV Infection in Children," expected to be distributed throughout the world later this year. It will address many types of questions, such as what can be done at the dispensary level to form the basis for estimating the cost of drugs needed for AIDS-related infections.

"We want to promote a national workshop approach that will eventually come up with national guidelines for clinical management of pediatric AIDS," says Dr. Rudolf Wabitsch, the medical officer responsible for clinical management of HIV infection for the WHO Global Programme on AIDS.

Country-specific guidelines, for example, help in estimating the need for antibiotics, antifungals, oral rehydration, ointments for skin infections and tuberculosis drugs for children. "Clinical guidelines would allow a country to estimate these drug requirements," explains Dr. Wabitsch. "Currently, countries have no standard management guidelines for care. Current budget estimates have little relationship to reality. If you can agree on standard guidelines, then you can start seeing what it costs."

Dr. Wabitsch points to Zimbabwe as an example of how the process has begun to work. That country has developed standard treatment guidelines which form the basis for estimating drug requirements and costs.

Conclusion

Pediatric AIDS began as another manifestation of an adult epidemic. However, it has rapidly become a massive

International Meeting on Contraceptive Advances

The Society for the Advancement of Contraception will hold its 7th International Meeting November 4-9, 1990 in Singapore.

The meeting will feature presentations on male contraception, contraception and women's health, contraception and malignancy, surgical contraception, fertility awareness, and long-acting progestin methods.

Discussions will also focus on AIDS and other sexually transmitted diseases, contraception for teenagers, the perimenopausal patient, periodic abstinence, and lactation.

Presenters will provide information on the latest advances in contraceptive technology, basic research and clinical practice. The gathering brings together international agencies and large pharmaceutical companies involved in the development and marketing of contraceptives.

The meeting is organized by the Obstetrical and Gynaecological Society of Singapore and co-sponsored by several international organizations, including Family Health International, the World Health Organization, the International Planned Parenthood Federation, the Association for Voluntary Surgical Contraception and WOOMB (World Organization of Ovulation Methods, Billings). Additional information is available from: Society for the Advancement of Contraception, c/o Department of Obstetrics and Gynaecology, National University Hospital, Lower Kent Ridge Road, Singapore 0511, Republic of Singapore.

Pediatric AIDS

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problem with its own research needs, intervention strategies, and basic cultural and political issues. Behind all of this is an urgent need to reduce HIV transmission to children, which means preventing HIV transmission among adults.

"AIDS has to become part of every health campaign there is," says Ms. Preble of UNICEF.

Dr. Lamptey of FHI states the central issue in this way: "We should be putting emphasis on preventing mothers from getting HIV in the first place."

Meanwhile, the numbers of children affected by the pandemic mount, both those infected with the virus as well as uninfected children whose parents have died of AIDS. The needs of such children make the scale of human losses associated with AIDS even more real.

"There is a need to act," Dr. Mann told the 1989 Paris conference, "both for the immediate reduction of harm, and to change the underlying realities which create and perpetuate vulnerability of women, mothers and children to HIV infection and disease. We must act; we must be practical — and we must also be bold.... For AIDS provides a unique and unprecedented opportunity to fight discrimination, to speak more openly about sexuality, and to strengthen educational and health programs for all."

– *William R. Finger*

Footnotes

[1] LA Valleroy et al., The Impact of HIV-1 Infection on Child Survival in the Developing World, *AIDS*, July 1990.

[2] UNICEF, The State of the World's Children 1988, Oxford University Press, p. 1.

[3] Some researchers believe HIV infection can be transmitted by breastfeeding as well, although evidence is very minimal. For more information, see HIV and Breastfeeding: Risks and Realities, *network*, 11(2), 1990.

[4] Studies have found a wide range of transmission rates of HIV from mother to child, as summarized in: PPiot and JHarris, The Epidemiology of HIV/AIDS in Africa, *The Handbook for AIDS Prevention in Africa*, Family Health International, 1990, p. 13; JPape and WJohnson Jr., Perinatal Transmission of the Human Immunodeficiency Virus, *AIDS: Profile of an Epidemic*, Pan American Health Organization, 1989, p. 74; and JChin et al., Mother-to-Infant Transmission of HIV: An Increasing Global Problem, *Maternal and Child Care in Developing Countries*, Ott Publishers, 1989, p. 300.

[5] ZA Stein, HIV Prevention: The Need for Methods Women Can Use, *American Journal of Public Health*, 80(4), April 1990, p. 460.

[6] For a more detailed review of blood transfusion issues, see AIDS and Blood Transfusions: Ensuring Safe Blood Supplies, *network*, 11(2), 1990.

[7] AIDS and Children: A Family Disease, A Mini-Dossier, The Panos Institute in conjunction with Save The Children, November 1989.

[8] EAPreble, Impact of HIV/AIDS on African Children, *Social Science & Medicine*, 31(6), 1990, in press.

"A program directed at postpartum women is attractive because it reaches women of proven fecundity at a time when they are likely to be interested in the benefits of family planning."

Postpartum

Continued from page 1

ability to space the births of their children at least two years apart," says Dr. Nancy Williamson, Director of Family Health International's Program Evaluation Division. "Ideally, a postpartum program should offer women information about a variety of contraceptive options and help them begin using the most appropriate method at the most appropriate time."

While the concept of postpartum contraception is not new,[1] family planning providers have been slow to embrace this approach. Many family planning programs are aimed exclusively at women who are not postpartum — often with restrictive policies that make postpartum women ineligible for contraception. Even when women seek family planning services during the postpartum period, they frequently are turned away. In an attempt to avoid giving contraceptives to women who may have already become pregnant in the postpartum period, some programs have policies against offering certain contraceptives before the resumption of menses.

As part of a collaborative international effort to develop strategies for expanding postpartum contraceptive options, FHI is sponsoring a series of expert meetings. The first one, co-sponsored by IMSS and the Mexican Ministry of Health, will be held September 17-20, 1990 in Mexico City; subsequent regional meetings are planned for Africa and Asia.

"We need to stop thinking about postpartum contraception only in terms of specific methods and technology," says Dr. Roberto Rivera, Director of FHI's Clinical Trials Division. "We need to think of it instead as a comprehensive strategy for providing family planning services in the postpartum period."

An integrated approach

Integrating family planning services into existing maternity care programs is considered an effective way to reach postpartum women. As part of a policy statement issued following an expert meeting in November 1989, the International Planned Parenthood Federation's International Medical Advisory Panel noted: "Family planning programs should collaborate with maternity services in the provision of education and counseling for postpartum women in need of contraception, in the provision of referral services, and in training health personnel."[2]

Combining family planning with maternity care is convenient for both provider and client. Such an approach utilizes existing facilities and personnel, making family planning more cost-effective and enhancing the acceptability of contraception by associating it with an already trusted institution. Moreover, it takes advantage of a rare opportunity to reach women who might receive no other medical care.

"A program directed at postpartum women is attractive because it reaches women of proven fecundity at a time when they are likely to be interested in the benefits of family planning," says Dr. Rivera.

Postpartum contraceptive services are needed by women who have experienced cesarean sections or terminated pregnancies, as well as those having full-term vaginal deliveries. Postpartum women can use most of the same contraceptive methods available to other women, including IUDs, condoms and sterilization. They may also use hormonal methods, including oral contraceptives and long-acting implants and injectables; however, when to begin using hormonal contraception depends on the method chosen and whether the woman is breastfeeding (see related article on Postpartum Options on page 12).

Challenging old assumptions

Historically, maternity care programs have not been set up to offer contraceptive counseling and services; their primary objective has been to assist with childbirth. After the delivery, health-care providers frequently advise new mothers to return for contraception in six weeks (42 days). However, women return to fertility at varying times; some non-breastfeeding women will begin ovulating again at four weeks postpartum, others at seven weeks; women who are breastfeeding might not ovulate again for six to 24 months.

In addition, providers may assume that new mothers do not need contraception because they will not resume sexual activity right away. While some cultures have taboos against coitus for new mothers, studies show that some couples resume sexual relations much sooner than six weeks postpartum, sometimes within two to three weeks after delivery.

More importantly, many women in rural developing areas cannot travel to a distant clinic after delivery; they resume sexual relations and risk another pregnancy when they begin ovulating

again if they are without contraception.

"These women are at risk for unwanted pregnancy," says Gaston Farr, Research Associate in FHI's Clinical Trials Division. "After they have the infant, they are told to come back in six or seven weeks to get an IUD or start the Pill. If they wait too long, by the time they actually do come back, they might be pregnant again. And many don't come back at all."

Timing is important

Ideally, family planning counseling should begin well before a woman delivers. During prenatal visits, women should be advised about contraceptive choices suitable to their needs. Then they can carefully consider this information and choose a contraceptive method to be started at the appropriate time; if appropriate, they might begin using a method or undergo sterilization before returning home.

In rural areas where women are unlikely to come to the hospital before delivery for prenatal care, family planning clinics located closer to their homes could coordinate with hospital maternity services to provide prenatal care — including counseling about contraceptive options.

Mexico's postpartum contraception program combines extensive prenatal counseling, assessment of the risks associated with reproduction, and institutional training.

Another program, started as a pilot project in Tunisia, combines family planning with maternity and pediatric services. In places where access and tradition allow women to return to a hospital or clinic for postpartum visits, family planners have a chance to broaden the focus of postpartum health beyond contraception to address the whole spectrum of a mother's concerns: the well-being of her infant, her personal health, and her ability to control her fertility.

Combining well-baby care with family planning visits creates many incentives for new mothers to return to the clinic for follow-up care for themselves and their newborns. For example, of the 9,240 women who delivered at a large hospital in Sfax, Tunisia, during 1987, 83 percent (7,686) returned with their infants for their scheduled follow-up visits 40 days later, according to a report by the Population Council.[3]

Cultural factors. Taking into account local cultural practices is the key to the success of any family planning program. For example, the 40th postpartum day has special significance in Tunisia and other countries where Muslim tradition discourages new mothers from resuming sexual relations until then. Tying the follow-up visit to that day marking the end of a new mother's convalescence assures that those women who adhere to the tradition will receive contraceptive advice and services in the postpartum period at about the time they need protection.

Another postpartum program, in Sri Lanka, also reports high rates of utilization and acceptance of family planning, particularly sterilization. About 85 percent of deliveries in that country take place in hospitals or clinical settings, reports Dr. Sriani Basnayake, Medical Director of the Family Planning Association of Sri Lanka.

"Women are given advice on family planning at antenatal visits and during the period of hospitalization for the delivery," says Dr. Basnayake. "Mothers who choose sterilization are advised to undergo the procedure before leaving the hospital, while others are encouraged to return to a clinic in six weeks for a child-spacing method as well as to receive immunizations and other health-care services for the baby."

Again, cultural factors are relevant to the timing of service delivery. According to widely practiced local custom, women live in their parents' home after giving birth and do not return to their husbands for three months; therefore waiting six weeks for contraception presents no problem, as long as women are able to return to the clinic for contraception before they resume sexual relations.

Counseling is crucial

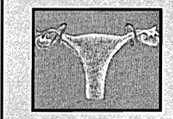
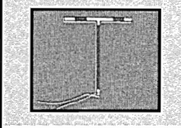
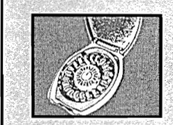
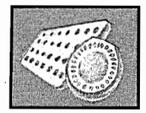
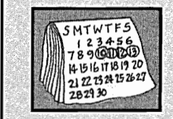
Counseling is an important component of postpartum contraception, for a woman must have adequate information before she chooses a contraceptive method. Providers must assess each woman individually, with regard to her age, fertility status, number of children, health, coital patterns, religious beliefs, and local customs, and whether or not she intends to fully breastfeed. Then the couple, along with their providers, must attempt to match their needs with the safest and most effective contraceptive method available.

Providing adequate counseling can be difficult when the woman's only contact with medical care occurs during labor and

Continued on page 15

Counseling is an important component of postpartum contraception, for a woman must have adequate information before she chooses a contraceptive method.

Postpartum Contraceptive Methods

	Methods	Timing of Introduction	Advantages	Disadvantages	Comments / Questions
	Female Sterilization	Can be performed immediately after vaginal delivery, cesarean section, or termination of pregnancy.	Offers permanent protection from an unwanted pregnancy. Fallopian tubes are easier to reach surgically in postpartum period. Highly effective. No effect on breastfeeding.	Irreversible. Pregnancy and childbirth may unduly influence a woman's decision to have no more children. She may regret it later. Although postpartum fallopian tubes may be more accessible, they can be more difficult to occlude.	Requires careful and sensitive counseling and full informed consent, to avoid later regret. Only appropriate for couples who want no more children.
	Male Sterilization	When convenient, a husband could have a vasectomy while his wife is hospitalized for labor and delivery.	Highly effective. No effect on breastfeeding.	Irreversible. Like the new mother, the new father may later regret this decision and want more children.	Requires careful and sensitive counseling and full informed consent, to avoid later regret. Only appropriate for couples who want no more children.
	IUDs	Can be inserted within 10 minutes of placental delivery by skilled and experienced provider. (Can also be inserted through abdominal incision during cesarean section.)	Highly effective reversible method. Does not appear to effect quantity or quality of breastmilk. Can be performed while woman is hospitalized for delivery.	Concerns about bleeding, perforation and expulsion. Increased risk for pelvic inflammatory disease for women at risk for STDs.	Requires training, skill and experience for proper insertion. Not suitable for women at risk for STDs.
	Barrier Methods	Condoms and spermicides (foams, vaginal inserts, creams and jellies) can be used as soon as intercourse resumes. Diaphragm and cervical cap cannot be used until uterus has returned to normal size, four to six weeks postpartum.	No effect on lactation. Condoms and spermicides could be given to women at hospital. Lubricated condoms and spermicides can be useful because of increased vaginal dryness during the postpartum period. Condoms provide protection against AIDS and other STDs.	Not as effective against pregnancy as other methods. The major limitation is acceptability.	The natural contraceptive protection offered by breastfeeding can enhance effectiveness of condoms.
	Progestin-only Oral Contraceptives	Experts disagree about when nursing women should begin the minipill despite research showing progestin-only contraceptives do not suppress lactation. Some suggest waiting until six weeks postpartum.	Highly effective when used correctly.	Requires strict daily regimen to be most effective. Experts do not agree on when breastfeeding women should start because of potential effect of steroid on suckling infant. Breakthrough bleeding is common for both lactating and non-lactating women.	Concerns about effect on suckling infant.
	Combined Oral Contraceptives	Not the preferred method for lactating women. In situations where combined pills are the only option, debate exists over when nursing women should begin.	Highly effective when used correctly.	Combined oral contraceptives have been shown to reduce milk volume. Researchers do not know yet what effects the small amounts of hormones that reach infants through breastmilk may have on infant growth or development.	Concerns about effect on suckling infant.
	Implants (NORPLANT®) & Injectables	Disagreement over when to begin for breastfeeding women; some experts advise waiting six weeks after delivery. Non-breastfeeding women may start immediately.	Active ingredients delivered automatically via skin implant or injection. Long-acting effects.	Some researchers suggest it may be advisable to wait six weeks to begin.	Concerns about effect on lactation and on suckling infant.
	Breastfeeding	May begin immediately after delivery. Provides contraceptive effect for up to six months or until return of menses or supplemental feeding if these occur before six months.	Provides nutritional, immunological, psychological benefits. Provides natural contraceptive effect by itself or as a complement to other methods.	Women may not be able to predict precisely when fertility returns. Some work situations may make it difficult to breastfeed fully.	Women need information about how to breastfeed fully and when to begin a complementary method.
	Natural Family Planning	Fertility awareness methods could begin immediately.	No effect on lactation.	Research is underway to discover best way to teach nursing women to detect mucus changes during lactation, but current knowledge demands prolonged periods of abstinence and reliance on detection of very minimal mucus changes.	More information needed on how to predict the return to fertility in nursing women.

Based on information from Family Health International, the Association for Voluntary Surgical Contraception, International Planned Parenthood Federation, Institute for International Studies in Natural Family Planning at Georgetown University, and the Population Council.

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POSTPARTUM OPTIONS: MATCHING THE METHOD TO INDIVIDUAL NEEDS

The contraceptive methods and technology that are available for postpartum women are similar to those used by other women.

Several safe and effective contraceptive options exist for postpartum women — whether they experience vaginal delivery or cesarean section or a terminated pregnancy. Sterilization, IUDs, condoms and spermicides can be used in the postpartum period, depending on the personal needs of each woman. Hormonal methods may also be used, such as oral contraceptives (OCs) and long-acting implants and injectables; however researchers disagree on how soon after delivery to introduce hormonal methods to breastfeeding women, due to concerns about the potential effect on breast milk and infant development.

Breastfeeding itself can be viewed as a postpartum child-spacing method or used in combination with other methods to provide the highest level of protection (see separate article on breastfeeding on page 16). However, even when a new mother fully breastfeeds, she will eventually need to choose an additional method as the contraceptive effect of breastfeeding wanes.

In fact, the contraceptive methods and technology that are available for postpartum women are similar to those used by other women. Health-care providers counseling postpartum women must consider a variety of issues, such as each woman's personal and biological needs, her religious beliefs and cultural practices, whether she plans to have additional children, and the availability of each method. These are the same factors family planners would consider in advising women at any other time.

However, there are additional issues for postpartum women to consider before choosing a contraceptive method. There are also areas of disagreement or controversy. These will be extensively reviewed and discussed at the International Conference on Postpartum Contraception, September 17-20 in Mexico City (see Editorial).

The following provides a summary of the main characteristics of postpartum contraceptive technology. Additional information on postpartum methods, including suggested guidelines for safe and effective use, will appear in a future issue of **network**, following the Mexico City conference.

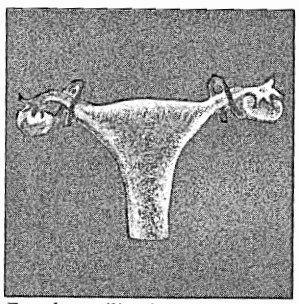
Sterilization

Both male and female sterilization are effective and convenient methods for postpartum couples seeking permanent protection from pregnancy. Vasectomy is simpler, safer and less expensive than female surgical sterilization, according to Dr. Douglas Huber, Medical Director of the Association for Voluntary Surgical Contraception (AVSC). In some cases, it may be convenient for a husband to have a vasectomy while his wife is hospitalized during childbirth.

Voluntary female sterilization is only suitable for women who are certain that they want no more children. The number of women undergoing tubal ligation immediately after delivery has increased remarkably in recent years.[1] In many countries, it is the most common time for women to have access to this procedure. Sterilization is safe and convenient for both the woman and the provider. It is cost-effective since it involves an efficient use of health-care personnel and facilities.

Additionally, the size and location of the postpartum uterus make it easier to reach the fallopian tubes when performing minilaparotomy. Often, the procedure can be done with local anesthesia and the woman does not need to stay in the hospital longer than she would for a normal birth and delivery.

Surgical procedures. In the developing world, minilaparotomy is the most common postpartum sterilization approach for both medical and programmatic reasons. It can be performed under local anesthesia by trained paramedical staff, and the instruments are inexpensive and easy to maintain.



Female sterilization

By contrast, laparoscopy during the immediate postpartum period requires highly experienced providers, more expensive and sophisticated instruments, and often general anesthesia. Although rare, there is a greater risk of injury to the enlarged uterus than with the minilaparotomy.

The Pomeroy ligation technique (in which the tubes are tied off with sutures) has been used effectively with postpartum women. FHI will be submitting to the U.S. Food and Drug Administration a request

for a secondary indication allowing for postpartum use of a clip as well. A clip is a mechanical device which could accommodate the larger postpartum fallopian tubes. The Silastic® ring is less suitable for immediate postpartum application because it is harder to apply to the enlarged fallopian tubes.[2]

The regret factor. Experts agree that the chief drawback to sterilization during the immediate postpartum period is the heightened risk that the woman may later regret her decision, particularly if her newborn becomes ill or dies. "A significant proportion of postpartum women tend to be highly motivated to end fertility during this period," warns Dr. I-cheng Chi, Associate Director of FHI's Clinical Trials Division.

Careful prenatal counseling, informed consent and patient selection can minimize the occurrence of regret. Family planning providers should emphasize the permanence of sterilization and the availability of alternative reversible postpartum methods. Informed consent should be obtained before a woman is sedated or in labor.

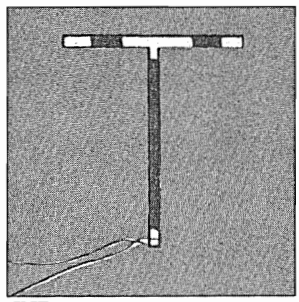
"The woman needs to make a thoughtful, informed choice well in advance of labor," says FHI's Dr. Chi. "This is especially important for women with risk factors for regret, such as younger women and women of low parity and those having medically-indicated C-sections."

IUDs

When labor and delivery are normal, an intrauterine device (IUD) may be inserted by a trained professional within 10 minutes following expulsion of the placenta — while the woman is still in the delivery room.

Postplacental insertion appears to be safe, with no greater risk of infection, bleeding or perforation.[3] Postplacental insertion is especially practical in areas where childbirth may be the only occasion for women to obtain an IUD from a trained health-care provider. Nurse-midwives and other health-care providers can safely insert IUDs. However, all providers, including physicians, need special training in screening, counseling, insertion technique and follow-up.[4]

Other advantages of postplacental insertion are that the occasional bleeding that accompanies insertion is masked by vaginal discharges, or lochia, associated with childbirth; for breastfeeding women, the initial heavy menstrual periods associated with IUDs are partly mitigated by lactational amenorrhea. In addition, the dilated cervical canal makes postplacental insertion less painful.



IUD

Concerns. Researchers have been concerned about the rate of expulsions associated with IUDs inserted in the postpartum period. Early reports showed substantially higher expulsion rates for postpartum insertions than for those performed at other times. More recent studies showed improved expulsion rates for IUDs inserted by experienced practitioners immediately following placental delivery; however the improved rates were still higher than for IUDs inserted in non-postpartum women.[5]

Dr. Michel Thiery, former Chair and Professor of Obstetrics at University Hospital in Ghent, Belgium, and his colleague, Dr. Henry Van Kets, Assistant Professor, believe the expulsion rates can be significantly reduced when experienced providers insert the device high in the fundus of the uterine cavity. Research on the copper-bearing IUDs commonly used for interval insertion suggests that correct fundal placement is the chief factor in reducing expulsion rates.[6] Researchers continue to experiment with new IUDs in an attempt to reduce the incidence of expulsion during the period of uterine involution.

Post C-section insertion. When a cesarean section is necessary, an IUD can also be inserted through the abdominal incision. Research suggests insertion in this fashion poses no greater risk of infection than a vaginal insertion, and the rates of expulsion are substantially lower than with postpartum vaginal insertions after a vaginal delivery.[7]

Counseling IUD users. As with all methods, successful IUD use depends on careful patient screening. Women should not be advised to use IUDs if they have, or are at risk for, sexually transmitted diseases (STDs); hence, IUDs are most suitable for women who are in stable, mutually faithful relationships. In addition, potential IUD users should be informed that side effects may include spotting, bleeding or cramping and that — in women at risk for STDs — IUD use can increase the risk for pelvic inflammatory disease and subsequent infertility.

"The woman needs to make a thoughtful, informed choice, well in advance of labor."

Hormonal methods

Various hormonal methods may be advisable for postpartum women, depending on their particular situations. Such methods include oral contraceptives (progestin-only mini-pills as well as combined progestin-estrogen formulations) and long-acting implants and injectables.

However, researchers continue to debate the long-term effects of various hormonal methods on mothers' milk and infant health. For this reason, experts disagree on when it is safe for breastfeeding mothers to begin using hormonal methods; some say they should wait as long as six weeks after delivery for progestin-only methods and at least six months for combined OCs.[8] For non-breastfeeding women, some research suggests waiting until six weeks postpartum to initiate combined OCs in view of the heightened risk of thromboembolic disease (blood clotting) associated with use before that time.[9]

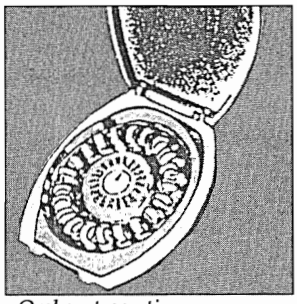
Studies of progestin-only methods suggest that very small amounts of hormones can reach infants through breast milk and therefore probably do not pose significant health risks for mother and baby. Research also suggests that progestin-only methods have either no effect or a positive effect on the quantity and quality of breast milk, unlike combined progestin-estrogen OCs, which have been found to decrease milk supply.[10,11]

The decision about when new mothers may begin taking progestin-only mini-pills depends on programmatic factors and breastfeeding habits.

Mini-pills. The decision about when new mothers may begin taking progestin-only mini-pills depends on programmatic factors and breastfeeding habits. Kathy Kennedy, Research Associate in FHI's Program Evaluation Division, suggests that in rural areas where access to family planning is limited, breastfeeding women could be given a few cycles of progestin-only pills after delivery with instructions to begin taking them at the first sign of return to fertility.

"These women would not be doubly protected by using the pill when they are naturally infertile," Ms. Kennedy says. "But they would have a several-month supply to begin using when they really need it, and the family planning program would be conserving its commodities appropriately."

The primary limitation of the mini-pill is that it must be taken regularly every day, to ensure that hormones are delivered continuously throughout the cycle. This concern is offset somewhat in women who are breastfeeding, as lactation provides them added protection from pregnancy (see related article on breastfeeding). Another problem is that progestin-only methods are not yet available in many developing countries.



Oral contraceptives

Combined OCs. For non-breastfeeding women who do not smoke and have no history of diabetes, hypertension or heart disease, OCs containing both progestin and estrogen are safe and effective when taken according to package instructions. Although they are not the preferred method for breastfeeding women, combined OCs may be considered where mini-pills are not available, especially if breastfeeding is well established. However, researchers do not agree on when it is safe for nursing women to begin taking combined OCs.

Implants and injectables. Long-acting progestin-only methods (injectables and subdermal implants) may offer safe and effective options for the nursing mother. However, like other hormonal methods, there is disagreement about when it is safe for breastfeeding women to begin using implants and injectables; some suggest waiting six weeks after delivery. Injectables such as Depo-provera and Noristerat provide contraceptive protection for two to three months after the progestin is injected. NORPLANT® implants provide up to five years of protection by means of low-dose progestin-releasing capsules surgically inserted beneath the skin of a woman's arm.

For nonbreastfeeding women, the use of implants or injectables could be started in the sixth postpartum week or, in some circumstances, right after delivery.

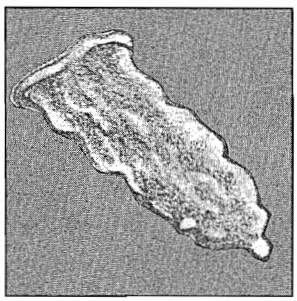
Condoms and spermicides

Although couples tend to use condoms and spermicides less efficiently than other contraceptive methods, they are still a viable option for many postpartum women. If a woman is nursing, the contraceptive effects of breastfeeding can enhance the effectiveness of condoms and spermicides.

Condoms do not have any effect on the quality or quantity of breast milk. Additionally, spermicides may alleviate the vaginal dryness common in lactating

women during intercourse. Finally, supplies of condoms and spermicides can be provided at delivery and used whenever the couple resumes sexual relations.

However, condoms are not readily available in all parts of the world. Additionally, to protect against pregnancy, they must be used each time sexual intercourse occurs. Another limitation of condoms is their acceptability, according to Dr. Robin Foldesy, Director of FHI's Materials Technology Division. "Condoms are appropriate for postpartum women if they and their partners are willing to use them," he says.



Condom

Vaginal barrier options. Diaphragms and cervical caps are less suitable for immediate postpartum use as they cannot be fitted until the genital tract has returned to its normal shape — generally between four and six weeks after delivery. Moreover they need to be refitted when a woman loses 5 to 10 pounds.

Periodic abstinence

Periodic abstinence, or natural family planning, relies on daily charting of basal body temperatures and/or cervical mucus to detect the return to ovulation. Prediction and recognition of ovulation poses problems during breastfeeding because the usual indicators of ovulation may be difficult to interpret. Basal body temperature patterns are erratic when a mother's sleeping is interrupted by breastfeeding, and mucus patterns can be more subtle or seemingly absent in lactating women.

Until more information is available about predicting the return of fertility in nursing women, experts recommend this method only for experienced users of fertility awareness techniques or highly motivated women who receive extensive education and support. ■

– *Sara Townsend*

Footnotes

[1] D Huber. Advances in Voluntary Surgical Contraception, *Outlook*, 6(1):2, 1988.

[2] D Huber. Voluntary Surgical Contraception, in *Contraceptive Technology: International Edition*, 1989, p. 217.

[3] I Chi, G Farr. Postpartum IUD Contraception — A Review of an International Experience, *Advances in Contraception*, 5:127-146, 1989.

[4] IUDS: A New Look, *Population Reports*, Series B, No. 5, 16(1): 1, 1988, (reprinted 1989).

[5] Based on interviews with Drs. Chi, Thiery and Van Kets. Reported rates of expulsion after postplacental insertion differ tremendously depending on the types of IUD used, the way the IUD was inserted, the experience of the inserters and the completeness of reporting, according to Dr. Chi. Drs. Thiery and Van Kets say that if inserted correctly, postplacental expulsion rates are 7 to 10 per 100 women — comparable to expulsions for interval insertions; they have reported expulsions as low as 5 to 6 per 100 women for postplacental insertions.

[6] I Chi, op cit.

[7] Ibid.

[8] Lower-Dose Pills, *Population Reports*, Series A, No. 7, p. 16, November 1988.

[9] W Fuller. Family Planning in the Postpartum Period, *Clinical Obstetrics and Gynecology*, 23(4): 1082, 1980.

[10] Ibid.

[11] FHI has just completed a major study comparing the effects of progestin-only contraceptive methods and non-hormonal methods on lactating women and their newborns. Analysis of the data has not been completed at this time.

Postpartum

Continued from page 9

childbirth, and her hospital stay is only a few hours.

Providers must be particularly careful in counseling postpartum women about sterilization; women leaving the delivery room saying they want no more children may feel differently after they return home (see related story on Postpartum Options). Finally, providers must also consider whether the woman is likely to return after delivery.

Despite such challenges, combining family planning counseling and services with existing maternity services can result in greater access and choice to the millions of women delivering in clinics and hospitals who otherwise might not space their next pregnancy. ■

– *Sara Townsend*

Footnotes

[1] The Population Council sponsored a multi-country, postpartum program during the 1970s.

[2] *IPPF Medical Bulletin*, 24(2):3, 1990.

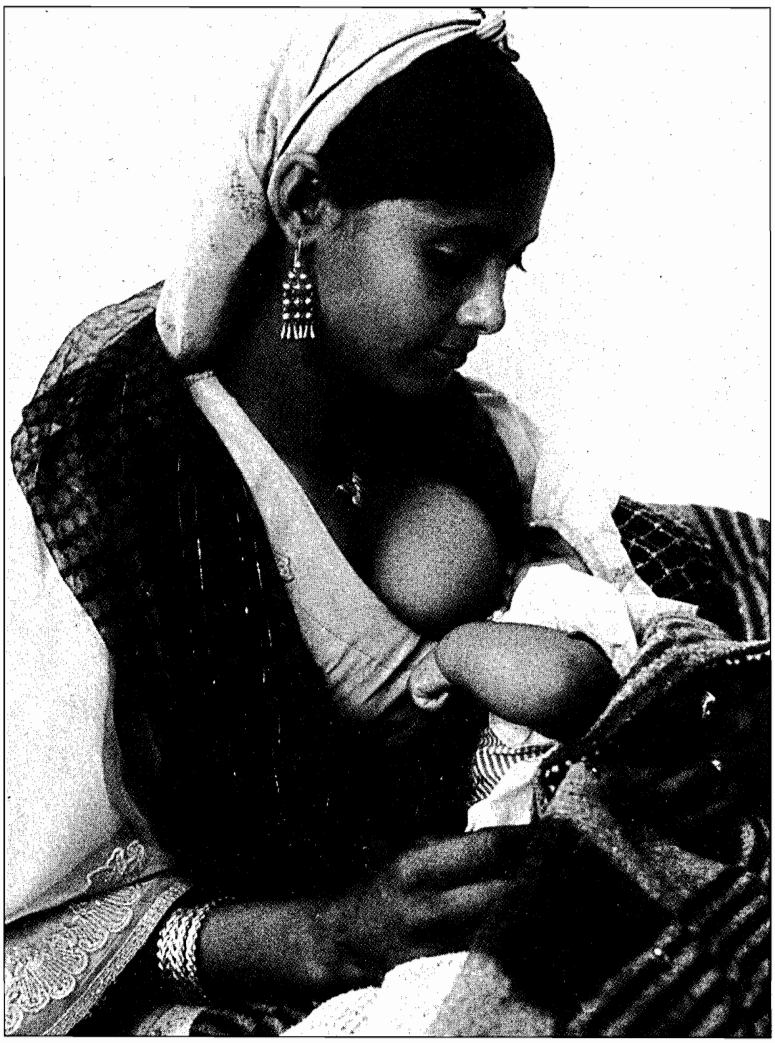
[3] Coeytaux F. Celebrating mother and child on the fortieth day: the Sfax, Tunisia postpartum program. Quality/Calidad/Qualite. Population Council 1989 (1), p. 5.

BREASTFEEDING AS A POSTPARTUM CONTRACEPTIVE METHOD

In addition to its nutritional, immunological and psychological benefits, breastfeeding is a natural contraceptive and can be highly effective either by itself or as a complement to other methods.

In fact, during the first six months postpartum, breastfeeding provides 98 percent protection from pregnancy if the mother is fully nursing and still amenorrheic.[1] Breast suckling stimulates the release of hormones which have the effect of suppressing ovulation. This contraceptive effect is strongest during lactational amenorrhea.

However, the length of postpartum amenorrhea is quite variable. The Bellagio guidelines[2] for breastfeeding women suggest that the risk of pregnancy increases significantly at six months postpartum — or when menstruation resumes or supplemental feeding is introduced, if these occur before six months. Moreover, the natural contraceptive effect of breastfeeding is known to extend well beyond six months for many women in developing countries. In the majority of Asian and African countries, the average duration of lactational amenorrhea is longer than six months. For example, it is 12 months in Zimbabwe.



M. Jacot / WHO

No matter how long a woman breastfeeds, she will not be able to suppress ovulation indefinitely. Even exclusive breastfeeding will not necessarily postpone fecundity for the duration of breastfeeding or for all women. Because the nursing mother normally can neither control nor predict precisely when the contraceptive effects of breastfeeding will end, it is appropriate to encourage her to choose another method before she is at risk of pregnancy. The Bellagio guidelines may help a woman decide when to begin using another method.

New recommendations by the International Medical Advisory Panel of the International Planned Parenthood Federation (IPPF) call for providers to encourage full breastfeeding for all women.[3] "Breastfeeding should not be discontinued to start the use of contraception," according to the IPPF statement. "For nursing mothers, the chosen method must not adversely affect the success of lactation or the health of the infant."

For nursing mothers who desire or need added contraceptive protection, the most effective options for the postpartum period are sterilization, IUDs and barrier methods, if they are acceptable to the woman and there are no medical contraindications. Additionally, health-care providers may consider advising nursing women about the use of progestin-only methods ("mini-pills", implants and injectables); however, researchers continue to disagree on how soon after delivery it is safe for breastfeeding women to begin using such methods (see related article on Postpartum Options). ■

– *Sara Townsend*

Footnotes

[1] Consensus Statement: Breastfeeding as a Family Planning Method. *Lancet*, 2:1204-1205, 1988.

[2] KI Kennedy et al. Consensus Statement on the Use of Breastfeeding as a Family Planning Method: Bellagio, Italy, August 1988, *Contraception* 39(5):479, 1989.

[3] *IPPF Medical Bulletin*, 24(2):3, 1990.

HOW ONE POSTPARTUM PROGRAM WORKS

Last year, nearly 650,000 Mexican women delivered babies in hospitals administered by the Mexican Institute of Social Security (IMSS). More than half of these women, 356,000, went home with something more — a new method of contraception.

IMSS provided a valuable service to these maternity patients as part of a concerted effort to offer contraceptive information and options to women in the immediate postpartum period. Moreover, 39 percent of the new postpartum contraceptors (136,000 women) would otherwise not have received any family planning services, according to IMSS estimates.

Building on this success, IMSS officials hope to expand delivery of postpartum services to even more women. "We want to increase the rate [of postpartum acceptors] to 80 percent in the next three or four years," says Dr. Sergio Correu, Deputy Director of the IMSS Family Planning Directorate. "Some of the metropolitan hospitals are already at 95 percent."

The IMSS model is just one example of a postpartum contraceptive program tailored to the needs of local women. It shows how family planning services can be integrated into a nationwide prenatal and obstetric care system. Understanding how the IMSS program evolved and hopes to expand provides a valuable picture for providers and policymakers in other countries who may be considering a similar program.

The central lessons from the IMSS experience involve three interrelated issues: thorough staff training, integration of contraceptive counseling into every stage of prenatal and obstetric care, and a range of contraceptive methods along with good communication with the doctors who administer these methods.

Training

IMSS has responsibility for providing primary health care for about half of the 83 million people in Mexico. In 1967, IMSS began family planning activities and today provides 40 percent of all Mexican family planning services, explains Dr. Jorge Martinez Manautou, Chief of the IMSS Family Planning Directorate. The postpartum aspect of this program began in a focused, concentrated fashion in 1982, although it had been a part of family planning for many years in Mexico. IMSS officials say this new emphasis resulted from seeing so many unprotected women in the postpartum period, especially women with reproductive health risks.

"The philosophy behind the postpartum approach is the health of the woman," says Dr. Martinez Manautou. For pregnant women with reproductive risk factors, postpartum contraception is advisable "unless a clear medical contraindication prevents it," explains a recent IMSS report.

IMSS also recommends postpartum contraception for women without reproductive risk factors. "We want to help the women have longer intervals between children," explains Dr. Martinez Manautou. "It is very important to cover as many as we can after delivery."

To do that, Dr. Martinez Manautou, Dr. Correu and their staff have developed a thorough training system that incorporates contraceptive counseling through the entire IMSS system of 311,000 employees, more than 900 outpatient clinics and more than 200 hospitals with obstetrical and gynecological services.

"At the outpatient clinics, family planning is the responsibility of the overall general medicine teams, who do respiratory, general health, all services," says Dr. Martinez Manautou. At the second and third levels of service — the regional and sub-regional hospitals — the gynecologists and obstetricians incorporate contraceptive discussions into their routine care.

Counseling

In urban areas, contraceptive counseling — including information on various available methods — begins long before the baby is born. "The first level of attention is the outpatient clinic for prenatal care," says Dr. Correu. "There, all patients have an evaluation for reproductive risk, for 16 risk factors. We want to know what the woman's medical condition was before she became pregnant."

The results of the evaluation affect the contraceptive choices available to the woman. "We focus on the risk factors," he adds. "It's a reproductive health issue." After the evaluation, the woman is then informed about the benefits and risks of different contraceptive methods. Thus, counseling takes place at the prenatal clinic where a woman has time to

The IMSS program shows how family planning services can be integrated into a nationwide prenatal and obstetric care system.

understand the contraceptive options available to her. Some husbands also participate in this process.

Cultural issues can be an obstacle to contraceptive acceptance and need to be addressed during counseling. "In the past, religious beliefs and the influence of the husband have limited the degree of acceptance," says Dr. Correu. "But these obstacles are diminishing in part because the postpartum program emphasizes the medical importance of spacing births. The increasing acceptance of the postpartum program is another reason that these cultural barriers are relaxing."

When a woman enters the hospital for delivery, hospital staff ask her about the contraceptive information given to her during her prenatal period, and the type of method suggested by her family physician.

Counseling takes place at the prenatal clinic where a woman has time to understand the contraceptive options available to her.

Methods

Currently, the IMSS postpartum program offers intrauterine devices (IUDs), female sterilization and progestin-only "mini-pills." In urban areas, about seven of every 10 postpartum acceptors in 1989 left the hospital with an IUD; nearly three of 10 chose to be sterilized. Only 1 percent of the 356,000 postpartum acceptors chose mini-pills.

The IMSS postpartum program is anxious to use other contraceptive options as well, including long-acting injectables and NORPLANT® implants, and, for men, no-scalpel vasectomies.

"We are very anxious to have NORPLANT®," says Dr. Martinez Manautou. "Injectables will also be a tremendous help to our program. But these methods are not yet available. They will help prolong the interval between children. We have to cover a big portion of the other 50 percent [not currently accepting contraception]." Dr. Martinez Manautou views the acceptance of new methods by the IMSS doctors as critical for expanding the use of other methods. "We had to convince the physicians to use the IUD," he says. "We have to be in close contact with them, ask them to do research into side effects. Without the physicians, there would be no program, not here or anywhere in the world."

Conclusion

The postpartum program is a central part of overall IMSS family planning services. About one-third of all contraceptive acceptors served by IMSS are reached through its postpartum program, almost all in urban areas. The other two-thirds are reached through routine family planning services.

Family planning officials from around the world have begun to visit the IMSS to learn how a national postpartum contraceptive program works. In January 1990, IMSS organized a week-long course for five Turkish physicians, with two days of classroom orientation and three days of training at outpatient clinics and hospitals.

"The training course was well-organized, highly informative, and clearly demonstrated the strength of the IMSS program," says Diane Catotti, FHI's Senior Program Officer for Latin America, who participated in the training session. "The IMSS is in a good position to function as a training center for practitioners and policymakers interested in establishing or expanding a postpartum program in their own country." ■

– *William R. Finger*

resources

Informed Consent Guidelines Available

Informed Consent and Voluntary Sterilization is now available in French, Spanish and English from the Association for Voluntary Surgical Contraception.

AVSC prepared these guidelines to help sterilization providers ensure that clients make free and informed decisions about ending their fertility.

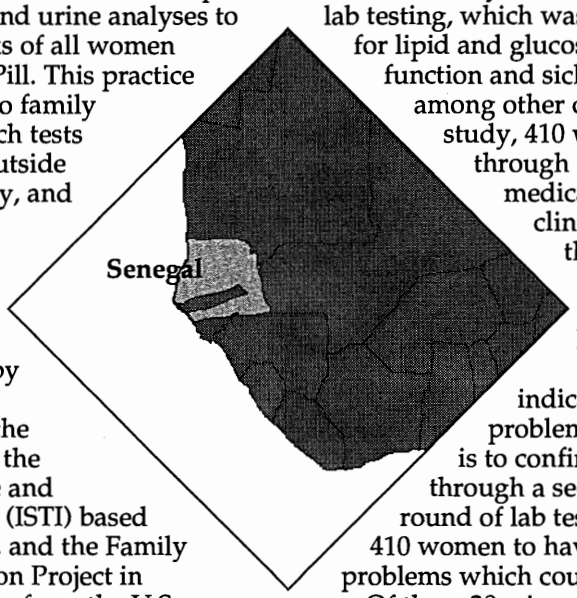
This booklet provides information on the nature and elements of informed consent for voluntary sterilization and presents guidelines on how informed consent activities should be implemented and supervised.

The guidelines are designed for program managers, couselors and providers in Francophone Africa, Latin America and the Caribbean, and are suitable for other French- and Spanish-speaking countries.

Up to 10 copies are available free of charge in English, and up to five copies in French and Spanish. Additional copies are US$2 each, plus 15 percent for shipping. For information and orders, please contact Phyllis Butta, Program Manager, AVSC, 122 East 42nd Street, New York, NY 10168 USA; telephone 212-351-2538; fax 212-599-0959. ■

SENEGAL CHANGES OC TESTING POLICY

Women in Senegal can now get prescriptions for oral contraceptives (OCs) without laboratory tests. The policy of the government had been to use Pap smears, blood tests and urine analyses to assess the health risks of all women wanting to take the Pill. This practice had reduced access to family planning because such tests were not available outside Dakar, the capital city, and because testing everyone was very expensive.



The change came as a result of research supported by Family Health International (FHI), the University of Dakar, the International Science and Technology Institute (ISTI) based in Washington, D.C., and the Family Health and Population Project in Senegal, with funding from the U.S. Agency for International Development.

This nine-month study culminated in a pivotal meeting in Dakar. In February 1990, 150 physicians, family planning providers, nurses and midwives attended a three-day colloquium on "Laboratory Testing and Hormonal Contraception." The meeting examined issues related to Senegal's policy requiring lab tests for women wishing to use OCs. Senegal government officials also attended, with the Minister of Health opening the meeting and the Minister of Social Development closing it.

Family planning experts from the African countries of Benin, Burkina Faso, Cote d'Ivoire, Niger and Morocco presented papers, along with three experts from Senegal and one from Belgium. On the final day, conference participants drafted a statement called the Dakar Resolution. Its two main recommendations were to eliminate systematic lab testing prior to OC prescription and to improve clinic screening procedures for all family planning methods. Following discussion, the full conference endorsed the Dakar Resolution. Before the colloquium adjourned, the Senegal Minister of Social Development added official approval to the Resolution.

The research project leading to the conference analyzed the role of this type of lab testing, which was designed to check for lipid and glucose levels, liver function and sickle cell disease, among other conditions. In the study, 410 women were tested through clinical exams and medical histories at three clinic sites, and through free laborary tests at the Pasteur Institute of Dakar. If a laboratory test indicates a medical problem, standard practice is to confirm the problem through a second test. The first round of lab tests found 20 of the 410 women to have possible problems which could preclude OC use. Of these 20, nine were retested (11 could not be located or refused the second test). Of the nine who were retested, only one was found to have a possible problem, a high blood glucose level (1.83 g/l).

Meanwhile, the clinic exams found five of the 410 women to have potential problems. For four women, the problems surfaced in taking the medical history; a physical exam found a potential problem — high blood pressure — in the fifth woman. Only one of these five women was among the women found in the lab tests to have possible problems.

The consensus of study investigators was that systematic lab testing was unnecessary. As a screening device, laboratory testing was expensive and found very few women at risk for using OCs.

Senegal officials had promoted this lab test in the first place in response to concerns about health risks associated with oral contraceptives. This study and the Dakar Resolution have added to the body of research showing that in both developing and industrialized nations, the health risks associated with pregnancy are greater than those asociated with taking the Pill. ■

The impact of AIDS on women and children has highlighted the "imbalances, deficiencies and inequities in existing health and social systems."

Dr. Jonathan Mann, Former Director, WHO Global Programme on AIDS *(see page 3)*

NEW FHI PUBLICATIONS

90-03 M Potts, PJ Feldblum. Changing Behavior: Barrier Methods in High-Risk Populations. In: *Heterosexual Transmission of AIDS*, NJ Alexander, HL Gabelnick, JF Spieler, Eds. (New York: Alan R. Liss, 1990), p. 69.

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90-17 M Potts. Pakistan: Safe Motherhood. *Lancet* 335(8694):903, 1990.

90-18 Family Health International. Vote with Conscience (editorial). *Lancet* 335(8695):943, 1990.

90-19 Family Health International. No Regrets. *Lancet* 335(8699):1188, 1990.

90-20 C Sakondhavat, L Potter. Further Testing of Female Condoms (letter). *Brit J Fam Plann* 15(4):129, 1990.

90-21 I Chi. Vasectomy and Testicular Cancer (letter). *Brit Med J* 300(6729):944, 1990.

FHI publications are available at no cost. For copies, please write to: Ms. Debbie Wade, Family Health International, P.O. Box 13950, Research Triangle Park, NC 27709 USA.

FAMILY HEALTH INTERNATIONAL

network

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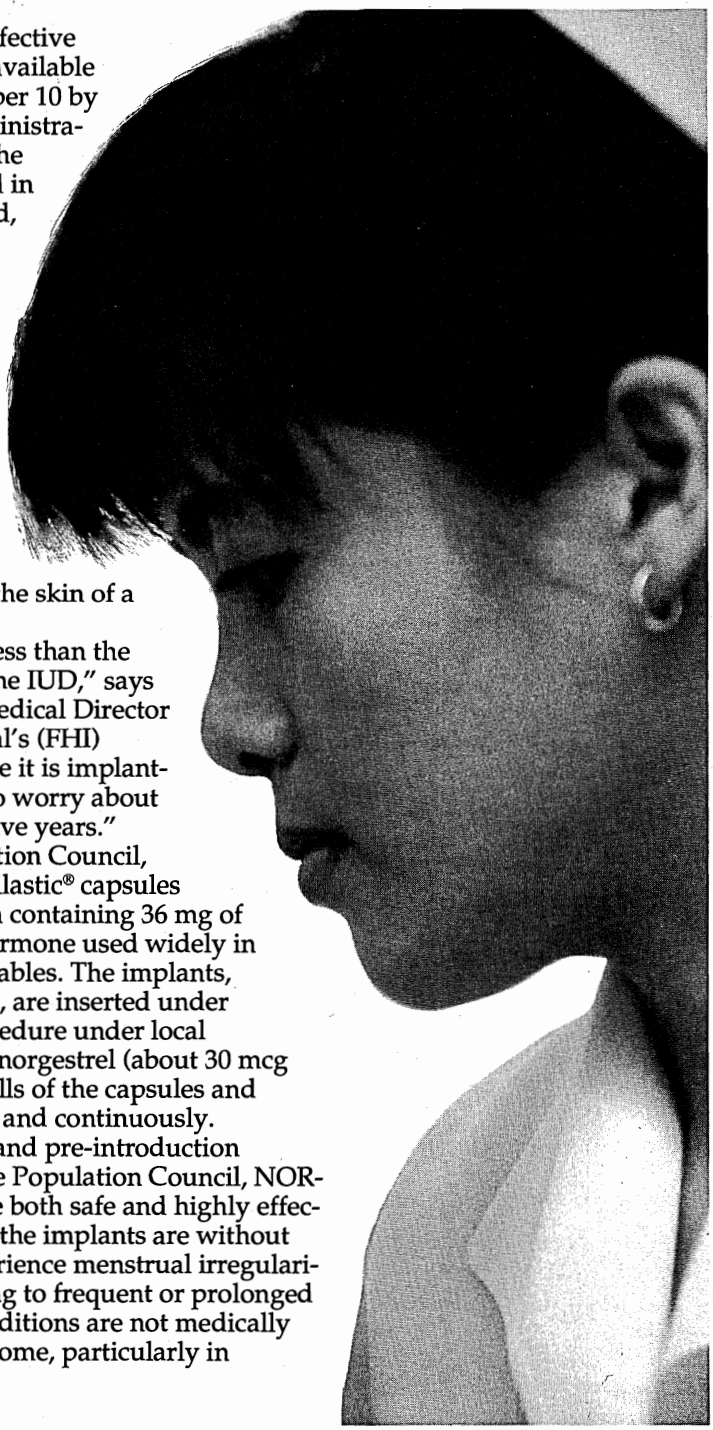
NORPLANT®: FIRST IN A NEW GENERATION OF LONG-ACTING HORMONAL METHODS



Lance Woodruff

NORPLANT®*, the most effective reversible contraceptive available today, was approved December 10 by the U.S. Food and Drug Administration (FDA) for marketing in the United States. Now approved in 17 countries around the world, NORPLANT has already been used by more than 700,000 women. FDA approval probably will lead to use in many other countries.

What is revolutionary about NORPLANT is the way it delivers hormones to the bloodstream continuously for five years, via six match-size capsules inserted under the skin of a woman's upper arm.

"It has a higher effectiveness than the Pill, and the convenience of the IUD," says Dr. Gary Grubb, Associate Medical Director of Family Health International's (FHI) Clinical Trials Division. "Once it is implanted the woman doesn't have to worry about contraception for as long as five years."

Developed by The Population Council, NORPLANT consists of six Silastic® capsules (about 34 mm in length), each containing 36 mg of levonorgestrel, a synthetic hormone used widely in oral contraceptives and injectables. The implants, which are non-biodegradable, are inserted under the skin during a simple procedure under local anesthetic. Low doses of levonorgestrel (about 30 mcg daily) diffuse through the walls of the capsules and enter the bloodstream slowly and continuously.

In extensive clinical trials and pre-introduction evaluations sponsored by The Population Council, NORPLANT has been shown to be both safe and highly effective. This does not mean that the implants are without side effects. Many users experience menstrual irregularities — from mid-cycle spotting to frequent or prolonged bleeding. Although these conditions are not medically harmful, they can be troublesome, particularly in

Continued on page 5

editorial

FAMILY PLANNING IS CRUCIAL TO CHILD SURVIVAL

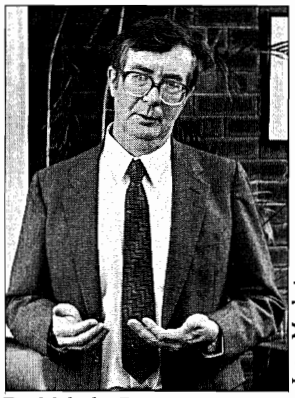
The World Summit for Children, held at the United Nations in September, has focused international attention on the urgent needs of the world's infants and children. Even as some 70 heads of state attended this historic one-day gathering, an estimated 50,000 infants and children died — a tragedy that occurs day after day throughout the year.

More than 170 million infants and children are expected to die during this decade. Unfortunately the Summit did not allocate funds to address these shameful statistics. Nevertheless, the world's leaders did embrace the UN's goals to expand immunizations, reduce infant and maternal mortality, improve family planning, eradicate polio, and ensure a primary education for children everywhere.

Dr. Nafis Sadik, Executive Director of the United Nations Population Fund (UNFPA), emphasized family planning as a crucial component to any strategy for improving child survival. She pointed out that children born less than two years apart are up to twice as likely to die as those born after a longer birth interval.

"Children from planned families are not only more likely to survive," she said, "they are also more likely to have happy, healthy childhoods, to go to school, and to grow into healthy, educated adults with good prospects."

A recent report written by FHI underscores this point. The report, entitled "Child Survival: The Role of Family Planning," states that contraceptive use can help save the lives of infants and children directly and indirectly. Family planning, including breastfeeding, is among the most cost-effective ways of reducing infant mortality. Family planning:


Jerry Markatos

Dr. Malcolm Potts

- allows very young women, whose infants are prone to higher mortality, to delay childbearing until a later age;
- allows older and especially high parity women, whose infants are at higher risk of dying, to stop having babies;
- contributes to longer intervals between births;
- reduces maternal mortality.

The report also emphasizes that child survival and family planning affect each other: Family planning can improve child survival, and child survival can increase the demand for family planning. A review of historical data shows that a decline in the birth rate may precede a reduction in infant mortality, as occurred in 19th century Britain. Or, as is happening in Kenya, a reduction in infant mortality may precede a decline in the birth rate.

Still, while traditional child survival measures are widely applauded, contraception often remains controversial. As a result, family planning has sometimes not received the support it merits as a critical component of child survival programs.

In fact, the goals of the World Summit for Children cannot be reached without expanding *both* traditional child survival programs and family planning services. ■

— Dr. Malcolm Potts, President, FHI

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Journal Features Breastfeeding in Asia

The *Asia-Pacific Population Journal* (Vol. 5, No. 1, 1990) features a collection of papers on breastfeeding in Asia, published by the Population Division of the United Nations Economic and Social Commission for Asia and the Pacific (ESCAP), in collaboration with Family Health International.

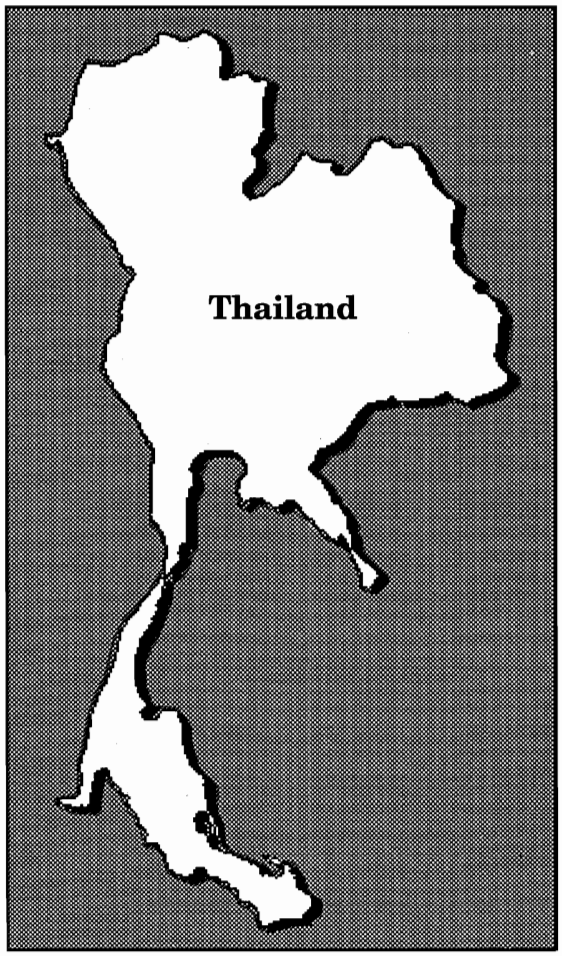
The volume includes original papers on breastfeeding trends, determinants and policies in several countries of the region. Publication was made possible with financial support from ESCAP and the UN Population Fund (UNFPA). For a complimentary copy, please write to: Editor, Asia-Pacific Population Journal, ESCAP, Population Division, The United Nations Building, Rajadamnern Avenue, Bangkok 10200, Thailand. ■

AIDS AND FAMILY PLANNING: THAILAND CONFERENCE BREAKS NEW GROUND

Family planning professionals from throughout Thailand met in July to discuss ways that AIDS prevention and education can become part of the overall service delivery system. This is believed to be the first nationwide conference on AIDS and family planning held in the developing world.

"The primary achievement of the conference is the exposure of family planning personnel to the implication of AIDS for their target group — the mother and child," says Dr. Surin Pinichpongse, Senior Expert in Preventive Medicine at the Thailand Ministry of Public Health. "It also presented an opportunity for family planning providers to understand their potential role in AIDS prevention and control."

Held in Pattaya, Thailand, the two-day seminar drew more than 220 participants, primarily obstetricians and gynecologists who oversee government family planning clinics in regional and provincial hospitals. Others attending included nongovernmental family planning professionals and Thai government officials. The conference was co-sponsored by the Thailand Ministry of Public Health (MOPH), the Thailand Fertility Research Association (TFRA) and Family Health International (FHI), with funding from the U.S. Agency for International Development and the William and Flora Hewlett Foundation.



Chad Adams

HIV in Asia

The meeting was the latest in a series of recent efforts by Thailand's MOPH to address the increasing local prevalence of the human immunodeficiency virus (HIV), which causes AIDS. In 1989, in cooperation with the World Health Organization's Global Programme on AIDS, the MOPH began a data-gathering system called "sentinel surveillance." The new data revealed that HIV infection was spreading within the Thai population, particularly to commercial sex workers, their clients, the clients' spouses, and newborns.

The Thailand data reflect a larger, alarming pattern. The World Health Organization (WHO) reports accelerating infection rates worldwide, with surprising new data on Asia. WHO figures indicate that the total number of HIV-infected persons in Asia has risen from virtually nil two years ago to an estimated total of at least 500,000.

Thailand MOPH officials have begun to release their surveillance data showing the spread of the infection. The MOPH has also recently created a new AIDS division to bring attention to the problem. As of September 1990, the Ministry had documented 22,075 cases of persons infected with HIV in Thailand, including 53 persons with AIDS. Officials of the Ministry and WHO estimate that the number of HIV-infected persons in Thailand is actually much higher, estimated between 50,000 and 100,000.

A strong national family planning program

The Ministry's recognition of the growing seriousness of the spread of HIV helped lead to the conference on AIDS and family planning. An equally important factor was also at work — the long, successful record of the Thailand National Family Planning Program. The program has received regional and worldwide

"There is a crucial need to develop specific counseling materials."

recognition for its innovative approaches to family planning and its effectiveness in helping to reduce population growth.

"The success of Thailand's National Family Planning Program can be attributed to the cooperative endeavor between the government and the non-governmental organizations creating a nationwide network for service delivery," says Dr. Surin of the MOPH. "Utilization of the same service network will accelerate the AIDS prevention and control program."

Involving the family planning system in AIDS-prevention efforts has been a slow process in Thailand, as it has been in other countries. Initially, prevention projects focused on select groups with the highest infection rates — intravenous drug users, homosexual men and commercial sex workers. But Ministry officials now recognize the urgency of utilizing existing infrastructures to reach a wider target population.

The conference

The AIDS and family planning conference was the first time many obstetricians and gynecologists in Thailand had heard a thorough explanation of basic AIDS information. The meeting began with presentations by Thai experts on HIV/AIDS and covered biomedical questions, prevalence rates, contraception, psychological issues, and protection of workers at family planning and maternal and child health clinics.

"There has been a fear of transmission of HIV at medical clinics themselves," says Dr. Suporn Koetsawang, Secretary General of the TFRA and Director of the Family Planning Research Center at the Department of Obstetrics and Gynecology, Mahidol University, Siriraj Hospital in Bangkok.

During working sessions participants discussed the advantages and disadvantages of anonymous HIV testing and whether persons infected with HIV should be told of their status. In addition, they raised concerns about how to ensure safe blood supplies and the need for protective garments for providers who may be dealing with persons infected with the AIDS virus.

Participants also debated various approaches to integrating AIDS prevention efforts within the family planning system. For example, some pointed out that mass education had worked well for expanding contraceptive use because there was a latent demand for services. But others wondered if this approach would work for AIDS because of the different nature of the target population and the relative lack of demand for preventive services.

The conference provided a forum for family planning professionals and policymakers to begin addressing such issues. "The potential for such a conference is enormous because of the possibility of approaching the subjects of sexual behavior and of condom use — important issues that family planning programs and AIDS prevention programs should be addressing," says Dr. Tony Klouda, Coordinator of the AIDS Prevention Unit at the International Planned Parenthood Federation (IPPF).

"AIDS prevention campaigns in the region have tended to concentrate on the use of fear rather than exploring sexual behavior and condom use," says Dr. Klouda. Since 1987, IPPF has held regional workshops (including one in Thailand) to encourage their affiliates in about 125 countries to discuss AIDS education in the broad context of sexuality and sexual health.

Next steps

Thai officials hope that the conference will lead to research and intervention projects. "The challenges ahead are diversified and multidimensional," says Dr. Surin of the Ministry. "There is a crucial need, for example, to develop specific counseling materials."

Thai family planning program officials have already begun thinking of different ways to educate men and women. The first week in December 1990 was named "Women and AIDS" week as one way to get women's groups involved in the AIDS prevention and counseling campaign.

Involving men who visit commercial sex workers presents other challenges. "Men will be counseled by girlfriends, wives or mothers on modes of HIV transmission, avoidance of contacts with high-risk groups and the importance of a well-knit family that exudes warmth and affection," says Dr. Surin.

The next goal of the Ministry of Public Health, says Dr. Surin, is to integrate family planning and AIDS prevention and control efforts "by AIDS education to family planning acceptors, counseling to known contacts of HIV-infected cases, and provision of family planning services to couples found to be HIV-infected."

Long-term goals determined at the conference include getting family planning services workers more involved in AIDS

Continued on page 5

WHO Guidelines on AIDS and Family Planning

The concept of integrating AIDS education and prevention efforts into existing family planning systems is attracting growing interest around the world. In May 1990, the World Health Organization (WHO) published new guidelines on "AIDS and Family Planning," which had been reviewed during a consultation of international experts held at FHI in 1989.[1] The 82-page booklet sets forth reasons to pay special attention to AIDS through maternal and child health and family planning (MCH/FP) programs.

"Women bring their questions and concerns about HIV infections . . . to MCH/FP workers — often the first and only health workers that many women see," the guidelines state. "Sexual intercourse is the major way by which HIV is transmitted in most countries. MCH/FP programs are directly concerned with people's reproductive health."

The booklet shows why AIDS has permanently altered the way that professionals must view family planning. The choice of various contraceptive methods must now take into consideration the degree of risk for HIV transmission faced by women and men.

A companion volume on AIDS and maternal and child health is also being completed. The two sets of guidelines will eventually be combined into a single publication. ■

— *William R. Finger*

[1] Key contributors to the draft included: Dr. H. Petersen, Dr. R. Senie and Mr. G. West of the Centers for Disease Control in Atlanta, Georgia, USA; Dr. P. Senanayake, International Planned Parenthood Federation, London, England; and Dr. N. Williamson, Family Health International.

"AIDS Prevention: Guidelines for MCH/FP Programme Managers, I. AIDS and Family Planning" is available from WHO by writing to: World Health Organization MCH/FP, 1211 Geneva 27, Switzerland; or from FHI, by writing to: Publications Assistant, Family Health International, P.O. Box 13950, Research Triangle Park NC 27709.

NORPLANT

Continued from page 1

cultures that restrict social or sexual activities during menses.

Despite these disadvantages, many women continue to use NORPLANT. In eight pre-introduction studies conducted by FHI for The Population Council, 95 percent of NORPLANT users continued after the first year, a higher first-year continuation rate than for either the IUD (70-80 percent) or the Pill (49-50 percent). However, studies in several countries show cumulative continuation rates falling off each year — due to bleeding irregularities or a desire to become pregnant — declining to a range of 25 to 78 percent at five years.

Introducing NORPLANT into general and widespread use involves complicated programmatic issues, such as how to ensure that providers have adequate training in insertion, removal and patient counseling; how to follow up NORPLANT users and contact them for removal when five years have elapsed; how to ensure access to removal for women who wish to discontinue in less than five years; and what it will cost to provide the implants and insert and remove them.

With regulatory approval in the United States and other countries, attention must be focused on such issues, and on bringing NORPLANT beyond the controlled circumstances of clinical trials into full-fledged service program use. Information on both clinical and programmatic issues related to wider use of NORPLANT appears in a series of articles in this issue of *network*, beginning on page six. ■

* NORPLANT® is the registered trademark of The Population Council for subdermal levonorgestrel implants.

AIDS and Family Planning

Continued from page 4

prevention activities — condom resupply, promotion of condoms in high-risk couples and verbal screening of client populations for persons who may be at risk of HIV. Family planning services are available at some 18,000 family planning clinics and hospitals in Thailand, about half of them funded by the government. In addition, condoms are available at nearly 10,000 pharmacies.

Thailand's experiences in exploring the potential links between AIDS prevention and family planning will provide important information for other countries grappling with the increasing spread of HIV.

"Meetings such as the Thailand conference are very important," says Dr. Susan Hassig, Operations Research Specialist for FHI's AIDSTECH Division. "We need such efforts to lay the groundwork for pilot intervention and research projects addressing AIDS as it relates to family planning." ■

— *William R. Finger*

Thailand's experience in exploring potential links between AIDS prevention and family planning will provide important information for other countries.

NORPLANT®: SAFE AND HIGHLY EFFECTIVE

"NORPLANT has proven more effective than any other reversible method and, for most women, equal in effectiveness to sterilization."

Extensive clinical trials and preintroductory evaluations sponsored by The Population Council and Family Health International (FHI) indicate that NORPLANT® is safe, long-acting, reversible and highly effective.

Over the past two decades, more than 55,000 women in 46 countries have volunteered to test NORPLANT, the first product to provide continuous, long-acting protection from pregnancy through the use of hormonal implants.

"NORPLANT has certainly proven more effective than any other reversible method in actual use, and, for most women, is equal in effectiveness to sterilization," says Dr. Gary Grubb, Associate Medical Director of FHI's Clinical Trials Division. FHI-sponsored studies have monitored some 8,000 women in 12 countries.

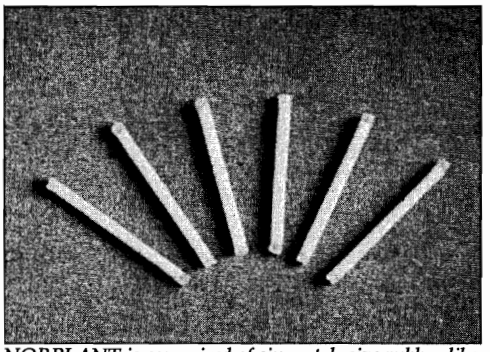
Data from Population Council and FHI research, as well as from Leiras, the manufacturer, indicate that NORPLANT is at least 99 percent effective in preventing pregnancy. This makes NORPLANT even more effective than the Pill and the IUD in actual use. While the implants contain a hormone similar to that used in some oral contraceptives (OCs), they have the added advantage of providing continuous low-dose protection, with no requirement for the woman to take a daily pill. Finally, NORPLANT contains no estrogen, the steroid believed to be responsible for the most serious side effects associated with combined (estrogen/progestin) OCs, such as heart attacks and strokes.

An important finding in studies by The Population Council is that NORPLANT's efficacy rate is influenced by the woman's weight. Among heavier women — those weighing more than 70 kg — cumulative five-year pregnancy rates were more than twice as high as for women weighing less than 70 kg. Still, even for the heaviest women, NORPLANT was 91.5 percent effective — more effective than OCs in actual use.[1]

It should also be noted that NORPLANT, like other hormonal methods, may have reduced effectiveness when combined with certain medications, such as phenytoin or carbamazepine, and drugs that induce secretion of liver enzymes.

Bleeding and other side effects

"NORPLANT is one of the safest hormonal methods," says Dr. C. Wayne Bardin, Director of The Population Council's Center for Biomedical Research. "The amount of progestin released daily is small, less than half the levonorgestrel ingested in low-dose OCs over five years. And it releases the steroid at a constant low rate, avoiding the initial heavy dose typical of injectables and the daily surge of hormones associated with OCs."



NORPLANT is comprised of six match-size rubber-like capsules filled with levonorgestrel.

As with all progestin-only methods, the most frequently reported side effect is a change in menstrual bleeding patterns. In clinical and field trials, 60 to nearly 100 percent of NORPLANT users experienced irregular menstrual bleeding, most commonly spotting, prolonged or frequent bleeding. Amenorrhea and heavy bleeding were not as common. Menstrual irregularities usually decreased after the first six months following insertion.

In FHI-sponsored trials in Sri Lanka and the Philippines, almost all the women using NORPLANT reported bleeding disruptions in the first year of use.[2] Still, more than 95 percent continued use after the first year.

While many women report irregular bleeding, these occurrences are not medically harmful. Researchers say that the mid-cycle blood loss is less than that which occurs during normal menses, and that NORPLANT users are not more likely to become anemic. In fact, studies show women using NORPLANT often have significantly increased hemoglobin levels — indicating an improved state of health.[3]

Still, such menstrual changes can pose problems for many women. "Even though the bleeding irregularities may not be a serious medical problem, they can be a major inconvenience," says Dr. Grubb. Moreover, frequent or prolonged bleeding is particularly problematic where cultural or religious customs restrict social or sexual activities while a woman is bleeding. Amenorrhea, a rarer condition, can

make it difficult for a woman to determine if she is pregnant.

So far there is no recommended medical treatment for irregular bleeding associated with progestin use. However, FHI-sponsored research suggests that counseling women in advance about the potential bleeding irregularities associated with NORPLANT may have a positive effect on their overall satisfaction with the method.[4]

NORPLANT and breastfeeding. Steroids are not the method of first choice for lactating women because of concerns about potential long-term effects on infant growth and health. One study of 60 women using NORPLANT four to six weeks postpartum indicates no ill effects on lactation or infant growth. [5] In addition, studies of the progestin-only minipill, which contains similar ingredients, show no adverse effects on infant growth and health. [6] Still, current product information for both the minipill and NORPLANT suggests breastfeeding women should not initiate use prior to six weeks after delivery.

Ectopic pregnancy. While risk of pregnancy among NORPLANT users is extremely low, studies show some risk of ectopic pregnancy among women who do get pregnant while using the implants. Research indicates that the chance of having an ectopic pregnancy may increase with duration of use and possibly with weight.[7] Providers need to be alert to the possibility of ectopic pregnancy in NORPLANT users who have lower abdominal pain or symptoms of pregnancy.

Other considerations. Other commonly reported side effects from NORPLANT use include headaches, weight gain, acne and mood changes, the same complaints cited by users of OCs. [8]

Regarding contraindications, providers are advised to heed the restrictions given for other steroids. NORPLANT should not be used by women who have active thromboembolic disorders, undiagnosed abnormal genital bleeding, acute liver disease, benign or malignant liver tumors, or known or suspected breast cancer. Providers also are advised to caution NORPLANT users over age 35 against smoking cigarettes because of possible increased risks of cardiovascular side effects for smokers using hormonal methods.[9]

Continuation rates

Continuation rates have been high in the clinical and field trials of NORPLANT users conducted so far. According to multicenter studies sponsored by The Population Council, 76 to 99 percent of users continued after the first year. While the cumulative continuation rates drop over time, about half of the women elected to use NORPLANT beyond three years. Cumulative continuation rates for five years range from 25 to 78 percent.[10]

Researchers have reported significantly higher continuation rates among later cohorts of users in various trials. They attribute this to the increasing emphasis on counseling and information dissemination about the method.[11]

A recent three-year clinical evaluation of NORPLANT users in Singapore found that 69 percent continued to use the method after three years. Researchers found that bleeding irregularities and the desire to have a child were the primary reasons given for discontinuation.[12]

For these reasons, NORPLANT is considered most suitable for women who want a method that is easy to use and who wish to space their children several years apart. It is also suitable for women who wish to have no more children, particularly where sterilization is not available or is prohibited. NORPLANT is also appropriate for women who desire to use a contraceptive method that does not involve vaginal contact.

NORPLANT is inserted in the upper arm.

It is considered most suitable for women who want a method that is easy to use and that will allow them to space their children several years apart.

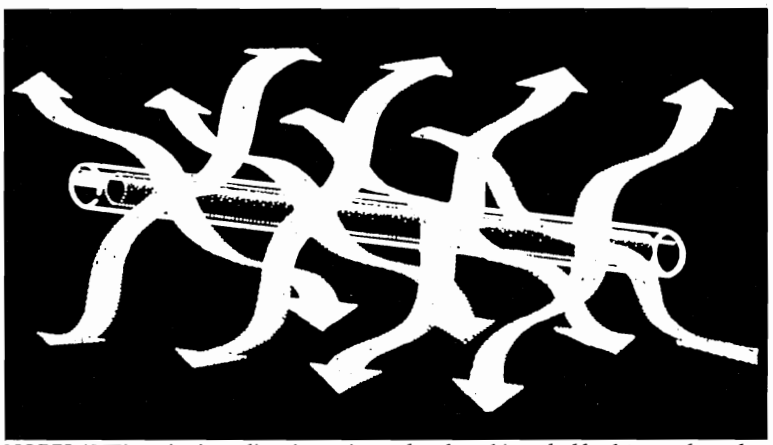
Long-acting and reversible

Although NORPLANT implants can be removed at any time, they are designed to provide effective contraceptive protection for up to five years. At that point they should be removed, since their effectiveness is reduced. As the risk of pregnancy

increases after five years, there is concern that women who do get pregnant will be at increased risk for ectopic pregnancy. If a woman wants to continue using NORPLANT for longer than five years, she should have a new set of implants inserted.

Once NORPLANT is removed, the woman's normal fertility is restored. Studies indicate that former NORPLANT users conceive as quickly as those who have never used the method, with no difference between those who used the method for longer than two years and those who stopped using the method before that time. [13]

Little evidence exists so far about the outcome of pregnancies following NORPLANT removals. However, studies of pregnancies following discontinuation of other levonorgestrel methods show no increase in pregnancy problems or abnormalities among newborns. [14] "Women are given much higher doses of steroid in other methods — and there appears to be no increased incidence of abnormal pregnancies," says Dr. Bardin of The Population Council.



NORPLANT's active ingredient is continuously released into the bloodstream through each of the six implanted capsules.

Long-term benefits and risks

With data gathered from 16 years of clinical and field studies, much is already known about how NORPLANT works. Still many questions remain unanswered about potential long-term health benefits and risks associated with its use.

In a joint effort, the World Health Organization, The Population Council, and FHI have been conducting a postmarketing surveillance study looking at large-scale, long-term use of NORPLANT around the world. In a controlled study comparing NORPLANT users to IUD users or sterilized women, 16,000 women in 18 countries are being monitored over a five-year period, even if they discontinue the method at any time.

This worldwide study of NORPLANT use will document the more common risks — risks for health problems that are more common than 1 in 1,000 users per year.

Other studies will focus on women who choose to continue using NORPLANT to learn more about which women are the best candidates for the method. ■

— *Sara Townsend*

Footnotes

[1] NORPLANT Levonorgestrel Implants: Summary of Scientific Data, The Population Council, in publication.

[2] S Balogh et al., Bleeding Patterns and Acceptability Among Norplant Users in Two Asian Countries, *Contraception* 39(5):541-553.

[3] O Fakeye and S Balogh, Effect of Contraceptive Use on Hemoglobin, Packed Cell Volume and Menstrual Bleeding Patterns, *Contraception* 39(3): 265, 1989.

[4] Op cit, Balogh. Another study by Thomas Kane et al. shows that couples have apprehension about NORPLANT, and suggests that women and their husbands should receive counseling. T T Kane, G Farr, B Janowitz, Initial Acceptability of Contraceptive Implants in Four Developing Countries. *International Family Planning Perspectives*, 16(2): 49-54, 1990.

[5] B Affandi et al., Effect of NORPLANT® on Mothers and Infants in the Postpartum Period. *Advances in Contraception*, 2(4): 371, 1986.

[6] M McCann et al., The Effects of a Progestin-only Oral Contraceptive (Levonorgestrel 0.03 mg) on Breastfeeding, *Contraception*, 40(6); 635, 1989.

[7] I Sivin, International Experience with NORPLANT® and NORPLANT®-2 Contraception, *Studies in Family Planning* 19: 81-94, 1988.

[8] P Darney et al., Acceptability and Perceptions of NORPLANT® among Users in San Francisco, USA, *Studies in Family Planning* 21(3): 159, 1990.

[9] NORPLANT® Contraceptive Subdermal Implants: Managerial and Technical Guidelines, World Health Organization, 1990, p. 7.

[10] Op cit, Sivin.

[11] Ibid, p. 91.

[12] K Singh, A Three Year Clinical Evaluation of NORPLANT® in Singapore Acceptors, *Advances in Contraception* 6:1-9, 1990.

[13] Op cit, Sivin.

[14] Ibid.

NORPLANT Counseling Guidelines

The Population Council has published a new booklet for health care providers on how to counsel potential NORPLANT acceptors. *NORPLANT: Guide to Effective Counseling* reviews counseling techniques and basic information about the implants. It is available for US$2.50 per copy from: The Population Council, 1 Dag Hammarskjold Plaza, New York, NY 10017 USA. ■

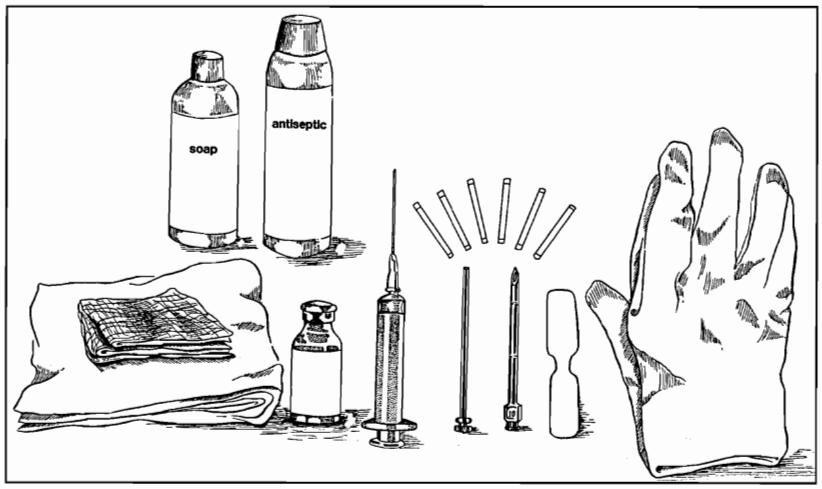
PROGRAMMATIC CHALLENGES: TRAINING, COUNSELING AND REMOVALS

An estimated 600,000 women across Indonesia receive daily, continuous contraceptive protection through NORPLANT® implants, according to local health officials. At least 50,000 women in Thailand are also using this innovative method. These are two countries with well-established national family planning programs, where NORPLANT has already progressed beyond clinical trials to large-scale use in the population. Other countries are moving in this direction as well.

"The government has done an outstanding job in promoting NORPLANT in Indonesia and many women now want to use it," says Dr. Sulaiman Sastrawinata, Executive Director of the Coordinating Board of Indonesian Fertility Research (BKS PENFIN), an association of 15 hospital research programs. "Now the great challenge is the logistics of meeting that demand, that is, having a sufficient supply of NORPLANT available throughout the country and through the private sector as well as the public sector."

"We should also have good counseling and follow-up services to encourage continuation of NORPLANT," adds Dr. Sulaiman. "It is an expensive method if it is not used for the [five-year] period it is meant to cover."

These are some of the programmatic challenges involved in taking NORPLANT beyond the controlled environment of a clinical trial into a country's family planning system, including primary health-care facilities. Such challenges include how to train providers in insertion, removal, counseling and service delivery; how to ensure that NORPLANT is removed upon request or at the end of five years; and how to provide adequate information and education to potential NORPLANT users, their spouses and the medical community.



PATH

Materials needed for NORPLANT® insertion include: surgical soap, antiseptic, sterile gauze, local anesthetic, syringe and needle, No. 10 trocar, six NORPLANT® capsules, butterfly (or ordinary) bandage, sterilized surgical clothes and rubber gloves.

Provider training

"You must stress training, training, training — that's the key to this method," says Dr. John Gill, a Senior Associate at The Population Council, who is based in Bangkok, Thailand. In 1990, the World Health Organization published a 134-page set of managerial and technical guidelines regarding NORPLANT use, which outlines three kinds of training needs: medical/clinical issues, service delivery management, and counseling.[1]

Medical/clinical issues. Although NORPLANT insertions and removals are simple procedures, they require specialized training. Research has shown that both physicians and non-physicians can effectively insert and remove NORPLANT if given the proper training.[2]

In addition, providers who are not trained to insert or remove NORPLANT can benefit from having enough information to offer women advice or refer them to trained providers. In 1984, the Indonesian Ministry of Health and the National Family Planning Board (BKKBN) provided such basic training to 12,000 midwives and nurses, including information on counseling, record keeping and management issues.[3]

A training curriculum designed for physicians, nurses and other health care workers has been developed by the Association for Voluntary Surgical Contraception (AVSC), Family Health International (FHI), The Population Council, and The Program for Appropriate Technology in Health (PATH). It contains printed and audio-visual materials for training sessions lasting five days and covering 18 modules. Field tested in Nigeria, Bangladesh and Kenya, the curriculum is designed to be adapted for use in any country. In addition, PATH has developed artificial arms that can be used for simulating NORPLANT insertion and removal techniques.

Service Delivery. Medical personnel must also be trained in storage of NORPLANT supplies, care of equipment, and, most important, sterile technique. This can

be particularly challenging in some rural settings. For example, in 1986, researchers from the University of Nairobi and Kenyatta National Hospital brought NORPLANT to four rural clinics in Kenya's Machakos district, with no electricity or running water.

In Nairobi, the needles, scalpels and insertion trocars were sterilized, packaged in individual kits with a NORPLANT set, and then taken to the Machakos clinics. "A team of one doctor and three nurses would go to these clinics and provide vaccinations and other MCH-FP services, including NORPLANT insertions, in a clinic located in the marketplace," explains Dr. Samson Wanjala, Chairman of the Department of Obstetrics and Gynecology, Kenyatta National Hospital. The team would bring the instruments back to Nairobi to be sterilized and used again.

Counseling is important at every stage.

Counseling. Perhaps most important of all, providers must also be adequately trained in patient screening and counseling. "Give the woman information," says Dr. Gill of The Population Council. "Lack of information has been the weakness of all family planning programs."

Counseling is important at every stage. Before the insertion takes place, the provider should clearly explain that NORPLANT is one of several contraceptive options, offering information on the advantages and disadvantages of each method available. The client should also be given information on the menstrual irregularities experienced by many NORPLANT users, and what to expect during insertion and removal. Women should also be told that NORPLANT is effective for up to five years, but that it may be removed by a trained provider at any time upon request.

Counseling also serves as a screening process for users. For example, if the woman indicates that her husband will object to the menstrual irregularities that often accompany NORPLANT use, the provider should consider counseling the husband. Or if the woman says she wants to have a child in two years, the provider might counsel her to consider using another method. If providers do not know how to screen and counsel potential NORPLANT users in this way, they may find some of their patients returning one or two months later requesting removal.

Studies underscore the importance of counseling for NORPLANT to be successful. A survey of more than 5,000 women in Bangladesh, Haiti, Nepal and Nigeria examined why clients did or did not select NORPLANT. Researchers found a "need for thorough counseling to reduce the apprehensions that both women and their husbands may have about this new method [including] menstrual irregularities, insertion and removal practices, side effects and return to fertility."[4]

The impact of counseling was clear in an acceptability study of 175 NORPLANT users in Sri Lanka and the Philippines. "Despite the high incidence of menstrual pattern changes, satisfaction with NORPLANT in these studies was quite high," according to the study, which was coordinated by FHI. "The key to the high degree of satisfaction may have been the counseling these women received; all the acceptors in each country stated that they had received sufficient information about the method."[5]

In addition to pre-insertion information, follow-up counseling is extremely important. "Answering questions helps a client cope with any problem or side effects," states the World Health Organization's (WHO) NORPLANT guide.

"Misunderstanding about NORPLANT can lead to early removal," says Sandor Balogh, FHI's Associate Director for Contraceptive Introduction. "Follow-up counseling can help ensure that women feel comfortable with the method and that they leave the clinic with confidence and with full understanding of any side effects they may encounter."

Access to removal

Providers should understand that women have the right to have the implants removed upon request. This principle appears throughout all of the NORPLANT introduction literature. "All elements of the introduction program ... must be planned to ensure access to removal at five years or earlier if the woman requests," states The Population Council's newsletter on NORPLANT.[6] The WHO guidelines emphasize that "counselors should reassure clients that removal is available on demand."[7]

Following this principle can be complicated, however. For example, when a woman requests that NORPLANT be removed after only a few months, the health care provider might be tempted to try to change her mind, aware that NORPLANT is much more cost effective if used for a longer period of time. Moreover, regardless of cost, the provider may believe that keeping NORPLANT is the best decision, for the sake of the woman's health and family planning needs. Hence, in discussing the advantages and disadvantages of NORPLANT, the provider

might convince a woman who had sought removal to change her mind.

In fact, the distinction may not always be clear between good patient counseling and patronizing the patient, between working with the woman to try NORPLANT for a while longer and coercing her to do so. Because doctors have such power to persuade, the principle of access to removal is especially fragile.

Follow-up

Closely related to the issue of access to removal is the challenge of how to follow up NORPLANT users to ensure that the implants are removed after five years, when their proven effectiveness is reduced. "We have focused a lot on NORPLANT introduction, but must reinforce the need to plan for five-year removal," says Karen Beattie, who heads The Population Council's contraceptive introduction program. "The fact that you have to remove after five years requires attention at the beginning of the project. We need mechanisms for tracking the women using NORPLANT, for reinforcing the knowledge that they must return for removal."

In Indonesia, with more than half a million NORPLANT users, preparations for removal services are critical. Women have a family planning card, which can be used to tell them when to return for removal. "It should be recorded on the family planning card," explains Dr. Gill of The Population Council. "That card should be the record."

In Bangladesh, the Bangladesh Fertility Research Program (BFRP) is attempting to build a tracking system into the expansion program. "We will try to establish a surveillance system, a national tracking system," says Dr. T.A. Chowdhury of the BFRP Executive Council. "We have some doubts that it can work, but we feel there is no harm in starting. It may point towards how we can develop other tracking systems. For example, maybe it can point us toward a national cancer registry."

Information and education

Obtaining clear and thorough information on what NORPLANT is and how it works poses a challenge to information programs. Radio jingles or billboard slogans that might work for condoms or the Pill will not explain NORPLANT. This is a new technology which requires substantial explanation. NORPLANT must be obtained at a clinic and cannot be bought at a pharmacy. It involves talking to health professionals, not just to a neighbor.

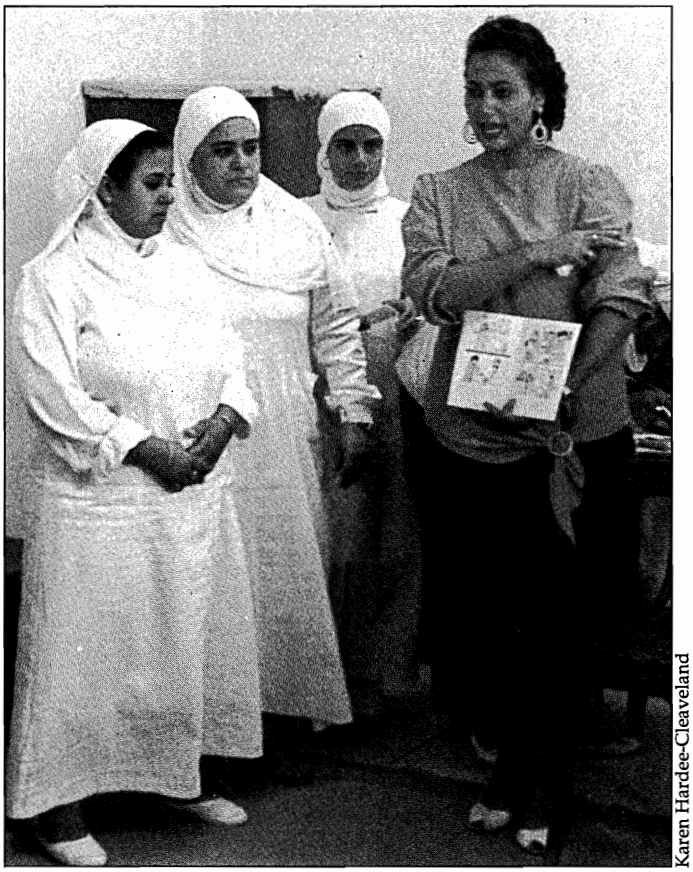
Studies have shown that good information can help NORPLANT be successful. In a series of focus-group discussions in the Dominican Republic, Egypt, Indonesia and Thailand, researchers worked with potential acceptors of NORPLANT, current users, discontinuers, husbands of women in each of these three groups, and service providers.

"The need for informational materials was often mentioned in all countries, especially for potential users and new acceptors, husbands of these women, and members of the medical community not providing NORPLANT services but treating women who are either using or considering using this family planning method," the study reported.[8] The study

Providers should understand that women have the right to have the implants removed upon request.

LEIRAS

Countries where NORPLANT has been used.



Karen Hardee-Cleaveland

Nurses learn about NORPLANT® at a family planning clinic at Ein Shams University in Cairo.

also highlighted specific suggestions from the groups. "Women in the Dominican Republic, Indonesia and Thailand suggested using videos in addition to informational print materials, particularly in clinic waiting rooms where potential acceptors spend a great deal of time."

Some ways to educate the broader medical community might include talks at professional meetings, clinics and hospitals, and articles in newsletters and health publications.

The WHO technical guidelines point out the value of making materials country-specific. In Bangladesh, the BFRP is using three separate brochures on NORPLANT — for users, husbands and counselors. Each was developed especially for Bangladesh. The WHO guidelines also point to the growing numbers of prototype materials available. This guidebook includes an appendix of sources of materials and information worldwide.

Conclusion

NORPLANT holds much promise as an effective, long-acting and reversible method. "But it is not a perfect solution," says Dr. Shyam Thapa, Senior Research Associate in FHI's Program Evaluation Division. "Now that we have the implant, we need to strengthen the contraceptive delivery system itself."

The issues related to training and counseling, access to removal, and patient tracking are further complicated by the specific needs of each country. For example, sterilization is prohibited or unpopular in many countries. There, NORPLANT may offer a practical alternative for women who wish to have no more children.

Similarly, supply and cost are crucial issues. In Thailand, a heavy import duty makes NORPLANT far more expensive than in Indonesia. Hence, NORPLANT is concentrated in the southern provinces of Thailand, where sterilization is not a popular form of contraception.

As the medical and family planning communities prepare for wide NORPLANT introduction, great attention must be given to applying the knowledge gained through controlled clinical trials to the general service delivery systems, both public and private.

"The method is out there now," says Ms. Beattie of The Population Council. "Now we have to integrate this new technology into the family planning service delivery system — and at the same time, take care of women's concerns and questions about the technology." ■

— *William R. Finger*

Footnotes

[1] Norplant Contraceptive Subdermal Implants: Managerial and Technical Guidelines, Programme of Maternal and Child Health including Family Planning, World Health Organization, 1990.

[2] B Affandi et al., Insertion and Removal of NORPLANT Contraceptive Implants by Physicians and Nonphysicians in an Indonesian Clinic, *Studies in Family Planning*, 18(5): 302-305, 1987.

[3] H Sutedi et al., Introduction of the NORPLANT Subdermal Contraceptive System into a Family Planning Program — Indonesia, The Population Council Regional Research Papers, South and East Asia, no date, p. 10.

[4] T Kane et al., Initial Acceptability of Contraceptive Implants in Four Developing Countries, *International Family Planning Perspectives*, 16(2):53, 1990.

[5] S Balogh et al., Bleeding Patterns and Acceptability Among NORPLANT Users in Two Asian Countries, *Contraception*, 39(5):552, 1989.

[6] NORPLANT Fact Sheet No. 6 — A Checklist for Managers, NORPLANT Worldwide, The Population Council, (14):3, 1990.

[7] Op. cit., World Health Organization, p. 29.

[8] M Zimmerman et al., Assessing the Acceptability of NORPLANT Implants in Four Countries: Findings from Focus Group Research, *Studies in Family Planning*, 21(2):99, 1990.

NORPLANT® INSERTION AND REMOVAL

MEXICO CITY — The woman on the examining table tenses as the doctor injects anesthesia in her upper arm. In a moment she relaxes and the procedure begins for implanting NORPLANT® at this clinic administered by the Mexican Institute of Social Security (IMSS).

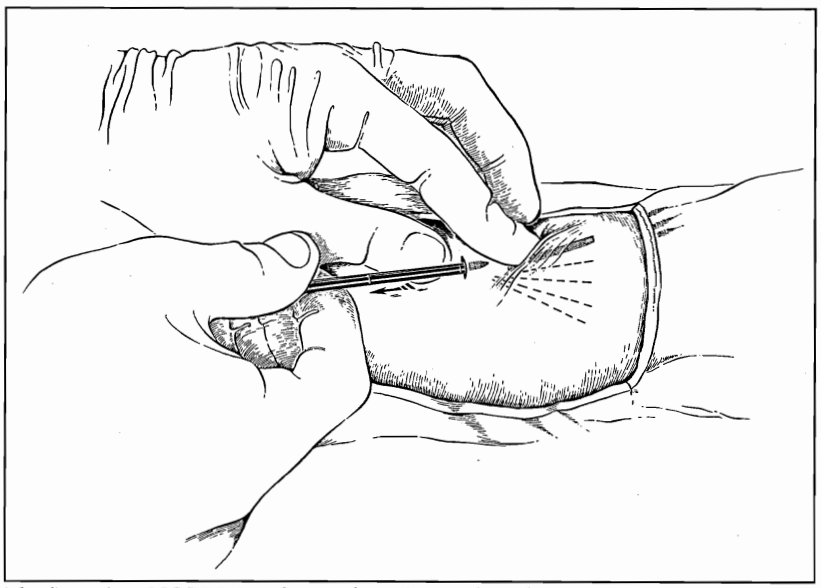
The doctor uses the sharp tip of the trocar — a hollow surgical needle — to make a small (2 mm) opening in the skin. He then inserts the tip of the trocar through the small puncture wound. (It is also common for clinicians to use a scalpel to make the incision and then insert the tip of the trocar into the opening.) Once the trocar tip is just under the skin, the doctor turns it upward to ensure subcutaneous placement of the implants.

The first of six NORPLANT capsules is loaded into the trocar. The doctor pushes it gently under the skin with the trocar's plunger. Then, holding the plunger steady, he withdraws the trocar until just the tip is left under the skin; the first capsule is now implanted just under the skin. He then turns the trocar slightly, about 15 degrees, so that another capsule can be implanted next to the first. The implants are inserted through the trocar one at a time, until all six take their place in a fan-like pattern.[1]

The trocar is removed and the puncture is closed with a butterfly bandage and covered with protective gauze. No sutures are required. About 10 minutes after the procedure begins, the woman — a mother of three — leaves the clinic protected from pregnancy for as long as five years.

Doctors and nurses can be trained to perform this minor surgical procedure required for insertion and removal of NORPLANT. However, clinicians familiar with the technique say it takes training and experience to become proficient. The implants must be inserted, with proper attention to depth and placement, just beneath the skin, says Dr. Francisco Alvarez-Sanchez, of PROFAMILIA, the Dominican Republic's Family Planning Association. Dr. Alvarez-Sanchez has trained more than 100 physicians at an international training center in Santo Domingo. "The trocar should be inserted at a shallow angle and tilted toward the surface of the skin, so that the implants remain just under the skin," he says.

To ensure that the implants do not lie so close to the elbow as to interfere with movement of the arm, the trocar is inserted 6-8 cm above the elbow. The implants — which are flexible and cannot break inside a woman's body — can be felt through the skin but usually are not visible.



PATH

The first of six NORPLANT® capsules is inserted in place.

To avoid inserting NORPLANT in a woman who may already be pregnant, the procedure should take place during menses or immediately after a terminated pregnancy. Breastfeeding women should wait until six weeks after delivery to have NORPLANT inserted.

Complications that occasionally may result from insertion include infection and expulsion of an implant. These problems are rare — less than one in 100 women in multi-country trials conducted by FHI. In an FHI-sponsored study of 2,674 NORPLANT users, one-year incidence rates of infection and expulsion were 0.8 percent and 0.4 percent, respectively.[2] Pain and itching at the insertion site occurred in 2 percent of all insertions.[3]

"These incidence rates vary widely among countries and clinics within a country," says Dr. Gary Grubb, Associate Medical Director of FHI's Clinical Trials Division.

In contrast to previous reports that complications occurred only during the first few weeks of NORPLANT use, FHI investigators have found complications occurring much later. For example, when an infection or expulsion does occur, it is commonly after the first two months of use. In addition, more than one-third (37.5 percent) of local reactions, including pain and itching, were reported after four months of use.[4]

Most complications are directly related to inexperience of the inserter, improper training or lack of sterile techniques, says Dr. C. Wayne Bardin, Director of The Population Council's Center for Medical Research. "NORPLANT insertions are similar to IUD insertions. If you insert the IUD in the wrong place, it's hard to get out," he says. "Similarly, if you insert the implant too deep, it's hard to retrieve."

Removal requires a slightly larger incision — 4 mm long — at the original site of insertion and usually takes about 15-30 minutes. "The ease and success of implant removals depend mostly on the proper placement during insertion," says Dr. Grubb.

If one or two capsules are hard to remove, the provider should ask the woman to return in two to four weeks when the wound is healed.

If a woman wishes to continue using NORPLANT for more than five years, another set of implants can be inserted when she has the first set removed. The second set can be placed through the same incision.

"It may also be the most desirable procedure cosmetically, but having only one puncture site also allows for the greatest amount of convenience, ease and comfort for the patients," says Dr. Bardin.

A local anesthetic is used for the removal procedure. In a recent acceptability study of 250 women in a five-year clinical trial of NORPLANT in the USA, 74 percent reported little or no pain at removal. Thirteen percent reported a great deal of pain; and 12 percent said they had moderate pain at removal.[5] ■

— *Sara Townsend*

It takes training and experience to become proficient at insertion and removal.

Footnotes

[1] For additional details on proper insertion and removal technique, see "Norplant Contraceptive Subdermal Implants: Managerial and Technical Guidelines," 1990. Programme of Maternal and Child Health including Family Planning, World Health Organization, 1211 Geneva 27, Switzerland.

[2] S Klavon and G Grubb, Insertion Site Complications During the First Year of NORPLANT Use, *Contraception* 41(1), 1990.

[3] Ibid.

[4] Ibid.

[5] P Darney et al. Acceptance and Perceptions of NORPLANT among Users in San Francisco, USA, *Studies in Family Planning* 21(3): 152, 1990.

BEYOND NORPLANT®

NORPLANT®* is not the first long-acting hormonal contraceptive method and it will probably not be the last.

Injectables have been available for over a decade, providing continuous delivery of contraceptive hormones to the bloodstream for 60 to 90 days. Such methods are considered better than oral contraceptives for women who might have trouble taking a pill every day. But injectables still require the woman to get a shot every two to three months.

The advantage of NORPLANT is that it provides even longer protection (up to five years), through the use of implants. However, the NORPLANT implants are not biodegradable and should be removed at the end of five years when their effectiveness begins to wane. This means that providers need to follow up NORPLANT users to ensure that the implants are removed at the appropriate time. Researchers are developing biodegradable implants, which could last one or two years, and would not require removal. These products are currently being tested in clinical trials.

In addition, another version of NORPLANT is under development that is designed to be easier to remove, but will not be available for several years. Called NORPLANT-II®, it consists of two rods made of a hormonal mixture, instead of six hormone-filled capsules.

Research is also underway to develop injectable biodegradable microspheres and microcapsules, as well as monthly injectables that combine estrogen and a progestin to minimize menstrual irregularities, and a vaginal ring that would also gradually release hormones to the bloodstream.

If these products can be developed, approved and distributed, women around the world may have several new family planning options to choose from by the turn of the century. ■

— *Sara Townsend*

*NORPLANT® is the registered trademark of The Population Council for subdermal levonorgestrel implants.

POSTPARTUM CONTRACEPTION CONFERENCE HELD

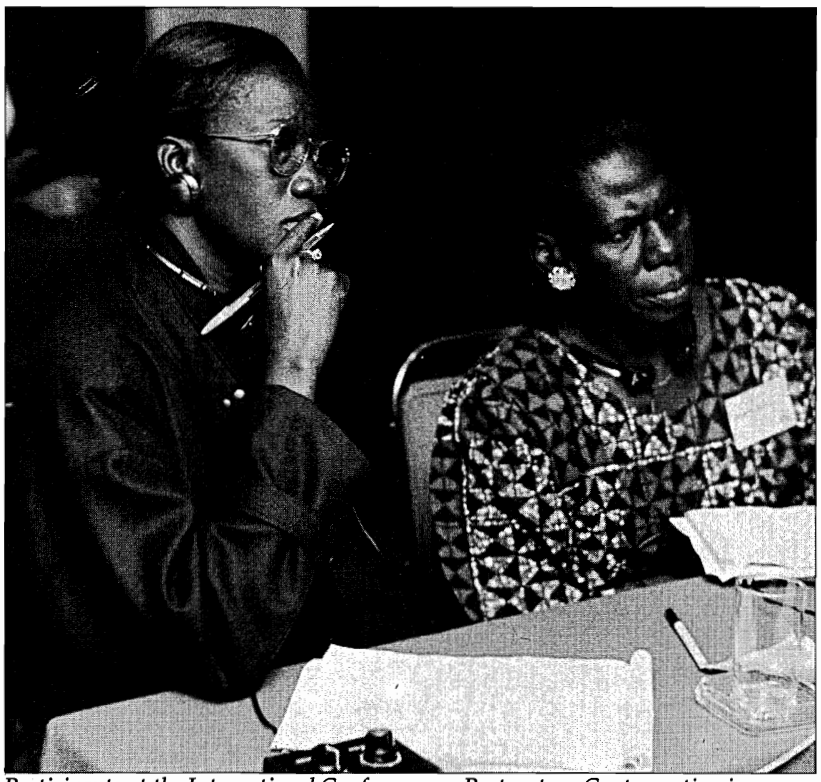
MEXICO CITY — More than 160 family planning experts from 48 countries gathered in Mexico City in September to explore new strategies for providing contraceptive services to millions of women in Latin America, Africa and Asia. The International Conference on Postpartum Contraception was sponsored by Family Health International (FHI) in collaboration with the Mexican Institute of Social Security (IMSS) and the Mexican Ministry of Health.

The conference featured presentations and workshops on research and programmatic issues associated with extending family planning services to postpartum women — that is, women who have recently completed or terminated a pregnancy.

In many parts of the developing world the only time some women receive medical care is during pregnancy, labor and childbirth. Yet many prenatal and obstetric care programs do not include family planning counseling and services. The extension of such services would provide protection against unwanted pregnancies for women who currently have little or no access to contraception.

Conference participants heard the latest information on clinical and biomedical aspects of various methods of postpartum contraception as well as behavioral and cultural factors affecting the use of contraception during the postpartum period. In addition, they discussed the appropriateness of various methods, focusing on the timing of introduction and the medical and programmatic advantages and disadvantages of each. There were also presentations on the importance of informed choice and quality of care.

The keynote address was given by Dr. Pramilla Senanayake, Assistant Secretary General of the London-based International Planned Parenthood Federation (IPPF). Dr. Senanayake noted that in the past 15 years there has been a rapid decline in the number of children desired by many couples in developing countries. Still, more babies will be born in the 1990s than in any decade in history. "These changes present a great challenge for the 1990s and beyond and for the demand for postpartum services," she said. "We must do all in our power to ensure that we do not also have an unprecedented number of pregnancies and infant deaths."



Juan López

Participants at the International Conference on Postpartum Contraception in Mexico City

Providing family planning services to postpartum and breastfeeding women can save the lives of both mothers and infants, said Dr. Senanayake, because it would allow women to space their children at healthier intervals. She also noted research suggesting that if all births were spaced at least two years apart, there would be 50,000 fewer maternal deaths and 500,000 fewer infant deaths each year.

"It is time that each and every family planning program develop a well-specified postpartum program as an integral component of the national family planning program," said Dr. Senanayake.

In delivering family planning services during the postpartum period, providers need to inform women about the health advantages and contraceptive values of breastfeeding, she added, while educating women about the need to combine breastfeeding with modern methods as the women return to fertility.

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90-23 K Kanchanasinith, P Piyapinyo, P Pitaktepsombati, S Vibulsresth, DS Gates, B Janowitz, M Robbins. Postpartum Sterilization by Nurse-Midwives in Thailand. *Int Fam Plann Perspect* 16(2):55, 1990.

90-24 P Bailey, AO Tsui, B Janowitz, R Dominik, L Araujo. A Study of Infant Mortality and Causes of Death in a Rural North-East Brazilian Community. *J Biosoc Sci* 22(3):349, 1990.

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90-27 I Chi, MG Farr, K Thompson, M Acosta, G Alvarado, R Rivera, J Bandaragoda, JD Betancourt. Is the Copper T 380A Device Associated with an Increased Risk of Removal Due to Bleeding and/or Pain? — An Analysis. *Contraception* 42(2):159, 1990.

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Postpartum

Continued from page 15

"Postpartum family planning makes sense and is desired by the overwhelming majority of women," said FHI President Malcolm Potts in his closing remarks. "We must plan ahead and make sure family planning choices are accessible, that the methods are compatible with breastfeeding and that they are introduced at an optimum time postpartum."

Following the three-day conference, a smaller group met for a special working session to establish priorities for future research on postpartum contraception. From a list of over 200 potential research projects, researchers in the final session reached a consensus on the top 30 and began outlining proposals for funding. FHI will assist in seeking funds for these projects. In addition, smaller regional meetings on postpartum contraception are planned for Africa and Asia. ■

For additional information on postpartum contraception, see **network** 11(3), August 1990.

FAMILY HEALTH INTERNATIONAL
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Special Issue on AIDS Prevention

STRATEGIES FOR BEHAVIOR CHANGE – SLOWING THE SPREAD OF AIDS

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AIDS is an emergency, especially in the developing world. While cures or vaccines may be years away at best, the number of HIV-infected people is increasing rapidly.

From 1990 to the year 2000, the number of HIV-infected people is expected to double, from 8-10 million to 15-20 million, according to the World Health Organization. Currently, about two-thirds of these people live in developing countries. Most of the new infections will occur among heterosexuals in the developing world.

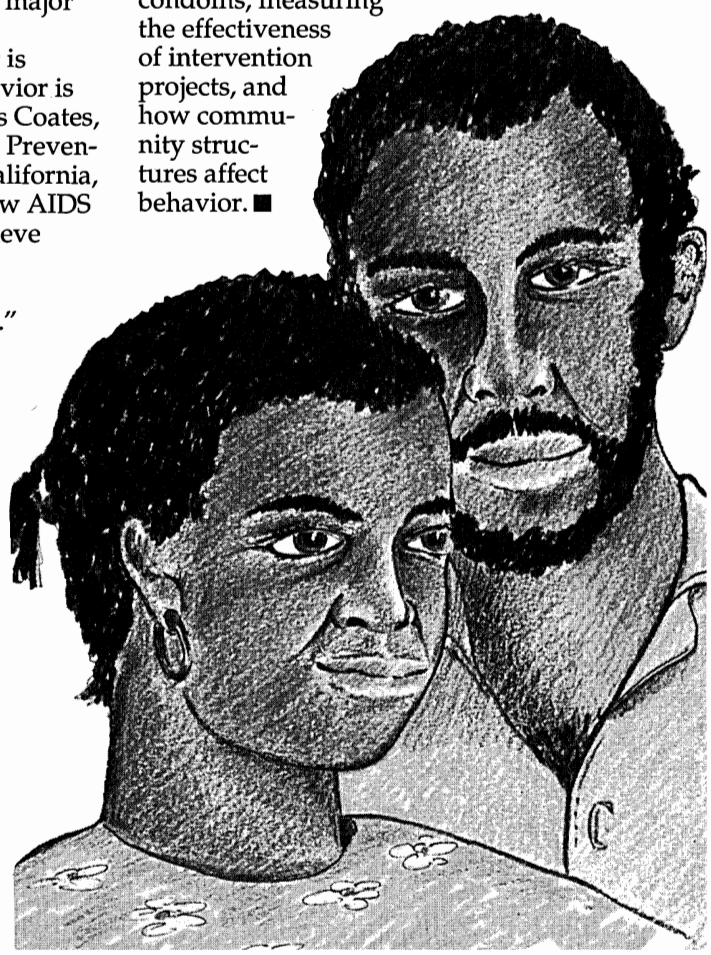
Sexual contact is the primary way that HIV is transmitted. Hence, the best way to slow HIV transmission is to modify sexual behaviors that spread the virus. Using condoms, a primary means of reducing HIV transmission, often requires a major change in behavior.

"Changing any health behavior is difficult, but changing sexual behavior is especially tricky," says Dr. Thomas Coates, Co-director of the Center for AIDS Prevention Studies at the University of California, San Francisco. "To understand how AIDS prevention programs can best achieve desired behavior changes, proven principles of behavior change can provide a valuable reference point."

Applying behavioral and other scientific principles to intervention projects has proven difficult. Cultural, political, and strategic barriers exist to launching and sustaining projects that can effectively slow the spread of HIV. Meanwhile, resources are limited, especially in countries where public health infrastructures are underdeveloped. Even so, a central approach in using limited resources to slow HIV transmission has emerged: the concept of targeted interventions.

"In a targeted intervention, projects focus resources at groups practicing behaviors that put them at high risk of HIV infection," explains Dr. Peter Lamptey, Director of AIDSTECH/FHI, the largest U.S. AIDS-intervention effort working in the developing world. "Many intervention projects seek to modify sexual behavior through education and through the promotion and distribution of condoms."

This issue of *network* examines strategies for behavior change to slow the spread of AIDS. Separate articles synthesize the lessons learned in each of three major intervention models. Other articles examine issues central to HIV-intervention efforts — how to develop effective AIDS education materials, social marketing of condoms, measuring the effectiveness of intervention projects, and how community structures affect behavior. ■



editorial

HOW INTERVENTION PROJECTS AFFECT SEXUAL BEHAVIOR

Sexual contact is the primary way that HIV infection is transmitted. The most efficient way to reduce the spread of HIV infection is for those at greatest risk of infection to modify their sexual behavior. Hence, AIDSTECH focuses on targeted intervention programs designed to reduce sexual transmission of HIV among people at greatest risk of infection.

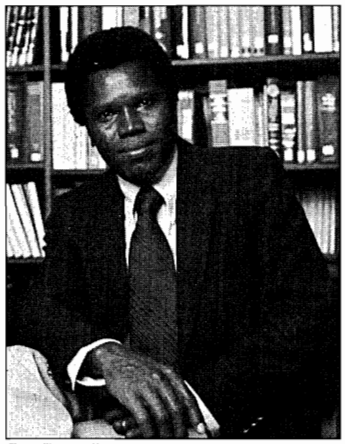
Such interventions, although absolutely critical to slowing the spread of AIDS, can be controversial. Consequently, gaining necessary government support for such work can be crucial for success at the local and at the national level.

At the local level, the Bulawayo City Council in Zimbabwe has worked with AIDSTECH to distribute condoms and to treat and prevent sexually transmitted diseases (STDs). Condom use and STD prevention are important means of reducing HIV transmission. The presence of an STD can increase the chance of HIV transmission by up to 100 times in a single act of intercourse.

At the national level, President Yoweri K. Museveni of Uganda recently reviewed findings from an AIDSTECH computer modeling project which demonstrated the extent to which consistent condom use could help reduce future HIV infection. Two days later, President Museveni expressed public support for condom use, reversing a long-held position against their use.

The long-term challenge is to implement and sustain projects that slow HIV transmission. To do this, we have focused our work on three types of targeted intervention models — peer education, clinic-based projects, and reaching men at work and in social settings. Integral to these efforts are condom promotion and distribution, including social marketing of condoms, designing effective AIDS education materials, and evaluating the effectiveness of intervention projects.

Peer education projects have been effective in expanding awareness of condoms and condom use, but four important questions have also emerged from this approach: whether pilot projects can be expanded to large areas, whether to pay the peer educators, how to affect the behavior of the prostitutes' clients, and how to combine condom distribution with the peer model.


Dr. Peter Lamptey

Clinics providing STD and family planning services offer a built-in infrastructure and serve people who may have an increased risk of HIV infection. While some clinics have shown they can deliver AIDS-prevention services — education, counseling and condoms — they cannot on their own reach all people at high risk of HIV infection.

Even when projects can reach men at the workplace and in social settings, altering men's sexual behavior is difficult. Some intervention projects also reach women at the workplace and in social settings.

AIDSTECH has worked in 45 countries, focusing on strategies for changing sexual behavior. What is clear from our experience is that a number of approaches are needed. There is no single answer. We believe that the intervention programs highlighted in this special issue of *network* have been successful, for example, in increasing condom use, one of the major indicators of changed sexual behavior.

But no matter how successful, these programs alone will not slow the spread of AIDS. They must be replicated, expanded and sustained in appropriate communities throughout the developing world. ■

— Dr. Peter Lamptey,
Director, AIDSTECH/FHI

AIDSTECH began in 1987, when Family Health International (FHI) and the U.S. Agency for International Development signed one of the largest single cooperative agreements between a government and a private organization to combat AIDS in the developing world. AIDSTECH is a division of FHI.

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PRINCIPLES OF BEHAVIOR CHANGE

"Excuse me, Sir," the hotel clerk says to the prospecitve guest."The hotel management requires that each guest show us his supply of condoms before he checks in." This message comes from a cartoon (right) which is appearing throughout Cameroon in West Africa.

The cartoon is designed to get people talking about condoms, which many people are not comfortable doing. But the purpose of the message is more than to make a private subject more public. Getting people to talk about condoms is often the first step towards getting people to use them. And, using condoms is one of the primary ways to slow the spread of HIV infection.

Changing any health behavior is difficult, but changing sexual behavior is especially tricky. To understand how AIDS prevention programs can best achieve desired behavior changes, proven principles of behavior change can provide a valuable reference point. Various organizations have developed behavior change models, including the U.S. National Academy of Sciences (NAS). The seven principles discussed below are based in part on the NAS work.

TRANSLATION: "Excuse me, Sir, the hotel management requires that each guest show us his supply of condoms before he checks in."

1. Providing information is the logical starting point in any behavior change effort. Individuals must understand the risks of engaging in behaviors that will transmit HIV, as well as the value of alternative behaviors, such as using condoms. *Information, although necessary, is rarely enough by itself to produce behavior change in most people.* Information campaigns must tell people what not to do, as well as what they should do to protect their health. The information must be easily understood and relevant to the individuals you are trying to reach.

2. Fear messages have limited use in motivating behavioral change. A certain level of threat and fear may help raise awareness about the need to change behaviors. However, *if fear is overwhelming it can hinder, rather than help, efforts to change.* Too much fear may cause people to deny they are at risk, to rationalize by pointing to others who have practiced similar health threatening behaviors and survived, or to adopt a fatalistic attitude, sometimes avoiding seeking medical care altogether.

Many early AIDS prevention programs based their campaigns on fear and threat messages, often featuring coffins, graveyards, and skull and crossbones. Unfortunately, these types of messages are still in use today even though posters and brochures with fear messages often encourage people to be suspicious of one another. The heightened fear, however, does not seem to result in significant changes in sexual behavior or other risky activities such as intravenous drug use.

These approaches may have also increased support for coercive or punitive measures against people with HIV — measures such as mandatory testing or quarantine. These measures are usually extraordinarily expensive and counterproductive from a public health perspective.

Fear may motivate people to seek protection, not by changing behavior, but by implementing coercive measures aimed at groups perceived to be at high risk. Overall, research to date indicates that appeals based on fear are likely to backfire, making the behavior even more resistant to change. In using such messages, it is important to consider the following:

Fear messages must strike a balance in the level of fear that is evoked. The level should be sufficiently high to motivate people to take action, but not so high that they are paralyzed with fear or even deny their risk. So, if fear is to be used, the message should empower people to take positive action in response to the message.

Using condoms may be more acceptable if people believe they are pleasurable, enjoyable and popular.

Fear-based information must provide specific steps people can take to protect their health. People must believe that the changes being proposed will do them some good, and they need viable alternatives to consider. Telling people that they will get AIDS if they have sex with many partners may evoke fear. Telling these same people that their risk will be lessened if they reduce their number of partners or use condoms may provide an escape within reach.

Attention needs to be drawn to the positive consequences of engaging in the healthy behavior. People who know that they *should* use condoms may be reluctant to try them because they have heard condoms are uncomfortable, reduce pleasure, or stay inside of the woman and cause disease. Drawing attention to the potential pleasurable aspects of condoms, while also emphasizing the health risks of unprotected intercourse, may help individuals realize that there is something they can do to protect themselves and, at the same time, increase their sexual satisfaction. Advertisers have long recognized that people are more likely to remember and heed messages that address their needs or support ideas they already believe in.

Altruism can be important. Individuals will often do for others what they would not do for themselves. People will change their behavior to avoid problems for their spouses, children, parents or kin. Concern for these people can be a powerful motivator and should not be disregarded. For example, individuals may be motivated to practice safer sex so that they can protect their family and be available to provide care for them.

This poster portrays a woman thinking "I hope he doesn't have AIDS," and a man thinking "I hope she doesn't have AIDS." Below the drawing the caption reads "You can't live on hopes."

3. People are more likely to try behaviors if they feel capable of performing them. Messages need to persuade people that they can implement the recommended changes. People can be convinced that they are capable of performing desired behaviors in three main ways.

It is important to teach people the skills for engaging in the desired behaviors. People need to have the opportunity to plan and rehearse in advance exactly how they will behave in a specific situation. Rehearsing ahead of time can build confidence by allowing people to have the experience of the new behavior before they actually need to perform it. For example, if the objective of the program is to teach commercial sex workers to have sex only if their client uses a condom, then rehearsing with them exactly what they are going to say to the client will increase the probability that they will actually use these negotiation skills with their clients.

Seeing examples of people engaging in the healthy behavior will help a person believe that he or she too can engage in that behavior. Posters or videos of couples negotiating the use of condoms, or commercial sex workers negotiating condom use with their clients, may help a person engage in that behavior in the future.

It is often easier to encourage people to substitute a behavior rather than to eliminate an unhealthy behavior altogether. Individuals engage in an unhealthy behavior because it is satisfying or pleasurable, or because "everyone else is doing it." To stop these behaviors altogether is difficult, because it means giving up pleasure or behaving in ways that are not popular. Thus, if instead of giving up the behavior altogether people can substitute something that is more healthy, and at the same time likely to be satisfying or popular, they are more likely to adopt and

maintain the practice of that behavior. For example, using condoms may be more acceptable to people as protection against STDs or HIV than giving up sex altogether. *Using condoms may be more acceptable if people believe they are pleasurable, enjoyable and popular.*

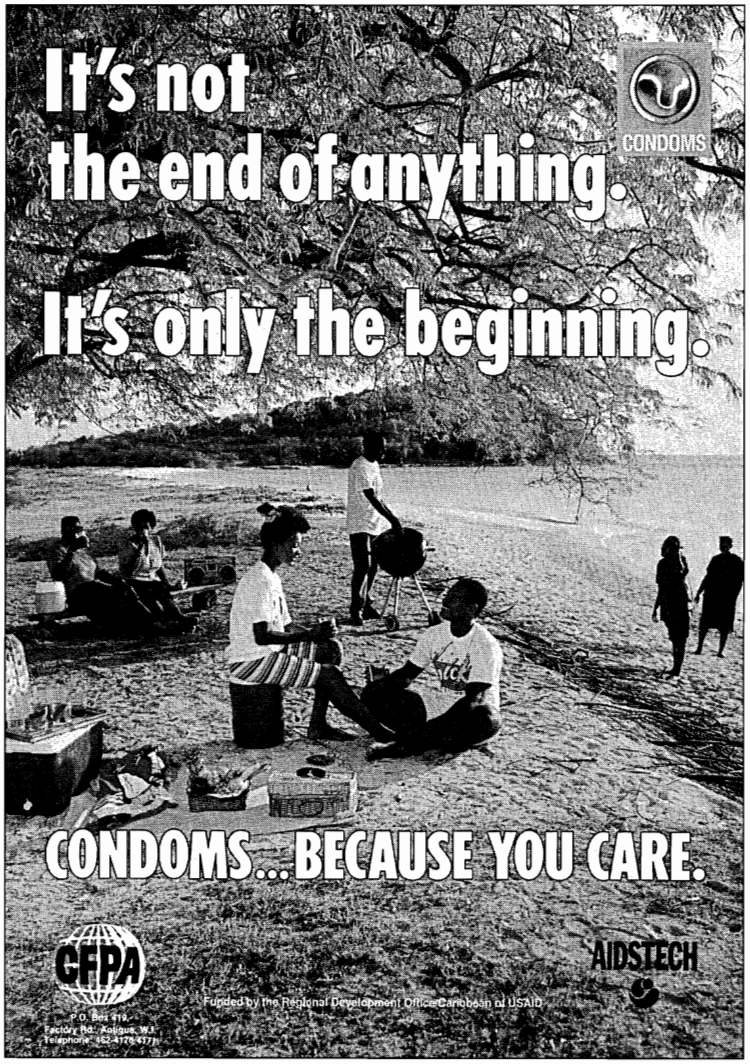
4. Individuals are more likely to adopt a new behavior if they are offered choices among alternatives. Campaigns will be more effective if people are offered even a limited number of alternatives. For example, a campaign that emphasizes only abstinence, or being with one partner, is less likely to succeed than a campaign that also emphasizes condoms as a third alternative. Similarly, if campaigns can emphasize other modes of sexual expression besides intercourse, such as non-penetrative sex or masturbation, they may be more effective than campaigns that focus only on intercourse.

5. Campaigns should create environments that encourage change. Our environment influences all of us to behave in healthy and unhealthy ways. For example, people find it more difficult to refuse alcohol in a bar or to use condoms if they think that everyone around them is continuing to drink and is not using condoms. The objective is to help people to avoid settings associated with unhealthy behaviors, to set up environments which encourage healthy behaviors, and to help people believe that the healthy alternative is expected and that everyone else is doing it. For example, if a shop displays condoms, and has them readily accessible with a sign that says "Everybody is using condoms these days," individuals might be more likely to buy them and to use them.

6. Change is more likely to occur if influential people in a community adopt the change. We often follow the lead of people we respect. The most successful behavioral change programs use influential leaders in a community, recruiting them to adopt the changes being advocated and to encourage others to do the same.

7. Relapse is expected. The reality is that no educational campaign is completely effective; not everyone will change and maintain new behaviors consistently. Individuals try new behaviors, but may slip back from time to time. Likewise, people who move into new environments are likely to adopt whatever behaviors are expected in that environment. Therefore, any program that seeks to maintain safe behaviors over time needs to build in ways to continue the campaign, to reinforce its messages, and to help people moving into new environments maintain their behaviors once there. ■

– Dr. Thomas Coates



Thomas Coates, a psychologist, is Professor of Medicine and Co-Director of the Center for AIDS Prevention Studies (CAPS) at the University of California, San Francisco, and Behavioral Advisor to AIDSTECH. He is active in AIDS prevention research and program development.

PLANNING AND PRE-TESTING: THE KEY TO EFFECTIVE AIDS EDUCATION MATERIALS

Focusing on a specific group with common characteristics — a target audience — directs the messages to the needs of that group

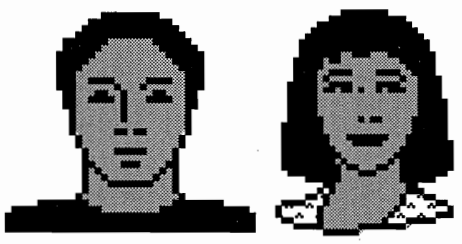
Last year, a sexually transmitted disease (STD) clinic in the Eastern Caribbean nation of St. Lucia needed educational materials on AIDS prevention. A draft brochure presented the information through stories and sketches of two fictional characters, Philip and Edwina.

Much thought went into the draft, but would the message in this draft reach the target audience — clients visiting an STD clinic? Several clients agreed to meet and discuss the brochure — before it was printed.

"He looks like a 'sweet boy'," one young woman said, referring to the sketch of Philip. "He is somebody I would not trust."

"She looks like a prostitute," another woman said, reacting to the sketch of Edwina. Others in the group agreed, saying that Edwina's earrings, hair and lipstick reminded them of a prostitute.

The patients did not identify with either Philip or Edwina. They also thought there was too much writing on the brochure. So the designer went back to work on a new draft.



Philip & Edwina: Phase I

The STD clinic in St. Lucia had a problem common to every AIDS prevention effort in the world. It needed educational materials that made sense to a specific audience. The seven steps followed in developing the brochure in St. Lucia outline a process that health educators call "constructing educational materials." In St. Lucia, it took three versions and three rounds of pre-testing to get the brochure right. Below is a checklist to use as guidelines in developing an educational message.

1. Choose your target audience. Whom do you want to reach? Focusing on a specific group with common characteristics — a target audience — directs the messages to the needs of that group. People respond to messages that reflect their particular needs or situation.

Target audiences for an AIDS prevention program have something in common related to the spread of HIV. These similarities can be age, sex, language, occupation, educational level, religion, medical condition or behaviors. In St. Lucia, program managers chose to target people who came to an STD clinic. People infected with an STD are at increased risk of HIV infection.

Other possible target audiences for AIDS prevention include health care workers, adolescents, commercial sex workers, military personnel, teachers, factory workers, truckers, and the clergy.

2. Know your target audience. Now that you have chosen your audience, you need to determine what kind of message will work best with this group. What will they hear? Read? Understand? Most importantly, what type of message will cause a change in behavior? Researching a target group's knowledge, attitudes and sexual practices regarding AIDS is crucial to developing an effective message.

Some key questions about the target audience need to be answered. What do they know about AIDS? What are their concerns about AIDS? How do they talk about AIDS? What behaviors put them at risk for HIV infection and what, if anything, are they currently doing to reduce that risk? What are common perceptions, myths, and fears about AIDS? What impact has AIDS had on this group? Other questions involve more general information. For example, what is the group's average reading level? Several techniques help answer these questions. "Quantitative" approaches such as surveys take time and can be expensive. Also, they may not be as useful as other approaches in revealing underlying feelings about AIDS-related issues.

More commonly, program managers use "qualitative" methods such as one-on-one interviews or focus groups, where small numbers of the target audience meet and talk. Group discussions with STD clinic clients in St. Lucia provided valuable insights about how to reach this audience. Clients did not know the term "STD," for example, but knew "VD" or "clap." "Rubbers" was the most common term for condoms. "Sleep with" was preferred to "have sex with."

Understanding how a group perceives the *benefits* of AIDS prevention also affects the message design. To influence health professionals, for example, a message may

need to address how people can avoid getting and spreading HIV infection. An entirely different type of message may appeal to an adolescent male, who is likely to be concerned as much or more with status as with health. A married man may be more concerned with protecting his unborn children than his own health.

Knowing what motivates your audience will help guide the choice of tone and approach. This information also helps you choose the right sources for delivering the message. Usually people view someone similar in language, values and social characteristics as the most trustworthy source for the message.

3. Choose key messages. For the St. Lucia campaign, planners initially hoped to deliver several messages including strategies for negotiating with a partner for condom use and information about the relationship between alcohol and sex. But they realized this was too complicated for their primary goal. Eventually, they focused on two points: People with STDs are at higher risk of getting HIV, and condom use reduces that risk.

Identifying the key points helps the target audience stay focused on the specific knowledge, attitude or practice that is to be changed. The messages need to be specific and clearly identify the benefit of heeding the message for the recipient. The number of key messages should be limited to about three.

4. Choose channels of communication. Once you have identified and researched your audience, and chosen your key messages, it is time to decide which media or other channels of information will reach the target group. What are your audience's media preferences and habits? What communication channels are available?

Several channels can provide more effective information dissemination than any single outlet, but some channels are more likely to reach specific audiences. Different channels do different jobs.

Mass media such as radio, TV, magazines and newspapers are best for sending simple messages to a large number of people quickly. With a highly specified target audience, such as St. Lucia's STD patients, the mass media would not be the best choice.

Instead, program managers there chose a pamphlet designed specifically for clients to read while waiting for their appointments. Pamphlets are known as ***"little media,"*** as are posters, videos, slides, audio cassettes, flipcharts, and give-aways (such as bags, matchbooks, hats, buttons, keychains). The "little media" approaches are best for reminding people again and again about complicated information likely to be forgetten quickly.

St. Lucia's STD clinic clients who receive the brochure on arrival at a clinic can review it before meeting with the staff. In concert with these print materials, ***interpersonal communication*** — face-to-face contact — works well in this setting because staff can reinforce and supplement messages and ideas included in the brochure. Other common locations for interpersonal communication are clubs, social groups, families, marketplaces, bars, and truck stops. ***Institutional networks*** such as schools, factories, hospitals, and unions are other options.

Philip & Edwina: Phase II

5. Pre-test. Now it is time to produce a first draft. In St. Lucia that meant drafting the brochure with the stories of Philip and Edwina along with artwork and graphics. Pre-testing through focus group discussions and interviews helps to ensure that the materials convey the desired messages and the audience understands them. This helps to avoid miscommunication and costly errors by pinpointing problems before final production and distribution.

Pre-testing reveals how participants respond not only to the content, but to the format, the colors, and the style. When pre-testing a text with images, such as the St. Lucia brochure, the text and images should be tested separately to identify any problems specific to either component.

In pre-tests of the materials in St. Lucia, focus groups were divided by gender to ensure that participants would feel comfortable talking about sexual matters.

After reading the story, each group was asked to talk about Philip and Edwina. Based on what they read, they were asked to tell, in their own words, what had happened to these two people. This retelling revealed the extent to which the target audience understood the stories and at the same time offered examples of the language commonly used to talk about these issues.

Identifying the key points helps the target audience stay focused on the specific knowledge, attitude or practice that is to be changed.

Before they were shown any of the draft artwork, the groups were asked to describe the characters. Did they think these stories were realistic? How would they feel if they were Philip or Edwina? What would they say to a sexual partner in this situation? Did they like Philip and Edwina? Did they seem like good people?

Philip & Edwina: Phase III

Following discussion of the text, the groups saw the draft artwork for the brochure. Focus group facilitators encouraged participants to share their opinions about the people whose pictures they were viewing.

In pre-testing several versions of a set of materials, it may be necessary to change the order in which the materials are presented in the different focus groups. The order in which people see materials can strongly influence how they react to them.

6. Modify and pre-test materials again. When deciding what changes to make, the concern should be with issues raised by many participants. If only a few people raised a question, this concern may not be a commonly held belief in the target group.

Pre-testing the St. Lucia brochure provided much information to help make it more effective. The participants spoke in much shorter sentences than those in which the original text had been drafted. The initial stories were too long and complicated. The revised text had fewer ideas expressed in the simpler language that the focus group participants used to re-tell the stories. In fact, the final version contained only half the amount of text.

AIDS outreach workers around the world report that motivations which influence HIV-related behavior often involve issues of respect and self-esteem. Pre-testing can provide information about social factors that influence respect, admiration, and trust among the target audience. For example, the interaction depicted between Philip and Edwina changed as a result of pre-testing. Women, in particular, insisted that it was crucial that Edwina be angry at Philip. Those who had learned about having an STD from their partner spoke of their anger at being told they had an STD. The brochure attempts to show those reactions.

In St. Lucia, pre-testing also revealed prevailing attitudes about condoms, STDs, and communication between sexual partners. Because the patients talked about feeling guilty for getting an STD several times during the interviews, the final brochure included information about not letting guilt stop you from getting help.

In addition to streamlining the text, the images of the characters underwent extensive revisions. The images of Philip and Edwina progressed from idealized movie-star images to more realistic, everyday portraits. Each new sketch received increased acceptance among the group participants.

Subsequent rounds of pre-testing should include at least three more focus groups or five more interviews. The groups should be similar to those used in the first round of pre-testing. If group responses to the revisions suggest the need for more revising, continue making

Philip & Edwina: Final

changes and pre-testing the materials until most focus group participants react positively.

7. Production and distribution. After the final materials are developed, they must be mass produced and distributed to the target audience. This distribution process often involves community leaders, government officials and others. Involving these various people early in the planning and revision process improves the chances they will support you in getting the final materials to the targeted audience. ■

–Marc L. Ostfield and LaHoma Smith Romocki

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INTERVENTION MODEL

REACHING MEN: AT WORK AND IN SOCIAL SETTINGS

A truck loaded with maize is parked at the Ruaha truckstop in central Tanzania, a country where more than 6 percent of the adult population is infected with the AIDS virus. The Zairian driver, on his way north along this major East African transport route, laughs as he looks at a meter-long sticker proclaiming "Condoms prevent AIDS."

"This is not a joke," says Flora, a barmaid at the truckstop, one of many who provide companionship to truckers passing through. She does her best to convince him to display the sticker on his truck. "How could you not agree to carry such a sticker?" The driver relents and places the sticker on the windshield of his rig. Whether he will also use condoms is another question, but he has taken an important first step toward taking AIDS seriously.

Truckers, like seafarers and soldiers, work under conditions which promote high-risk behavior for transmission of AIDS. Because they are highly mobile, they can spread HIV infection rapidly across large distances, and because of the time they spend away from home and family, they are more likely to practice high-risk behavior. A study of 68 truckers in southwest Uganda, for example, found that more than one of every three truck drivers was infected with HIV.[1] Similarly, HIV prevalence rates among the military are higher than for the rest of the general population.[2] These groups have something else in common as well: They are mostly men.

Reaching men with AIDS prevention messages is crucial to slowing the spread of HIV. "In developing countries, men are usually the major sexual decision makers," says Michael Welsh, AIDSTECH Associate Director for Intervention Programs. "Men put on the condoms. They have more economic power. They play the major role in sexual decision making."

Experts recognize the importance of involving men in AIDS prevention efforts but have found this goal difficult through targeted interventions. Even so, some early efforts have found that men can be receptive to AIDS prevention messages when approached where they work or where they gather for social reasons.

Targeting men at work and social settings can mean providing AIDS education and distributing condoms to soldiers in the Ghana Armed Forces, for example, or to civil servants, the police force or workers at restaurants, at barber shops, breweries or mines — and at bars and hotels along major truck routes in Tanzania.

Intervention in a Social Setting

The exchange between Flora and the Zairian trucker is one of many such exchanges taking place each day in Tanzania, thanks to a targeted intervention organized by the African Medical and Research Foundation (AMREF) with funding and technical assistance from AIDSTECH. Flora is one of 14 peer educators in this project, which targets transport workers and their partners along the major transporation route between Dar es Salaam, the Tanzanian capital, and Zambia to the south.

Mr. Christopher Mwaijanga (far right), Science Behavior Officer with AMREF in Tanzania, talks with truck drivers about the importance of using condoms.

The project distributes about 130,000 condoms a month over a several hundred kilometer area, as well as thousands of AIDS prevention posters, stickers and

Continued on page 15

PEER EDUCATION: CHANGING BEHAVIOR IN HARD-TO-REACH GROUPS

During the last two years in Ciudad Juarez, Mexico, about 75 prostitutes have assumed an additional role in their daily work. In this city of 600,000 on the U.S. border, these 75 seek paying customers and also work as peer health educators, or *promotoras*.

Until recently, the *promotoras* have taken their health messages to other prostitutes who work out of bars and brothels. The *promotoras* talk with their peers about how to prevent the spread of HIV infection and how to persuade customers to use condoms. Now, the *promotoras* are beginning to move beyond these regular work sites to a different section of Ciudad Juarez where prostitutes work independently on the street and in dance halls.

"This expansion is going better than I thought it was going to work," says Graciella de la Rosa, coordinator of the AIDS program in Ciudad Juarez. "The first phase raised the self-esteem of the prostitutes. It doesn't matter what zone (of the city) you are in, you are still a promoter of health."

The Juarez peer education project is one of 28 such efforts in 22 developing countries around the world supported since 1987 by AIDSTECH. In these programs, about 600 peer leaders have trained 21,000 prostitutes in AIDS education. In all of these projects, the peer educators promote the use of condoms and, in many projects, they also distribute condoms. Other international agencies have also supported peer education projects.

Peer educators promote the use of condoms and, in many projects, they also distribute condoms.

The peer education model is perhaps the most important means of changing high-risk behaviors among groups of people not easily reached through formal institutions. In the broad sense, "peer education" refers to any project where members of a group teach their peers. The peer education approach has been used in targeted interventions for AIDS prevention particularly among prostitutes.

This first generation of peer education projects among prostitutes has been an effective strategy for AIDS control. Two types of data show the impact peer educators have had on changing the behavior of prostitutes. "First, their knowledge about AIDS and about how to protect themselves against HIV transmission has increased," explains Michael Welsh, AIDSTECH's Associate Director for Intervention Programs. "Second, reported condom use among the sex workers and their partners has increased dramatically."

At the beginning of the Ciudad Juarez project, for example, only half of the women surveyed responded that HIV is transmitted via blood and sex. One year after peer education began, 98 percent identified blood and sex as modes of HIV transmission. At the beginning, 17 percent reported no condom use per ten acts of intercourse; this figure decreased to 1 percent a year later.

Such data have limitations, Welsh and others are quick to point out. *Actual* condom use may not be as high as *reported* condom use. Also, changes in knowledge, attitudes, and practices obtained in quantitative surveys may not be a sensitive enough measure of the issues in question.

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A peer leader counsels another woman on the use of condoms.

CLINIC-BASED INTERVENTION PROJECTS: STD AND FAMILY PLANNING PROGRAMS GET INVOLVED

For 15 years, the sexually transmitted diseases (STD) program in the popular Thai tourist city of Udorn has been working closely with 750 commercial sex workers. The clinic director, a veteran of the pioneering Thai family planning programs of the 1960s, has met regularly with brothel managers and prostitutes and incorporated their concerns into the service delivery approach. This program, in the northeastern section of Thailand, is part of a nationwide network of STD clinics.

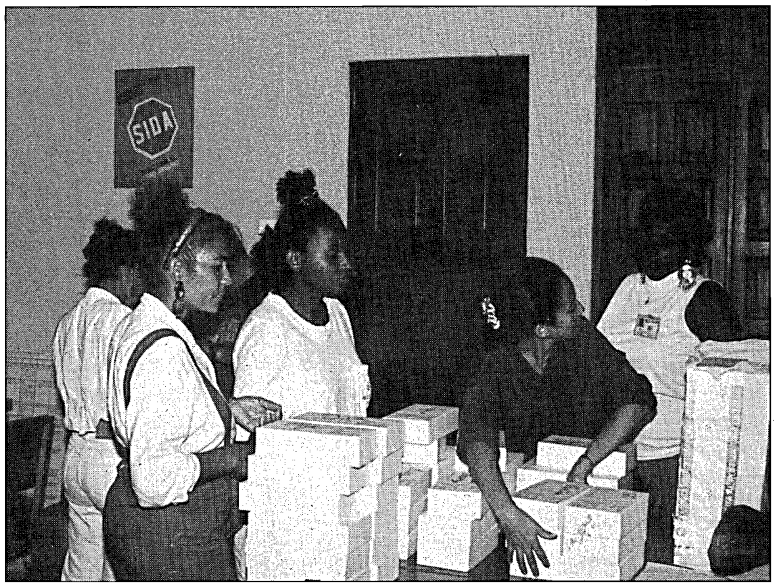
In the late 1980s, the clinic faced a challenge greater than treating and preventing gonorrhea, chancroid and syphilis. The Thai Ministry of Health, in conjunction with the Global Programme on AIDS, found that HIV was spreading in the Thai population, particularly among commercial sex workers (CSWs), their clients, and their clients' spouses. In 1989, 6 percent of the CSWs working in Udorn brothels were infected with HIV; throughout Thailand, 12 percent of CSWs in brothels were infected.

"Person-to-person education activities had to be increased," a recent report from Udorn explains. The clinic began recruiting and training outreach educators "to ensure that all CSWs in Udorn have the basic facts about AIDS and HIV." The services provided *at the clinic*, the study found, were "not enough."[1]

In the last two years, this STD program has trained outreach educators to work in eight brothels, has started a local AIDS prevention foundation supported by local businessmen, and has taken other innovative steps to incorporate AIDS prevention into its clinic structure.

Clinic-based projects such as the Udorn STD clinic are an important way to target groups at high-risk for transmitting HIV for two major reasons. First, such clinics serve a captive audience of people who may have an increased risk of becoming infected with HIV. Second, a clinic has a built-in infrastructure which is almost certainly more sustainable than creating an entirely new structure for AIDS education and prevention.

Other kinds of clinics also serve groups of people vulnerable to HIV infection and have an existing infrastructure, particularly family planning and primary health care clinics. All of these types of clinics are potentially important locations for intervention efforts. At the same time, each type has special considerations relating to the nature of AIDS prevention and to the wide variation of circumstances within developing countries.



Women involved in an AIDS-prevention project in the Dominican Republic get supplies of condoms at a distribution point.

In Africa, for example, countries such as Zambia and Senegal have a vertical network of specialized STD clinics while others such as Zimbabwe, Mozambique, and Zaire offer STD services through the primary health care system. Some African countries offer very limited STD services. In addition, few sub-Saharan African countries have well-developed family planning programs, with the important exceptions of Zimbabwe, Botswana, and Kenya.[2]

Many Asian countries, including Thailand, the Philippines and Sri Lanka, have well-developed family planning and STD networks. But AIDS has been slower to reach Asia, so these networks have only recently been forced to examine their role with AIDS intervention projects in large-scale ways.[3]

In Latin America, the spread of HIV has been more rapid than in most parts of Asia

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Peer Education

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"While our data are surrogate measures," says Welsh, "we know we can influence people with peer education."

These pilot projects have been effective in many ways, but they have also raised important questions about the role of peer education in the long-term fight against AIDS. Four central questions have emerged: whether pilot projects can be expanded to large areas, whether to pay the peer educators, how to affect the behavior of clients, and how to combine condom distribution with the peer model.

In the expansion phase, FEMAP will attempt to find other ways to reach clients.

Juarez Project Tackles New Questions

"At the beginning, it was very hard to get the project accepted in the community," says de la Rosa, coordinator of the Juarez project. In January 1989, the project was launched by the Federation of Private Mexican Family Planning Associations (FEMAP), with funding and technical assistance from AIDSTECH. "But now it is much easier because a lot of people are more receptive, less dependent on us."

De la Rosa heads a three-person, paid staff that has the job of identifying commercial sex workers interested in the project, training them as *promotoras*, establishing a system for distributing condoms, and keeping track of the overall peer education effort. FEMAP already had a base in the community through family planning and other health services, but the AIDS-education program was new. During the first 16 months of the project, FEMAP trained a total of 99 peer leaders, 75 of whom were still working at the end of this period, as well as three coordinators. The coordinators and *promotoras* work as volunteers.

In this first stage, FEMAP staff also established two condom distribution centers for the prostitutes in the target community, one at a bar and one at the home of one of the volunteer coordinators. This eliminated the administrative need to distribute condoms regularly to every *promotora*. Each *promotora* reaches about 20-30 prostitutes in the bars. In the second stage of the project among the street prostitutes, the numbers are expected to be larger.

"In one part of our new area, there were 200 prostitutes on the weekend, so the *promotora* can reach a lot of people," says de la Rosa.

The second phase of the project, begun in October 1990, has several important goals, including expansion and efforts to reach clients. The initial enthusiasm of the *promotoras* in reaching the non-establishment-based prostitutes bodes well for the expansion efforts. Taking the peer-model to other cities is also beginning; FEMAP is trying the same approach in Tijuana, another border town with heavy traffic across the U.S. border.

Several aspects of the FEMAP project make it an appealing model. First, it had an entrée into the community through its previous family planning and maternal and child health projects. Second, it has taken a volunteer approach from the beginning, using only a small staff to supervise and support the *promotoras*. A great deal of pride has evolved among the *promotoras* about their mission, which has eliminated the need for worrying about an ongoing budget to pay peer leaders.

"Prostitution in our society is usually a result of poverty and lack of education," explains de la Rosa. "There are not a lot of options. We are a Catholic country and prostitutes live with a lot of guilt that they are doing wrong. They don't have a lot of self-esteem and pride. They don't give a damn if they have AIDS or not. This peer education project has been so important because it has given them a chance to do something worthwhile with their lives."

In the expansion phase, FEMAP will attempt to find other ways to reach clients. In a survey in the first phase, there was little change in the degree of cooperation by clients when asked to wear a condom thus highlighting the need to target men in project activities. FEMAP staff plan to conduct focus groups with clients, hoping to find effective ways to reach this diverse population. In Mexico, urban men are more willing to use a condom than are rural men, who often display characteristics associated with "machismo." The farmer peasants may not want to use a condom, but at the same time they tend to have more communication with the prostitute, "who has the social role of a kind of mother to them," says de la Rosa. Understanding such cultural issues is fundamental to reaching clients.

The FEMAP approach offers many lessons on the value of using a volunteer system, on ways to expand, and on efforts to reach clients. But the most important issue regarding sustaining this project goes to a broader subject. De la Rosa puts it simply: "We need the condoms." Condom availability involves the overall supply in a country and the way that supply is distrib-

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but slower than in Africa. Many countries in that region have family planning and STD networks, some of which have begun incorporating AIDS education and prevention activities into their overall mission.

STD Clinics — A Natural Ally for Intervention

"There is growing evidence that STDs pose risk factors that facilitate the sexual transmission of HIV infection," report Dr. Peter Piot, Director of the World Health Organization's Collaborating Center on AIDS in Antwerp, Belgium, and Dr. Subhash Hira of the University Teaching Hospital, Lusaka, Zambia. "This evidence is very important to AIDS control programs, because patients with STDs are relatively easy to reach."[4]

AIDS itself is a sexually transmitted disease and has much in common with other STDs, with the deadly difference that AIDS is fatal and has no cure. But using condoms and limiting the number of partners can reduce the rate of transmission for AIDS as well as for other STDs.

In July 1990, the World Health Organization's Global Programme on AIDS held a consultation on AIDS and STDs, with 30 participants from 26 countries representing managers of AIDS control programs, STD control programs, combined AIDS and STD programs, clinical specialists, epidemiologists, and behavioral scientists. The consensus statement from that meeting strongly endorses coordination between AIDS and STD programs.

"Coordination minimizes duplication of staff, activities, and services, resulting in less costly programs," the statement explained, and it "increases overall program effectiveness when components of separate programs are ineffective owing to inadequate technical or managerial expertise, or insufficient funding."[5]

Using STD clinics in AIDS prevention projects makes sense on several levels. Information about AIDS transmission is similar to that about preventing other STDs. Distribution of condoms is important for AIDS and other STDS. And, perhaps most critically, if an intervention project can reduce the incidence of STDs in a targeted population, it can slow the spread of HIV infection, probably in a very significant way.

"STDs may be one of the major explanations for the rapid heterosexual spread of HIV in developing countries," explains Dr. David Sokal, AIDSTECH's Epidemiologist. Dr. Sokal and others, comparing groups with high and low STD levels, have estimated that the presence of an STD can multiply the chance of HIV transmission by a factor of 10 to 100. "If a woman with HIV infection has an open sore in her vagina, the chance of transmission to a man during a single act of intercourse may increase by up to 100 times," says Sokal.[6]

An STD clinic has limits, however, in its reach. Everyone at risk of HIV infection does not go to an STD clinic, nor are clinic locations or operating hours convenient for many people. The Udorn program has attempted to counter such handicaps by developing a second clinic, structured as a cooperative with commercial sex workers owning shares and operating with more flexible night-time hours. Having an STD clinic located in an area convenient to a target group helps to maximize the impact that clinic might have by serving as a base of operations.

In addition, STD clinics can work in conjunction with other efforts in a comprehensive, integrated approach to reducing sexual transmission of HIV. In the West African country of Cameroon, for example, the National AIDS Control Service (NACS) has used the resources of existing STD clinics as a way to expand its successful peer education project from Yaounde, the capital, to its largest city, Douala. (For more on the peer education intervention approach, see article on page 10.)

In Yaounde, peer educators are contacting commercial sex workers in bars, their homes, and on the street — wherever they can reach them. In the expansion phase of the Cameroon intervention efforts, the STD clinic is playing a more central role.

Recruitment of commercial sex workers in Douala is taking place primarily at the STD clinic, reports Dr. Marcel Monny-Lobe of the NACS project, describing the peer education effort.

The women are being referred to the STD clinic for education, condoms and treatment of STDs, as well as information about the services of the peer health educators. The STD clinic is integral to the overall intervention project, a natural ally.

Family Planning and Primary Care Clinics

"AIDS and family planning are married for better or worse, in intermediate and high HIV prevalence countries," says Dr. Nancy Williamson, director of FHI's

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"STDs may be one of the major explanations for the rapid heterosexual spread of HIV in developing countries."

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Program Evaluation Division and one of several authors of the recently released World Health Organization guidelines on AIDS and family planning.[7]

AIDS and family planning have a direct connection. Just as pregnancy can result from sex, HIV infection is sexually transmitted. In developing countries, most cases of HIV infection are due to heterosexual transmission. "Responsible sexuality is the key to prevention," says Dr. Williamson. "The use of one family planning method, condoms, is a means of preventing HIV infection."[8]

"The use of one family planning method, condoms, is a means of preventing HIV infection."

Despite this logical link, some family planning programs have been reluctant to become closely involved with such AIDS prevention efforts as counseling and routine condom distribution. In most family planning programs, condoms have not been promoted aggressively and, in some cases, have actually been discouraged as a method. "Condom promotion involves a major reorientation for many family planning programs," explains Dr. Williamson.

There are exceptions, however. The International Planned Parenthood Federation (IPPF), in particular, has encouraged its affiliates in about 125 countries to incorporate AIDS education into their family planning programs. "It's important to discuss AIDS education in the broad context of sexuality and sexual health," says Dr. Tony Klouda, Coordinator of the AIDS Prevention Unit of IPPF.

One such program is the Sociedade Civil Bem-Estar Familiar No Brasil (BEMFAM), the largest family planning organization in Brazil. A non-governmental, non-profit organization founded in 1965, BEMFAM has included AIDS prevention activities in its own programs and in those of its affiliates in Brazil. Many of these affiliates work directly with groups at high risk of HIV infection.

In 1990, BEMFAM took the link between family planning organizations and AIDS prevention one step beyond its own clinics. It sponsored five, week-long workshops held in several parts of Brazil. Various types of health professionals including government officials, primary care physicians and persons from advocacy groups participated in the curriculum, "Course for Health Professionals on the Prevention of AIDS." More people wanted to participate in the course than could be accommodated.

"There has been a lot of interest in these workshops," explains Dr. Ney Costa, BEMFAM Medical Coordinator, who appeared on Brazilian television describing the courses. "It is important for family planning organizations to incorporate education and prevention into their day-to-day operations and to help other groups do that as well."

Family planning programs and primary care facilities, particularly maternal and child health clinics, must continue to examine how targeted AIDS education and prevention activities relate to their ongoing services.

"No one is proposing that family planning programs drop their main mission of family planning," explains Dr. Williamson. "Family planning programs should favor AIDS prevention activities that enhance their capability to provide and expand good family planning services — counseling, social marketing, reaching underserved populations, and research."

Conclusion

In Brazil, Thailand, Cameroon, and throughout the developing world, clinic-based projects are playing an increasingly important role in efforts to prevent HIV transmission. There is greater awareness of the impact of STDs on HIV transmission. But many persons involved in field programs still may not be aware that the presence of an STD can increase the chance of HIV transmission by up to 100 times in a single act of intercourse. Meanwhile, family planning programs are also taking a broader interest in AIDS prevention.

Many practical lessons have emerged from the field during this first generation of clinic-based AIDS prevention projects. Specifically, clinics have shown that they *can* deliver AIDS prevention services — education, counseling and condoms.

But clinic-based projects cannot on their own reach all groups at high risk of HIV infection. They need to be part of a larger, integrated effort to slow the spread of AIDS. ■

– William R. Finger

Footnotes

[1] "AIDS Control Through the STD Network: Case Study of Udorn Province," AIDSTECH/FHI, Bangkok, Thailand, 1990, p. 5.

[2] N. Williamson and E. Boohene, "AIDS Prevention in Family Planning Programs," *The Handbook for AIDS Prevention in Africa*, Family Health International, 1990, p. 203ff.

[3] For more, see "AIDS and Family Planning:

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Reaching Men

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brochures — proof that with the right message and the right person delivering the message, one can reach men where they gather for lodging, drinking and casual sex. Whether these efforts will translate into the adoption of safer sex practices and a reduction in HIV transmission among these men and their partners is not yet known.

Like many public places where men gather, the Ruaha truck stop and bar where Flora works are not particularly conducive to prevention efforts. Designing messages that men will be receptive to in this environment is a challenge for volunteer health educators and the AMREF project staff. There is a lot of alcohol consumption during the interactions between truckers and barmaids. This works to block effective communication, discouraging both partners from practicing safe sex, including using condoms.

To overcome such barriers, the project staff determined how to design appropriate health education messages for the transport workers. They also trained eight graduate students from the University of Dar es Salaam on how to conduct a survey on knowledge, attitudes, and practices (KAP) regarding HIV transmission. These surveyors collected and analyzed data from the KAP surveys with truck drivers, their assistants and their sexual partners.

"Many of the surveyors were middle-aged people getting advanced degrees," explained Anne Outwater, AIDSTECH Resident Coordinator in Tanzania. "In Tanzania age is respected, so it was felt that asking such intimate questions of adults required people who could give an aura of trust and confidence."

AMREF also obtained the support of all involved, including the local and regional government, health workers, bar owners and bar maids. It has also familiarized all of these groups with the project's goals.

Next, the staff selected and trained Flora and other health educators to distribute condoms and to provide information on HIV infection and safer sex practices. This process involved seminars and focus groups with bar owners and bar maids, in consultation with local leaders. AMREF staff then obtained permission to set up condom dispensers in the offices of two major trucking companies, the Interfreight Trucking Company and Tanzania Breweries.

Despite these accomplishments, two important obstacles have developed. Setting up and sustaining a viable condom distribution system for the truckers has been difficult. In Tanzania, condom distribution is generally controlled by medical and paramedical personnel at district hospitals.

The lack of resources to expand the project has become another problem. It is a daily challenge for AMREF's health behavior officers to supervise and support people acting as educators and condom distributors over such a wide area. This will become more difficult as other planned interventions at trucking companies are implemented.

Workplace Interventions

In many ways, interventions targeted at men where they work are easier to implement than those reaching men where they gather for social reasons. AIDSTECH's experience in developing a targeted intervention for servicemen in the Ghana Armed Forces, for example, shows that using existing communications and logistical structures can be advantageous.

Initiated in 1990 with technical assistance from AIDSTECH, the intervention with the Ghana Armed Forces provides comprehensive health education and sexually transmitted disease services to servicemen in Ghana. The Ghanaian Government is considering expanding this targeted intervention with the military to reach the police force, another group of primarily young, sexually active men.

To begin the targeted intervention, the Ghana Armed Forces tested 1,600 servicemen for HIV. Using a KAP survey and focus group discussions, it identified servicemen's knowledge of risk factors for HIV transmission and other STDs, as well as prevention. Military health officers have been trained in counseling and prevention, and the Ghana Armed Forces set in place a condom promotion and distribution system. Health education materials with a military flavor and using military jargon are being developed, using results from the KAP data and focus groups. These materials are being designed to appeal to servicemen, and they reflect servicemen's attitudes about women and sexuality.

The Ghana project has some special characteristics that reflect its focus on the military, but it illustrates many of the advantages of reaching men at work.

First, the workplace has an existing infrastructure which can be used to reach certain groups at risk for AIDS.

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The workplace has an existing infrastructure which can be used to reach certain groups at risk for AIDS.

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Peer Education

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uted within the country. Peer educators work to promote condoms and often help distribute condoms as well.

Conclusion

The Mexico project offers valuable guideposts on many concrete issues. It also suggests the intangible factors at work. "Peer education by definition is highly concentrated," says Michael Welsh. "It is a constant reinforcement of an educational message, in contrast to the mass media, for example. But this personal contact takes a high level of trust."

Graciella de la Rosa takes this issue of trust a step further, to the level of inspiration. "When you believe in people and support people, they also believe in you," she says, speculating on how an expansion of their project to Tijuana might work. "It's a mutual way to help. It's a reciprocal hope. If we believe in the people of Tijuana, they will believe in us. And it can be that way in every part of the world." ■

– William R. Finger

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Thailand Conference Breaks New Ground," *network* 11(4):3, December 1990.

[4] P. Piot and S. Hira, "Control and Prevention of Sexually Transmitted Diseases," *The Handbook for AIDS Prevention in Africa*, Family Health International, 1990, p. 83ff.

[5] "Consensus Statement from the Consultation on Global Strategies for Coordination of AIDS and STD Control Programmes," Global Programme on AIDS and Programme of STDs, World Health Organization, Geneva, July 1990, p. 2.

[6] D. Sokal and B. Auvert, "Modeling of STDs and HIV: The Value of STD Surveillance and Control in AIDS Control Programs," *Sixth International Conference on AIDS*, June 1990, Abstract No. Th.C.738. Note that the risk of HIV transmission is increased in the presence of each of the genital ulcer diseases and in the presence of non-ulcerative STDs such as chlamydial infection, gonorrhea and trichomoniasis.

[7] "AIDS Prevention: Guidelines for MCH/FP Programme Managers," *AIDS and Family Planning*, Volume 1, World Health Organization, May 1990. A companion set of guidelines has been published on AIDS and Maternal and Child Health. Copies are available from WHO MCH/FP, 1211 Geneva 27, Switzerland or Publications Assistant, FHI, P.O. Box 13950, Research Triangle Park, NC 27709 USA.

[8] N. Williamson, "AIDS and Family Planning: Married, Divorced Or Just Living Together," Family Health International, November 1990.

INTERVENTION MODEL

Reaching Men

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Second, a message delivered in the workplace may have greater authority, credibility, or weight than one received in a more informal setting. The Ghana Armed Forces intervention, for example, uses the military chain of command to deliver AIDS prevention messages. "It's not hard for officers to get soldiers to listen," says LaHoma Romocki, AIDSTECH Information Education and Communication Associate working with the Ghana project. "There is an existing communications structure and an established system of authority."

Third, in the workplace men can be reached even when they are not accessible in clinic or social settings.

Reaching Men Remains a Challenge

Many of the opportunities and obstacles that have surfaced in interventions at the workplace and social settings are common to other types of targeted AIDS interventions. In addition, interventions targeting men need to focus particularly on three questions:

- What motivates men to change their high-risk behavior?
- What kinds of health education messages influence men most successfully?
- What kinds of people will men listen to concerning such a personal issue as using condoms?

The lessons of interventions targeted to men in social settings and workplaces are still emerging. Meanwhile, national AIDS committees, particularly in Africa, are exploring this approach. More countries will probably use such models as they strive to target men. ■

– Elizabeth T. Robinson

Elizabeth T. Robinson is Associate Director for Information at Family Health International; with reporting in Tanzania by Blastus Mwizarubi, AMREF Health Behavior Officer, and Anne Outwater, AIDSTECH Resident Coordinator, Tanzania.

Footnotes

[1] W. Carswell, G. Lloyd and J. Howells, "Prevalence of HIV-1 in East African Lorry Drivers," *AIDS* 3(11):759, 1989.

[2] P. Lamptey and M. Potts, "Targeting of Prevention Programs in Africa," *The Handbook for AIDS Prevention in Africa*, 1990, p. 151.

SOCIAL MARKETING OF CONDOMS: SELLING PROTECTION AND CHANGING BEHAVIOR

In 1987, fewer than half a million condoms were distributed usually for free in the large central African country of Zaire, mainly through government clinics. In 1990, total sales for condoms zoomed to 8 million — an 18-fold increase in three years. In 1991, sales are expected to double again to 16 million, in this country of 30 million people. This success is due to an approach known as "social marketing."

Put simply, social marketing refers to the application of for-profit sales and marketing techniques to a public health problem. Such an approach has been used for two decades to promote public health goals ranging from oral rehydration therapy to family planning. Social marketing has four essential elements: having the right product, at the right price, sold in the right place, with the right promotion. These four "P's", as they have come to be known, are central to any marketing strategy.[1]

In the 1970s, applying social marketing techniques to condom promotion had a major impact on expanding family planning efforts in Asia. This experience proved valuable when the AIDS epidemic erupted in the 1980s. Condom use is one of the few known ways to reduce the risk of HIV transmission.

"AIDS opened up the possibility of condom promotion in sub-Saharan Africa," says Laurie Liskin, one of the authors of a comprehensive study of condoms to be published later this year in the *Population Reports* series produced by The Johns Hopkins University.[2] "For the first time, we had the political sanction to begin large-scale contraceptive social marketing. This really paved the way for aggressive promotion, marketing and widespread distribution of condoms."

Using social marketing of condoms to help prevent AIDS can be successful in several ways. "Developing countries can't afford to give away enough condoms for everyone. Social marketing recovers some of the costs, and it shifts health care away from the public sector, generally an inefficient segment of their economies," explains Dr. Peter Lamptey, a Ghanaian physician and Director of AIDSTECH.

At the same time, Dr. Lamptey and others point out that social marketing campaigns can have disadvantages or at least raise difficult policy issues. Three important questions involve sustainability, targeting populations, and dual-purpose promotion. How can a program sustain a steady supply of condoms and maintain an ongoing distribution system? Second, should programs target high-risk groups or try to reach the general population, in light of cost and other issues? Third, should the social marketing of condoms in an AIDS prevention program also be designed for family planning purposes?

To address such questions, one must first understand how a social marketing campaign such as that in Zaire works.

Successes in Zaire

In 1987, the Zaire National AIDS Committee launched a condom social marketing campaign designed to curb sexual transmission of AIDS in Zaire, working with a non-profit organization called Population Services International (PSI). In 1989, Zaire expanded social marketing efforts with funding and

John Tierney / New York Times Photo

Mr. Vangu Tsumbu (center) travels the Congo River by dugout canoe distributing condoms in Zaire.

technical support from AIDSTECH.

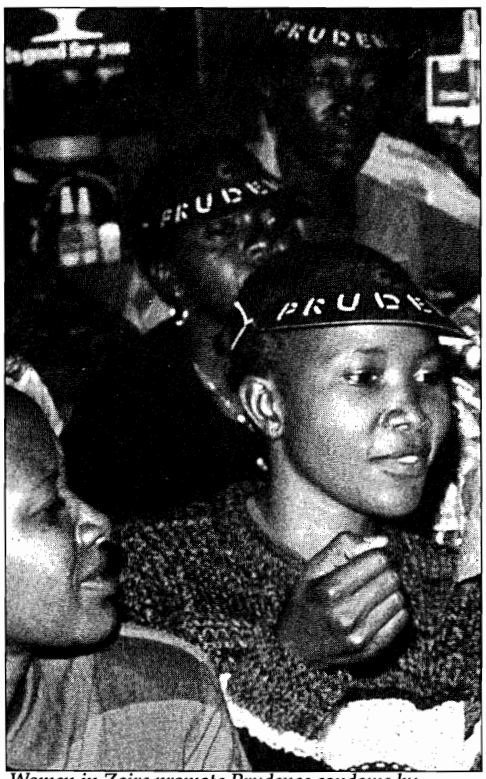
Product. The first step was to find the right product. Creating a desirable product image to promote brand loyalty is key to any successful marketing campaign. Careful consumer research in Zaire produced the name, Prudence. "That name and its packaging design and logo were designed specifically for Zaire after consumer research assured us that the final product was culturally acceptable as well as appealing to target consumers," says Carlos Ferreros, who headed the PSI program in Zaire after spending more than a decade in Asia and Latin America marketing consumer products such as Vicks cough drops and Gillette razors.

"Prudence is a particularly useful brand name because the message can be interpreted to mean behavioral change beyond condom use," says Ferreros. The name conveys the message of responsible behavior and creates opportunities for inoffensive and effective advertising. Plus, the name lends itself to clever and effective advertising.

"'Love with Prudence,' for example, serves doubly as a brand promoter as well as evoking the image of responsible behavior," says Ferreros.

"Consumer reaction to the product itself has been excellent," says Jim Spilsbury, coordinator of AIDSTECH projects in French-speaking countries in Africa, including Zaire. "Retailers report that Prudence has acquired a reputation as a high quality product, most likely because of its packaging."

Projet de Marketing Social - Zaire



Women in Zaire promote Prudence condoms by wearing sun visors.

In many areas of Zaire, condoms sold or distributed prior to the campaign had no special exterior packaging.

Place. Prior to the Prudence program, condoms were available primarily through government distribution. Turning to commercial outlets, primarily private pharmacies and medical centers, resulted in condom sales jumping more than 400 percent in the first year Prudence was on the market.

"Using the private sector and its distribution networks makes condoms readily available to people in ways that public health programs usually cannot," says Ferreros. After the first year, Prudence marketing extended to less formal settings. "You can buy Coca-Cola, beer, cigarettes just about anywhere," says Ferreros. "No matter how bad the roads are, no matter how rural the village, there's always some villager getting commercial goods out there."

In 1989, the Zaire National AIDS Committee agreed to target Prudence to specific groups of people at high risk for contracting AIDS, especially commercial sex workers and their clients. Distribution efforts expanded to include such non-traditional retail outlets as bars, hotels and social clubs.

"Clearly we needed to have condoms available at those places where persons practicing risky behaviors congregate and where these individuals often arrange their sexual encounters — bars and nightclubs," explains Spilsbury.

Social marketing not only makes condoms more widely available but it gives consumers access to condoms *when* they really need them. "There used to be no place to get a condom at midnight," said Ferreros, "and people often feel uncomfortable getting condoms from clinics. At a grocery or a bar, no one asks them to register."

Consumer research provided information about where to target consumers. For instance, market surveys showed that a large population of commercial sex workers and their clients ride the Zaire (Congo) River barges, so Prudence salesmen took to the docks and boats, some of them riding into the interior of the country.

A recent front-page story in *The New York Times* tracked a former autoparts salesman named Vangu Tsumbu on his journey up the river into central Zaire, selling condoms from dugout canoes. Armed with promotional items such as eye-catching gravity-feed condom dispensers and a wooden phallus to demonstrate proper condom use, Tsumbu asked potential customers, "Do you know there is a new disease for which there is no cure?"[3]

Price. The right price must be low enough for consumers to afford but high enough for merchants to make a profit from sales. The merchants need to be able

to sell condoms at a profit margin comparable with their other products. In most developing countries, few consumers can afford market-price condoms. Typically, government agencies or donors like USAID supply the condoms free in social marketing projects. Then wholesalers and merchants can sell them for a low price while still making a profit.

In Zaire, retailers generally sell a package of three condoms for about 11 US cents, or a dozen for about 45 cents — about half the price of a large bottle of beer. This system keeps the price of Prudence substantially lower than that of other brands sold in pharmacies yet also provides sufficient profit margins to motivate retailers to keep the product in stock.

"Charging modest prices for condoms does not deter use and may even increase demand," says Liskin, co-author of the condom report. "Charging for condoms means that clients are more likely to perceive Prudence as a high quality product, that program revenues can cover some or most of the program costs, and that retailers and distributors have a financial incentive to carry and promote condoms."[4]

In determining recommended retail prices for Prudence in Zaire, Ferreros said, market researchers considered the following: minimum wage, public transport fares, costs of popular products such as cigarettes and soft drinks, and the most common denomination in the local currency. "You want a price that is both affordable and lends to easy, quick and discrete purchasing at the retail level," he says. "A condom should not cost more than a small pack of aspirin or gum."

Initially, government or public health officials may resist the notion of hawking condoms. "Now, they realize the value of selling condoms for profit," says Ferreros. "The condoms get out there and people are motivated to use them."

Promotion. Commercial marketing techniques motivate consumers to buy condoms in Zaire. Like any advertising expert, Prudence campaign directors divided potential consumers into market segments and then based promotional strategies on each specific group's existing values, attitudes and motivations. A government policy banning all condom advertising through mass media outlets required the promotion campaign to use other channels.

Using materials at the point of purchase is the cornerstone of the Prudence promotion campaign. Posters, pocket calendars, and beer coasters at retail outlets help create product awareness as well as overcome initial barriers to acceptability. They also encourage impulse buying as they do with any other product.

As with any product, marketing begins with consumer research. Using the traditional advertising tools of market surveys, focus groups and consumer interviews, the Prudence group carefully selected the logo, color scheme and slogan for the advertising campaign and display materials.

An AIDS-prevention message printed on the back of a small calendar promotes Prudence condoms.

Special promotions have been highly effective. Bar staff often wear Prudence T-shirts, and some bars even have Prudence murals. Promotions at fairs and concerts offer prevention information, free condoms and demonstration of proper use on wooden models. At special Prudence-sponsored rock concerts, anyone with a pack of Prudence gets reduced admission. Some of Zaire's top stars have released Prudence-produced songs for airing on the radio.

Lessons for the Future

The number of condoms sold is perhaps the greatest measure of the social marketing success in Zaire, along with the fact that Prudence has evolved into the generic term for condom. Prudence is distributed in 7000 retail outlets, including 300 bars and hotels. In areas targeted for distribution, Prudence condoms are available from all wholesalers, 90 percent of the pharmacies, and 70 percent of the medical centers.

The success of Prudence in Zaire has inspired similar programs in other African countries in particular. In Cameroon, a social marketing program has made an impressive start, selling 2 million Prudence condoms in its first year. A pilot project in Burundi sold 94,000 condoms in five months, targeting an area with a population of 226,000. Similar programs are underway in about ten African countries as well as in Brazil, Haiti, and India. Behind the glowing condom sales figures, however, lie some potential obstacles.

Sustainability. Effective, ongoing social marketing of condoms must have an adequate and predictable supply of inexpensive condoms. Too much success can actually create some problems for sustainability, says Dr. Duff Gillespie,

Despite the success of social marketing programs for HIV prevention, these issues of sustainability, targeted populations, and dual-purpose promotion involve complex questions.

BEST AVAILABLE

Director of the USAID Office of Population.

"The most dramatic thing we have learned in the 1970s and 1980s is that there are very few economic and social settings in which social marketing doesn't work," explains Dr. Gillespie. "One consequence of this success is that even though social marketing is efficient and relatively inexpensive, the volume of commodities needed to maintain it is awesome. The ability of donor organizations and governments to maintain it is approaching something of a crisis."[5]

Donor organizations have recognized that successful social marketing programs have put a huge demand on condom supplies. At recent meetings to address this problem, experts have begun developing various approaches to ensure adequate condom supplies.

A closely related issue is how to sustain expensive promotion and media efforts — an essential part of the early social marketing campaigns to fight AIDS. Thus far, substantial donor funds have supported these expensive promotional campaigns. Zaire's condom sales might not be as successful without such an emphasis on media and promotional materials.

Targeted Population. Sales data help measure a project's success but they do not tell who bought the condoms. In Zaire, where condoms were virtually unknown until the Prudence campaign began, marketing includes condom advertising for family planning and AIDS prevention. In some areas, however, condoms are targeted to prevent HIV transmission among groups practicing high-risk behaviors.

To assess whether the Zaire project was effective at reaching target populations, project staff asked customers as they entered or left retail stores why they were using the condoms. In one survey, about three of every four customers cited AIDS prevention as a reason for buying condoms. Eighty percent of that group said they practiced high-risk activities.[6]

Dual-purpose Promotion. The issue of targeting social marketing campaigns raises questions of cost and long-term involvement of condom sales with family planning efforts. The broadening awareness of the need to prevent further transmission of HIV as quickly as possible has meant that policymakers and even religious leaders are more receptive to the benefits of condom promotion. This allows more promotion of condoms for both preventing sexually transmitted diseases and for family planning.

"For the first time condoms are now being widely promoted for prevention of both pregnancy and STDs," says Liskin. Some social marketing programs designed to combat AIDS are marketing condoms simply for "protection," implying both pregnancy and disease prevention. Marketing condoms for multi-purpose protection differs from traditional clinic-based family planning programs, which often emphasized only the contraceptive use of condoms, and from many early AIDS prevention programs, which focused only on HIV prevention. Initial efforts at trying to capture both markets at once appear to be working. In Zaire, for example, condom popularity is on the rise for both kinds of protection.

Despite the success of social marketing programs for HIV prevention, these issues of sustainability, targeted populations, and dual-purpose promotion involve complex questions. Answers often vary depending upon the circumstances in a particular country, including the HIV prevalence rates, the existing family planning program, and other factors.

While social marketing may not be a perfect solution, the success of these initial efforts in Africa offers one of the few clear signs of progress against the spread of AIDS. As HIV prevalence rates rise in Latin America and Asia, emerging programs on these continents will benefit from experience gained in Africa. ■

– Sara Townsend

While social marketing may not be a perfect solution, the success of these initial efforts in Africa offers one of the few clear signs of progress against the spread of AIDS.

Footnotes

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MEASURING THE EFFECTIVENESS OF TARGETED INTERVENTIONS

A central approach in using limited resources to slow HIV transmission has emerged: the concept of targeted interventions. Using this approach, projects focus resources at groups practicing behaviors that put them at high risk of HIV infection. Since the primary mode of HIV infection is sexual transmission, many intervention projects seek to modify sexual behavior through education and through the promotion and distribution of condoms.

The specific strategies of targeted interventions vary extensively, depending upon such factors as HIV prevalence rates, rural or urban circumstances, cultural issues, geographical issues, and the structure of the commercial sex industry. While the strategies vary, all intervention projects have a common need: to know whether they are effective in slowing HIV transmission.

How do AIDS intervention project managers know if they are targeting their resources in the appropriate way? How do they know if they have set the right goals and undertaken the best activities for reducing HIV transmission? Put another way, how do you measure the effectiveness of a targeted intervention project?

Measuring the impact of efforts to prevent AIDS is far more difficult than with measles, small pox or most infectious diseases. AIDS has a long incubation period, which means reported AIDS cases reflect events that occurred at an uncertain point in the past, even eight or ten years ago. In addition, measuring the number of new cases of HIV infection during a given time span, called HIV *incidence*, is extremely difficult and very expensive.

HIV *prevalence* rates — existing cases, with no information on *when* the infection was acquired — are not valid indicators of project effectiveness. Many factors affect HIV prevalence rates, such as changes in reporting methods, service availability and migration patterns, as well as prevention efforts in targeted intervention projects.

While such difficulties have become clear in the first generation of AIDS intervention projections, some clues have emerged regarding measuring project effectiveness. Using a single measurement, such as changed HIV incidence levels, is expensive and difficult. This would require a well-funded research context with a limited number of people being tested and is not practical for most intervention projects.

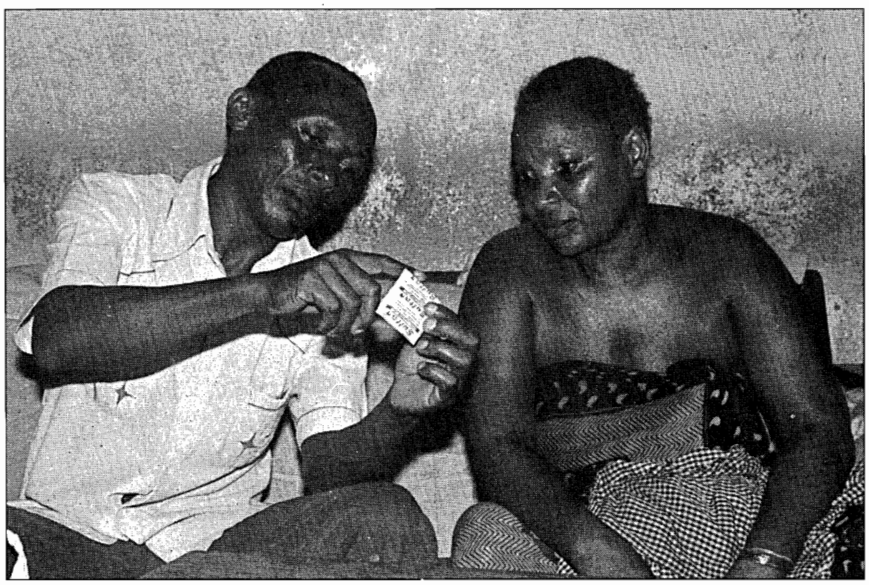
However, multiple sources of information, used together, can indicate the effectiveness of a project. The four most useful indicators for determining if a project is reducing HIV transmission are:

- reported condom use,
- reported number of sexual partners,
- condom sales, and
- incidence of sexually transmitted diseases (STDs).

Data on any one of these four, viewed in isolation, may be misleading. But using as many of these as possible together can be a strong indicator that a project is effective in slowing the spread of HIV. This is true during the initial program design, while monitoring program activities, and when undertaking a formal program evaluation.

In gathering data for these indicators, three basic methods are used. Quantitative methods, particularly survey instruments, are often the primary source of data for these indicators. Second, qualitative methods such as in-depth interviews and focus groups can provide useful information. Third, direct observation is used. Medical data from clinical examinations, medical tests and medical record review can be used to estimate STD incidence.

Multiple sources of information, used together, can indicate the effectiveness of a project.



A peer educator whose success in distributing condoms has earned him the nickname "Bwana Condom" discusses condom use with a local woman.

Reported Condom Use

Most targeted intervention projects seek to modify sexual behavior. Using con-

doms is a primary means of reducing the potential for HIV transmission. But knowing whether a person actually uses a condom is difficult. The only way to be certain is to observe that behavior, which is generally not possible. *Reported* condom use is, therefore, a surrogate measurement, a substitute for actual observance of condom use.

To determine whether there is an increase in reported condom use over some period of time, projects need to consider various data collection systems. Usually, questions about condom use are included on surveys of knowledge, attitudes and practices (KAP) regarding HIV and AIDS.

A good way to gather data for this issue is to ask about condom use during the last sex act. This limits the report to a short span of time. Using such an approach, a project in Zimbabwe got reports that were consistent between prostitutes and clients. Such consistency suggests that the reported use was generally consistent with the actual use.

Another method that seems to work is a one-week recall of condom use. The data begin to lose validity the longer the time period covered by the question. Other methods of comparing the consistency between reported and actual use include focus groups and reports from peer educators.

Condoms *sold* are a better indicator than condoms *distributed free.*

Reported Number of Sexual Partners

Another important factor that can reduce HIV transmission is to reduce the number of sexual partners. This is a form of modifying sexual behavior. More sexual partners means there is more chance for HIV transmission. Change in the number of sexual partners is a particularly important measurement for intervention projects targeting men in workplace and social settings. It is also important data for clinic-based intervention projects working with men and women, especially STD clinics.

A sign identifies an AIDS prevention and family planning clinic in Ciudad Juarez, Mexico.

In Trinidad, for example, KAP surveys are measuring changes in numbers of sexual partners after various types of AIDS-education efforts. This indicator, used together with reported condom use and condom sales or distribution figures, will indicate whether the project is helping to slow HIV transmission.

Condom Sales

Condom sales figures can be a valuable indicator of an intervention project's success for several reasons. Condoms *sold* are a better indicator than condoms *distributed free.* When a person buys a condom, it indicates more of a commitment to using it than if he or she got the condom for nothing. Some buyers might purchase out of curiosity but repeated buying indicates use.

In Cameroon, for example, projects in three cities are targeting high-risk groups. Prostitutes who are peer educators are also selling condoms. The project is keeping data on the number of condoms sold to serve as an indicator of its success. In addition, the project is also gathering data on condom purchasing behaviors. It is asking STD patients, men in bars, and the prostitutes themselves about condom purchasing issues.

Because condom use is such an important part of AIDS prevention campaigns, it is important to validate data on reported condom use as much as possible. When condom sales figures are not available, the number of condoms distributed might help validate reported condom use.

Data on condoms distributed free have more meaning if part of a peer education project. While free, the condoms have been given along with a specific education message, sometimes with role playing and other techniques to help prostitutes convince clients to use the condoms. These free condoms are more likely to be used than if the condoms were handed out at random on a street corner.

In an intervention project in Mali, for example, 82 prostitutes reported using about 62,000 condoms during a six-month period. During that same period, 58,000 condoms were distributed among those prostitutes — the only source of condoms they had. Comparing the two numbers suggests that the reported condom use was exaggerated but not greatly. The data on condoms distributed in this peer education project helps validate the data on reported use.

Incidence of Sexually Transmitted Diseases

Many intervention projects target clients going to STD clinics. Behavior change (reduction of numbers of partners and condom use) that reduces HIV incidence will in all probability reduce the incidence of STDs as well; therefore, STD incidence is an excellent proxy for HIV incidence. Treatment and further prevention of STDs will affect the transmission of HIV but do not necessarily result in behavior change. Research has found that the presence of an STD can increase the chance of HIV transmission by up to 100 times in a single act of intercourse. Hence, reducing the incidence of STDs in a specific population or area can have a very important impact on HIV transmission rates.

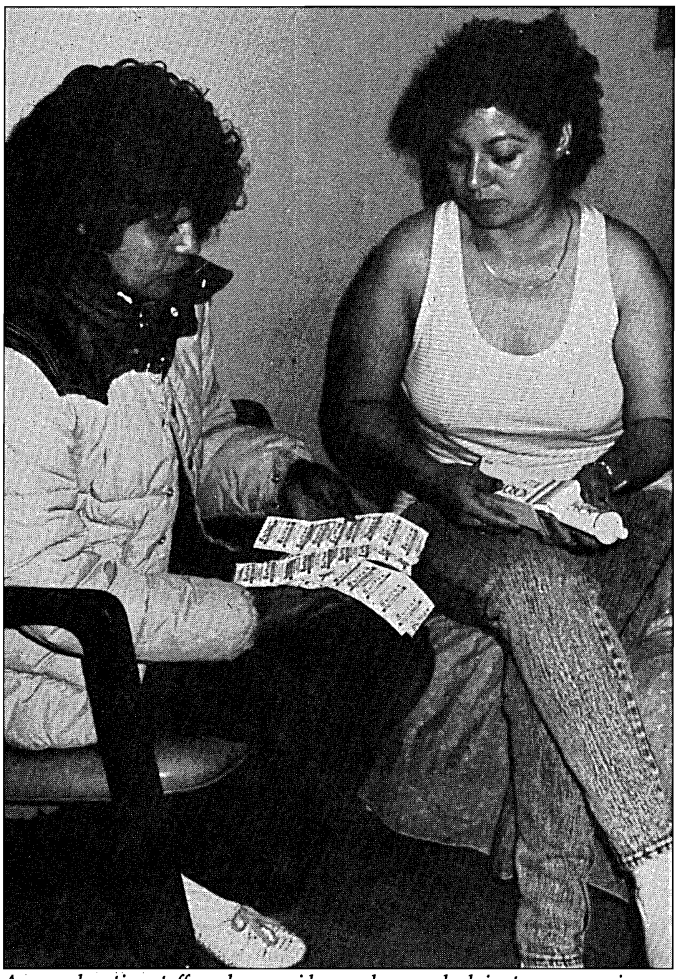
Measuring a change in STD incidence is costly and requires an infrastructure for testing. Observing the number of STD cases can be more easily obtained. While even the number of STD cases is not easy to measure in most intervention projects, some research-based projects have found that the number of STD cases can be an indicator of project success, especially when examined in conjunction with other indicators.

Conclusion

All targeted intervention projects need to have some ways to measure whether they are successful in slowing the spread of HIV. Multiple indicators are important to use because measuring changes in HIV incidence is not practical for an intervention effort targeted to a specific group or area.

To evaluate an expanded intervention project in Ghana, for example, project staff are now using KAP surveys focusing on condom use among prostitutes and clients. The survey is also asking clients about the number of sex partners. At the same time, peer health educators are distributing condoms. Plans are underway to expand the condom sales approach, which will add condom sales data to the available indicators of success. Over time, the project hopes to see a decrease in the number of sexual partners for men and an increase in condom use. Eventually, the project also hopes to develop a system to track STD incidence as well.

The four indicators named above — reported condom use, reported number of sexual partners, condom sales, and incidence of STDs — are not the only types of data that can be valuable in evaluating a targeted intervention project. Others can also be important.



A peer education staff worker provides condoms and advice to a woman in Ciudad Juarez, Mexico.

While researchers might agree or disagree about which are the best indicators, those persons experienced in evaluating intervention projects agree that multiple indicators must be used for an accurate picture of a project's success.

– Dr. Susan Hassig

Susan Hassig is the Operations Research Specialist in AIDSTECH.

COMMUNITY STRUCTURE AFFECTS BEHAVIOR

All of us are social creatures, living and working together in communities involving complex kinship, economic and other patterns. These community structures affect everyone's behavior. When an effort is made to change behavior, this community context needs to be considered.

Anthropologists have identified five central aspects of a community's structure that affect individual behavior. These five may be referred to collectively as KEPRA, the acronym formed by using the first letter of each of the components: kinship patterns (K), economics (E), politics (P), religion (R), and associations (A) — KEPRA.

Most AIDS education and intervention programs seek to change behaviors that have a high risk of transmitting HIV infection. A discussion of the KEPRA framework indicates the critical importance of cultural and community issues to AIDS prevention efforts. The questions below are just a few of the many that could be asked. The answers to these questions will vary enormously depending upon the unique circumstances of each community.

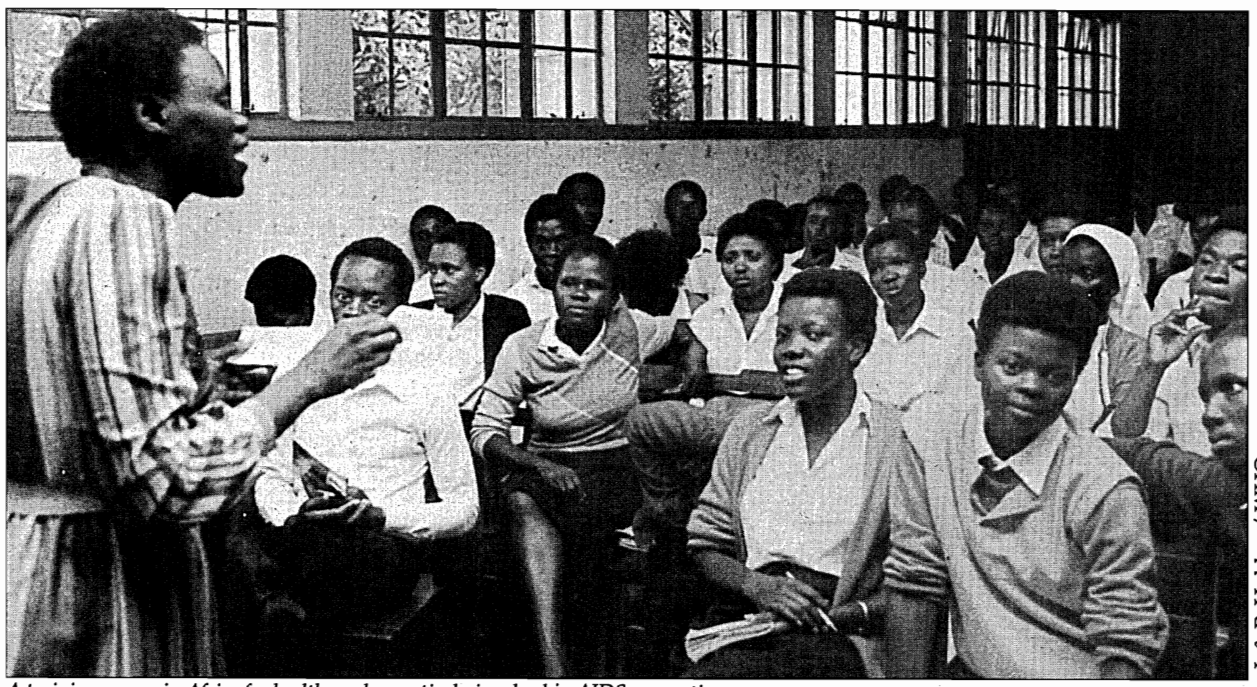
Kinship Patterns. How people are related to each other is central to AIDS prevention. Do children belong to mother, father, both? What happens to a man's wife (wives) when he dies? To his children? What happens to a woman when her husband dies? To her children? What is considered appropriate behavior between children and adults? Between in-laws?

Among the Basoga people in Uganda, sex education of daughters is the responsibility of the "senga," or paternal aunt. An AIDS information campaign targeted to rural women in Basoga needs to recognize the critical role of the "senga" in providing sex education to young women. There are many examples of such culturally specific kinship patterns that affect AIDS prevention.

Economics. Different cultures have varying views on the ways people make a living. In addition, men and women vary in the amount of time they engage in economic survival activities. In many urban areas, the provision of sexual services for money or another form of material support (commercial sex) occurs for a variety of reasons.

In Thailand, for example, poor families from rural areas bring teenage daughters to the city and make an exchange with a brothel manager — the daughter's services as a prostitute in exchange for a water buffalo (or some other basic necessity of life). In Kenya, young women going from rural areas to Nairobi may engage in temporary commercial sex to provide for basic subsistence needs, while searching for wage employment.

Such individual and community economic situations influence a target group's ability to hear, understand, and act on



J. & P. Hubley / WHO

A training course in Africa for health workers actively involved in AIDS prevention.

messages which promote safer sexual practices.

Politics. This term applies to politics in the broadest sense, including decisions about community, government, and family affairs. Which people are considered important in the community and why? The factors that give individuals status and power are part of the political aspect of KEPRA, such as money, education, children, land, job, political office, royal standing, and tribal structure.

In each society, people are considered important for different reasons. Politics involves getting people to do what you want them to do, through influence, exchange of resources, persuasion, consensus, or coercion. It is important to know who a community considers to be important, and if possible, to persuade those persons to speak out on behalf of AIDS education campaigns. Those persons may be in overt positions of power and responsibility, such as national Ministers of Health or factory owners. Or those persons may be peers with power to influence through persuasion.

In a factory in Monterey, Mexico, the city health officer asked a floor supervisor and a canteen worker to explain to their fellow workers how and why a new AIDS education program was going to be introduced in the factory. This was a better strategy than asking the same thing of the factory's director. Although the director had more authority over his personnel by virtue of his position, the supervisor and canteen worker commanded more respect and were better liked by their peers, and were therefore more effective in persuading their friends to participate in the program.

Religion. Is organized religion important in the setting for the intervention project? What do religious personnel say to their followers about sex and sexual practices? What do people believe causes sickness or disease? How do people explain the relationship of the dead (especially family members) to the living? Are there rituals involving ancestors or spirits of dead persons? All of these questions belong in the broad arena of a community's religion.

AIDS education campaigns must be sensitive to and realistic about the strength of religious beliefs among the target population. In many cultures people believe sickness and death are caused by evil or displeased spirits of deceased relatives. Acknowledging the existence and power of such beliefs increases the credibility of a project. One village health worker in western Uganda began a discussion about AIDS with rural women by saying, "We all know that some diseases and some deaths are caused by spells. But not AIDS — slim. AIDS is different."

Associations. Apart from government agencies, many formal and informal organizations exist to address social issues, such as trade unions, women's groups, burial societies, and AIDS support groups. Who belongs to these groups? How is membership determined? What benefits do members derive?

The AIDS Support Organization (TASO) in Uganda was created to deliver counseling and economic support services to persons with AIDS and their families. Most communities have a range of *informal* organizations that can be tapped to provide economic and/or emotional assistance to persons with AIDS and their families. For example, men and women in many communities in Cameroon participate in "djangis," a kind of revolving credit society that monthly or bimonthly permits one member to collect a sum of money that he or she working alone would not have been able to save.

Members of such "informal" associations have developed strong ties based on mutual obligations. While originally created to provide mutual economic benefits, these informal associations are ideal mechanisms for communicating AIDS prevention messages and/or developing support systems for persons with AIDS.

KEPRA. The questions raised in each of the five sections above suggest the many types of issues that can guide program managers in developing more effective AIDS prevention efforts. All five elements of a community structure — kinship patterns, economics, politics, religion, and associations — should be viewed together with principles of behavior change (see article on page 3). The more AIDS educators know about a society's KEPRA, the better they will be able to design and deliver appropriate intervention programs. ■

–Carol Jaenson

Carol Jaenson is the Behavioral Science Specialist in AIDSTECH.

COMPUTER MODELING OF THE AIDS EPIDEMIC

Although AIDS will undoubtedly be recorded as the worst plague to strike the world in this century, it is a "slow-motion" epidemic. Because the average incubation of HIV infection is about 10 years, the standard approaches to infectious disease surveillance and control are irrelevant. Computer models of the AIDS epidemic can fill this gap. These models are essential for understanding the dynamics of the epidemic and for planning control programs.

There are two basic ways to test different disease control strategies: conduct field studies or use a computer model. In the case of measles, for example, field studies can be conducted within a few months, or a year or two at most, simply by following the number of new cases of the disease in a given time period, that is, the incidence rate.

With the AIDS epidemic, similar studies of control strategies are practically impossible, because of the long incubation period. The few rigorous field studies of control strategies that are being planned are likely to cost millions of dollars and take three to five years to complete. In contrast, once a satisfactory computer model is developed, comparing the effectiveness of various control strategies takes only a matter of weeks or months.

Computer models can project how AIDS will affect population growth, the need for health care services, the economy of a given area, and other issues. Models of the epidemic can estimate the costs and benefits of control programs and can demonstrate the wisdom of an early investment of resources in AIDS prevention. It can also be applied to specific strategies for behavior change discussed in this collection of articles.

Collaborating with the U.S. Department of State's Interagency Working Group on Computer Modeling of the AIDS Epidemic and others, AIDSTECH has helped developed several different models. One of the simpler models can estimate the number of adult and childhood AIDS cases based on HIV seroprevalence estimates. A more complex simulation model, called the "iwgAIDS model," actually recreates the epidemic inside the computer, using a complex program to mimic the social, sexual and drug using behaviors, and the relationships of different population groups as they affect the epidemic.

Mathematical modeling of the AIDS epidemic can provide reasoned estimates for policymakers who want to know:

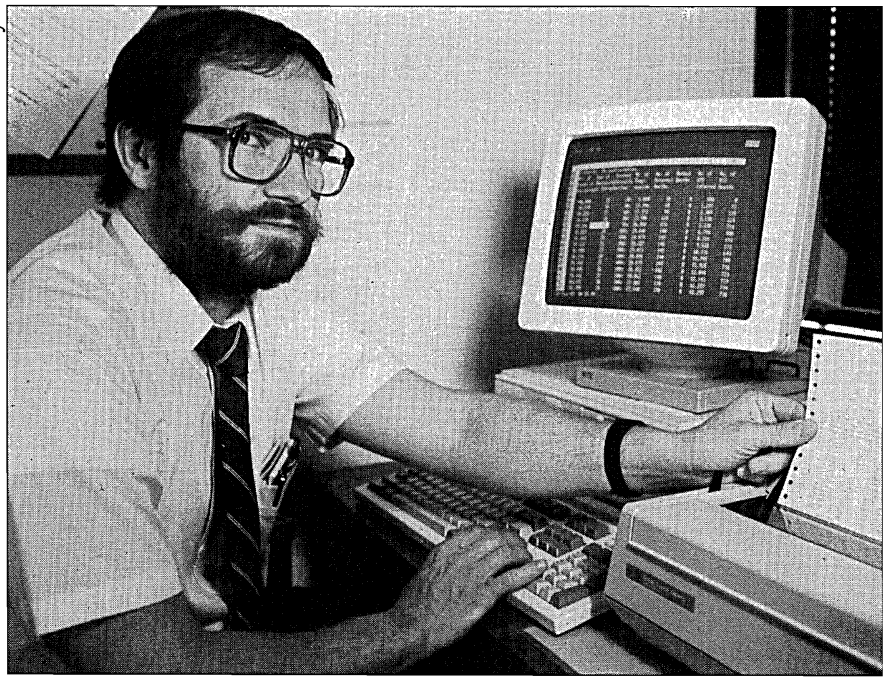
- How many AIDS cases will there be in the coming years?
- Will AIDS have a greater impact than other diseases such as malaria or measles?
- What are the relative costs of prevention programs compared with the future costs of treatment?
- What are the relative effects of different intervention strategies?

The application of these models in a particular country is done in a spirit of technology transfer. The estimates generated by the modeling process become the property of a country's national AIDS control program, to be used to improve policy decisions at the national level. ■

— Dr. David C. Sokal

Dr. Sokal is the Epidemiology Specialist for AIDSTECH.

Tom Klosky



Dr. David Sokal works on computer models of the AIDS epidemic.

CHANGING BEHAVIORS TO REDUCE HIV INFECTION THROUGH BLOOD TRANSFUSIONS

Blood transfusions may cause up to 10 percent of AIDS cases in some countries. Screening blood for HIV has had a tremendous impact on reducing the spread of HIV through blood transfusion. But further measures are needed. Interventions which can have a significant impact involve behavior change by physicians, blood donor recruiters and blood donors themselves.

Many physicians may need to change their behavior regarding when to perform blood transfusions. Often blood transfusions are administered without weighing the risks of transfusion. Up to 80 percent of transfused blood in developing countries is given to women and children, often inappropriately for conditions of anemia.

To change transfusion practices, physicians must first be made aware of acceptable alternatives to transfusion. Physicians can work together to define clear indications for transfusion and to develop country-specific guidelines for blood transfusion. In Cameroon, for example, in 1989, 45 physicians and blood bank managers participated in a workshop to establish guidelines for appropriate blood transfusions in that country.

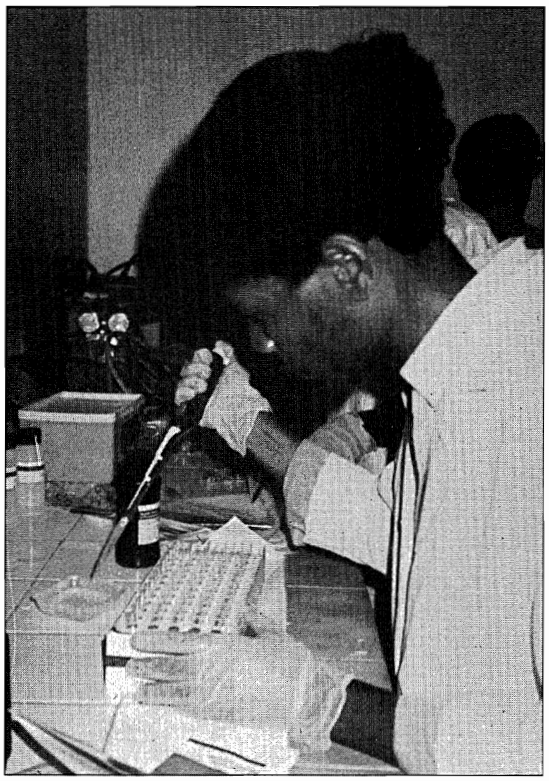
Such efforts will contribute to improved blood transfusion practices, thus reducing the transmission of HIV.

Recruiters of blood donors can also help to reduce HIV infection by carefully selecting and recruiting safe blood donors. Many areas of the world rely heavily on paid blood donors to meet transfusion needs. In some countries the vast majority of donors are related to the recipient and donate specifically on his or her behalf.

Both paid donors and relatives of recipients have been shown to be at higher risk for HIV infection than volunteer blood donors. Recruiters need to increase their efforts to convince healthy people at low risk of HIV infection of the benefits of donating blood. Research is needed to identify fears and misconceptions concerning free and voluntary donation and to determine what motivates those who donate. Donors belonging to clearly defined low-risk groups such as young male students in low prevalence areas should be selectively recruited.

Finally, changing the behavior of potential donors themselves can reduce HIV transmission. Educating blood donors about risk factors of HIV infection is important to persuade some possible donors not to give blood — called a donor "deferral program." Blood donors should reflect upon their behavior, assess the possibility that they may be infected, and not donate if there is a chance they will be spreading the virus.

It is up to the recruiters and local blood transfusion services to make this deferral approach a success. Research is needed to identify risk behaviors and to determine the best way to present to potential donors the option of not giving blood. For example, should this be done in writing or verbally, among groups or on an individual basis? These questions involve the confidentiality of the potential donors and should be handled carefully.



Screening blood has greatly reduced the spread of HIV through transfusions.

AIDSTECH is working towards reducing HIV infection through blood transfusion by sponsoring workshops on "Improving Blood Transfusion Practices" and by supporting research on blood donor motivation and on risk behaviors associated with HIV infection in blood donor populations. Results from these studies will be used to improve selective blood donor recruitment and develop guidelines for donor deferral. ■

— *Sheila Mitchell*

Sheila Mitchell is a Laboratory Specialist for AIDSTECH.

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network

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A BRIGHT FUTURE FOR IUDS: NEW TECHNOLOGY AND RESEARCH TRIGGER EXPANDED INTEREST

IUD The future of the intrauterine device (IUD) is brighter than it has been for the past 20 years. Newer devices are safer and more effective than ever before. Problems with bleeding, spontaneous expulsion and pain are being addressed with new technologies. And perhaps most importantly, increased understanding of pelvic inflammatory disease (PID) has led the mainstream scientific community to moderate the once-sweeping indictment of IUDs as a cause of PID. Pelvic inflammatory disease is no more frequent among IUD users than among the general population, if proper subject selection and proper insertion and monitoring techniques are used.

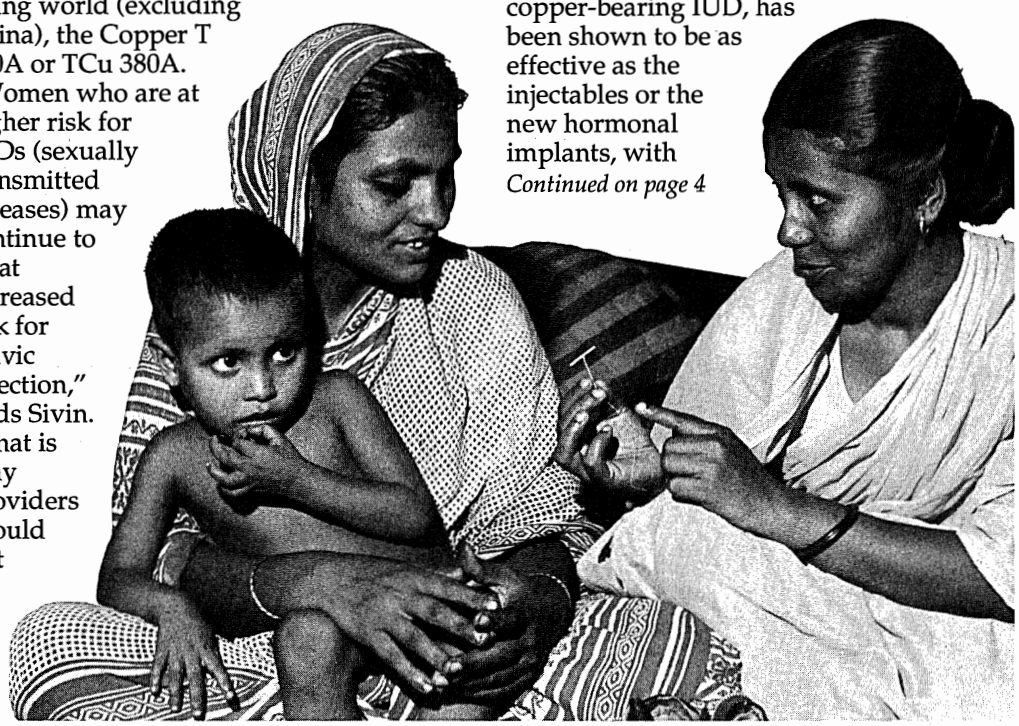
"Women who receive the IUD today according to the currently accepted criteria for IUD use are at extremely low risk for PID," says Irving Sivin, Senior Associate at the Population Council. This U.S.-based research organization developed the IUD currently used most widely in the developing world (excluding China), the Copper T 380A or TCu 380A. "Women who are at higher risk for STDs (sexually transmitted diseases) may continue to be at increased risk for pelvic infection," adds Sivin. "That is why providers should not insert IUDs in these women."

Currently, 85 million women use an IUD, making it the most widely used reversible form of contraception worldwide. Sixty of the 85 million are in China, and another 11 million are in developed nations, particularly in Europe.

The remaining 14 million users are concentrated in only a handful of developing countries — notably, Indonesia (13 percent of reproductive-age couples), Mexico (11 percent of reproductive-age couples), Egypt (8 percent), and India (4 percent). In most of these countries, the number of IUD users has been climbing steadily, as the figure on page 4 shows. In Indonesia, for example, the percentage of reproductive-age couples using IUDs tripled from 1975 to 1985 (from 4 to 12 percent).

Historically, IUDs have trailed only sterilization and injectables in contraceptive reliability. Now, the TCu 380A, a copper-bearing IUD, has been shown to be as effective as the injectables or the new hormonal implants, with

Continued on page 4



BEST AVAILABLE

FHI CELEBRATES 20TH ANNIVERSARY

In 1971, a handful of researchers at the University of North Carolina School of Public Health launched what was to become over the next 20 years a private institution with some 200 staff members and an annual budget exceeding $21 million — Family Health International (FHI).

During much of that growth, from 1978 to 1991, Dr. Malcolm Potts was the FHI chief executive. In 1991, Dr. Potts became President Emeritus of FHI, a global ambassador promoting the mission of family planning, reproductive health, contraceptive development, and AIDS prevention. Based in England, he is exploring European-based population initiatives. In the essay beginning on page 22, Dr. Potts discusses what has gone right and wrong in the short history of family planning, including FHI's role in this history. He also identifies challenges for the future, for AIDS prevention as well as family planning.

FHI began operations at the dawn of the worldwide family planning effort. In 1967, the United Nations created a trust fund devoted to population issues, now called the United Nations Population Fund or UNFPA. In 1968, the U.S. Congress first allotted foreign aid funds for family planning; eventually the United States became the largest family planning donor in the world. The same year *The Population Bomb* by Paul Ehrlich appeared. Less than a generation later, the population bomb continues to explode. ■

FHI

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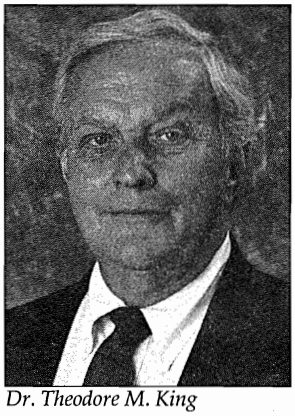
DR. THEODORE M. KING NAMED PRESIDENT

Dr. Theodore M. King, an internationally known expert on women's reproductive health, has been named president of Family Health International (FHI), effective August 1, announced Dr. Torrey Brown, chairman of FHI's Board of Directors. Dr. King comes to FHI from Johns Hopkins University, where he served as Vice President for Medical Affairs and president of the Johns Hopkins Program for International Education in Gynecology and Obstetrics (JHPIEGO).


Alex Treml

Dr. Theodore M. King

"We are delighted to welcome Dr. King to Family Health International," says FHI Board Secretary Dr. Arthur Christakos, who chaired FHI's Executive Search Committee. "Dr. King is widely known in the medical and population field. He is internationally respected for his expertise in female reproduction and his work in clinical research and teaching. He shares FHI's commitment to improving reproductive health, slowing the spread of AIDS, and making safe and effective contraceptive choices available to couples around the world. He also brings a strong personal interest in improving preventive reproductive health care services and using international health resources more effectively."

Dr. King received his Ph.D. in physiology from Michigan State University and his M.D. from the University of Illinois School of Medicine in Chicago. He completed his residency in obstetrics and gynecology at Columbia-Presbyterian Medical Center in New York City. From 1968-71 he served as chairman of obstetrics and gynecology at Albany Medical College, Albany, New York, and from 1971-83 was chairman of the Department of Obstetrics and Gynecology at Johns Hopkins University School of Medicine in Baltimore, Maryland. He has published more than 150 scientific papers, with a focus on adolescent fertility, abortion and female sterilization.

Dr. King served as chairman of the Food and Drug Administration's Obstetrics and Gynecology Advisory Committee from 1974-78, and is former president of the American Association of Planned Parenthood Physicians. He has held consultancies with the Ministry of Health for the Republic of Korea, and as external examiner for the University of Nigeria, in Enugu, Nigeria, and the University of Nairobi, in Nairobi, Kenya, among other such positions.

In addition to his duties at JHPIEGO, Dr. King was professor in the Department of Gynecology and Obstetrics at Johns Hopkins University School of Medicine. He is a member of the Medical Advisory Board of the International Women's Health Coalition. ■

COUNSELING ABOUT SIDE EFFECTS IMPROVES CONTRACEPTIVE CONTINUATION

In much of Africa, family planning programs focus on motivating women to accept contraception. Data from clinics suggest that many women use contraceptives for only a short time, and little is known about why some women continue and others do not.

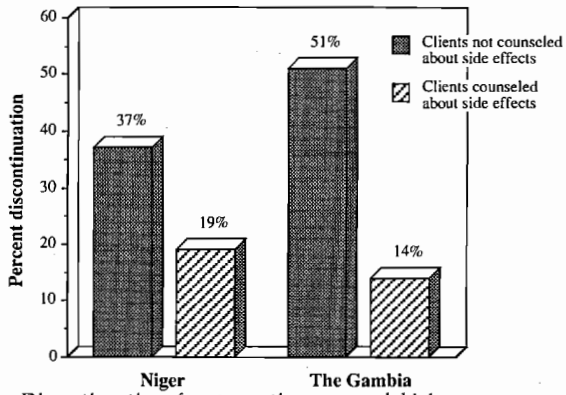
Two recent studies partially sponsored by FHI found insufficient counseling about potential side effects to be a principal reason that women stop using contraception. A variety of contraceptive methods, including oral contraceptives, intrauterine devices, injectables, and barrier devices, were used in the studies, conducted in Niger and The Gambia in collaboration with Niger's National Center for Family Health (CNSF) and The Gambia Family Planning Association (GFPA).

The Niger study involved 650 women who began using contraception. After seven months, about 70 percent were continuing. The most common reasons cited for stopping use of a method were side effects and fear of side effects.

Clients who felt that they were not well counseled were nearly twice as likely to abandon contraception as were clients who considered themselves to have been adequately warned of potential side effects (37 percent versus 19 percent). These findings suggest that better counseling about what side effects women should expect could improve continuation rates.

Results from the Gambia study, involving 570 new contraceptors, had similar results. Women who perceived they were not adequately counseled were three times as likely to stop contracepting as those who felt they received sufficient information about side effects (46 percent versus 14 percent). About 72 percent were continuing contraception after seven months.

Counseling and early contraceptive discontinuation in Niger and The Gambia, 1990



Discontinuation of contraception was much higher among clients who reported that they were not adequately counseled about side effects.

Both studies suggest that many women might not discontinue using contraceptives if given more thorough counseling about side effects. Another similar study is planned for Senegal. Information about discontinuation rates may help policy makers and program managers improve service delivery and reduce costs of services.

In response to recommendations in the FHI report, the Niger government has revised its training curriculum for midwives in family planning clinics to emphasize counseling about side effects. In addition, development of a public information campaign to dispell rumors about side effects of various contraceptives is underway in Niger. ■

FHI Receives $168 Million AIDS Prevention Grant

The U.S. Agency for International Development (A.I.D.) has awarded FHI a $168 million grant to assist countries in Africa, Asia, Latin America and the Caribbean to expand HIV prevention and control programs.

The grant, announced in August 1991, is to be spent over five years. It is the largest by any government for international work to slow the AIDS pandemic.

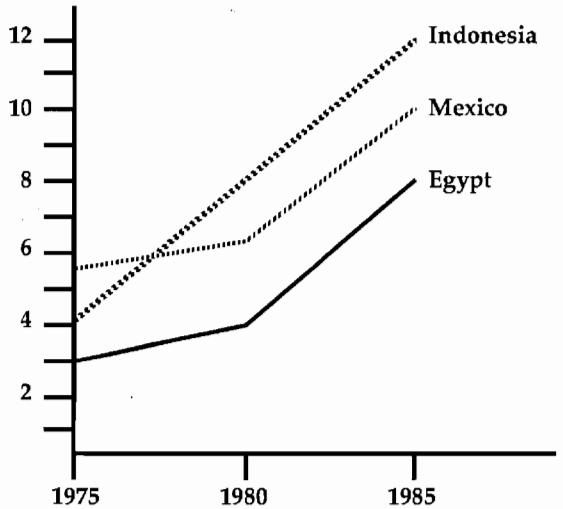
"A reduction in the number of sexual partners, the widespread use of condoms and the control of sexually transmitted diseases (STDs) offer the only currently available protection against HIV infection for sexually active people," explains Dr. Peter Lamptey, who will direct the new project. Therefore, FHI's new project will emphasize three key interventions: reducing numbers of sexual partners; increasing the demand for condoms and increasing access to condoms through innovative marketing programs; and training developing country health personnel in diagnosis and treatment for STDs. The project will also encourage private sector participation in these efforts.

"The new program will continue to complement the leadership of the World Health Organization's Global Programme on AIDS, which coordinates international AIDS prevention efforts," says Dr. Theodore King, President of FHI.

FHI initiated the current AIDSTECH project in 1987 with a five-year, $40 million A.I.D. grant for AIDS prevention activities.

IUD *Story continued from page 1*

Trends in Percentages of Women of Reproductive Age Using IUDs in Selected Countries



Source: W. Parker Mauldin and Sheldon J. Segal, Prevalence of Contraceptive Use: Trends and Issues, *Studies in Family Planning* 19(6), 1988.

fewer than one woman out of 100 (0.3) becoming pregnant after using this IUD for a year. This finding and other data are discussed in a report on clinical trials conducted by Family Health International in 23 developing countries from 1985 to 1989 (see page 6).

The FHI study, involving some 10,000 women, found that with the new generation of copper-bearing IUDs, removals due to bleeding and pain are declining (now about 3 to 4 per 100 women, compared to about 7 per 100 women previously). At the same time, continuation rates are increasing at the end of one year: 80 to 89 per 100 women with the copper-bearing IUD compared to earlier generation IUDs of 71 to 79 per 100 women.

The high continuation rates and the recognized period of efficacy of up to six years for the TCu 380A make IUDs highly cost-effective compared to other reversible methods, despite the initial costs of insertion and follow-up visits. IUDs do not require user compliance, as do condoms, oral contraceptives and injectables.

With that good news comes a major boost from the influential U.S. scientific community. "Research published in the last 10 years shows evidence that IUDs are safe for most women," explains Dr. David Grimes, Professor of Obstetrics/Gynecology and Preventive Medicine at the University of Southern California School of Medicine and a national expert on PID.

In the early 1980s in the United States, IUD use was linked to PID following research findings that one IUD in particular, the Dalkon Shield, was dangerous to women's health. This research led to litigation by more than 100,000 IUD users who sought financial compensation for damages to their health. That controversy led to a sharp decline in IUD use in the United States. Eventually, reassessment of a series of studies has shed new light on the relationship between PID and IUDs (see article on page 10).

The U.S. controversy over PID resulted in closer and more widespread attention to who should and should not use an IUD, as shown below. The IUD is not recommended for any woman with multiple sexual partners, or any woman whose partner has multiple partners, primarily because she is at risk of becoming infected with a sexually transmitted disease and would not be

IUDs Are Appropriate for:

1. Women who want reversible contraception to space births or limit family size.
2. Women who have had at least one child.
3. Breastfeeding women.

IUDs Are Not Appropriate for:

1. Women with multiple sex partners or women whose partners have multiple partners. Women at risk of becoming infected with sexually transmitted disease, including HIV.
2. Women who have a history of pelvic inflammatory disease since their last pregnancy.
3. Women who have not borne children.
4. Women with undiagnosed menstrual problems, any diseases of the uterus or any history of ectopic pregnancy.

protected by an IUD. Women who want reversible contraception to space births or limit family size are well suited for IUDs, provided they are not at risk of becoming infected with a sexually transmitted disease.

A woman having a baby is a prime candidate for an IUD. In the developing world, childbirth may be one of the few times a woman receives medical care in a clinic or hospital. When labor and delivery are normal, IUDs may be inserted by a trained health care provider within 10 minutes following expulsion of the placenta. IUDs are also safe for breastfeeding women. In 1990, FHI sponsored a worldwide conference in Mexico City on postpartum contraception, at which service providers and policy makers emphasized that IUDs are a viable option for most women.[1]

There are some disadvantages to the IUD. Besides being the wrong choice for certain groups of women, IUD insertion and removal require trained health care personnel. Insertion must be done under antiseptic conditions to guard against infection. Follow-up exams must be performed during the first three months after insertion to check on the position of the IUD. Also, IUDs do not provide any protection against STDs, including the AIDS virus, HIV.

On balance, the IUD is an excellent method for many women, and could become more widely used in many countries. "The 1990s have brought new options such as Norplant and the progestin ring," says Sivin. "But clearly there is not any new or old method as effective, acceptable and inexpensive as IUDs." ■

Footnote

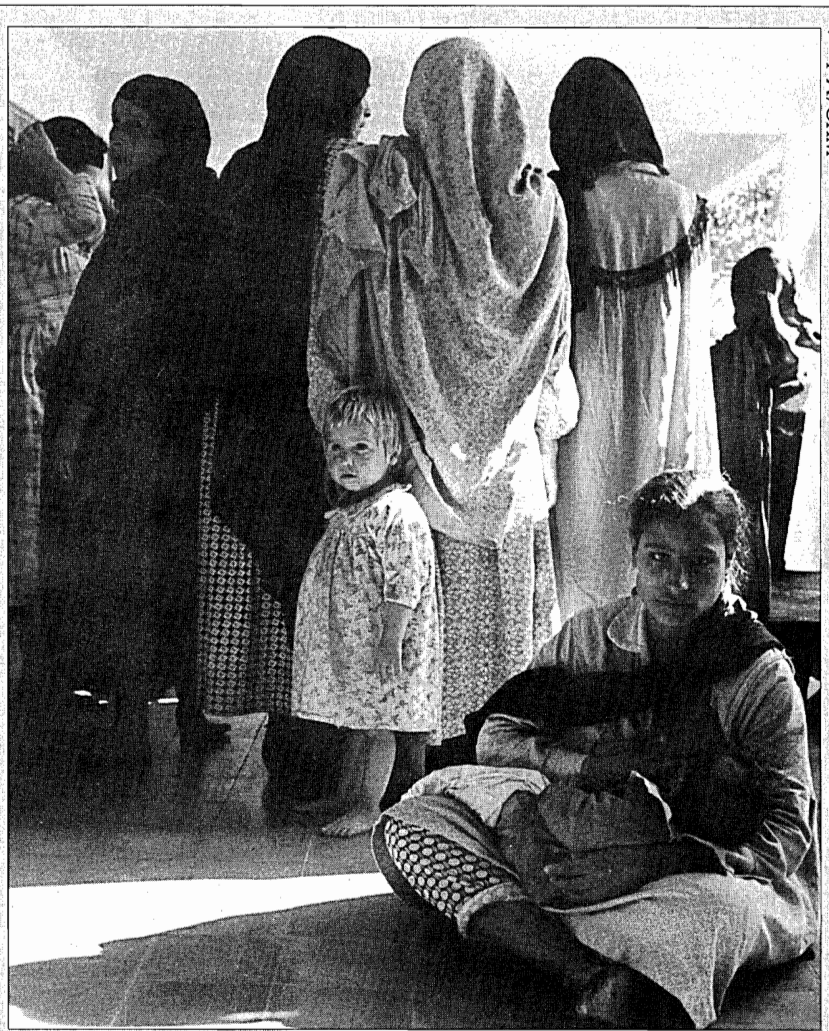
[1] See *network* 11(3), which contains a series of articles on postpartum issues.

Breastfeeding Women Are Good IUD Candidates

Breastfeeding women are good candidates for IUD use. Many studies have shown that there is no discernible decrease in either the quantity or the quality of breastmilk among lactating IUD users.[1] A recent analysis of FHI's international IUD data set shows that breastfeeding women experienced easier and less painful IUD insertion than women who were not breastfeeding. Also, breastfeeding women who were amenorrheic at the time of insertion were less likely to have removals due to bleeding or pain complications. Further, there was no apparent increased risk of other adverse effects, such as uterine perforation or intermenstrual pelvic pain, among women using the TCu 380A IUD who were breastfeeding at the time of insertion.

Footnote

[1] S. Zacharias *et al.*, Effects of hormonal and nonhormonal contraceptives on lactation and incidence of pregnancy, *Contraception*, vol. 3, no. 33 (1989): 203-213; M.H. Labbok, Interactions of contraceptive use and lactation, ed. J.W. Sciarra, *Gynecology and Obstetrics* (Philadelphia: J.B. Lippencott Company, 1982), vol. 6, chap. 36, pp.4-5.



WHO/M. Jacot

Family planning is offered as part of maternal and child health services at this Egyptian clinic.

USE OF IUDS IN DEVELOPING COUNTRIES: A COMPARATIVE STUDY

IUD From 1985 to 1989, Family Health International conducted a multi-center clinical trial on intrauterine devices (IUDs) in 23 developing countries, monitoring some 10,000 women. This study concentrated on copper-bearing IUDs, comparing the Copper T 380A IUD (TCu 380A) to those commonly used in each country where the trial was conducted. This unique data set was used to compare IUDs for accidental pregnancies, safety, acceptability and other issues.

This report summarizes findings from the FHI 10,000-person data set for four types of IUDs — the Lippes Loop from the first generation and three copper-bearing devices: the TCu 380A, the Multiload 250 and the TCu 200. Each of these IUDs is available in various parts of the developing world. The study found the copper-bearing IUDs to be highly effective and generally safe when used by appropriate women under proper medical conditions.

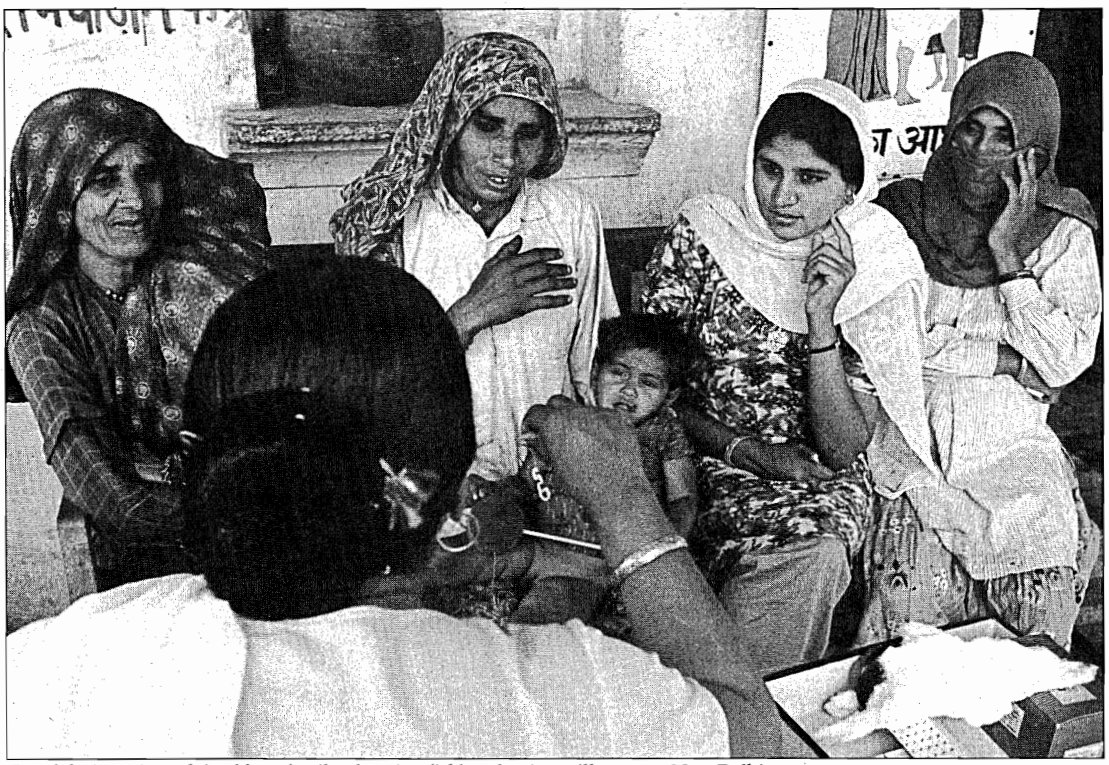
Accidental pregnancies with these IUDs were fewer than with the pill, and some IUDs were as effective as Norplant, the long-acting implant. For every 100 women using the Copper T 380A for one year, there was less than one pregnancy (rate = 0.3). Rates of continuation, from 80 to 89 per 100 women at the end of one year, are generally better than with the previous generation of IUDs (with rates ranging from 71 to 79 per 100 women after one year of use). The number of involuntary expulsions and removals due to bleeding and pain is less with the copper-bearing IUDs (3.1 to 4.1 per 100 women for expulsions and 2.8 to 7.6 per 100 women for bleeding and pain) when compared to the earlier types of IUDs (6.3 to 7.8 for expulsion; 4.5 to 9.8 for bleeding and pain).

In the modern era of family planning, two generations of IUDs have been used. In the 1960s, the dominant IUDs had no copper or hormones and hence became known as "non-medicated" IUDs. Some of the best known devices introduced then were the Lippes Loop and two no longer on the market, the Saf-T-Coil and the Dalkon Shield.

In the 1970s and 1980s, the major innovations involved adding copper (Cu) and varying the "T" shape, leading to acronyms for IUDs such as "TCu." The most popular of these IUDs are the TCu 200 (first marketed in 1972), the Multiload 250 (marketed in 1974, known as the MLCu 250 or Multiload), and the TCu 380A (marketed in 1982). Today these IUDs are the most widely used in the developing world (outside of China, where stainless steel rings and uterine cavity-shaped devices are more common).

The medical literature discussing the risks associated with IUDs is based largely on studies of the first generation non-medicated IUDs.[1] These IUDs, with a few significant exceptions such as the Lippes Loop, are no longer in general use. Risks of uterine perforation, bleeding or pelvic pain associated with those early IUDs are often greater than risks associated with copper-bearing IUDs. For example, most copper-bearing

United Nations



Use of the IUD is explained by a family planning fieldworker in a village near New Delhi.

IUDs, smaller in size than non-medicated IUDs, have not been shown to cause the same degree of uterine trauma as did the first generation devices.

Studies have consistently shown the effectiveness and safety of currently available copper-bearing IUDs.[2] Yet family planning providers continue to have concerns about IUD use, primarily about their safety. Foremost are questions about the increased risk of pelvic inflammatory disease (PID), increased menstrual blood loss, pelvic pain, ectopic pregnancy, uterine perforation, and infertility.

All contraceptive methods have recognized risks and benefits. This FHI study has shown that the risks associated with IUDs are not of sufficient magnitude to overshadow the benefits. IUDs are ideally suited for women who want an effective, long-lasting contraceptive method requiring little effort. Successful and safe IUD use depends on the type of IUD inserted and on the judgment and skill of the provider.

Careful screening of women is essential. The box on page 4 shows which women should and should not use an IUD. Insertion of the IUD high in the uterine cavity by properly trained health care personnel, under sterile conditions using disinfected instruments, will reduce pain during insertion and minimize the chance of perforation, infection, and expulsion. Careful follow-up in the first three months after insertion will reduce the potential for PID by detecting infections early before they ascend into the upper reproductive tract. After the initial three months, periodic follow-up and ready access to medical care will minimize risk of potential complications (such as expulsion, menstrual pain, or PID). Informed, empathetic and timely counseling helps a woman recognize signs (such as heavy bleeding or pelvic pain) that may call for immediate medical attention.

Effectiveness and Acceptability

The accidental pregnancy rates for these four IUDs range from 0.3 per 100 women in a single year for the TCu 380A to 2.3 for the TCu 200 and Lippes Loop. All of these rates are generally lower than for the pill, and the best rate matches those for implants and injectables. To be most meaningful, the accidental pregnancy rates need to be viewed together with the continuation rate among users and the lifespan of the device (see Table 1 on page 8).

Copper-bearing IUDs have an effective lifespan of three to six years, as approved by regulatory agencies. In 1989, for example, the U.S. Food and Drug Administration accepted the TCu 380A, which has the highest efficacy rate, as having an effective life of six years. Data have indicated that the TCu 380A may be effective for up to eight years.

The Multiload 250, which is not T-shaped but has flexible arms with spurs, had the best continuation rate in this study; 89 per 100 women continued to use it at the end of a year. But the TCu 380A was close behind at 86 per 100 women. The Lippes Loop, at 84 per 100, did well, especially when considering that involuntary expulsions accounted for 6 of the 16 non-continuations per 100 women.

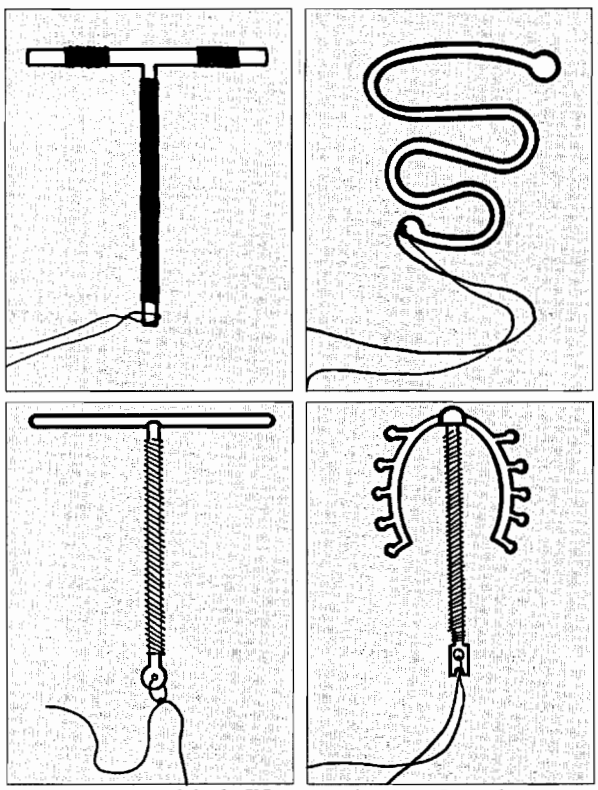
Continuation rates reported for IUD use tend to be higher than those for oral contraceptives, condoms, and injectables.[3] Once an IUD is in place, a woman is less likely to discontinue than a woman using other forms of reversible contraception. Continuation rates in the FHI data ranged from 70 to 80 per 100 women two years after insertion.

IUDs are ideally suited for women who want an effective, long-lasting contraceptive method requiring little effort.

Complications and Safety

While the effectiveness of the IUD in preventing pregnancy is generally well accepted, assurances about safety continue to be hampered by misconceptions. Research throughout the 1980s has shown that new copper IUDs pose far fewer risks to women who are appropriate candidates for an IUD than some have previously assumed.[4] Reducing the occurrence of IUD-associated complications, such as pain, bleeding, expulsion and PID, continues to be an important task.

Bleeding. The most frequent reason for stopping IUD use continues to be menstrual bleeding. About 5 per 100 women using the TCu 380A requested to have it removed in the first year due to bleeding, while 20



Grace Wang

Joyce Hopkins

Clockwise from top left: the TCu 380A, the Lippes Loop, the MLCu 250, and the TCu 200.

percent of users complained of increased menstrual bleeding. These numbers are considerably lower than those reported for first generation, non-medicated IUDs.[5] Even so, early discontinuation of IUD use because of bleeding concerns family planning providers throughout the developing world. Development of hormone-releasing IUDs may help address this problem (see article on page 9).

Once an IUD is in place, a woman is less likely to discontinue than a woman using other forms of reversible contraception.

Expulsion Rates. FHI research has shown expulsion rates for the copper IUDs to be consistently lower than those of IUDs used predominantly in the 1970s.[6,7] Expulsions may occur without signs or symptoms that are noticeable to the user; often an expulsion is detected only after the woman has experienced an unintended pregnancy. Most expulsions occur within three months after IUD insertion. It is recommended that IUD acceptors have an early clinical check-up to confirm that the device remains in place.

Efforts to reduce IUD expulsion include making IUDs smaller and more flexible to conform more with the interior shape of the uterus, and anchoring the device into the uterine wall with a knotted thread.

Pelvic Inflammatory Disease. Some women have a higher chance of developing pelvic inflammatory disease (PID) than the general population of women of childbearing age. Women with multiple sexual partners and women whose partners have multiple partners are at risk for sexually transmitted diseases, including PID. These women were not allowed to participate in the clinical trials being discussed here. Providers knowledgeable about factors putting women at risk of PID would follow a similar procedure.

In these studies, women using the three copper-bearing IUDs had PID rates ranging from 1.7 to 2.9 per 100 women at the end of one year. The Lippes Loop, from the first generation of IUDs, had a slightly higher PID rate of 3.8 per 100 women at the end of one year. PID rates among women using any of the IUDs available today compare favorably with PID rates found in the general population of women of childbearing age in developing countries. Put another way, these IUDs, when inserted into women who are appropriate candidates for IUDs, do not appear to significantly increase the risk of PID. This study indicates that women at low risk of acquiring sexually transmitted diseases appear to have little or no risk of IUD-related PID (see article on page 10 for more).

TCu 380A Has Best Results

This study was designed to test the increasingly popular TCu 380A with other IUDs commonly used in developing countries. The data show that among the four IUDs compared here, the TCu 380A clearly had the best record when viewing accidental pregnancies, continuation rates and lifespan together.

None of the four IUDs fared

Continued on page 12

TABLE 1. A COMPARISON OF FOUR IUDs

(per 100 women after one year of use)

	Effectiveness and Acceptability			Complications and Safety		
	Accidental Pregnancy Rate	Continuation Rate	Approved Lifespan	Removals due to Bleeding/Pain	Expulsion Rate	PID Rate
TCu 380A	0.3	86.4	6 years	4.6	3.1	2.9
TCu 200	2.3	80.2	4 years	7.6	4.1	2.9
Lippes Loop	2.3	83.9	10 years	2.9	6.4	3.8
MLCu 250	1.2	88.6	3 years	2.8	3.8	1.7

Note: The rates are based on gross-cumulative lifetable rates from approximately 10,000 women in clinical trials which FHI conducted in 23 countries from 1985 to 1989.

NEW DEVELOPMENTS IN INTRAUTERINE DEVICES

IUD Researchers are pursuing solutions to problems that remain with the current generation of IUDs in use. The first generation of IUDs, dominant in the 1960s, had no copper or hormones and was known as "non-medicated" IUDs. The second generation, marketed in the 1970s and 1980s, added primarily copper to the IUDs and variations of the "T" shape.[1] The three types of IUDs described below might be viewed as the third generation of IUDs.

The TCu 380A has become one of the most popular IUDs used in family planning programs throughout the world. It has been shown to have one of the lowest pregnancy rates among all contraceptive methods available. Yet two problems occur with the use of this IUD: spontaneous expulsion and patient requests for early removal due to bleeding and pain. Both of these problems have contributed to lower than desired continuation rates.

Three newly developed IUDs may help reduce some common side effects related to IUD use while maintaining high contraceptive efficacy. These are the Copper Safe 300 or Cu-SAFE 300, the FlexiGard 330 or Copper-Fix 330, and the levonorgestrel-releasing IUD. Each of these devices has design modifications expected to reduce the incidence of expulsion or bleeding and pain complications. None is currently being used in the open market.

Copper Safe 300. More commonly known as the Cu-SAFE IUD, this IUD was developed to fit the dimensions of the uterine cavity. The crossarm of the plastic body bends inward, so that protrusions of the IUD frame will not irritate the uterine wall. The Cu-SAFE is flexible, lightweight and smaller than other copper-bearing IUDs so that it will conform to the interior shape of the uterus throughout the menstrual cycle. Penetration into the uterus and Fallopian tubes is generally avoided, thereby reducing bleeding and pain.

Because of its smaller size and high degree of flexibility, the Cu-SAFE 300 does not require pre-insertion loading into an inserter tube with plunger. Instead, the IUD can be inserted with one hand using a simple procedure known as "push-in, control, withdraw." This system works well for women who have a relatively narrow endocervical canal. Initial data on efficacy, expulsion and removals due to bleeding and pain are favorable.

Copper-Fix. Also known as the FlexiGard 330, this IUD was developed in the late 1980s. It does not have a frame but has six copper sleeves on a single filament of polypropylene thread. It has a total copper surface area of 330 square mm. The end of the thread is knotted and anchored at the fundus of the endometrial cavity into the myometrium. The upper and lower sleeves are crimped to the thread to prevent the copper sleeves from sliding into the vagina. The insertion procedure requires some training but is considered to be easy once mastered.

Early studies have shown favorable results. Currently, a study in 26 centers in Europe, the United States and Canada involving 3,200 patients is comparing this device to the TCu 380A. The World Health Organization is also funding a large clinical trial involving 6,000 patients in 30 sites in 13 developing countries as well as the Soviet Union and China.

Hormonal. A levonorgestrel-releasing IUD (LNG-IUD) represents a method of contraception that combines the positive characteristics of oral contraceptives, IUDs, and steroid-releasing implants. It is especially attractive for women suffering from menorraghia and dysmenorrhea, as well as for those who experience increased menstrual blood loss when using copper IUDs. One LNG-releasing IUD has been developed by Leiras and registered in Finland. The company has plans for expanded registration in the European Economic Community. The U.S.-based Population Council is pursuing with the U.S. Food and Drug Administration possible U.S. approval procedures.

The LNG-IUD has a daily release rate of 20 mcg of levonorgestrel and has an estimated effective lifespan of up to seven years after insertion. A major benefit of levonorgestrel released in the uterine cavity is a reduction in menstrual blood loss. One benefit of decreased menstrual blood loss is a rise in hemoglobin and iron stores, important concerns since iron deficiency anemia often accompanies copper-IUD use. Lastly, use of levonorgestrel has been associated with a significant reduction in menstrual pain. ■

— Gaston Farr
Associate Director, Clinical Trials Division

Each of these devices has design modifications expected to reduce the incidence of expulsion or bleeding and pain complications.

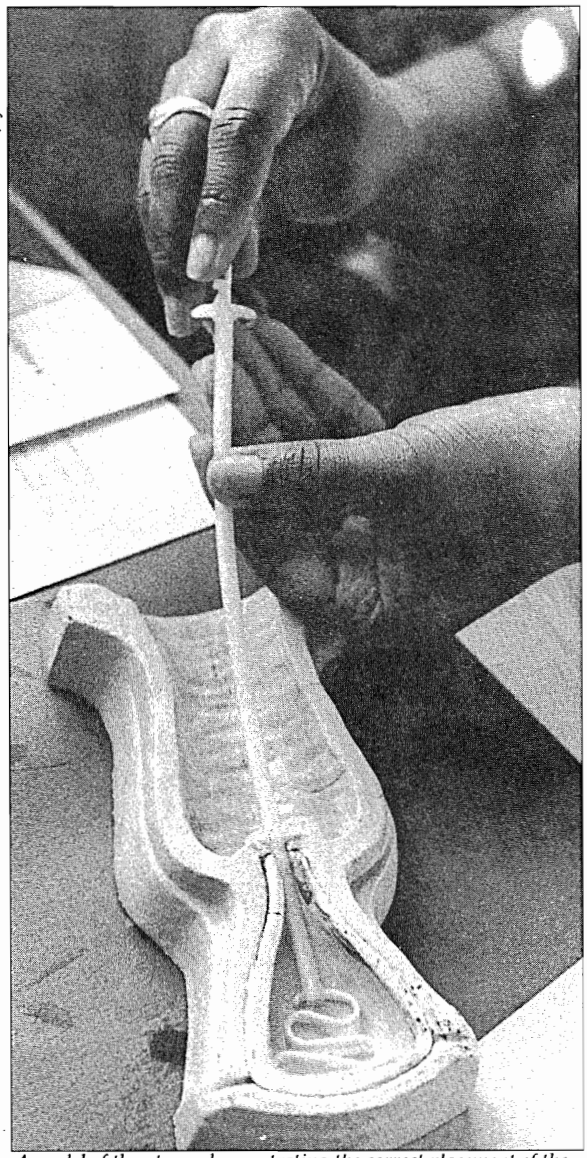
Footnote

[1] A few IUDs in this second generation also contain progestin. This type of IUD is used primarily in the United States.

MANY WOMEN CAN USE IUDS WITHOUT INCREASING RISK OF PID

IUD Most experts now believe that the current generation of intrauterine devices does not significantly increase the risk of pelvic inflammatory disease (PID) and subsequent infertility, as long as proper selection criteria for IUD candidates is followed.[1]

Epidemiologic studies in the late 1970s and early 1980s in the United States indicated that IUD use significantly increased a woman's chance of developing PID. These reports concluded that IUD users were as much as 10 times more at risk for PID than women not using IUDs.



WHO / J. Littlewood

A model of the uterus demonstrating the correct placement of the Lippes Loop.

Over the past 15 years, however, scientists have learned more about causes of PID in general and its relation to IUD use specifically. A second generation of copper-bearing IUDs has been developed; these IUDs pose a lower risk for PID than do the first generation of devices. The early research indicting IUDs has been called into question because the methodology originally used in PID studies did not take into account such factors as the number of sexual partners of IUD users.[2] Also, the early research overstated the risk because the control groups were protected against PID by use of barrier methods and oral contraceptives.

"FHI research suggests there is virtually no link between IUDs and PID for women not exposed to sexually transmitted diseases," explains Dr. Roberto Rivera, Director of FHI's Clinical Trials Division. "The data suggest that PID is no more frequent in IUD users than in the general population. Based on these findings, PID does not appear to be a major risk for IUD users" (see Table 1 on page 8).

Dr. David Grimes, a U.S. expert on PID and Chair of the National Medical Committee of Planned Parenthood Federation of America, says "Research published in the last ten years shows evidence that IUDs are safe for most women."

The U.S. Centers for Disease Control is slightly more cautious in its 1991 guidelines for IUD use: "Women who use intrauterine devices are probably at increased risk of PID that may not be STD-related. Most of this increased risk occurs in the first months after insertion of an IUD."[3]

What Is PID?

PID is a syndrome consisting of infection of the endometrium, Fallopian tubes, and/or ovaries. PID is usually caused by an infection ascending through the cervix. The infection can be from various sources, including childbirth, but the most common source is a sexually transmitted disease. When STDs such as gonorrhea or chlamydial infection are not treated promptly, they have a chance to spread from the lower female reproductive tract to the upper tract.

Even though PID can usually be cured with antibiotics, the damage it causes is often permanent. Unrecognized and untreated, PID can result in infertility and lead to chronic debilitating pelvic pain, ectopic pregnancy, and death.

PID is fairly common in the general population and afflicts IUD users and non-users alike. It is the major preventable cause of female infertility in developing countries and may affect as many as one in five women. The few studies of the prevalence of PID in developing countries have found proportions as high as 20 percent among village women in Kenya, Uganda and India.[4]

Laparoscopy is the most accurate diagnostic method for PID, but most of the world must rely on clinical diagnosis, which unfortunately is unreliable. Such common PID symptoms as unusual vaginal discharge, lower abdominal or pelvic pain, and fever are the same as those for other disorders. Such symptoms often

do not appear in the early stages of the disease or the symptoms can be so mild that women do not notice them. A high index of clinical suspicion and careful evaluation of symptoms and physical findings are required for adequate treatment of patients.

How Is PID Related to IUD Use?

Most diagnosed IUD-related pelvic infection occurs in the first three months after IUD insertion. These cases are thought to result from uterine contamination that occurs during insertion. Bacteria present in the endocervix can be carried with the IUD as it passes into the uterus. This can certainly happen with *abnormal* bacteria present because of an infection such as an STD. It might also happen with the *normal* bacteria.

Most IUD-related pelvic infections result from sexually transmitted infections, but a small percentage of PID is caused by the ascent of bacteria normally present in the healthy vagina or cervix. This potential risk exists for women regardless of their risk for STDs. However, the elevated risk is minimal and lasts only for three months. Thereafter, these women are not at significantly higher risk for PID than are non-users.

In the late 1960s and early 1970s, providers commonly inserted IUDs in young, sexually active women who had not borne a child, the very women who experts now believe have an elevated risk for PID regardless of IUD use. Today, women with more than one sexual partner are considered at high risk for STDs. These women are more likely to have infections in the cervix that may be carried up into the upper reproductive tract during the IUD insertion process. Hence, the IUD is not recommended for use by these women.

An Effective Option

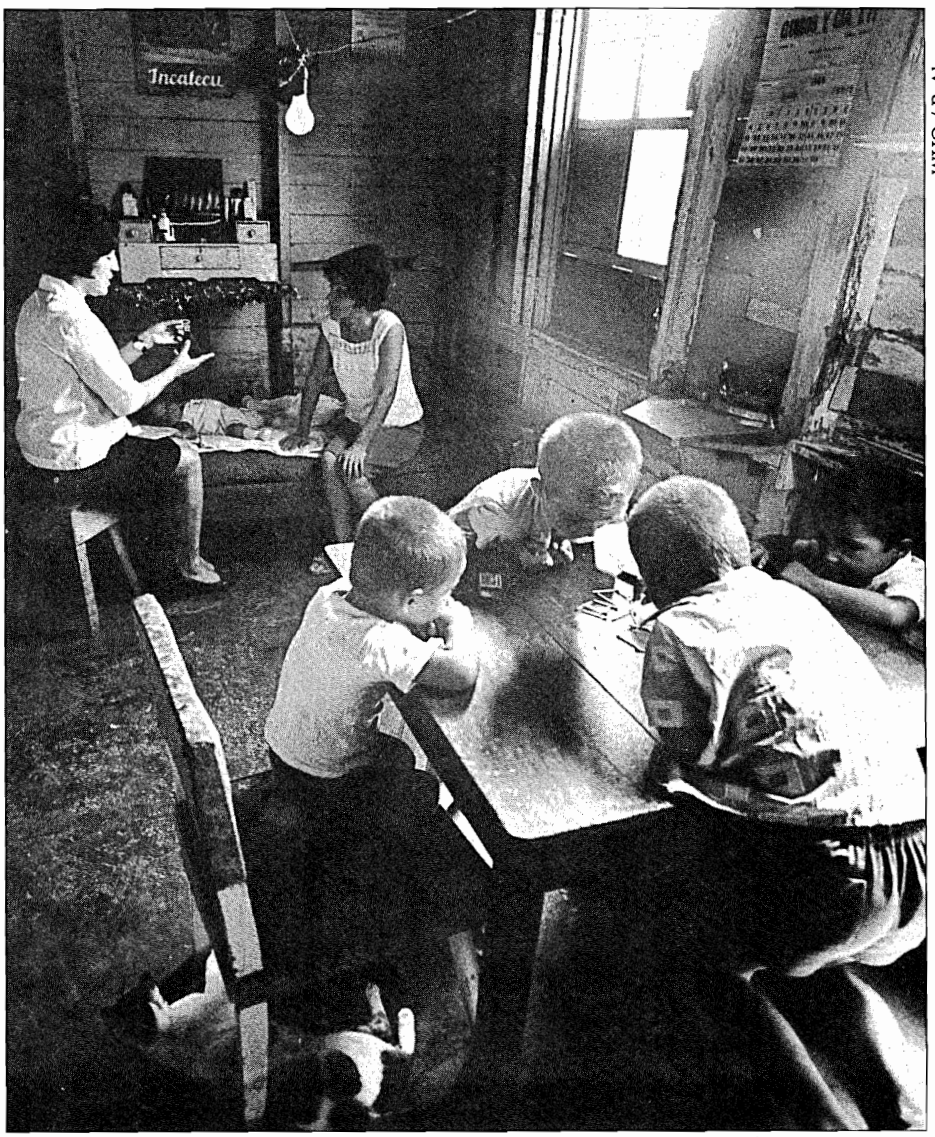
One theory about IUD-related PID presumes that the insertion process introduces new bacteria into the uterine cavity and hence the risk of infection might be reduced by using a prophylactic antibiotic at the time of insertion.

Data from FHI studies in Nigeria and Kenya do not support this theory. The women who did not receive antibiotic prophylaxis at the time of IUD insertion showed no greater risk of PID in the first 90 days than women who did receive the antibiotic.[5]

"FHI studies do not offer evidence to support use of prophylactic antibiotics at IUD insertion," says Dr. Rivera.

Still, researchers continue to study the effects of prophylactic antibiotics on rates of PID. A new study launched by the U.S. National Institutes of Health will compare the incidence of PID in the first three months following IUD insertion among women receiving and not receiving antibiotics at insertion.

Another theory about IUD-related PID is that bacteria ascends by way of the string attached to some IUDs. In a study among 1,300 women, FHI also found this theory not to be true.[6] Women using an IUD with a string did not show a significantly higher risk of infection in the first



WHO / P. Almasy

A health visitor in Costa Rica discusses family planning with a young mother during a home visit.

"Research published in the last ten years shows evidence that IUDs are safe for most women."

year of use than did women using the IUD without the marker string attached.

In this study as well as in the Nigerian and Kenyan studies on antibiotics, the careful selection of IUD users, sterile insertion procedures, and follow-up during the first three months after insertion (to detect and treat any infections that may develop) were most likely the reasons for decreased risk of IUD-induced PID. This reinforces the important notion that following these criteria can minimize the risk of PID among IUD users.

The new information clarifying the link between PID and IUD use has led to a new generation of IUD users who are likely to be at lower risk than the general population for PID. Family planning experts now hope that information will translate into greater utilization of one of the world's safest and most effective contraceptive methods. ■

— *Sara Townsend*

Footnotes

[1] D.A. Grimes *et al.*, IUDs and pelvic infection, *American Journal of Gynecologic Health*, III (suppl. 3), 1989, pp. 23-26; A.M. Kaunitz and D.A. Grimes, Good news about contraceptives and PID, *Contemporary Ob/Gyn*, March, 1986, pp. 153-157.

[2] R.A. Kronmal *et al.*, IUD and PID: The Women's Health Study Reanalyzed, *Journal of Clinical Epidemiology*, 44(2):109-122, 1991.

[3] Centers for Disease Control, Pelvic inflammatory disease: guidelines for prevention and management, *Morbidity and Mortality Weekly Report*, 40 (no. RR-5), 1991.

[4] J. Wasserheit, The significance and scope of reproductive tract infections among Third World women, *International Journal of Gynecology and Obstetrics* (suppl. 3), 1989, pp. 154-55.

[5] O.A. Ladipo *et al.*, Prevention of IUD-related pelvic infection: the efficacy of prophylactic doxycycline at IUD insertion, *Advances in Contraception* vol. 7, no. 1 (1991), pp. 43-53; and S.K.A. Sinei *et al.*, Preventing IUD-related pelvic infection: the efficacy of prophylactic doxycycline at insertion, *British Journal of Obstetrics and Gynaecology*, 97:412-441, 1990.

[6] M. Potts *et al.*, IUDs and PID: a comparative trial of strings versus stringless devices, *Advances in Contraception* vol. 7, no. 2/3 (1991), pp. 231-240.

IUD *Story continued from page 8*

substantially better than the others in the measurements of complications and safety (bleeding, expulsion and PID). For example, the TCu 380A had the lowest expulsion rate, but the Multiload had the lowest rate of removals due to bleeding, pain or PID.

The next generation of IUDs now being developed is addressing specifically the nagging concerns about complications and safety. In the meantime, this five-year study involving 10,000 women in 23 countries demonstrated that the TCu 380A is the best IUD to use in most circumstances. ■

— *Gaston Farr with Amy Burdan*

Gaston Farr, Associate Director in FHI's Clinical Trials Division, coordinates IUD research at FHI. Amy Burdan is a technical writer in the Clinical Trials Division.

Footnotes

[1] D.W. Kaufman *et al.*, The effect of different types of intrauterine devices on the risk of pelvic inflammatory disease, *Journal of the American Medical Association* 250(6):759-762, 1983; N.C. Lee *et al.*, Type of intrauterine device and the risk of pelvic inflammatory disease, *Obstetrics and Gynecology* 62(1):1-6, 1983; D.A. Edleman *et al.*, Intrauterine devices and their complications, *Contraception* 19(5):449-454, 1979; and W. L. Faulkner *et al.*, Intrauterine devices and acute pelvic inflammatory disease, *Journal of the American Medical Association* 235 (17):1851-1853, 1976.

[2] H.J. Tatum *et al.*, The new ParaGard copper T 380A intrauterine device, *Medical Digest* 9(1):1-5. 1989; M.L. Cox, Intrauterine contraception today, *The British Journal of Family Planning*, 16:123-124, 1991; W.A.A. Van Os, IUD: past, present, future, *Advances in Contraception* 5: 205-212, 1989; WHO, The TCu 380A, TCu 220C, Multiload 250 and Nova T IUDs at 3, 5 and 7 years of use: results from three randomized multicentre trials, *Contraception* 42(2):141-158, 1990; and I. Sivin and R. Schmidt, Effectiveness of IUDs: a review, *Contraception* 36(1):55-84.

[3] IUDs - a new look, *Population Reports*, Series B, Number 5, March 1988; and S. Harlap *et al.*, *Preventing Pregnancy, Protecting Health: a New Look at Birth Control Choices in the United States*. New York: The Alan Guttmacher Institute, pp. 33-39, 1991.

[4] I-c Chi *et al.*, Insertional pain and other IUD insertion-related rare events for breastfeeding and non-breastfeeding women: a decade's experience in developing countries, *Advances in Contraception*, 5:101-119, 1989; H.J. Tatum, A new IUD offering more copper, better results, *Contemporary Ob/Gyn*, 1988:36-47, 1988; and references under footnote 2.

[5] I-c Chi *et al.*, Is the Copper T 380A device associated with an increased risk of removal due to bleeding and/or pain? *Contraception* 42(2):159-169, 1990; J. Guillebaud and J. Bonnar, Longer though lighter menstrual and intermenstrual bleeding with copper as compared to inert intrauterine devices, *British Journal of Obstetrics and Gynecology* 85(9):707-712, 1978; Edleman (footnote 1); and Population Reports (footnote 3).

[6] H.J. Tatum and E.B. Connell, A decade of intrauterine contraception: 1976-1986, *Fertility and Sterility* 46(2):173-192, 1986; H.J. Tatum, A new IUD offering more copper, better results, *Contemporary Ob/Gyn*, 1988:36-47, 1988; and references under footnote 2.

[7] These clinical trials focused only on IUD acceptors. For a more adequate assessment of the risk of IUD associated PID, a study comparing a control group of non-IUD users and IUD users would be necessary.

health resources

'FACTS FOR LIFE' TRANSLATIONS AVAILABLE IN 114 LANGUAGES

Facts for Life, a 78-page booklet published by UNICEF, explains low-cost health measures that can save millions of children's lives in the developing world. It has been translated into 114 languages by UNICEF, the World Health Organization and UNESCO. In addition, national adaptations of the booklet have been published in many countries. These versions include chapters on health issues of particular importance in those countries.

Nearly three and a half million copies are in use in 89 countries. For example, it is available in seven major Zambian languages.

A companion book to *Facts for Life*, titled *All for Health*, is now also available. This guide to health promotion shows how community members — from religious leaders to artists and entertainers to business leaders — can play an integral role in promoting child health. It describes the methods of health education and summarizes the essential steps in health communication.

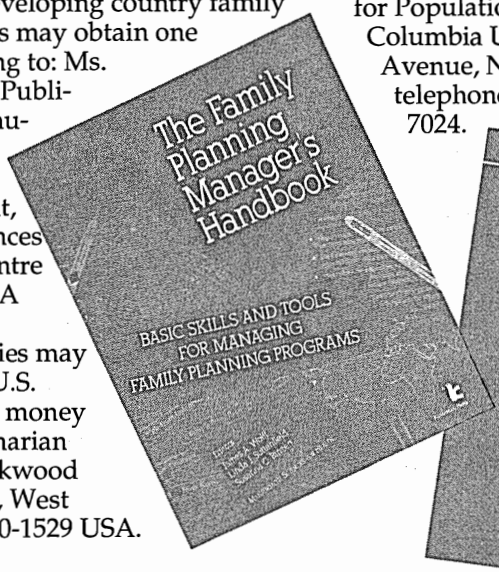
Both *Facts for Life* and *All for Health* are available for U.S. $1.00 each from local UNICEF offices worldwide or from UNICEF headquarters: FACTS FOR LIFE Unit, H-10F, UNICEF House, 3 UN Plaza, New York, NY 10017 USA. *Facts For Life* is no longer available from FHI.

NEW HANDBOOK FOR FAMILY PLANNING PROGRAM MANAGERS

The Family Planning Manager's Handbook: Basic Skills and Tools for Managing Family Planning Programs is a 374-page manual designed for managers of family planning programs. This handbook includes sections on planning, coordination, staffing, supervision, training, financial management, contraceptive logistics, and program sustainability. In addition, it offers sample forms, worksheets and country examples.

Managers of developing country family planning programs may obtain one copy free by writing to: Ms. Linda Suttenfield, Publications and Communications, Family Planning Management Development, Management Sciences for Health, 400 Centre Street, Newton, MA 02158 USA.

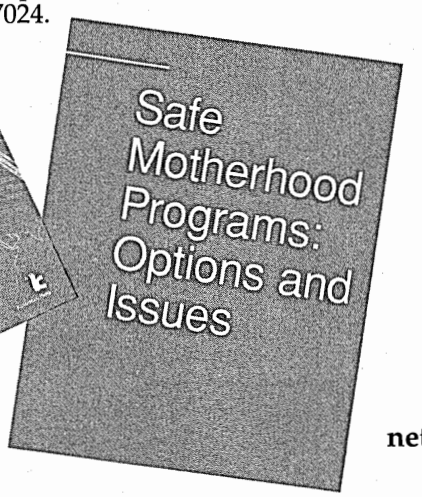
Additional copies may be purchased for U.S. $34.95 by check or money order. Write: Kumarian Press, Inc., 630 Oakwood Avenue, Suite 119, West Hartford, CT 06110-1529 USA.



MATERNAL MORTALITY REPORT AVAILABLE

Safe Motherhood Programs: Options and Issues, a publication designed to inform health professionals, program planners and policymakers about current research on maternal mortality, is available from Columbia University's Center for Population and Family Health.

The 61-page report examines strategies for reducing pregnancy-related deaths among women in developing countries. It is available only in English. Single copies are distributed free to requesters from developing countries by contacting: Center for Population and Family Health, Columbia University, 60 Haven Avenue, New York, NY 10032 USA; telephone 212-305-8880; fax 212-305-7024.



USING ORAL CONTRACEPTIVES CORRECTLY: PROGRESS ON PACKAGE INSTRUCTIONS

"When I took the yellow (pill) I bled, so I had to go back to the white," says a 40-year old woman from a rural section of Egypt. "One time I did not find the white so I took the yellow, and I became tired so I immediately (returned to) the white."

This woman has given birth to six children, four of them still living. She is counting on the pill to keep her from having more children. If she takes it correctly, she will have a very slim chance of having another child. Taken properly, the pill is 99 percent effective in preventing pregnancy. But her experiences in taking the pill, along with those of other women in a recent study in Egypt, indicate the many reasons why the pill is not as effective as it could be.[1]

WHO / C. Chit

Women from Lampang Province in northern Thailand listen to an explanation of oral contraceptives.

About 63 million women worldwide use oral contraceptives (OCs), about 8 percent of all married women of reproductive age. It is the second most widely used reversible form of contraception, behind the IUD.

Recent research has shown that from 6 to 20 percent of pill users may become pregnant because of incorrect pill use.[2] Reducing this rate by just 1 percent through better pill taking could reduce accidental pregnancies by as many as 630,000 per year (1 percent of 63 million users).

"These figures were a great revelation to me and a starting point for my enormous interest in this area," says Dr. Pramilla Senanayake, Assistant Secretary-General of the International Planned Parenthood Federation (IPPF). "These are women who actually want contraception and are using it. Yet we have a large number of pregnancies that could be avoided. This is a problem that can be solved."

Dr. Malcolm Potts, President Emeritus of Family Health International (FHI), adds: "Improving oral contraceptive use could be as important in preventing unplanned pregnancies as inventing a new method of contraception."

Only a handful of studies has examined the problem of correct pill usage.[3] Even so, a clear consensus has emerged: Use of the pill is not nearly as effective in reducing pregnancies as it can be. Until recently, researchers had not identified the major reasons why the pill was not taken correctly nor had they proposed steps that might correct the various problems. There is recent action on both fronts.

"The three primary targets for improving pill use are first, improving the written instructions in the pill packs," says Dr. Linda Potter, who has directed research on correct pill use for FHI since 1987. "Second, the instructions from the providers need to be correct. Third is the user herself, her understanding of the instructions and her motivation to follow them."

The U.S. Food and Drug Administration (FDA) recently directed OC manufacturers to improve the instructions in the pill packs according to specific guidelines for consistency and clarity. But simpler and more consistent instructions, even if developed quickly by all manufacturers throughout the world, are only the first step. Providers also must be trained to tell users the same things that the package instructions say.

"The next step is for providers to give clear and consistent information to the women using the pill," says Dr. Senanayake. "This includes pictorial information for users who can't read. All of this leads

to the third aspect of the issue — users correctly taking the pill."

Why the Pill Is Hard to Take Correctly

Frequently over the 30-year life of the pill, the saying has been, "It's easy to take. Just remember to take a pill every day." That conventional wisdom has persisted because little research has been conducted on actual experience in taking the pill. Now, researchers have discovered that the opposite is true: The pill can be hard to take correctly, especially for semi-literate or illiterate populations.

Correctly taken, most pills work by suppressing ovulation to prevent pregnancy. In the 1960s and 1970s, pills had much higher levels of estrogen and progestin than do pills today. The hormonal levels have been reduced to lower the frequency of side effects, but they are so low today that missing even one pill could result in ovulation.[4]

Instructions from manufacturers and providers on how to use the pills vary extensively. In developing countries, there are packets with cycles of 21, 22, 28 and 35 days. Knowing when to start the first cycle and subsequent cycles is difficult without perfectly clear instructions. The instructions must be clear on the package, clear from the provider and consistent between the two.

The correct pattern is to take contraceptive pills for 21 days without interruption, then wait seven days and start the next cycle of the hormonal pills. Pills packaged in 28-day cycles include 21 hormonal pills and seven hormone-free pills, called "reminder" pills. The reminder pills, often containing iron, fill the seven-day gap. Hence, a woman can take a pill every day. But even with such "reminders," problems can occur.

In the study in Egypt mentioned earlier, one woman complained of continuous spotting (light bleeding) even though she was taking a pill every night. When she showed her pill packet to the researcher, her problem became clear. She was taking the pills in a vertical pattern, which in that packaging system meant she was taking contraceptive pills for three days and on every fourth day, an iron "reminder" pill containing no hormones. She should have been taking all of the 21 hormonal pills and then the seven non-hormonal pills.

In many countries, pill users get incorrect instructions on how to take the pill from their provider. For example, providers in developing countries have often advised women to start each pill pack on the fifth day of menses. This is incorrect because, depending upon when a woman's menstrual cycle begins, starting on the fifth day of menses may extend the hormone-

"Improving oral contraceptive use could be as important in preventing unplanned pregnancies as inventing a new method of contraception."

Major Types of Oral Contraceptives

Below are simple descriptions of the three major types of oral contraceptives in use today. All three types of OCs can be packaged in many different ways.

1. Monophasic combined pill. This OC contains both estrogen and progestin, now at low levels so as to minimize side effects, 35 mg. or less of estrogen and one to two mg. of progestin. At these dosage levels, ovulation can occur if even one pill is missed; this is most likely to occur if a pill is missed at the beginning or end of the 21-day hormonal cycle. This type of combined pill is "monophasic" because the dosage levels of estrogen and progestin remain the same through the cycle of 21 pills.

2. Triphasic combined pill. This OC is packaged to provide one week each of three different levels of estrogen and progestin, to simulate the body's natural hormonal fluctuations. The triphasic has less progestin than monophasic pills, thus reducing the impact on blood pressure, fatigue and other side effects. There is more breakthrough ovulation and bleeding with the triphasic than the monophasic pill because of the lower progestin levels. Each month's pack contains three colors of pills, one for each hormonal combination; a 28-day cycle package contains a fourth color for the reminder/vitamin pills. Taking the pills out of the correct color sequence increases the chance of pregnancy. Even so, researchers have not established whether triphasics have higher compliance-related failure rates than the low-dose monophasic pills.

3. Progestin-only "mini" pill. Available since 1973, these are recommended for women who experience estrogen-related side effects, such as headaches or hypertension, and for breastfeeding women. In developing countries, a very small percentage of OC users — perhaps as low as 1 percent — use the mini pill. The mini pill requires 28 hormonal pills with no pill-free period in each cycle. Hence, the instructions for taking the mini pill differ from the combined pill.

Recommendations on OC Use Proposed by FHI and Endorsed by the U.S. FDA, 1991

Recommendations for Content and Format of Patient Package Insert

1. All patient package insert (PPI) instructions for using oral contraceptives should be essentially the same.

2. All OC patient package inserts should include instructions for the following:
- general information regarding correct oral contraceptive use, as well as initial start date options (Sunday start and Day 1 start);
- what to do when one, two and three or more pills are missed;
- when and for how long to use back-up methods.

3. All OC patient package inserts should be presented in an easily readable format. They should:
- use words and phrases that are clearly understood and written at a fifth to sixth grade (U.S.) reading level;
- appear as a separate, clearly defined section of the PPI;
- be written in large print;
- include a picture of the pill pack, clearly labeling where to start, in what direction to take the pills for weeks 1 through 3, and the "reminder" pills in 28-pill packs.

Recommendations on OC Packaging

1. A brief summary of the instructions for missed pills (including use of back-up methods) should be included separately, on heavy plasticized paper, to keep in the pill pack at all times.

2. All pill packs should be designed so that pills are started in a left-to-right (clockwise) direction.

3. No pill packs should have start dates "frozen" to Sunday or any other day; the package should be designed to allow starting on any day of the week.

Source: "Recommendations for Improving Instructions for Taking Oral Contraceptives," prepared for U.S. Food and Drug Administration Advisory Committee on Fertility and Maternal Health Drugs, February 8, 1991, Family Health International, pp. 2-1 ff. In addition to these general recommendations for use of combined estrogen/progestin OCs, FHI proposed specific instructions for the content of package inserts, which are too long to reproduce here. The FDA also endorsed these proposed instructions.

free period past the seven-day period during which no hormonal pill is needed. If she takes no hormonal pill for more than seven days, there is a potential risk of ovulation.

Only a few of the 96 women in the Egyptian study described a correct way of taking the pill. Some women said they did not use the pill if their husbands were out of town; others skipped pills if the side effects were too bothersome. In some cases, women followed instructions they had been given, but the instructions were incorrect.

If a woman does not take the pill on schedule, she needs to use a backup for at least the next seven days. Options include using condoms, diaphragms or spermicides. Pill users are rarely provided with these options or instructions on using them.

"Correct, continuous oral contraceptive use is not a simple matter of 'just take one every day,' which is all many women are told," explains Dr. Potter. "It becomes particularly complex once pills are missed."

Instructions in Pill Packets to Be Improved

Research over the last four years, including FHI-sponsored research in Egypt and in Colombia,[5] led to a meeting of OC experts held at FHI in July 1990. Following this meeting, the U.S. FDA requested that FHI draft simplified and standardized instructions for FDA consideration. In February 1991, the FDA held a hearing on the proposed recommendations.

The recommendations evolved from an analysis of instructions currently being provided in the United States by nine manufacturers for 56 brands of pills, and on instructions developed by selected family planning organizations and providers. The analysis considered biomedical issues as well as user issues such as clarity and readability. It incorporated instructions from guidelines adopted by the IPPF and by manufacturers in the United Kingdom. At the hearing, the FDA was encouraged to consider the recommendations in a worldwide context.

FHI made three basic recommendations

regarding content and format. Instructions of all manufacturers should be essentially the same. Basic information needed for full protection should be included in all instructions. All information should be presented in an easily readable form. Other recommendations addressed such specific points as suggested start dates and instructions regarding missed pills. Draft language for the contents of the pill packet instructions was also presented to the FDA.

On March 12, 1991, Dr. Solomon Sobel of the FDA wrote to the major U.S. OC manufacturers that the FDA's Fertility and Maternal Health Drugs Advisory Committee "unanimously endorsed the recommendations made by Family Health International" to standardize and simplify directions for use of oral contraceptives. Dr. Sobel continued, "FDA concurs with the recommendations of the Committee and, accordingly, requests that you and all other OC manufacturers submit expeditiously draft labeling implementing these recommendations."

This FDA letter is a significant step toward more standardized and simpler instructions from U.S. manufacturers of the pill. At this point, however, the FDA and the manufacturers have not yet reached a formal agreement regarding the standardized instructions. After two years of negotiation in the United Kingdom, the two major family planning organizations have reached agreement with all but one of the OC manufacturers on a set of standardized instructions for OC use in that country.[6]

Getting the Word Out

Even when clear and consistent instructions for the pill package inserts are adopted in the United States and other countries, providers must then give consistent and clear instructions. Providers must be able to advise women correctly and do so clearly and simply, particularly for non-readers who must rely on pictorial presentations.

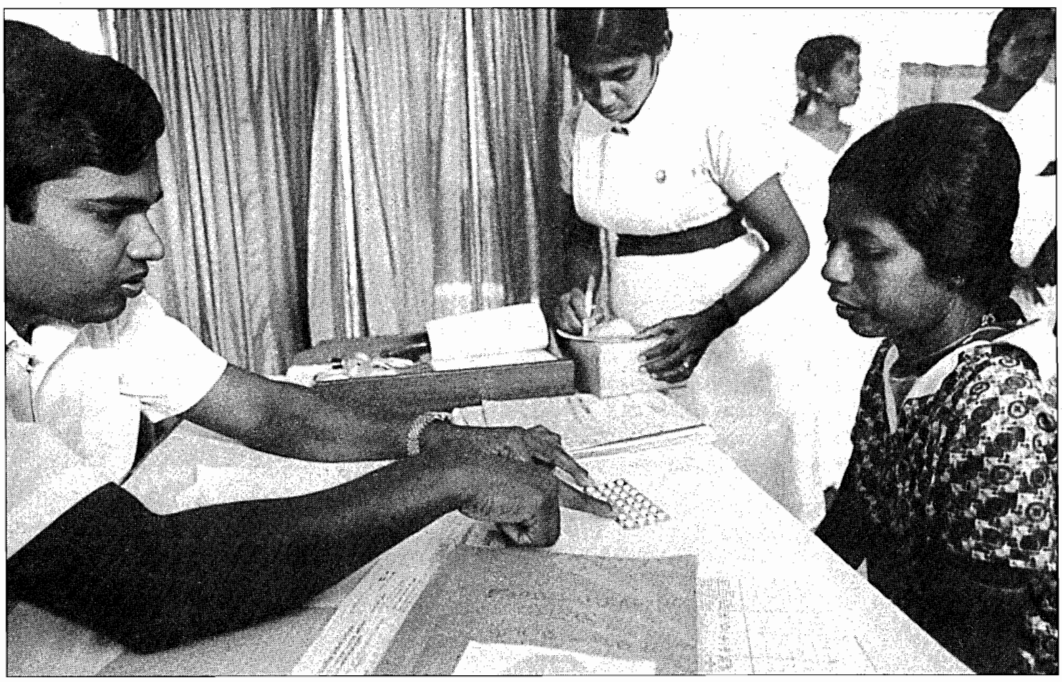
This fall in Harare, Zimbabwe, IPPF is co-sponsoring a workshop on community-based distribution of contraceptives for its affiliates in Anglophone African countries. "We will be talking about proper use of the pill at that meeting," says Dr. Senanayake of IPPF, which has already disseminated information on correct pill use to its affiliates, almost all of which are nongovernmental organizations, in more than 130 countries throughout the world.

"I'm hoping that this issue will be spread to the other countries and their family planning programs in due course," she adds. "We hope the issue will also become important to the UNFPA [United Nations Population Fund] and through that organization this information will reach national governmental family planning programs."

While the steps ahead are time consuming and difficult, the rewards will be worthwhile. Missing a day or two of taking the pill does not necessarily mean an unplanned pregnancy, but it may have this consequence. Each missed pill further increases the risk of pregnancy. If women use the pill correctly, they will avoid almost all unplanned pregnancies. Currently, however, the 63 million women using the pill must cope with contradictions and variations on the package instructions, incorrect or inconsistent information on use from providers, and their own lack of clear understanding about using the pill.

"There are three prongs to the problem and to the solution," says Dr. Senanayake. "It is the woman herself, the package instructions she gets, and the information she is provided with in pictorial and

Continued on page 27



WHO / J. Mohr

A Sri Lankan woman makes her first visit to a family planning clinic in Colombo.

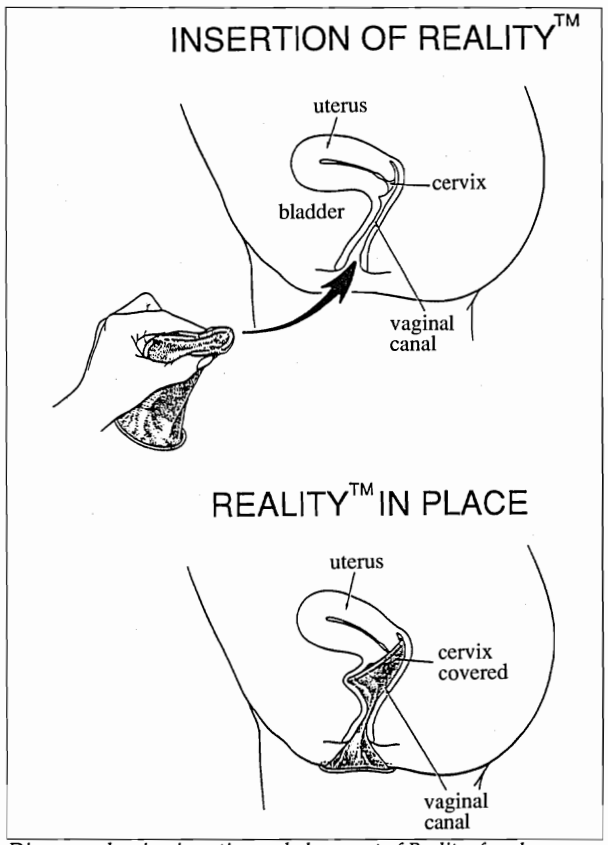
FEMALE CONDOM — NEW BARRIER DEVICE SOON TO BE AVAILABLE

Women may soon have their own condom — a new contraceptive device that may also offer protection against sexually transmitted diseases (STDs). The "female condom" is a disposable sheath of latex or soft plastic, worn inside the vagina.

Many effective methods of birth control are controlled by women, but the main method of STD protection — the male condom — is not. In the wake of the AIDS pandemic, giving women the potential to protect their sexual health is more urgent than ever.

"The real success in family planning has come because women use female methods that don't interfere with intercourse," says Tony Bennett, FHI's resident coordinator in Thailand, who has monitored several female condom studies there. "If we're going to translate that experience to HIV, we need to have female methods."

Every contraceptive device has limitations, however, and the female condom is no exception. Affordability may be one major drawback. In addition, even when a woman has the device and wants to use it, she may be unable to convince her partner to accept it. Moreover, questions remain as to how effective and acceptable this option may be.



Diagrams showing insertion and placement of Reality female condom.

At least three versions of the female condom are in development. Two designs, both made of latex, are still in the early stages of testing. A third version, made of a plastic material, has undergone extensive testing and is expected to be on the market in Europe this fall and available worldwide in 1992.

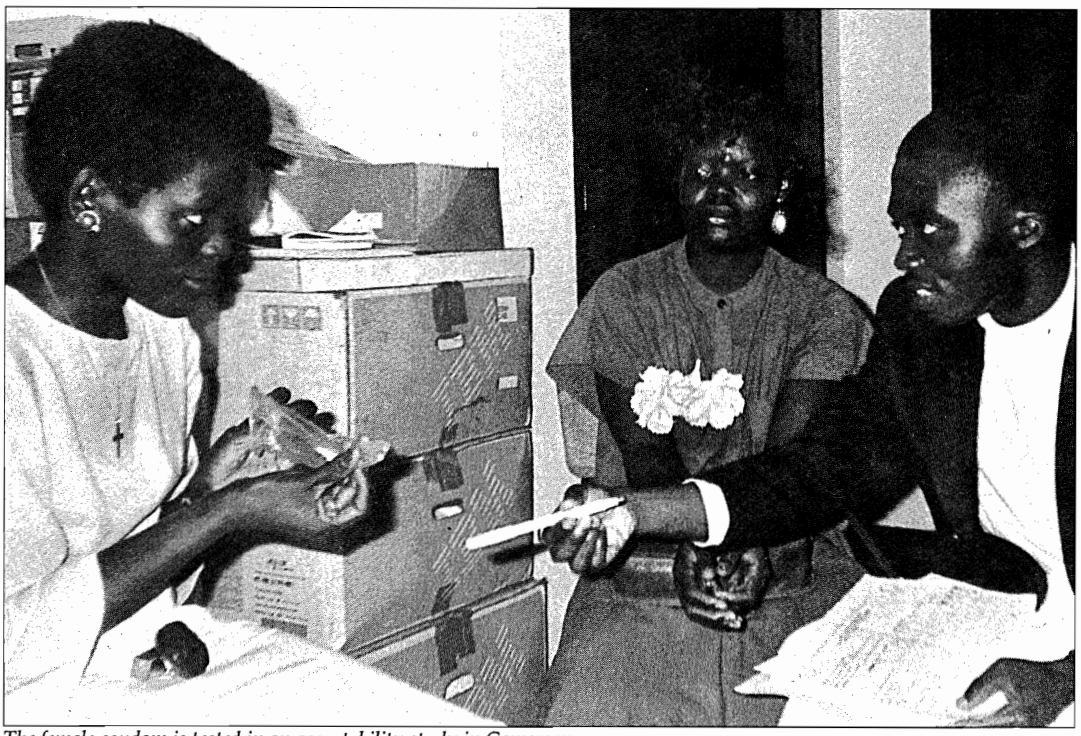
The plastic female condom has a polyurethane plastic tube, 17 cm long, and resembles a large male condom with a ring at both ends, one ring positioned outside the vulva and a second ring inside the vagina (see diagram below, left). The free-floating ring inside the sheath acts as an insertion mechanism and internal anchor. The device is inserted inside the vagina like a diaphragm, with the inner ring fitting behind the pubic bone. The other ring remains outside the vagina. This design prevents contact between the vagina and the penis, as well as separating the vulva from the scrotum and base of the penis during intercourse.

The plastic female condom will be the first new non-prescription contraceptive to appear in nearly a decade. If it is approved by the United States Food and Drug Administration, the female condom will sell commercially for about U.S.$2 — eight to twenty times the average price of the male condom in developing countries. It is not clear what bulk rates to the public sector would be in developing countries, but few consumers in the developing world can even afford market-price male condoms. If it is to be widely used, the female condom will have to be distributed free or at subsidized prices.

Is the Female Condom an Effective Contraceptive?

The plastic female condom has undergone extensive testing. Since 1988, more than 1,500 women in clinical trials around the world have used it. So far, researchers have monitored over 28,000 uses of the new device at 72 research centers worldwide.

FHI is conducting studies on both contraceptive efficacy and acceptability of the plastic female condom. In collaboration with the Contraceptive Research and



FHI / Tom Turk

The female condom is tested in an acceptability study in Cameroon.

Development (CONRAD) program, FHI is conducting clinical trials to determine contraceptive effectiveness at nine sites in Mexico, the Dominican Republic and the United States.

As with the male condom, laboratory studies have shown that an unbroken polyurethane female condom is impermeable to organisms smaller than sperm. Researchers using machines that simulate intercourse conditions to detect leakage report that HIV, cytomegalovirus (CMV) and even one of the smallest known viruses — Hepatitis B — do not penetrate an intact plastic female condom.[1]

Some research suggests that the risk of vaginal exposure to seminal fluid is less with a plastic female condom than with a latex male condom.[2] Studies on breakage rates have shown that female condoms compare favorably with male condoms.[3]

How Acceptable Is the Female Condom?

Inevitably the female condom is compared to the smaller and more familiar male condom. Indeed, if approved by regulatory agencies, the female condom will share two of the same features: minimum side effects and over-the-counter availability. Also, it is easy to learn to use, requiring only a booklet of instructions and illustrations.[4] The female condom may offer several advantages over the male condom.

The female condom covers a broader area of the male and female genitalia than does the male condom. Hence, it may provide protection against STDs such as herpes simplex, which can cause lesions in places not covered by the male condom. The female condom may be less disruptive to the sexual mood because it can be inserted well in advance of intercourse. Some men say the female condom allows greater sexual pleasure than does the male condom, possibly because the penis moves freely within it. Also, unlike condoms made of latex, the plastic female condom can be used with oil-based lubricants without deteriorating.

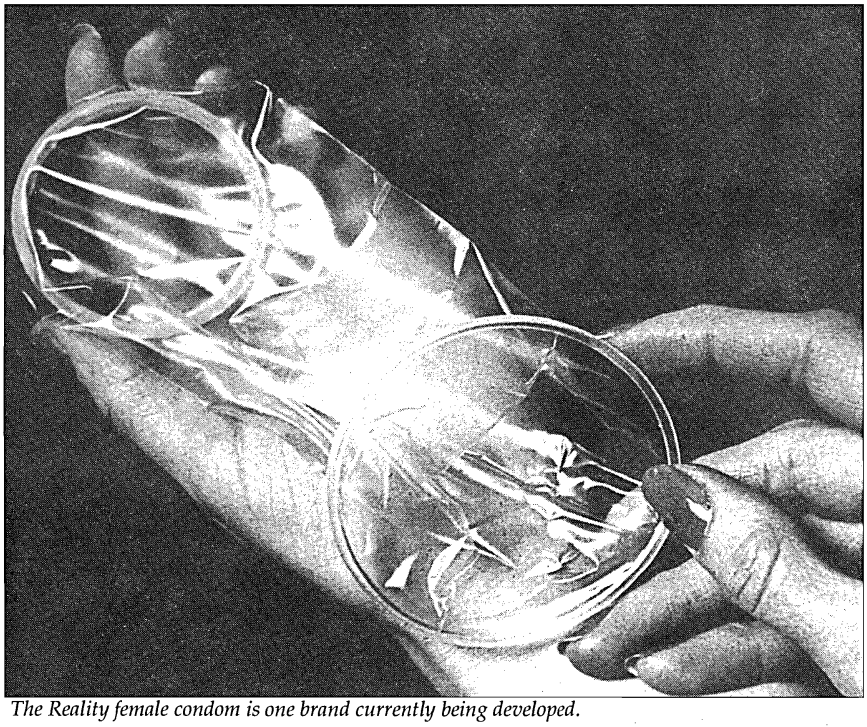
Studies examining users' reactions to the female condom indicate the device may be moderately acceptable among a variety of women, ranging from prostitutes to women in long-term monogamous relationships. The female condom may be more popular in areas or populations with a high incidence of HIV or other STDs, in cultures where women have the power to choose birth control or STD protection, and where it is acceptable for women to touch their genitals.

A small number of studies have shown the female condom may be acceptable to women at low risk for STDs. A recent FHI study of married or monogamous couples in Nairobi, Kenya, suggests the female condom was somewhat acceptable as a means of family planning.[5] During the initial phase of a U.S. efficacy trial, a majority of the married or monogamous women participating in the study rated the female condom more acceptable than other

barrier methods such as the diaphragm or male condom.[6] About half of the participants said they would continue using the female condom if it were available.

Protection Against HIV and Other STDs?

Even if the female condom is found to be effective as a contraceptive, the device will have to be studied further to determine how effective it might be in preventing STDs. Results from initial acceptability studies of the device indicate that women seeking STD and HIV protection, especially those who perceive themselves at high risk, might use the device if it were to become available.



Wisconsin Pharmacal

The Reality female condom is one brand currently being developed.

Recent studies among prostitutes in Africa and Asia suggest that some might use the female condom to protect themselves. In a study among 38 prostitutes in Cameroon, for example, 36 reported liking the female condom. When asked why they liked it, the most commonly cited reason was fear of HIV infection.[7]

Dr. Marcel Monny-Lobé, of the Central Hospital in Yaounde, coordinated the study. "If a man says 'no' to a male condom, he often permitted her [the prostitute] to protect herself [with the female condom]," explains Dr. Monny-Lobé.

All of these women used the male condom regularly. Asked how their clients liked female condoms compared to male condoms, 28 of 38 said their clients liked the female condom as much or more than the male condom. Thirty-three of 38 prostitutes said they would use the female condom in the future. No direct information on male attitudes is available.

The female condom, if available and used regularly, could be a valuable means of slowing the rapid spread of HIV among prostitutes. In Thailand, for example, the female condom appears to be popular among the lower-income brothel and street workers, who have much reason to fear contracting HIV but, for economic reasons, are less able to turn away clients who refuse a male condom.[8]

Given a choice between a male or female condom, both men and women were more likely to prefer the male condom in the Thailand study. But when the male condom was not an option, women preferred the female condom to unprotected sex. "The women are glad to have an alternative to the male condom," says Bennett. "They feel empowered to protect themselves when men are not cooperative." Some women in the Thailand study noted that the female condom is easier to use with intoxicated clients than is the male condom.

In focus groups conducted with 40 U.S. intravenous drug users and their partners, 70 percent said they favored the female condom over the male condom. Men reported preferring the female condom's loose fit. Both men and women said they favored the female device because they thought it gave them greater protection against STDs.[9]

What Are the Disadvantages?

The female condom has some of the same disadvantages as the male condom. As with the male condom, men and women complain that the female condom inhibits pleasure or spontaneity. Also, its effectiveness will depend on the motivation to use it.

One drawback specific to the female condom is the way it looks. Some say it resembles a plastic bag; others say it appears large and cumbersome. Men complain about seeing part of the device hanging out of the vagina.

The device was designed to give women control over their reproductive health, not to enhance sex. "No one is going to argue that the device isn't obtrusive or different-looking," says Carol Joanis, Associate Director of Market Research for FHI's Program Evaluation Division. "Women use it because they need it."

Some women have reported problems with the design of the device, most commonly that the inner ring can cause discomfort. Researchers have suggested that the device might be more acceptable if the polyurethane inner ring, which holds the device in place, were modified to be smaller, thinner and softer.

But the major barrier to use is likely to be the cost of the device. Because the female condom is expensive compared to the male condom, it is not likely to be distributed as widely or promoted as a substitute for the male condom — especially in developing countries, where commercial marketing may not make the product available to those who need it most. A heavily subsidized social marketing system and a totally subsidized distribution process appear to be the only ways the female condom will reach significant numbers of women in most developing countries.

The device is designed for a single use. But despite clear instructions about this point, women may be tempted to re-use the device for more than one episode of sex, given the high cost of the device and its durability. If the device is re-used by prostitutes and not washed between uses, the female condom could actually contribute to disease transmission.

Conclusion

Data on efficacy are not available yet, but information from acceptability studies suggests that the female condom may be potentially acceptable to certain groups of women. This may not mean that many women will use it in everyday circumstances, however. Male condom use is extremely low in most countries, despite faring well in acceptability tests. In Kenya, for example, with the world's second fastest growing population and a high and increasing HIV prevalence rate, less than one percent of married couples use male condoms despite substantial efforts in past years to distribute them.

New generations of female condoms could address some of the drawbacks already identified (see box below). Even so, Dr. Malcolm Potts, President Emeritus of

Continued on page 27

Research Slated on Unresolved Issues

Obstacles to widespread acceptance and use of the first generation of female condoms include problems of fit, comfort, ease of use, device aesthetics and cost. Research is seeking to determine whether higher levels of acceptability can be achieved by minimizing some of these drawbacks. FHI hopes to assess the possibility of re-using the device, evaluate the acceptability of a device that includes an applicator for insertion, and examine the impact of positioning the female condom as a second choice to the male condom.

The female condom is currently designed for one use only. Even with clear instructions that the device is not for re-use, some women will be likely to do so. FHI plans to study durability after repeated washes and feasibility of washing, drying, and storing female condoms. The female condom can play only a minor role in family planning or STD control in the developing world unless re-use proves feasible and safe, says Dr. Malcolm Potts, President Emeritus of FHI. "Supplying the developing world with disposable barrier methods – even with the less costly male condom – is an extraordinarily expensive task," he says. A female condom that can be inserted without women having to touch their genitals might enhance acceptability of the device in certain populations.

FHI plans to compare acceptability of the current model, which is inserted like a diaphragm, and a version that does not require insertion by hand. One such design uses an applicator similar to that of many tampons. Another is a bikini panty with a built-in rolled condom that fits over the opening of the vagina.

Future FHI research will assess whether the availability of female condoms in addition to male condoms would reduce the incidence of unprotected intercourse. Some studies suggest the female condom is most acceptable as a second choice or "back-up" to the male condom. Its goal then is to serve as an alternative to having sex with no protection from STD transmission. Even if the female condom proves to be more acceptable as a back-up method rather than the method of first choice for many women, it gives women a choice to offer men and may result in more widespread use of condoms overall.

—*Sara Townsend*

FAMILY PLANNING, AIDS, AND FHI

An Essay by FHI President Emeritus Dr. Malcolm Potts

When Family Health International began in 1971, there were 3.6 billion people on Earth. As FHI celebrates its 20th birthday in 1991, the world's population has increased 50 percent, to 5.4 billion. During these years, FHI and other organizations throughout the world have made great strides toward developing new and improved contraceptive options and helping to make them available. Yet since 1971, there have been more births, maternal deaths, induced abortions, and infant deaths than in any 20 years of history. What has gone wrong? What has gone right? And what are the prospects ahead?

In the 1990s, the number of women of fertile age in developing countries will increase by almost 30 percent. The world's population will at least double sometime in the next century, with 95 percent of the new births occurring in developing countries. If we don't take steps now to slow this growth trend, the population could triple, to some 15 billion before it finally stabilizes.

To accommodate for this increase and to achieve contraceptive prevalences consistent with the United Nations population projection of 6.25 billion in the year 2000, at least 130 million new contraceptive users must be recruited in this decade. Probably even larger numbers would respond to adequate service choices. In 1988, there were about 350 million contraceptive users.

In the last 20 years, some extraordinary successes in family planning have occurred. Family sizes have declined markedly in many countries for two fundamental reasons. First, people all over the world, when aware that family planning services are available, have demonstrated they want smaller families. Second, current contraceptive technologies, though not perfect, have worked well in a wide range of cultures and contexts.

But there have been disappointments as well. The single factor most often lacking has been the political will to make sufficient family planning choices available to all who need them.

Over the years, however, the global political will to make family planning available has increased. Most developing countries have now formulated thoughtful population policies. However, many of these governments lack the resources to implement the stated policies through effective programs.

The Family Planning Revolution

In the 1960s and early 1970s, when family planning programs in developing countries got underway, many analysts believed that birth rates would fall only after marked advances in socioeconomic development or when parents could be sure their children would survive. While wealth, education, and improved maternal and child health services accelerate the trend toward smaller families, the family

WHO / T. Farkas

Health educators talk with women in Nepal.

planning experiences of the 1970s and 1980s have also shown that the birth rate goes down when family planning choices are available.

Surveys show that between 50 and 80 percent of married women in developing countries want to limit or space future births. Demand for contraception increases when a good family planning program is in place. Family planning services create the demand. A latent demand for fewer children may exist, but it does not occur in isolation from opportunities for planning or spacing births.

By making family planning options available in innovative ways over the last two decades, some countries have achieved marked progress in an extraordinarily short period of time. In the United States, it took 58 years to go from a total fertility rate of 6 to 3.5 live births per woman. In countries such as Thailand, Colombia, South Korea, Sri Lanka, and Indonesia, the family size has fallen from 6 to 3.5 two to four times as rapidly as it did in the United States. This process took 15 years in Colombia and only eight years in Thailand (see Figure 1).

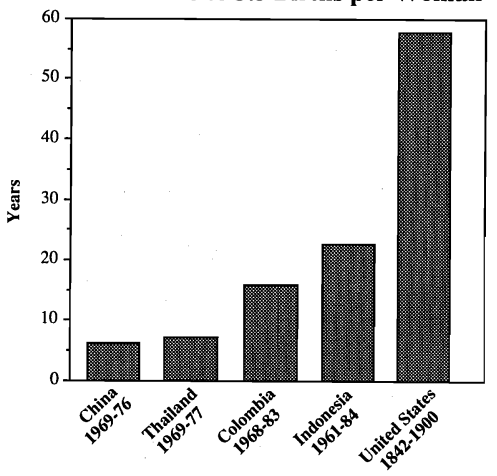
In general, countries have made more progress in creating demand and lowering fertility when they have offered many types of methods through various distribution systems. The Thailand national family planning system, for example, made injectable contraceptives available, and used nurses to insert IUDs. Mechai Viravaidya had the brilliant idea of celebrating the King's birthday with a vasectomy festival. The government of Thailand also encouraged private organizations to participate in family planning. The contraceptive prevalence in Thailand is now higher than it was in Britain when I began working as a doctor.

As contraceptive services have become more available, prevalence has increased. In the process, the family planning world realized that existing technologies, for all their shortcomings, work. For every option, there is a balance of benefits and risks. While voluntary sterilization has become vastly easier to perform, it is still very difficult to reverse. While IUDs are highly effective, they must be inserted under sanitary circumstances and monitored closely in the first several months.

Societies vary in how they assess the tradeoffs of different contraceptive methods. China lowered its total fertility rate from 6 to 3.5 in an astounding seven years but only with vigorous enforcement of a one-child policy. In some Islamic countries, unusual bleeding patterns among women are viewed a religious problem, making some methods less acceptable than others. In the United States, when a single type of IUD was found to cause problems, use of all IUDs plummeted.

Research concerning new contraceptive technology as well as programmatic issues is crucial, for different but complementary reasons. Programmatic research on current technologies examines which existing contraceptives are most acceptable and why. This research is needed now and can produce quick results. Contraceptive development research, on the other hand, is a long-term venture. While this research is essential, it will help primarily in the next century. Efforts to limit the exponential population growth during the 1990s will depend largely on existing technologies.

Figure 1
Time Taken for Total Rate of Fertility to Decline from 6 to 3.5 Births per Woman



FHI's Contribution

Many organizations have contributed to the population revolution, from international groups such as the United Nations Fund for Population Activities and the International Planned Parenthood Federation to our collegial organizations in the United States, such as the Population Council, the Association for Voluntary Surgical Contraception, and the Pathfinder Fund. Within this larger community, FHI has had the privilege of making important contributions.

Dr. Reimert Ravenholt, who spearheaded the U.S. Government's initial involvement in family planning, and Dr. Elton Kessel, then at the University of North Carolina, developed the vision of FHI (originally called the International Fertility Research Program). The vision was to bring about scientifically driven improvements to contraceptive techniques and to have them used in the developing world.

Over the years, FHI has concentrated on improving and developing specific contraceptive methods, while at the same time building a worldwide network of colleagues concerned about family planning in their countries. Concentrating on such methods as voluntary surgical contraception, IUDs, oral contraceptives, breastfeeding and Norplant provided FHI with a

front-row seat in the family planning revolution. FHI has worked with government ministries and institutions, local and international private sector organizations, universities, hospitals, and researchers in more than 90 countries. The box on page 25 highlights some of FHI's major accomplishments.

If FHI were merely a group of professionals in North Carolina, it would have made little progress. Its strength lies in its network of friends and partners around the world, who help define the questions to be studied, conduct the research and apply the results to help families enjoy better health and wider choices.

Many of our studies throw light on the acceptability (or nonacceptability) of various methods of contraception. In addition, we have pioneered research on the attitudes of providers of family planning, who are often crucially important in determining what methods are actually used.

The long-term use of drugs and devices for contraception demands careful attention to safety. In 1983, FHI began a separate division of Reproductive Epidemiology to monitor long-term risks and benefits of contraceptives. This division has examined cancer and contraceptive use and the contraceptive needs of special groups such as women with sickle cell disease. Another of this division's areas of concentration, preventing sexually transmitted diseases (STDs), helped position FHI for another great challenge of our times.

Even more than family planning, AIDS points out the gap between what needs to be achieved and what is actually taking place. FHI entered the field of AIDS prevention because we were already looking at barrier methods of contraception and the spread of STDs and because we were fortunate to have Dr. Peter Lamptey on our staff, whose skills and experience were ideally suited to lead an AIDS intervention project.

The Challenges Ahead

The prime need over the next 20 years is to mobilize the resources that are going to be needed to apply the lessons learned in the last two decades on the necessary scale. The demand for contraception is such that the number of users could be doubled in the coming ten years. There must be a global commitment supporting universal access to family planning by the end of the millennium. The supply of condoms for AIDS prevention alone is going to cost hundreds of millions of dollars each year.

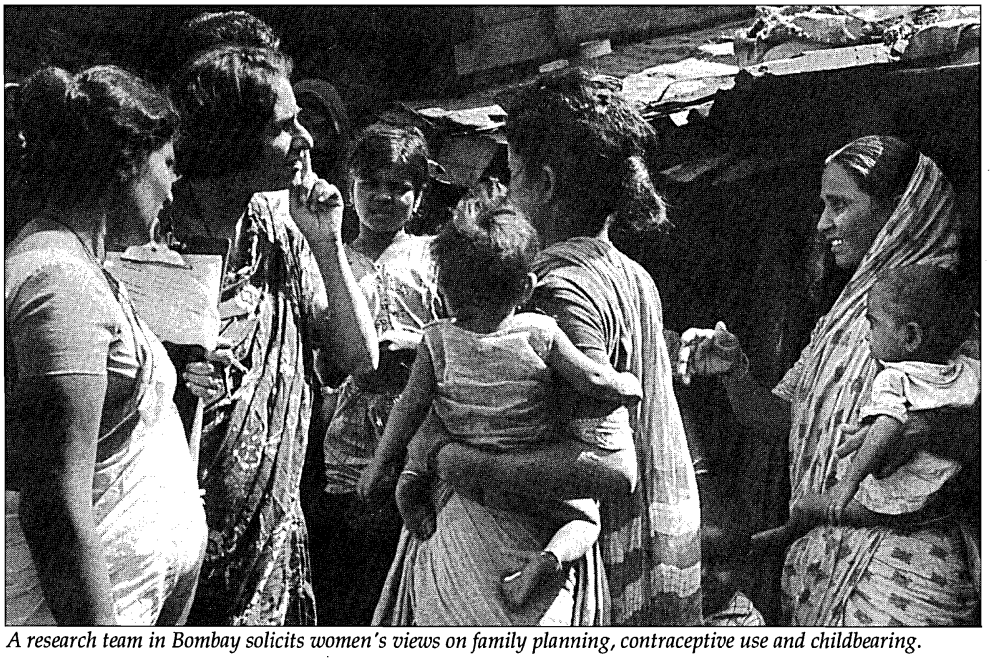
FHI has acquired an enviable reputation for thinking ahead and for spotting new problems — and opportunities — as soon as they arise. I believe the 1990s will prove the most challenging, the most exciting and the most rewarding of any decade of our professional lives. This is the kernel of development: to apply technologies in such a way that poor countries can benefit from the experience of rich countries and achieve comparable levels of development more rapidly than they would otherwise have done. This is our challenge ahead.

Why the gap — between two decades of steady progress by FHI and its sister organizations, and the sad fact of tens of millions of unintended pregnancies, an infant death every two seconds and a maternal death every minute, most of which could be prevented by the application of current technologies? Tragically, politicians, civil servants and, yes, even theologians have retarded rather than accelerated change in the areas of reproductive health.

Currently, the AIDS virus is moving more rapidly than human institutions can respond to it. With AIDS, unlike family planning, the relevant patterns of human behavior are not ahead of the problem but lag many years or even decades behind it. Some governments deny that AIDS is becoming a problem at exactly the stage in the evolution of the epidemic when interventions could be most effective.

AIDS prevention activities

WHO / E. Schwab



A research team in Bombay solicits women's views on family planning, contraceptive use and childbearing.

have some common ground with family planning. Like family planning, AIDS demands a respect and concern for individuals, the sharing of objective information so that people can make their own choices, and practical, low-cost services which can be readily extended to tens of millions of individuals.

AIDS is going to be a much more expensive disease than some people currently appreciate. This epidemic will probably kill as many as one in six adults in some countries. That is now the ratio of HIV infection in parts of East Africa. AIDS has become more than a health problem; it is a major development issue and must be funded accordingly. In those parts of the world where the HIV infection is still rare and the disease is taking off, new administrative systems that can react with uncommon speed to new problems are essential.

We are nearly two years into the last decade of the millennium. Our overriding goal for the 1990s must be to get family planning and AIDS prevention into top gear. Sometime in the next ten to twenty years, a day will dawn when fewer babies will be born than the year before and the date of that inflection in the curve of human population growth will be a good predictor of whether the planet is going to have to accommodate a final stable population of 10 billion or 15 billion inhabitants.

I see the efforts in Europe and the regional offices I hope FHI will develop as part of an integrated, rational effort at new levels of activity. I hope that such steps will help FHI become an even more significant global institution in our next 20 years.

The many decades it will take before population eventually stabilizes will also be the years that human society has to move from its present dependence on fossil fuels and gross environmental destruction to a biologically sustainable economy. That may well be the most difficult challenge in the history of humankind. Whether it can even be achieved will to a considerable extent be influenced by the size and rate of future population growth.

— Dr. Malcolm Potts,
FHI President Emeritus

Major Accomplishments at FHI, 1971-1991

1. Female Voluntary Surgical Contraception (VSC). FHI was at the forefront of the change from laparotomy and surgical cutting and tying of the Fallopian tubes to the introduction of minilaparotomy, laparoscopy, and the use of occlusive devices. This has helped to make VSC the birth control method used by more couples of childbearing age than any other method.

2. Breastfeeding. We helped to put breastfeeding back on the map as the world's most accessible and least expensive family planning method, through the 1988 "Bellagio Guidelines" and a decade of scientific research.

3. IUDs. We conducted numerous studies on many types of IUDs, focusing most recently on postpartum use and on a better understanding of rare events, such as uterine perforation or infection.

4. Oral Contraceptives. FHI provided the scientific rationale for low-dose versus standard-dose pills and for progestin-only pills for lactating women. Research focused on improved pill use could prove to be extremely important; most pregnancies that occur on the pill are the result of errors in taking tablets. This current research on pill use has the potential to prevent literally millions of unintended pregnancies in the 1990s (see article on page 14).

5. FDA Approvals. Given the current climate for drug regulation in the West, contraceptive development is necessarily expensive. FHI's research led to FDA approval of the Today Sponge, which is now marketed in a number of countries. FHI is proud to have coordinated a large number of clinical trials for Norplant, developed by the Population Council and registered with the FDA in 1990.

6. Plastic and Female Condoms. FHI is at an exciting stage in developing a plastic condom. It is an attempt to widen the range of barrier methods from which couples can choose, to complement the existing option of the latex sheath. FHI is also currently testing a female condom. One or both of these important new products may come to fruition.

7. Maternal and Infant Health. FHI's pioneering Reproductive Age Mortality Survey (RAMOS) studies began in 1981. We, along with other groups, provided the impetus for the landmark International Safe Motherhood Conference in Kenya (1987) and have continued our emphasis on reproductive health.

8. AIDS Prevention. In 1987, with its new AIDSTECH division, FHI became one of the largest organizations in the world involved in AIDS prevention activities.

RESEARCHERS ASSESS DATA ON LONG-TERM SAFETY OF NON-SURGICAL STERILIZATION METHOD

Family Health International (FHI) has initiated a study to examine the long-term safety of quinacrine hydrochloride, a chemical used for non-surgical sterilization. The study was prompted by concern about several cases of cancer found in women who received quinacrine in clinical trials conducted in Chile in the 1970s and 1980s.

"Although the short-term safety of quinacrine non-surgical sterilization has been clearly demonstrated, data on long-term safety have not been available until now," says Dr. Thomas Petrick, FHI Director of Medical Affairs. "With 12 years since the first sterilizations using quinacrine, we can begin to assess whether there are long-term health effects of the procedure."

Surgical sterilization is the most prevalent contraceptive method worldwide, yet the demand for female sterilization in many countries exceeds the current capacity of health systems to provide sterilization services. Non-surgical sterilization procedures such as those using quinacrine were developed in an effort to meet the demand for safe and effective permanent methods that could be offered by trained paramedical staff.

Since the 1940s, quinacrine hydrochloride has been used as a treatment for malaria. In the late 1960s, quinacrine was discovered to be an effective means of occluding the Fallopian tubes for the purpose of contraceptive sterilization. Introduced for that purpose in Chile by Dr. Jaime Zipper in about 1970, it has since been studied in Indonesia, India, Pakistan, Malaysia, Mexico, Vietnam and the United States.

"This method has great potential for preventing pregnancies among older women who have already had a lot of children — the women who account for much of the maternal mortality and morbidity in developing countries," says Dr. Elton Kessel, FHI's first executive director, who helped initiate the early quinacrine trials in Chile. "It is inexpensive, acceptable and technically easy to deliver in developing countries."

To accomplish sterilization, quinacrine pellets are delivered transcervically using an IUD inserter. Two insertions are used, one month apart. Other contraception is necessary between insertions.

In an effort to maximize efficacy while minimizing side effects, the composition of the pellets and the number of insertions have varied somewhat over the years. Dr. Zipper and others reported in 1987 that insertions in 112 women resulted in a 98 percent efficacy rate after one year.[1] Recent studies indicate that the addition of 50 mgs of diclofenac (an antiprostaglandin) improves efficacy still further.

Like all contraceptive options, quinacrine has advantages and disadvantages (see box). The insertion procedure is quick and inexpensive and can be performed by paramedical personnel with none of the risks of surgery. As with many new applications of drugs, however, there is no information about the long-term safety for the women using it.

From the late 1970s through 1986, FHI supported three clinical trials of quinacrine hydrochloride use among a total of 572 women in Chile. FHI has continued to monitor the health of these women. During this long-term follow-up process, eight cases of malignancy involving six different anatomical sites were recently detected.

To address this issue, FHI has initiated a retrospective study of Chilean women who have used quinacrine; the study, supported by the Mellon Foundation, will utilize interviews with the women and examinations of their medical records.

"There have been enough malignancies and abnormalities reported in the uterus and endometrium [the lining of the uterus] to examine whether the incidence of malignancy, especially genital, is increased in women receiving quinacrine sterilization," says Dr. Petrick. "The study is designed to clarify whether there exists a significant difference in incidence of malignancies between the general population and the population receiving quinacrine."

The new study will try to determine whether there is an association between

Non-surgical Female Sterilization: Quinacrine Pellets

Advantages

- none of the risks associated with surgery: no incision, no general anesthesia
- no hospitalization, short recuperation
- can be performed by paramedicals on outpatient basis
- effective pregnancy prevention

Disadvantages

- requires two applications
- long-term safety not known
- unlikely that the method can be reversed
- potential for ectopic pregnancy
- other contraception necessary between insertions

sterilization using quinacrine hydrochloride pellets and the development of malignancy at any anatomical site. The study will attempt to include women from the FHI-sponsored clinical trials and all other Chilean women known to have been sterilized with quinacrine pellets.

FHI is conducting the study in conjunction with an independent consultant experienced in a methodology for examining small groups of cancer cases — a methodology called cluster analysis. Results from this study are expected to become available in 1992. ■

Footnote

[1] J. Zipper *et al.*, Efficacy of two insertions of 100-minute releasing quinacrine hydrochloride pellets for non-surgical female sterilization, *Advances in Contraception*, 3(1987), 255-261.

Female Condom

Continued from page 21

FHI, cautions that many of the world's women, in fact, may have no more power to use a female condom than they do to insist that men use a male condom.

"We need to develop women's methods that are less visible, something a woman can use without her partner knowing," says Dr. Potts. "But in the meantime, the female condom appears to offer a new contraceptive choice and hope for STD protection. If a woman asks a man to wear a male condom and he says 'no,' her choices now are to take the risk or get out of bed. A female condom gives her another option." ■

—Sara Townsend

Footnotes

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[4] T. Bennett, Expanded trial of the female condom. *Preliminary Report*, February 1991.

[5] Ruminjo, *op. cit.*

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In addition, the World Health Organization Special Programme of Research, Development and Research Training in Human Reproduction, in collaboration with WHO's Global Programme on AIDS, has been conducting acceptability research among sex workers in Thailand.

[9] S. Muska *et al.* The WPC-333 Female Condom: Perceptions of Male and Female Drug Users. *Abstract No. MD4257, VIII International Conference on AIDS*, Florence, Italy, June 16-21, 1991.

OC Use

Continued from page 17

written form. But in the end, it is the woman herself who has to internalize the instructions and information and use the pill in a correct and consistent way." ■

— William R. Finger

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[2] See for example, J.E. Laing, Continuation and Effectiveness of Oral Contraceptive Practice, *Studies in Family Planning*, 16: 138-153, 1985; W. Rinehard *et al.* (eds.), Low-dose pills, *Population Reports*, Series A, No. 7, Nov. 1988; and for an overview of the literature, L. Potter *et al.*, What Do We Know About How Women Take the Pill? *Studies in Family Planning*, in press, Sept./Oct. 1991.

[3] "An exhaustive literature search found only 13 published studies from six countries that had collected quantitative data on compliance," report L. Potter *et al.* The authors explain that three studies were conducted before 1975; seven were based on clinic-based samples; and only three were in developing countries. See L. Potter *et al.*, What Do We Know About How Women Take the Pill? *Studies in Family Planning*, in press, Sept./Oct. 1991.

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FAMILY HEALTH INTERNATIONAL

network

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Closer Review of Condom Breakage Leading to More Reliable Product

The deadly consequences of infection with HIV have focused new concern on condom reliability — specifically, whether condoms break when used.

Historically, researchers have measured condom effectiveness by focusing on how consistently condoms are used, either for pregnancy prevention or for protection from such diseases as gonorrhea and syphilis. But research has now begun to examine more closely how well condoms actually work.

"For the first time, we are taking an in-depth look at how reliable condoms really are," says Dr. Robin Foldesy, Director of Materials Technology Division at Family Health International (FHI). "We have identified the major factors that affect condom reliability and are beginning to understand their relative importance."

Three stages in the life of a condom affect whether it breaks when used: the manufacturing process, the duration and conditions of storage, and human use. The series of articles in this issue of *network* reports on each of these three stages and how each affects the reliability of condoms.

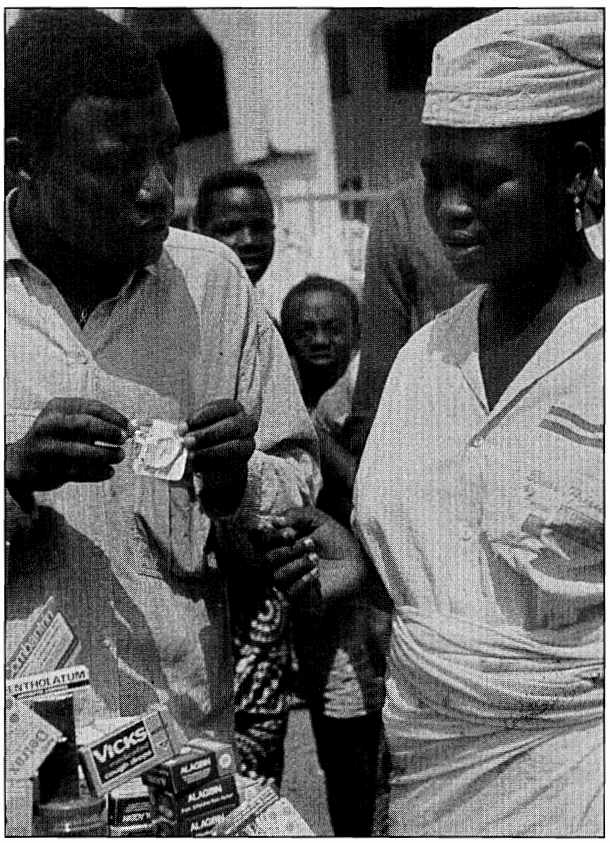
Worldwide, an estimated six billion condoms are used each year. The U.S. Agency for International Development (A.I.D.), the largest donor of condoms to developing countries, delivered about 800 million condoms overseas last year. The United Nations Population Fund and the International Planned Parenthood Federation delivered the next largest totals, about 98 million and 18 million, respectively.

Experts on condom issues welcome research that can enhance the understanding of what causes condoms to break, because the degree of condom reliability affects how likely couples are to use condoms. While this research continues, they emphasize the importance of using condoms now.

"Apart from changing people's behavior, there is not a better method than using condoms to protect people from the spread of AIDS," says Mark Rilling, Program Analyst at A.I.D. in charge of contraceptive commodity quality assurance, including condoms. "With proper attention to procurement specifications, manufacturing, storage and use, condoms have been proven to be highly reliable for prevention of sexually transmitted diseases and pregnancy."

Laurie Liskin, of The Johns Hopkins School of Hygiene and Public Health and author of its recent issue of *Population Reports*, "Condoms — Now More Than Ever," adds, "Despite the possibility of condom breakage, it is always safer to use a condom than not to use one." ■

— *William R. Finger*



health news

Recommendations on Breastfeeding and HIV Transmission Debated

Women who become infected with HIV *after* giving birth may transmit the AIDS virus to their infant through breastmilk, according to a recently published article by Dr. Philippe Van de Perre and others in the *New England Medical Journal.*[1]

"HIV-1 infection can be transmitted from mothers to infants during the postnatal period," wrote Dr. Van de Perre in the article, which is based on a study of 212 women in Rwanda. "Seronegative mothers at risk for HIV-1 infection should be counseled about the high risk of transmitting the virus to their children should they seroconvert. Moreover, when a safe alternative to breastfeeding is available, women at risk for seroconversion should refrain from breastfeeding their babies."

Family planning and AIDS researchers at Family Health International (FHI), in a letter published in a subsequent issue of this prestigious U.S. journal, expressed concern that Van de Perre's article directs the policy discussion in the wrong direction — encouraging alternatives to breastfeeding rather than promoting safe sex among new mothers at risk of acquiring HIV.[2]

They point out that the recommendation in Dr. Van de Perre's article may not be appropriate for Rwanda, where most women are at some risk of acquiring HIV and safe alternatives to breastfeeding are mostly unavailable.

"A mother in this situation *does* have another option, however, and that is to practice safe sex (abstinence, intercourse only with an uninfected partner, using condoms consistently and correctly)," wrote Dr. Nancy Williamson, Director of FHI's Program Evaluation Division. "These behaviors would not only reduce the risk of HIV transmission to the infant, but *would also protect the mother* from infection. At the same time, the infant would receive all the known benefits of breastmilk."

Footnotes

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2. N Williamson, C Visness, K Kennedy, et al. Safe Sex to Prevent Postnatal HIV Transmission. *New England Journal of Medicine.* In press.

New Policies in Niger Increase Access to Contraception

Niger's national family planning program recently approved a series of recommendations for improving access to contraceptives. These recommendations, developed in a four-day Contraceptive Technology Update conference held in Niamey, the capital city, in October 1991, will improve access to oral contraceptives (OCs), injectables, IUDs and sterilization.

About 150 family planning workers, managers, policy makers, and donors from across Niger gathered for the meeting sponsored by Family Health International (FHI) and Niger's Family Health and Demography Project (PSFD), with funding from the U.S. Agency for International Development.

Prior to the conference, FHI, PSFD staff and Ministry family planning officials had identified obstacles to widespread use of family planning methods in Niger and recommended strategies for reducing those barriers. Family planning experts from Africa and Europe presented papers on these subjects and facilitated the drafting of recommendations to address these barriers during working group sessions on the final day of the conference.

Niger's national family planning program then approved recommendations to simplify the provision of OCs in urban areas and ease restrictions in rural zones on the re-supply of pills by village health workers. As a result, pill acceptors in Niamey will no longer be required to undergo extensive laboratory testing after their first year of use.

The government also eased the criteria that women must meet in order to get a prescription for injectable contraceptives. Previous restrictions required that women eligible to use injectables have four or five living children and stemmed from a common misperception that injectables can cause infertility. Now, to use injectables, women can be younger than 35 and are required to have only two living children.

Participants at the meeting also examined why sterilization and immediate postpartum insertion of IUDs are not widely used in Niger. They identified a lack of communication between clients and providers as a major barrier to effective family planning. To improve information and dispel widespread rumors about sterilization, the family plan-

Continued on next page

FHI

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International Family Planning Meetings

Programmatic Research Issues Examined

Family planning researchers from eight countries gathered in Indonesia recently for a two-week workshop on programmatic (or operations) research. The workshop, sponsored by Family Health International (FHI) and The Population Council in Bandung in August 1991, trained staff from family planning research organizations in developing countries to design and implement programmatic research in their countries. Studying how family planning programs operate can help to determine how to promote and provide different contraceptive technologies in diverse cultures and program settings.

The 24 participants discussed constraints facing the family planning programs in their countries and then worked in groups to develop draft proposals on various plans to improve family planning service delivery. Group topics included: a situation analysis of family planning services in Nepal; promotion of family planning among men in Egypt; an intervention to test the introduction of postpartum family planning services in Kenya; and expansion of permanent contraception in Indonesia.

For more information about using programmatic research to improve family planning service delivery, write to FHI for *Improving Family Planning: A Decade of FHI's Programmatic Research.* The *Handbook for Family Planning Operations Research Design* is available from The Population Council (One Dag Hammarskjold Plaza, New York, NY 10017).

Acceptability Task Force Launched

In July 1991, 30 family planning providers and contraceptive acceptability experts exchanged ideas on how to develop better and more acceptable contraceptives for developing countries. The group, representing the World Health Organization and experts from Nepal, Bangladesh, Nigeria, The Gambia, Egypt, Mexico, Brazil and the United States, convened at FHI headquarters in North Carolina for an "International Acceptability Task Force" meeting.

Discussions at the meeting focused on four types of methods: chemical barriers, physical barriers, long-acting steroids and sterilization.

The group concluded that many factors affect the acceptability of a contraceptive method, including whether it is approved by regulatory agencies, attitudes of local family planning policy makers and providers, the level of trust between client and provider, the quality of services, how the method is presented to the client and what it is called, its cost, and the characteristics of the method itself — safety, efficacy, convenience and aesthetic appeal.

This information will help FHI and other organizations working to introduce and promote contraceptive technology to anticipate any potential acceptability problems with the products.

"We believe that sharing concerns at an early stage in the contraceptive development process will help us make decisions about products and, ultimately, improve the acceptability of our products to developing country users," said Dr. Roberto Rivera, FHI Director of Clinical Trials.

Participants discussed ideas on research approaches and how to improve acceptability research, and exchanged views on future directions for both products and acceptability research.

The meeting, sponsored by FHI, was supported by the U.S. Agency for International Development and the Mellon Foundation.

> Sharing concerns at an early stage in the contraceptive development process will improve the acceptability of our products.

New policies *from previous page*

ning program plans to train staff in sterilization counseling and to provide information and education materials for midwives. To address the lack of access to postpartum contraception, Niger will initiate immediate postpartum insertion of IUDs at maternity clinics.

Niger officials cited local FHI research and similar FHI-sponsored conferences in Senegal, Mexico and Togo as their prime sources of information and inspiration for change. As a result of the meeting in Dakar, Senegal, held in February 1990, the Government of Senegal approved a similar list of recommendations to increase access to family planning.

U.S. FDA Extends Effective Use of the Copper T380A IUD from Six to Eight Years

The U.S. Food and Drug Administration (FDA) has approved extension of the use of the Copper T 380A intrauterine device (IUD) from six to eight years.

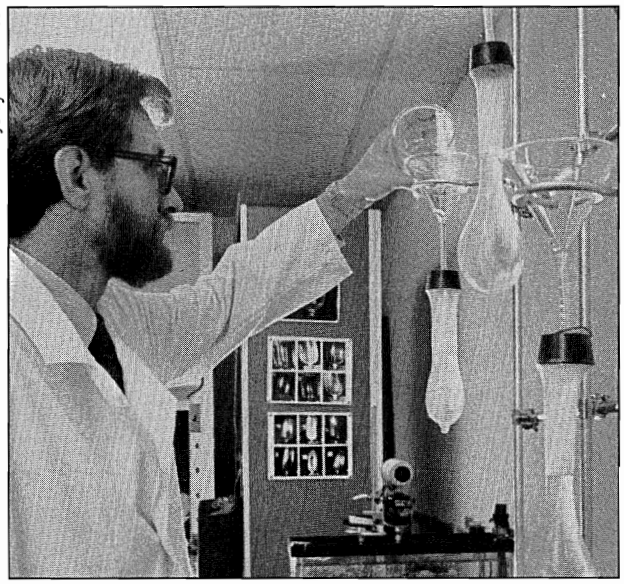
The extension of the lifespan for the TCu 380A, approved in August 1991, was based on data from a multinational clinical trial conducted by the World Health Organization, a comparative study of 2,800 women in nine countries.

Condom Manufacturing Standards Improving

With the rapid spread of AIDS in many developing countries, family planning providers are more concerned than ever that the condoms they receive be of the highest quality. AIDS prevention projects also want the best quality condoms available. Traditional standards of condom quality have been based primarily on laboratory tests applied at the manufacturing stage. In recent years, these standards have been receiving closer scrutiny.

"We need to learn more about the standards used for laboratory testing," explains Dr. Robin Foldesy, Director of Materials Technology Division, Family Health International (FHI). "We now realize that some of the tests used in the lab may not always reflect the actual stresses condoms get in human use."

Meanwhile, the U.S. Agency for International Development (A.I.D.) and other donors of condoms to developing countries must choose from various sets of standards for testing condom quality. For the condoms it sends overseas, A.I.D. sets specifications that include an air-inflation test. Experts have found this test to be a good indicator of whether a condom will break during use. The specifications used by A.I.D. are more stringent than are those required for the condoms sold in the United States, which do not include the air-inflation test.



Jerry Markatos

In 1991, 138,000 condoms were tested at the laboratory at FHI. Here, condoms are tested for water leakage.

In addition, samples of condoms purchased by A.I.D. are submitted to a round of quality tests in an independent laboratory. Generally, U.S. manufacturers do not have an independent agency re-test the condoms they produce.

The language used to describe standards and test procedures for condoms can be highly technical. Measurements of "water leakage" (pinholes), "tensile strength" and "air inflation" — the three key tests used to measure condom reliability — are not commonly understood by people involved in condom distribution programs. A basic knowledge of condom manufacturing and testing can assist family planning and public health officials to better understand issues related to condom reliability. This information can also increase the confidence of family planning providers in condoms.

Condoms Lose Strength with Age

Nearly all condoms are made of latex, which is derived from rubber. Latex forms a continuous barrier that protects against the passage of sperm and viruses, including the human immunodeficiency virus (HIV) that causes AIDS.

Most manufacturers produce several types of condoms, typically standard and extra-strength styles in both lubricated and non-lubricated forms. The strength of these condoms, as measured in laboratory tests, can vary from one brand to another and from one style to another.[1] Even among individual condoms of the same brand and style produced from the same batch of latex, strength can vary due to slight variations in the production process. The stronger the condom, the less likely it is to break when used.

During the first few months after manufacture, most condoms get stronger as the molecules take final shape in what is known as a "curing" process. Once curing is complete, however, condom strength gradually declines as the latex ages. Because of this, FHI recommends not using or distributing condoms that are more than five years old, even if stored in optimal conditions. (See the article on page 6 for more on storage issues.)

Standards for New Condoms

To ensure a basic level of reliability, major manufacturers electronically test all condoms for pinholes and non-uniformity in latex thickness. In addition to this, some 30 countries and the major donor agencies have established standards or specifications governing size and strength, among other qualities.[2] Compliance with these standards or specifications typically involves testing several hundred sample condoms randomly pulled from production lots that range in size from 35,000 to 500,000 condoms.

Specifications followed by A.I.D. set acceptable ranges for condom size and minimum requirements for performance in water leakage, tensile strength, and air inflation, as well as lubrication and package integrity. Other major donors of condoms include the United Nations Population Fund (UNFPA), the International Planned Parenthood Federation, the World Health Organization, and more recently, the World Bank and the Euro-

pean Economic Community. These donors have followed various sets of standards.

Because of the high cost of laboratory tests, most countries and donor agencies require manufacturers to perform compliance testing on their own condoms. In 1990, A.I.D. added a quality assurance step by having a third party, Family Health International, test a portion of the condoms going overseas. On a monthly basis, FHI technicians go to the manufacturing sites of these companies and randomly sample about 7 percent of all condom lots produced that month for A.I.D. FHI tests these condoms in its laboratory in North Carolina.

Water Leakage. Leakage is typically checked by filling the condom with a specified amount of water. If any moisture or leaks appear on the outside of the condom, it fails the test. Because the water test involves stretching the condom to as much as four times its original size, some people also consider this to be a good measure of strength, as well.

"The water test is the best, in my opinion," says Bradley Pugh, Vice President of Scientific Affairs for Aladan Corporation, a U.S. condom manufacturer, "because it puts pressure on the closed end of the condom where most breakages occur in human use."

Tensile Strength. The tensile test involves cutting a section out of the middle of the condom and stretching it to the point of breaking. Manufacturers use this test to assure consistent strength from one batch of condoms to the next. Since this test evaluates only a small section of the condom, some researchers do not consider it a reliable predictor of breakage in human use.

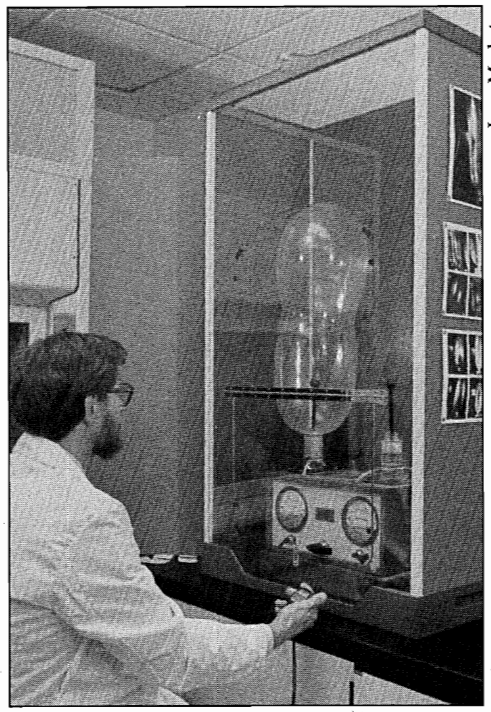
While asserting that condoms need to be made from rubber with good tensile properties, a 1991 Australian study concluded that tensile testing "does not offer any added assurance against a condom breaking in human use."[3] The study subjected condoms that had broken in use to tensile tests and found that they showed "similar tensile properties to those which had not [broken in human use]. All passed tensile test criteria. Thus, the inclusion of tensile testing in national standards for condoms is not sufficient to insure strong products."

FHI has reached a similar conclusion in preliminary findings. "We have conducted studies to determine how closely various laboratory measures of strength predict breakage in human use," says Eli Carter, Senior Project Manager in FHI's Materials Technology Division. "Our preliminary results indicate that tensile strength is not a good indicator when evaluating condoms that have been in storage."[4]

Air Inflation. In this test, condoms are inflated with air until they burst. Air inflation of condoms tests the strength of the entire condom rather than a specific section from the center of the condom, as in the tensile test. In addition, air inflation can detect localized flaws in the latex. Most importantly, perhaps, recent research has found that the air-burst test appears to be a good indicator of whether a condom will break during use.

Dr. Michael Free, of the Program for Appropriate Technology in Health, and other researchers applied the air-burst test to several lots of new condoms exposed to varying levels of ultraviolet light and to a lot of condoms aged under field conditions for more than 40 months. Then the researchers distributed unbroken condoms from the various lots to 130 Indonesian men to use. These participants were instructed to return all used condoms. Each condom returned after use was cleaned and examined. The unbroken condoms were subjected to the air-burst test.

"A comparison of the air burst volume data for a sample of unused and used condoms from the same treatment group indicates that most of the condoms that broke during use had air-burst volumes below 11 liters," the study concluded. "Therefore, a significant downward shift in the burst strength distribution as measured in the laboratory is likely to result in an increased breakage rate during use."[5]



Jerry Markatos

Daniel Hedgpeth, Senior Laboratory Analyst at FHI, conducts the air-inflation test on a condom sampled from a manufacturer.

Future Standards

The standards maintained by various nations and donor agencies vary in technical details and specific requirements. The standards recommended by the International Organization for Standardization (ISO), used by many countries and donor agencies, require both an air-burst and a tensile test for strength. Condoms manufactured for use in the United States follow a standard developed by the American Society for Testing and Materials, which includes a tensile but not an air-burst test.

The condoms purchased by A.I.D. must pass both tensile and air-burst tests, a more stringent requirement than is applied to condoms manufactured for use in the United States. In addition, A.I.D. condoms are tested by an independent agency. Hence, A.I.D. condoms are among the most reliable avail-

Continued on page 9

Proper Condom Storage Essential for Reliability

In 1989, the U.S. Agency for International Development (A.I.D.) in Barbados requested and had shipped 2.5 million condoms to Trinidad for distribution to new AIDS prevention projects in several Caribbean countries. The number was far more than the local programs had ever managed for contraceptive use and overwhelmed local storage capacity. Meanwhile, the AIDS prevention projects were slow in starting, and there were far more condoms than could be used in a reasonable time.

Program managers in Latin America, Asia and Africa are increasingly facing similar circumstances. Many of them have little or no experience with condom storage. Storage and handling practices that may be adequate for other family planning devices such as IUDs or oral contraceptives are not generally acceptable for condoms. Heat, poor ventilation, humidity and other environmental factors can damage condoms quickly, and the damage is often not visible to the eye.

What do program managers need to know about condom storage and distribution systems? How do storage and distribution affect whether condoms break — and thus expose a person to HIV transmission or to an unwanted pregnancy?

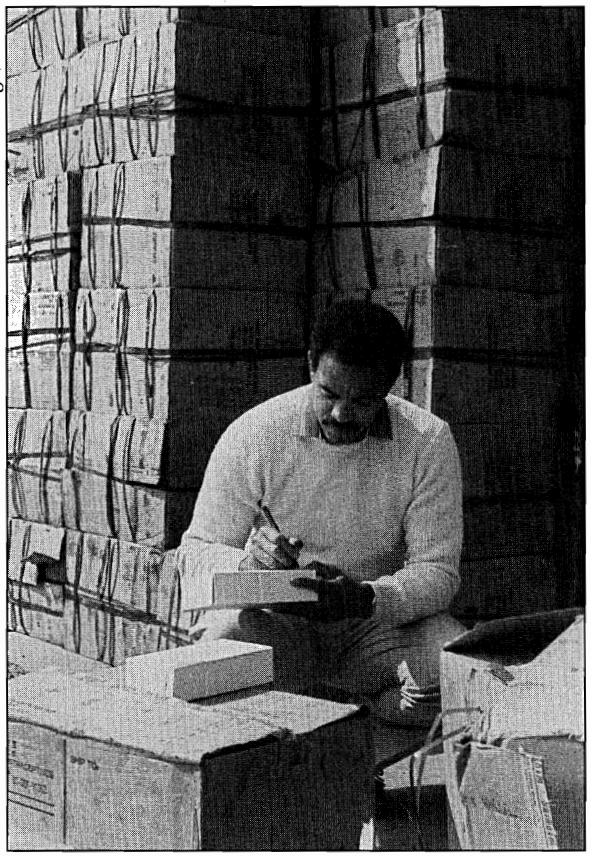
The Trinidad experience illustrates how experts are addressing such questions. Learning of the oversupply problem, A.I.D. officials contacted other AIDS prevention programs in the region and learned that several needed condoms. But were the condoms in Trinidad reliable enough to distribute? Would they break when used?

"I found one non-air-conditioned warehouse where the cartons of condoms were stacked so high that the bottom ones were all crushed," says Elise Levin, Logistics Advisor with John Snow Inc., the U.S. firm under contract with A.I.D. for family planning logistics management support in developing countries.

While some damage was clearly visible, the quality of most of the condoms could not be known without laboratory testing. Samples from three separate inventories totaling 2.2 million condoms were sent to the condom testing laboratory at Family Health International (FHI) in the United States. Of these, FHI found 1.2 million acceptable without qualification, 500,000 acceptable so long as they were distributed for use immediately, and 500,000 not usable.

"In the late 1980s, we shipped large numbers of condoms around the world to be sure that planned AIDS prevention projects could get started," explains Mark Rilling, Program Analyst at A.I.D. in charge of contraceptive commodity quality assurance, including condoms. "We did this knowing that some of the condoms might have to be destroyed if these projects were slow to start or projected use rates were overstated — and despite poor storage conditions in many countries. We're a lot more experienced and sophisticated now."

Researchers and managers have reached consensus on many aspects of proper storage and management of condom supplies. However, research that goes beyond laboratory tests to condom breakage in human use is still limited. Experts have not yet agreed on the level of scientific accuracy of the testing systems currently used to assess the strength of condoms that may have deteriorated in storage.



Sandor Balogh/FHI

Eli Carter, Senior Project Manager at FHI, inspects cases of condoms stored in a warehouse in Nepal. The condoms were purchased by AID/Nepal.

Storage Factors Affect Condom Breakage

As a condom ages, it gradually loses strength and, therefore, is more likely to break. Improper storage conditions can accelerate the deterioration process. Proper storage procedures should be followed to ensure that a condom is at its maximum strength when it is used. Three primary factors affect the deterioration of condoms during storage: packaging, storage conditions and management of supplies.

Packaging. Condoms are generally packaged in either foil or plastic to protect them from the damaging effects of ultraviolet light, humidity and air pollutants, especially ozone. Even prolonged exposure to the oxygen present in air can accelerate condom deterioration. Air pollution in urban settings can reduce the strength of condoms when package seals do not stay intact.

A research team from the University of Southern California School of Medicine unpackaged commercially available condoms and exposed them to ozone levels commonly present in urban smog conditions. "After 24 hours' exposure to ozone, the latex surface was covered with craters, and after 48 hours the [air] pressure required to burst the condom was 44 percent that of control samples," the study found.[1]

Both plastic and foil packaging have been shown in laboratory tests to be effective in protecting condoms from air pollutants.[2] Research is comparing the effectiveness of the two types of packaging in protecting condoms from deterioration in actual storage conditions. A.I.D. currently purchases condoms packaged in plastic.

Storage Conditions. Exposure to a combination of high temperature and humidity is known to cause a steady deterioration in condom strength, and humidity alone is suspected of doing the same — even when condom packaging is not damaged.

"In Barbados, condoms from A.I.D. were stored in a building right beside the sea," says Gail Goodridge, formerly Senior Health Advisor with the A.I.D. Mission in Barbados and now Chief of Focused Program Countries for FHI's AIDS Technical Support Project. "It was assumed this was a good location because the building was cool, well-ventilated, and the condoms properly stacked. Then we started hearing anecdotal evidence that the condoms were breaking. We subsequently had the supplies tested and found out they had deteriorated to the point where they were unsafe for human use. We suspected that this deterioration might be due to the salty, humid conditions in the warehouse."

FHI is currently comparing condom deterioration in three different climate zones. Condom stocks have been placed in three Mexican cities: Juarez, which is hot and dry; Merida, which is hot and humid; and Mexico City, which is hot and humid with chronic air pollution. FHI is testing samples from each lot at regular intervals, both with laboratory measurements and for breakage in human use.

While the exact impact of heat, humidity and related environmental conditions is not yet clear, enough is known to develop overall guidelines. In "Managing Condom Supplies," the World Health Organization recommends, for example, that cartons be stored so that the manufacturing dates can easily be read and that they be stacked no more than five cartons high to prevent crushing. The WHO document also explains that condom storage facilities should not be above 40 degrees centigrade and that condoms "must at all costs be stored in an oil-free environment."[3] Oil is known to cause condoms to deteriorate rapidly.

Sandor Balogh/FHI

Employees of a social marketing program in Nepal package A.I.D.-purchased condoms into envelopes printed with the program's name and logo.

FHI has also summarized storage guidelines on a poster which is being distributed to condom storage facilities and managers throughout the world (see page 8). It points out, for example, the importance of inspecting cartons for signs of damage: "Do not use or distribute condoms in packages that have been crushed, or punctured by fork lift, or damaged by water."

Management of Supplies. Minimizing the length of time that condoms are in storage requires good management. Ideally, program managers would accurately estimate in advance how many condoms will be needed within the next year. They would then order enough condoms to have some stock at all times, but not *so much* that overstocked supplies begin to deteriorate in storage. Managing supplies is a balancing act that, experts say, can be hard to maintain.

"It is difficult to estimate accurately how many condoms are going to be needed by a program over the next 12 months," says Rilling of A.I.D. "Ideally, we don't want condoms sitting in a central warehouse or in a regional distribution center for more than six months. This is impractical in some countries."

Good management of supplies also means proper distribution. It is important to distribute the oldest condoms in a warehouse first, so long as the condoms have not been in storage too long. But how long is "too long"? Storage conditions affect this answer, as was the case with the condoms stored in Trinidad.

How Long Can Condoms Remain Reliable When Stored?

Due to variations in packaging, storage and management of supplies, experts have

not arrived at clear recommendations regarding the reliability of condoms by the age of the condom lots. But several guidelines do exist.

Condoms more than five years old *should not* be used, even if stored under optimal conditions. Condoms which were stored overseas for less than two years, on the other hand, have proved reliable in laboratory and human-use studies conducted by FHI.

"For the two-year to five-year period, we need to test condom lots to be sure that they are reliable," explains Eli Carter, Senior Project Manager in FHI's Division of Materials Technology.

Testing Condoms in Storage

In order to avoid the distribution of unreliable condoms, organizations such as A.I.D., FHI, WHO, John Snow Inc. and the Program for Appropriate Technology in Health (PATH) are emphasizing the need to monitor condom stocks. Condom deterioration is often invisible, and that means that condoms need to be tested in a laboratory to measure their strength.

A.I.D. and WHO have assisted developing countries to develop their own testing capabilities. Most recently, under contract with the WHO Global Programme on AIDS, PATH has established nine condom testing stations in Africa. PATH installed the testing equipment, trained the personnel and conducted an initial performance audit. Any such large-scale and technical project faces difficulties with staff turnover, equipment maintenance, and, in the case of condoms, clear testing standards (see article on page 4).

Some U.S. agencies have questioned the wisdom of using these laboratories to evaluate condom stocks. "We are not opposed to labs in developing countries testing condoms," says Rilling of A.I.D. "We are, however, concerned about a lab whose quality is unknown. Our approach at A.I.D. is this: Before an overseas Mission agrees to destroy a significant stock of condoms based on test results of a local laboratory, that Mission should sample those stocks and send them to the United States for confirmation testing at FHI."

FHI has conducted systematic checks of A.I.D.-supplied condom stocks in more than a dozen developing countries. Samples are brought to FHI's lab in the United States and subjected to water leakage, tensile and air-inflation tests, as was done with the Trinidad lots. Based on the results of air inflation tests, condom lots are rated according to a measure known as the Condom Quality Index (CQI).

The CQI is a mathematical treatment of air-burst volume data. It transforms the individual burst volumes of a group of tested condoms into a group value that is expressed on a scale of zero to 100, the highest possible score. Presumably, the higher the value, the better the quality of the condoms.

The laboratory test results and the CQI scores on the three lots of condoms from Trinidad were the basis for the FHI recommendations on whether the condoms should be used. Those recommended for release "without condition" had a CQI score of 76. The lot to be used immediately had a CQI score of 47, while the rejected lot scored 30.[4]

Accuracy of Tests

To assess how well the CQI and other laboratory tests predict breakage rates of condoms in human use, FHI brought 20 condom lots stored throughout the world to its U.S. laboratory. The only previous study of this sort used just four different condom lots, a sample size which is insufficient for thorough statistical analysis. Also, only one of the four lots was aged under field conditions.[5]

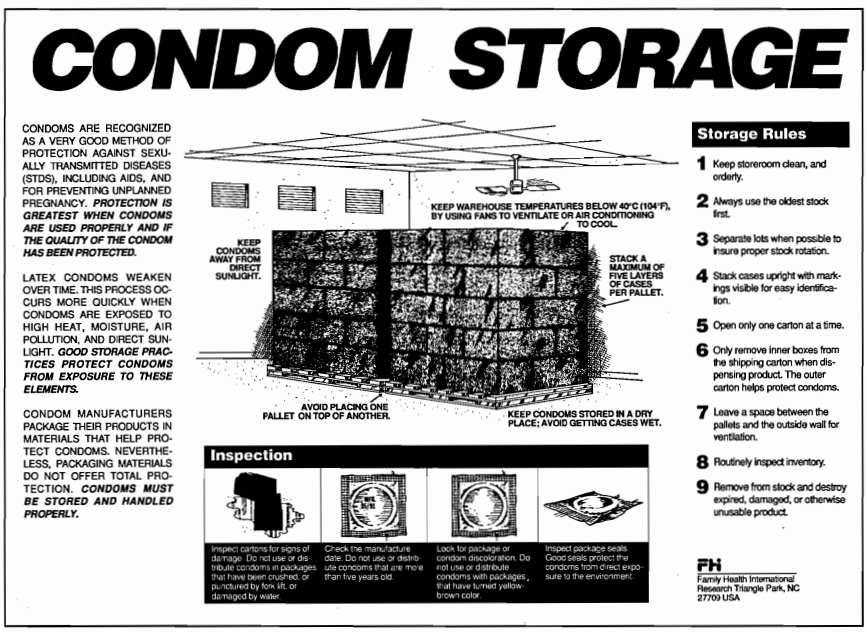
In the FHI study, the condom lots were chosen based upon their CQI score, the issue under study. The CQI scores of the condom lots ranged from 7 to 100. The condoms were of various ages and were stored under various conditions.

Three hundred couples were recruited to test the condoms during vaginal intercourse. Each couple tested one condom from each of the 20 lots over a four-month period. From these couples' reports, human-use breakage rates were calculated and compared to the CQI score and other laboratory tests. The CQI appeared to be a relatively good predictor of human-use breakage, with a correlation of .75.[6]

"The .75 is a fairly good correlation, but

Continued on next page

This poster was designed to instruct staff of condom warehouses on correct storage practices. Free copies are available from FHI.



Storage *Continued from previous page*

we would like to see a better one," says FHI's Carter, who anticipates that testing of condom stocks will become more widespread and that testing procedures will be continually refined to more accurately predict breakage in human use.

He adds, "Coupled with improved in-country logistics for ordering, transporting, storing and distributing condoms, users should be receiving a better quality product in the coming years."■

— John Manuel and William R. Finger

John Manuel was a consultant to FHI for this issue of network.

Footnotes

1. L Clark, RP Sherwin, RF Baker. Latex Condom Deterioration Accelerated by Environmental Factors: I. Ozone. *Contraception*. 1989; 39(3): 245-51.
2. RF Baker, RP Sherwin, GS Bernstein, et al. Precautions when Lightning Strikes During the Monsoon: the Effect of Ozone on Condoms. *Journal of the American Medical Association*. 1988; 260(10): 1404-05.
3. Managing Condom Supplies. World Health Organization Global Programme on AIDS, Draft 9, April 13, 1990.
4. Letter from Eli Carter, Family Health International, to Elise Levin, John Snow Inc. April 16, 1990.
5. MJ Free, J Hutchings, F Lubis, et al. An Assessment of Burst Strength Distribution Data for Monitoring Quality of Condom Stocks in Developing Countries. *Contraception*. 1986; 33(3): 285-99. This study concluded that a "Condom Deterioration Index calculated from regular periodic testing of stored condom stocks is a convenient and sensitive means of monitoring trends in the distribution and deterioration of condom strength."
6. A correlation is the extent to which two or more variables are related — in this case, the CQI and human-use breakage — and specifically, the extent to which one variable changes in response to a change in the other. The study also found a correlation of .75 for the tensile elongation test, which is a different test than tensile strength. A perfect correlation is 1.0.

Manufacturing *Continued from page 5*

able in the developing world.

As data accumulate on condom breakage in human use, pressure is growing to develop new tests that better predict breakage in human use. "Current tests were developed only as reasonable quality control measures, and they may not be as relevant to actual coitus as was initially thought," says Bruce Voeller, President of the U.S.-based Mariposa Education and Research Foundation, which conducts extensive research in this field. "Better tests need to be developed and adopted."

The Johns Hopkins School of Hygiene and Public Health, in its recently released comprehensive report, "Condoms — Now More Than Ever," makes a number of suggestions about tests at the manufacturing stage. The report points out, for example, that the current standards for "extra-strong" condoms do not clearly distinguish between several manufacturers' "standard" and "extra-strong" condoms. Hence, consumers cannot easily tell which brand of condom shows the greatest strength in various tests.

The report calls on the world health community to "further investigate how well various tests of condom strength and leakage reflect the reliability of condoms in actual use" and to "adopt the most realistic tests."[6]

In the meantime, condom users can be assured that newly manufactured condoms that meet A.I.D. specifications are reliable, subject to what happens to the condoms after they are shipped overseas.

"Most condoms far exceed the minimum standards set by various organizations," says FHI's Carter. "If they are properly stored and if they are properly used, condoms should be reliable when used. Unfortunately, these are two big issues that affect condom breakage, as much or even more than the laboratory tests used to ensure the quality of newly manufactured condoms."■

— John Manuel and William R. Finger

John Manuel was a consultant to FHI for this issue of network.

Footnotes

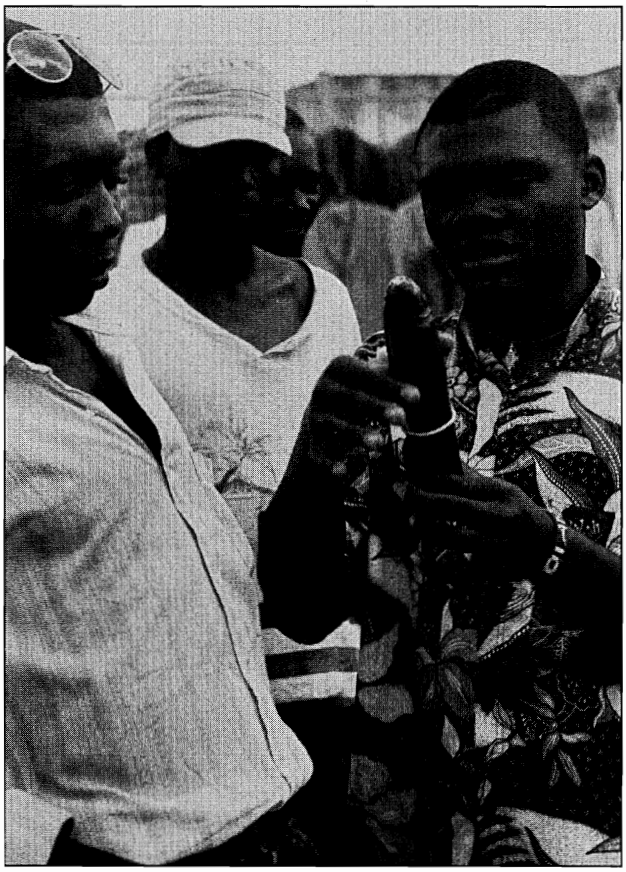
1. B Voeller, A Coulson, J Campeau, et al. Strength Comparisons of 'Extra-strength' Condoms from Two Manufacturers. Mariposa Occasional Paper #15, Mariposa Education and Research Foundation, January 1990.
2. Persons working in this field distinguish between standards and specifications. Standards, established by standard-setting agencies and some countries, include suggested levels of measurements of various tests. The word "specifications" refers to the levels and types of measurements included in a purchase contract, which may not exactly match an adopted standard. A.I.D. sets specifications for its condom purchases drawing on standards established by both the International Organization for Standardization and the American Society for Testing and Materials.
3. J Gerofi, G Shelley, B Donovan. A Study of the Relationship Between Tensile Testing of Condoms and Breakage in Use. *Contraception*. 1991; 43(2): 177-85.
4. The tensile test separately measures the strength and the elasticity of a condom. The preliminary FHI findings indicate that for condoms in storage, the tensile test for elasticity (or elongation) is a relatively good predictor of breakage in human use, while the measurement for strength is not.
5. MJ Free , J Hutchings, F Lubis, et al. An Assessment of Burst Strength Distribution Data for Monitoring Quality of Condom Stocks in Developing Countries. *Contraception*. 1986; 33(3): 285-99. *See also* MJ Free, E Skiens, M Morrow. Relationship Between Condom Strength and Failure During Use. *Contraception*. 1980; 22(1): 31-37.
6. L Liskin, et al. Condoms — Now More Than Ever. *Population Reports*. 1990; Series H, No. 8: 27.

Most condoms far exceed the minimum standards set by various organizations.

How Human Use Affects Condom Breakage

"I was concerned about HIV and was trying to use a condom," a Kenyan explained. "But I stopped because most of the condoms I used broke."

The man enrolled in a study of condom use in the hopes of finding a condom that would not break. He broke six of the ten condoms he tested, however, even though these condoms were of high quality, were pre-lubricated and had been stored properly.



A peer educator in Cameroon demonstrates the proper way to put on a condom, using a wooden model of a penis.

The reason his condoms were breaking became clear in a follow-up interview with researchers.

"I unrolled them [the condoms] and stretched them," the man said. "Then I pulled them on [my penis] like a sock." The man did not know that, in pulling on the condoms in this way, he was reducing the strength of the condoms. They subsequently broke during use.

This man was one of more than 1,700 people who participated in a series of studies on condom breakage conducted by Family Health International (FHI) over the last two years. The studies took place in eight countries in Asia, Latin America and Africa, as well as in the United States. Investigators found that the experience of the Kenyan man was not isolated but represented one of several factors causing condoms to break at rates that ranged among the study sites from 0 to 13 percent.[1]

Used properly and consistently, a condom is about 98 percent effective in preventing pregnancy and is considered highly effective in preventing the transmission of bacteria and viruses, including HIV.[2]

Prior to AIDS, the small number of studies of condom effectiveness focused on contraceptive use. These studies found that the rate of accidental pregnancies in the first year of condom use averaged about 12 percent.[3] The major contributing factor for accidental pregnancy is failure to use the condom. Breakage during use generally has not been examined as a separate cause.

When AIDS prevention became an important goal of condom use, understanding how often condoms break became more urgent. To protect against HIV transmission, condoms should be used during every act of intercourse. Hence, in studying the effectiveness of condoms, the questions of how often condoms break, and why, became primary issues to investigate.

Only a handful of studies has measured condom breakage during vaginal intercourse. The most reliable studies have found average breakage rates ranging from 0 to 13 percent.[4] Since contraceptive studies estimated average condom failure of about 12 percent due largely to *non-use*, these new findings of breakage rates *during use* appear far higher than experts previously suspected.

In an effort to understand the factors contributing to the breakage rates, FHI researchers interviewed individuals referred to as "breakers." These persons broke at least 20 percent of the condoms they tested. The researchers also interviewed the in-country investigators and family planning clinic personnel about practices that might contribute to condom breakage. The reasons for breakage fall into four general categories: incorrect methods of putting on condoms, use of oil-based lubricants, reuse of condoms, and duration or intensity of coitus.

"Understanding how each of these factors contributes to condom breakage is very important," explains Dr. Nancy Williamson, Director of FHI's Division of Program Evaluation, which coordinated the condom breakage studies. "Family planning and AIDS prevention programs are increasingly pro-

moting condom use. We need to be sure these efforts address the ways people are most likely to break condoms."

Major Human Factors in Breaking Condoms

All of the 1,700 participants in the FHI studies were given high-quality, lubricated condoms, which were manufactured and transported directly to the study sites. This ensured that the condoms in the studies were of equal quality. Most participants said they had used condoms prior to the studies. In addition, in-country staff, generally clinicians, instructed participants on proper condom use and told them to use a condom once during each act of vaginal intercourse. The condoms were to be used over a period ranging from one week to four months, depending upon the number of condoms tested in each study. The series of studies examined various questions about condom reliability.[5]

These studies collectively provide an important cross-cultural data base on condom use, since couples from Asia, Latin America, Africa and North America participated. "Most often, the problems were associated with individual sexual behaviors," says Carol Joanis, Associate Director of Marketing Research at FHI and director of the studies. "In the countries represented, we did not find many instances of culturally-based practices leading to condom breakage."

Some important issues not examined in the FHI studies should be noted. For example, anal sex, most common among homosexual men, has been shown to result in high levels of breakage.[6] Some countries have a substantially higher reported rate of male homosexuality than others. In addition, sexual practices in some countries affect condom use. The Bakiga tribe in Uganda, for example, practices "kacabari," which is hitting the penis up and down against the clitoris. This may result in the condom coming off.[7] Such issues are important to consider in understanding condom breakage.

Across all cultures, there are individual behaviors that can cause condoms to break at excessive rates. These fall into four general categories.

Incorrect Methods of Putting on Condoms. Even when people receive instructions about putting condoms on correctly, some use their own technique. Just as the Kenyan man weakened his condom by stretching it and pulling it on like a sock, others put condoms on in other ways that weaken them.

In Mexico, for example, investigators working with the FHI study reported that some condom users perceive condom quality as generally poor. Hence, a relatively common practice is to unroll and inspect condoms for holes or to blow them up like balloons to test for leakage. Such practices may reduce the strength of the condom.

Providing clear instructions on condom use improves a user's ability or willingness to put the condom on correctly. In Sri Lanka, for example, a man who attended a condom training session conducted by the Sri Lankan Family Planning Association reported that prior to that training, he frequently had condoms fall off during use. The reason, he came to realize, was that he placed the condom over just the head of the penis without unrolling it. After the training, he rolled the condom down entirely.

Use of Oil-based Lubricants. Most condoms manufactured today are packaged with lubricants. This makes a condom easier to put on and makes penetration easier during intercourse. The lubricants are usually water- or silicone-based, *not oil-based*. The manufacturing process includes a standard range of the amount of lubricant.

Some individuals prefer more lubrication than the packaged condom contains. Water-based lubricants are recommended for use with latex condoms. Yet oil-based lubricants, which dramatically weaken latex, are most readily available in developing countries. These include grease, lotions, animal or vegetable oils, and petroleum jelly. Mineral oil, a common ingredient of hand lotions and other lubricants, can cause a 90 percent decrease in condom strength after as little as 60 seconds of exposure, laboratory tests have found.[8]

"We don't have definitive research on how often oil-based lubricants are being used, but we do know that many of the breakages encountered by our study participants appear to have been caused by the use of oil-based lubricants," says FHI's Joanis. "The biggest problem appears to be that people don't know what is an oil-based lubricant and what is not."

A study at a U.S. site illustrates the problem. Given a list of both oil-based and water-based lubricants, more than half of the participants thought that baby oil was a suitable lubricant. About one-third thought massage oil or petroleum jelly could be used.[9]

Bill Richards/RTI

Many brands of condoms are available.

Water-based lubricants, which do not deteriorate latex condoms, are often not readily available in developing countries. "Human saliva is the only readily available water-based lubricant," says Joanis. Other water-based lubricants which could be used if available are contraceptive gel or cream, or K-Y jelly.

Lubricant levels can be on the low end of the manufacturer's acceptable range, as was the case in Mexico. Several condom "breakers" blamed insufficient lubricant for causing undue friction during intercourse, which may have contributed to the breakage. These couples did not use an additional lubricant. Furthermore, family planning professionals working with the study could recommend few suitable lubricants to their clients.

H. Anenden/WHO

In Kenya, a former prostitute now trains health workers to convey the message of "safe sex."

Reuse of Condoms. Latex condoms are designed to be used only once. After ejaculation, the penis should be taken out before it gets soft so that the condom does not slip off. Then, the condom should be taken off carefully so that none of the liquid (semen) it contains spills inside the woman. Finally, the condom should be thrown away. In practice, however, condoms are often reused, according to local researchers in the FHI studies in Kenya, Mexico and Jamaica.

In Mexico and Jamaica, men sometimes remove the condom after ejaculating and clean it for use at a later time. Because a man cleans a condom, he may not consider this to be "reuse." In Kenya, some family planning program staff and clients indicate they have interpreted the "single-use" instruction to mean that the condom could be used during one period of sexual activity, which could include several ejaculations.

Duration or Intensity of Coitus. While definitive data are not available on how long coitus, or intercourse, actually lasts in various cultures, studies in the United States indicate that coitus lasts an average of one to ten minutes.[10] The longer intercourse lasts, the greater the strain put on the condom. Several persons who participated in the FHI studies complained about condom breakage during prolonged intercourse. In Mexico and Sri Lanka, several men reported having intercourse that lasted 30 minutes, during which time they withdrew and rested but did not put on a new condom. Others reported vigorous intercourse after prolonged absences from their spouses.

Matching Education to Behaviors that Cause Breakage

As condom promotion expands, both for AIDS prevention and for family planning, concern about proper condom use is increasing. "Failure...is a key issue for research, yet it is a most difficult subject, given that contraceptive effectiveness of condoms is greatly affected by the characteristics and motivational level of the users," explains Dr. Axel Mundigo of the World Health Organization.[11]

Increased research on *motivation* for using condoms is underway, particularly by those involved with AIDS prevention. The issues involved range from preconceptions about condoms to social marketing and distribution of condoms, subjects beyond the scope of this article.[12]

The other key factor in understanding condom failure, Dr. Mundigo points out, is the way people use condoms. Matching education efforts about condom use with suspected *patterns of behavior* that cause breakage will help make condoms more reliable.

Increasingly, instructions for correct condom use are now included during basic counseling to individuals at family planning clinics and sexually transmitted disease clinics. Pamphlets and posters depicting correct usage are becoming increasingly available. A number of organizations have developed condom instructions, such as those shown on page 13. To make instructions most useful, materials should be pre-tested through in-depth individual interviews and focus groups.

"Condoms break in use more frequently than previously suspected," says Dr. Williamson. "We now have some guideposts as to what types of behavior lead to breakage. We need to inform condom users and providers about which errors users make. And

we need to continue to identify which problems are the most serious."■

— *William R. Finger with Markus Steiner, John Manuel and Carla Piedrahita*

Markus Steiner is Senior Program Analyst in FHI's Program Evaluation Division. John Manuel and Carla Piedrahita are FHI consultants.

Footnotes

1. The eight countries where the studies took place are: Ghana, Kenya and Mali in Africa; Nepal and Sri Lanka in Asia; and the Dominican Republic, Jamaica and Mexico in Latin America. Preliminary reports are available from some of the study sites, while other data are not yet fully analyzed.

2. R Hatcher, D Kowal, F Guest, et al. *Contraceptive Technology: International Edition*. Atlanta, Ga.: Printed Matter Incorporated; 1989: 337-38. "Though reliable information is not available, our guess is that method failure is relatively uncommon; we suspect that the failure rate during an initial year of use would be about 2 percent among *perfect users*" (emphasis added). Laboratory tests have shown that latex condoms prevent the transmission of HIV, and human-use tests suggest this also to be true.

3. J Trussell, R Hatcher, W Cates Jr, et al. Contraceptive Failure in the United States: An Update. *Studies in Family Planning*. 1990; 21(1), 51-54.

4. In addition to the FHI studies discussed here, see L Liskin, et al. Condoms — Now More Than Ever. *Population Reports*. 1990; Series H, No. 8: 10. See Table 4, a review of prospective studies of condom breakage during use. Several large retrospective studies in the United States have shown low breakage rates. Retrospective studies rely on memory and hence the results are considered less reliable. Prospective studies look forward, recording information from a selected group on the same statistical and medical issues.

5. The FHI studies involved seven different study protocols, testing various issues, including a smaller versus regular sized condom and an extra-strong versus a regular strength condom, among others. The condoms used in all of these studies were tested by the FHI condom laboratory.

6. S Golombok, J Sketchley, J Rust. Condom Failure Among Homosexual Men. *Journal of Acquired Immune Deficiency Syndromes*. 1989; 2(4): 404-09.

7. S Forster, K Furley. 1988 Public Awareness Survey on AIDS and Condoms in Uganda. *AIDS*. 1989; 3 (3): 147-54.

8. B Voeller, AH Coulson, GS Bernstein, et al. Mineral Oil Lubricants Cause Rapid Deterioration of Latex Condoms. *Contraception*. 1989; 39 (1): 95-102.

9. Preliminary findings from a study being conducted by FHI.

10. See AC Kinsey, WB Pomeroy, CE Martin. *Sexual Behavior in the Human Male*. Philadelphia: W.B. Saunders Co.; 1948, and WH Masters, VE Johnson, RC Kolodny. *Masters and Johnson on Sex and Human Loving*. Boston: Little, Brown; 1986.

11. A Mundigo. Condom Promotion and Use: Family Planning versus HIV Protection. *IPPF Medical Bulletin*. 1989; 23(6): 1-3.

12. For more on AIDS prevention projects, including an article on social marketing, write FHI for *network*, 12(1), June 1991, titled "Strategies for Behavior Change — Slowing the Spread of AIDS."

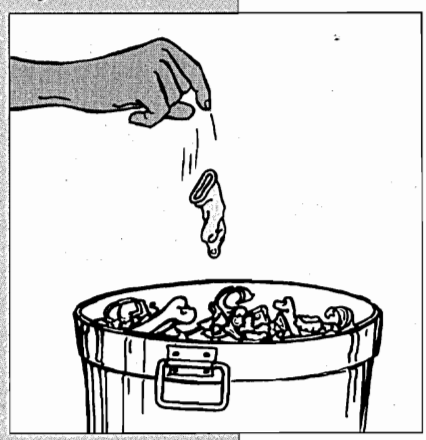
How to Use a Condom Correctly

Condoms provide reliable protection against accidental pregnancy and sexually transmitted disease only if they are properly used. The seven steps below appear on many of the AIDS-prevention materials distributed by FHI.

1. Carefully open package so condom does not tear. Do not unroll condom before putting it on.
2. If not circumcised, pull foreskin back. Squeeze tip of condom and put it on end of hard penis.
3. Continue squeezing tip while unrolling condom until it covers all of penis.
4. Always put condom on before entering partner.
5. After ejaculation (coming), hold rim of condom and pull penis and condom out before penis gets soft.
6. After withdrawal, slide condom off penis without spilling liquid (semen) inside woman.
7. Throw away or bury used condom.

Remember:

- Do not use grease, any oils including animal or vegetable oils, lotions or petroleum jelly to make condoms slippery. These make condoms break. Use only a jelly or cream that does not have oil in it.
- Use a condom each time you have sex.
- Use a condom only once.
- Store condoms in a cool, dry place.
- Do not use condoms that may be old or damaged. Do not use a condom if the package is broken, the condom is brittle or dried out, the color is uneven or changed, or if the condom is unusually sticky.



AIDSTECH/FHI

STD/AIDS Prevention: New Challenges for Family Planning Programs

In both developed and developing countries, family planning workers are being called upon to deal with increasing rates of sexually transmitted diseases (STDs), including AIDS. In some settings, this problem is seriously affecting the delivery of family planning services. At the same time, the rise of STDs also provides an opportunity for family planning programs to expand their role in preventive health.

Family Health International (FHI) has been actively involved in both international family planning and AIDS prevention activities. In 1989, FHI hosted a gathering of family planning and AIDS specialists to review the first international AIDS prevention guidelines for family planning program managers, published in 1990 by the World Health Organization (WHO). Since then, FHI has supported workshops on AIDS prevention for family planning workers in Kenya and Thailand.

"Family planning programs may want to expand into AIDS prevention activities that enhance their capability to provide good contraceptive services," explains Dr. Nancy Williamson, Director of FHI's Division of Program Evaluation and one of the authors of the WHO guidelines on family planning and AIDS. "No one is proposing that family planning programs drop their main mission of family planning. Starting STD treatment is not easy or cheap and may be impractical in many settings. It is only suggested that they offer services related to family planning and STDs."

While family planning providers throughout the world face different circumstances regarding AIDS, they have many of the same questions about how to adjust their programs to the AIDS epidemic. Here, Dr. Williamson addresses the questions most often raised. network *Associate Editor Sara Townsend conducted the interview.*

Family planning clinics are ideally suited to participate in AIDS prevention efforts.

World Bank

What do family planning and AIDS prevention have in common?

Family planning is a cluster of technologies that help couples have no more children than they want or to space the children they do want. AIDS is a fatal disease. Despite such a significant difference, fertility control and AIDS prevention have much in common. Both involve sex and couples in the reproductive ages. Both pregnancy and AIDS share a common means of prevention: responsible sexual behavior, including the use of condoms.

How is the AIDS epidemic affecting family planning programs in developing countries?

In countries with significant numbers of individuals infected with HIV, the epidemic has affected family planning programs by increasing the visibility and demand for one contraceptive method, namely condoms. It has also heightened concern about counseling and sterile procedures.

In a fundamental way, AIDS has changed how we view contraception. In addition to worrying about unwanted pregnancy, many women need to be concerned about STDs. AIDS has increased awareness of the need for controlling all STDs.

What are some ways the epidemic has had a negative impact on family planning programs?

This epidemic may put staff performing surgical procedures or having other contact with blood at risk of infection from infected clients unless universal precautions are strictly followed. Likewise, clients receiving an IUD, sterilization or injections may be put at risk of HIV infection from contaminated equipment or personnel.

Yet in many cases, family planning staff in developing countries have neither the knowledge nor the means to follow safety precautions — such as using gloves, masks and disposable equipment. Also, the need to purchase supplies like gloves may take resources away from other activities. In some settings, concerns about the risk of AIDS may make it more difficult to recruit and keep staff members, and may scare away clients.

How has AIDS affected condom promotion?

The use of condoms is a means of preventing AIDS, other STDs and unintended pregnancies. Condoms are being promoted as the primary method for protection against HIV transmission. Spermicides, a female-controlled method, may also provide some protection against HIV transmission (see article on page 23).

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. Promoting condoms aggressively requires a major reorientation for many family planning programs.

Family planning programs have attempted to legitimize contraceptive use, including condoms, among married couples. On the other hand, AIDS prevention programs often emphasize the use of condoms by prostitutes, clients of prostitutes, and persons having premarital or extramarital relations. Some family planning programs may fear that associating condoms with AIDS discredits family planning and reinforces the idea that condoms are "dirty." Family planning programs have been trying to counteract this notion for decades.

Which family planning clients need to use condoms?

Clients who are HIV positive and those who are at risk of HIV infection through sexual transmission must be counseled about safe sex, the need for using condoms and the correct use of condoms. *For these clients, condoms are necessary, regardless of whether they are using another method of family planning.*

What does condom promotion for HIV prevention entail?

Use of condoms for HIV prevention is much more demanding than for pregnancy prevention. As the chart on page 17 shows, for HIV prevention, condoms must be used *for every act of sexual intercourse*, even during menstruation and with an infertile partner. To prevent pregnancy, condoms must be used during the fertile time of the cycle and only if both partners are fertile.

Condoms are often more expensive per year of protection and more logistically demanding for a family planning program than contraceptive methods such as IUDs, pills or sterilization. Furthermore, clients at risk of HIV infection and an unwanted pregnancy may not totally trust in the contraceptive efficacy of condoms and may want to use a second method simultaneously, creating supply problems.

Are there contraceptive methods other than the condom that also affect women's chances of getting HIV?

Some methods may decrease or enhance the chances of contracting HIV, but for now the evidence is not well established. As researchers learn more about the relation of individual methods and HIV transmission, providers will need to adapt their recommendations. If research shows use of certain contraceptives increases the risk of contracting STDs, recommendations for those methods need to become more restrictive. Likewise, if research shows some methods are protective against HIV, then providers can promote those methods for protection against unwanted pregnancy and HIV infection.

Example of a Risk Assessment Checklist*

	Yes	Don't Know	No
A. Client behavior			
Have you had a sexually transmitted disease?	____	____	____
Have you shared drug needles or syringes with another person?	____	____	____
Have you had sex with a person whom you did not know well?	____	____	____
Have you exchanged sex for money or drugs?	____	____	____
Have you had many sexual partners?	____	____	____
B. Partner's behavior			
Have you had sex (vaginal, anal, or oral) with someone who:			
Has a sexually transmitted disease?	____	____	____
Shares drug needles or syringes?	____	____	____
Has had sex with a prostitute?	____	____	____
Has had multiple sexual partners?	____	____	____
Has had anal sex with you or someone else?	____	____	____
Has AIDS or HIV infection?	____	____	____
Has had sex with someone who has AIDS or HIV infection?	____	____	____

*This form is adapted from one published in *AIDS Prevention: Guidelines for MCH/FP Programme Managers, I. AIDS and Family Planning.* World Health Organization, 1990.

Sexual History

The following conditions put you at risk for AIDS: sex with bisexual partners, sex with multiple partners, intravenous (IV) drug use, intercourse with an IV drug user, anal intercourse, hemophilia.

Do you consider yourself at risk? ____Yes ____No ____Unsure

Having more than one sex partner increases the chance of sexual diseases:

Have you had a new sex partner in the past two months? ____Yes ____No

Have you had more than one sex partner in the last six months? ____Yes ____No

Does your sex partner have any other partners? ____Yes ____No

World Bank

Women and children wait outside a health clinic in Indonesia.

Should family planning counselors routinely recommend that people use two methods?

Aside from being costly, routinely advising clients to use two temporary methods — one for family planning and one for HIV/STD prevention — is likely to be futile, in light of recent research showing low compliance with just a single method. People at risk of HIV infection, however, should be told to use condoms, with or without other contraceptive protection.

How do family planning staff know whether a client is at risk for HIV infection?

Each family planning clinic must evaluate its own clientele to determine who may be at risk for HIV infection. Some family planning programs have begun to use risk assessment forms (see samples on page 15). Without asking HIV risk-assessment questions, there is no way for a family planning provider to know whether to recommend that a particular individual use condoms, with or without another method.

Should family planning providers counsel and provide services to HIV-infected clients?

Yes, absolutely. HIV-infected women need contraceptive services and counseling so that they understand the risks of having an infected child and have the means of preventing an unwanted pregnancy. They also need to protect their sexual partners from infection or reinfection. Unfortunately, this kind of counseling, which requires both time and skill, is not available in most family planning facilities. Yet without such counseling and contraceptive services, the numbers of AIDS-infected babies and AIDS orphans will increase even more rapidly than they already are.

Also, HIV-negative women who are at risk need to be counseled to help them reduce the risk of sex with infected partners.

Will the growing need for HIV prevention mean less support for family planning programs?

Worldwide donor funding for family planning programs (controlling for inflation) has stagnated over the past decade while the number of couples needing and desiring services has increased. Given the shortage of resources for family planning, family planning programs must widen their economic base if they are to become more involved in the prevention of AIDS. This may entail applying for funds from AIDS prevention programs. For a relatively moderate cost, some AIDS prevention activities can be added to family planning programs. But if family

Resources on Family Planning and AIDS

AIDS Prevention: Guidelines for MCH/FP Programme Managers, I. AIDS and Family Planning and AIDS Prevention and *II. AIDS and Maternal and Child Health* (World Health Organization, 1990). These guidelines can be adapted locally to train family planning workers. For a free copy, write Family Health Division, World Health Organization, 1211 Geneva 27, Switzerland.

Preventing a Crisis: AIDS and Family Planning Work (International Planned Parenthood Federation, 1988). This provides much practical information on how family planning programs can be involved in AIDS prevention. For copies, write IPPF, PO Box 759, Inner Circle, Regent's Park, London NW1 4LQ, England. A shorter version, entitled *Talking AIDS*, is also available.

All About AIDS — A Workbook (International Planned Parenthood Federation, 1991). Developed for use in the English-speaking Caribbean by the IPPF/Western Hemisphere Region, this 32-page booklet provides information about prevention of all STDs, the relationship between family planning methods and AIDS and instructions on condom use. For copies, write IPPF/WHR, 902 Broadway, 10th Floor, NY, NY 10010, U.S.A., ATTN: Florencia Roitstein.

planning organizations are to realize their wider potential to slow the spread of AIDS and STDs, they will need additional resources: funds, essential drugs to treat STDs, training and technical assistance.

What are the arguments* in favor *of adding AIDS prevention work to family planning organizations?

Family planning providers should be able to improve their condom distribution programs and condom education, which will help in preventing unwanted pregnancies and STDs, including HIV. The concern over AIDS is increasing interest in social marketing projects and other efforts to reach men and marginalized groups that traditionally have not been reached by family planning programs.

Training in how to do HIV risk counseling may improve overall counseling performance. Family planning programs may be able to tap new sources of financial support for this, such as AIDS prevention funds.

Many family planning programs have a unique contribution to make to HIV prevention because of their experience and skills in sex education. Most family planning workers have had some training in contraceptive risk-assessment counseling; this could be helpful in assessing risk for HIV infection. For example, family planning counselors already administer checklists for oral contraceptives and IUDs to identify women who can use these methods safely. These same workers could be trained to use HIV risk-assessment checklists.

Condom distribution, storage and education programs are already part of existing family planning programs and can be expanded. Finally, family planning leaders have experience in dealing with controversial issues.

What are the arguments* against *adding AIDS prevention to family planning programs?

First, there are concerns that the association with AIDS may harm family planning. Some fear that the reputation of family planning programs will suffer a setback. For years, these programs have been trying to disassociate condoms from illicit sex and make them acceptable for use within marriage. Emphasizing condoms for persons practising high-risk behaviors works against this effort. Also, AIDS prevention may distract family planning programs from their central mission. Asking them to do more could reduce the quality and quantity of their contraceptive services.

Secondly, there are concerns that family planning may not have much to offer AIDS prevention. Family planning programs traditionally have not had much contact with some of the populations involved in spreading AIDS, such as prostitutes and men. Also, although family planning programs deal with reproductive health issues, they seldom have had to deal as explicitly with specific sexual behaviors as is needed for AIDS prevention.

Others point out that few family planning programs have the ability or the funds to treat STDs, a crucial component in HIV control. Finally, some countries with serious AIDS problems have weak or non-existent family planning programs.

Which developing countries will need to modify their family planning programs in response to the AIDS epidemic?

No region is escaping the HIV epidemic, but clearly some areas have a higher prevalence. In most of the countries in sub-Saharan Africa and the Caribbean, and in Thailand, family planning programs need to address HIV infection in a significant way. At least some changes are necessary for India and most countries in Central and South America. Minor changes in family planning programs may be sufficient for countries in the Middle East and for Pakistan, Nepal, Sri Lanka, China, Indonesia, Philippines, and the Indochinese and Andean countries.

How should family planning programs be modified?

This will depend on the prevalence of HIV in their region or country. The options are numerous but some require additional funding so as not to interfere with family planning efforts. An early priority is education of family planning staff on AIDS and AIDS prevention and integration of AIDS prevention information into family planning materials and counseling. At the same time, family planning programs should increase their emphasis on universal precautions and sterile procedures.

HIV prevention will require more focus

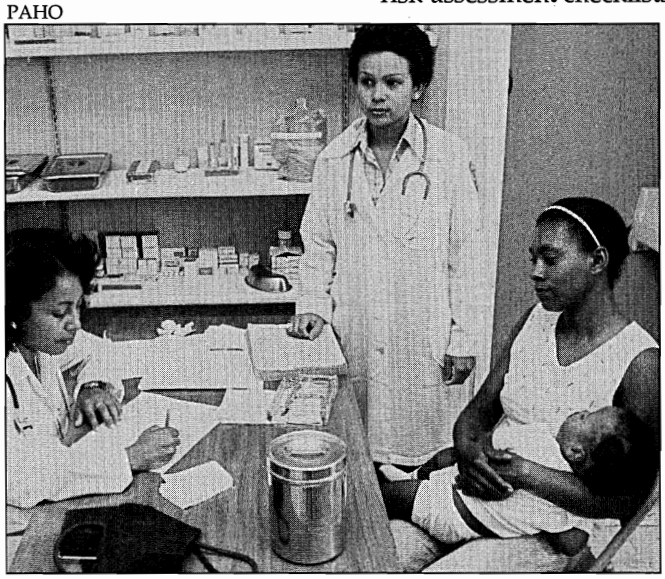
Many family planning programs have a unique contribution to make to HIV prevention because of their experience and skills in sex education.

Use of Condoms

	For HIV/STD prevention	For family planning
During fertile period of cycle with fertile partner	Yes	Yes
Woman is pregnant	Yes	No
Woman is amenorrheic (postpartum)	Yes	No
Woman is sterilized	Yes	No
Woman uses IUD, Norplant, or oral contraceptives	Yes	No
Man has vasectomy	Yes	No
Woman is post-menopausal	Yes	No

on condom education, promotion, quality assurance, logistics and distribution. Programs may want to develop and use HIV risk-assessment checklists to help clients decide whether they need to use condoms as their only method or in addition to another method.

PAHO



Family planning clinics are well-positioned to conduct surveys on safe sex behavior.

After considering which high-risk groups various family planning programs might be able to reach, staff may decide to develop projects with these groups. Family planning programs need to improve their STD referral or treatment services and reciprocally arrange to provide family planning services to clients of STD clinics.

Finally, family planning programs might integrate their AIDS prevention activities with national AIDS programs and include AIDS components in family planning research. For example, family planning organizations have conducted surveys of adolescent fertility, contraceptive use and rate of STDs. These surveys could be adapted to include AIDS risk factors and AIDS knowledge, attitudes and practices.

What have family planning programs actually begun to do?

Some efforts are emerging in government family planning programs. More have come from non-governmental family planning associations thus far, most of these affiliated with the International Planned Parenthood Federation.

The Government of Thailand has provided information on AIDS to family planning officers and encouraged them to develop AIDS prevention activities. In Colombia, PROFAMILIA has extended its advice about contraceptives to include AIDS information, with posters and leaflets about AIDS. Several family planning organizations in Central America have opened STD treatment facilities. In Brazil and Mexico, family planning organizations have actively promoted the use of condoms to homosexual men. Family planning organizations in the Caribbean have set up programs to distribute condoms to hotel guests. The Sri Lankan Family Planning Association has provided AIDS education to key participants in the tourism industry. Family planning researchers in Botswana and Zaire have conducted surveys on attitudes toward AIDS, knowledge of how HIV is transmitted, and safe sex behavior.

At this point, there has been no systematic inventory of what family planning organizations are doing in AIDS prevention. In addition, little research has been done to determine the effectiveness of the efforts that are being made. Nevertheless, it is likely that in the 1990s, more family planning organizations will be drawn into the fight to prevent STDs, including AIDS.

Finally, given the pros and cons, do you think family planning programs should incorporate AIDS prevention activities?

The increase in HIV and other STDs is simply a fact of life in many countries. In these settings, family planning organizations must adapt to it and make the best of the situation. *But no one is proposing that family planning programs drop their main mission of family planning.*

Based on anecdotal experience from family planning providers who have integrated AIDS prevention into their programs, it appears that AIDS prevention activities are not harmful if they involve only *minor* changes in procedures, if new activities are consistent with old ones, or if additional resources are made available for the new activities. In some cases, those new activities may strengthen family planning programs.

HIV risk-assessment screening — as opposed to counseling of people infected with HIV — should be relatively easy to integrate into existing family planning questionnaires. Counseling about condoms and the risks of having multiple partners should also fit easily into most family planning programs. Major changes would include expansion into STD testing and treatment or outreach to men or prostitutes.

Family planning programs should expand into AIDS prevention activities that enhance their capability to provide good contraceptive services. Having family planning workers attend courses in counseling for AIDS prevention could improve their skills in family planning counseling. Or starting a social marketing project for condoms could widen the geographical reach of the family planning program and attract new types of users. Conducting surveys of adolescents, research on acceptability and efficacy of condoms, and evaluations of the effectiveness of intervention programs are activities that support both family planning and HIV prevention services. ■

Worldwide Surveys Show Sharp Decline in Fertility Rates

In just 15 years, fertility rates throughout the developing world have declined by 30 percent, from 6.0 to 4.2 children born per woman of childbearing age. This represents almost one half of the decline needed to reach what experts consider the "replacement level" of fertility, 2.1 children per couple, a level at which the population base would no longer increase.

This new finding came in a keynote paper presented by Dr. Ronald Freedman of the University of Michigan Population Studies Center and Dr. Ann K. Blanc of Demographic and Health Surveys (DHS) at the Demographic and Health Surveys World Conference, held in Washington, D.C., in August 1991.

"A change of this magnitude in this relatively short period of time is extraordinary in that it involved challenging fundamental attitudes and behavior concerning the roles of family, of women and of children," they explained. The study compared fertility rates from the periods 1965-70 and 1980-85.[1]

The sharpest fertility declines occurred in Eastern Asia and Latin America, with significant declines as well in the rest of Asia and in North Africa. The fertility rate in sub-Saharan Africa as a whole remained virtually the same, but the rate in three countries in that region — Botswana, Kenya and Zimbabwe — did decline.

Dr. Olikoye Ransome-Kuti, Minister of Health in Nigeria, gave the keynote address at the DHS World Conference. "New skills must be developed to make management decisions and generate new policies based on the information provided by the data, bearing in mind the available resources, political sensitivities and the ecology," Dr. Ransome-Kuti said. About 650 people from 63 countries attended the conference.

This major international conference capped a seven-year survey and research effort by Demographic and Health Surveys, which began in 1984. This program has built on earlier survey work, particularly that of the World Fertility Survey (WFS), which coordinated the last such conference in 1984. Since 1980, various organizations, including DHS, have conducted about 100 sample surveys on demographic and health topics in 60 developing countries.

From 1984 to 1991, DHS conducted 36 surveys in 32 developing countries. The surveys gathered data from nationally representative samples with questions that were comparable among the countries. The goals of DHS are to provide surveyed countries with information useful for informed policy choices, to expand the international population and health data base, and to develop in participating countries the technical skills and resources necessary to conduct such surveys. Individual country reports began appearing in 1986 (see Table 1). DHS recently began releasing a "Comparative Studies" series comparing findings from the country surveys.

"The World Conference and the release of the DHS comparative studies series have brought the picture into focus," says Richard Cornelius, Coordinator for Demographic Research for the U.S. Agency for International Development's Office of Population, one

A village family in Honduras.

A. Jongen/UN

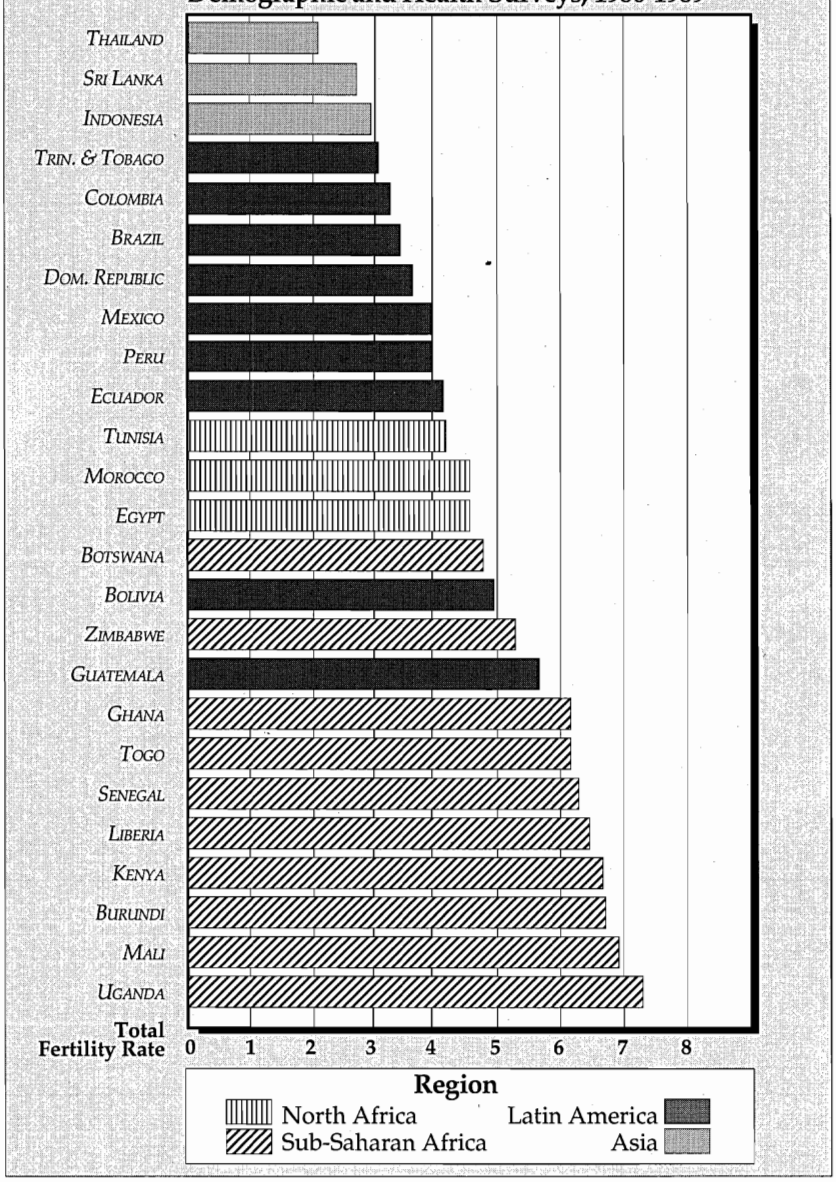
of the principal funding sources for DHS. "These have brought a large body of data into a single comparative framework. We can now speak with more confidence about what the trends have been worldwide."

The comparative DHS data can be used in conjunction with the earlier WFS data to provide even more information. Sixteen of the DHS surveys were conducted in countries which also had WFS surveys in the late 1970s.[2] In these countries in particular, there are dependable and thorough data on which analysis of trends in reproductive health can now be based for the first time in history. Many of the 32 countries covered in the DHS program will have repeat surveys, which will add to the data base available for trend analysis, says Martin Vaessen, Director of DHS.

Findings from the DHS surveys indicate marked regional differences in total fertility rates, with sub-Saharan Africa having the highest levels.

Table 1 ***Total Fertility Rate***

Women 15-44, 0-2 Years Before Survey
Demographic and Health Surveys, 1986-1989



All of the DHS surveys were implemented by in-country organizations, usually a government ministry, research institute or national population office. Most surveys asked questions only of women, ages 15-49. The surveys in Ghana, Kenya, Mali and Burundi also interviewed men. More than 180,000 women were interviewed in the 32 countries. In addition to the basic population questions, countries could select from among 11 additional modules. The most frequently used modules concerned height and weight of children, service availability and health. Only a few surveys included questions specifically about AIDS, social marketing, natural family planning or pill compliance.

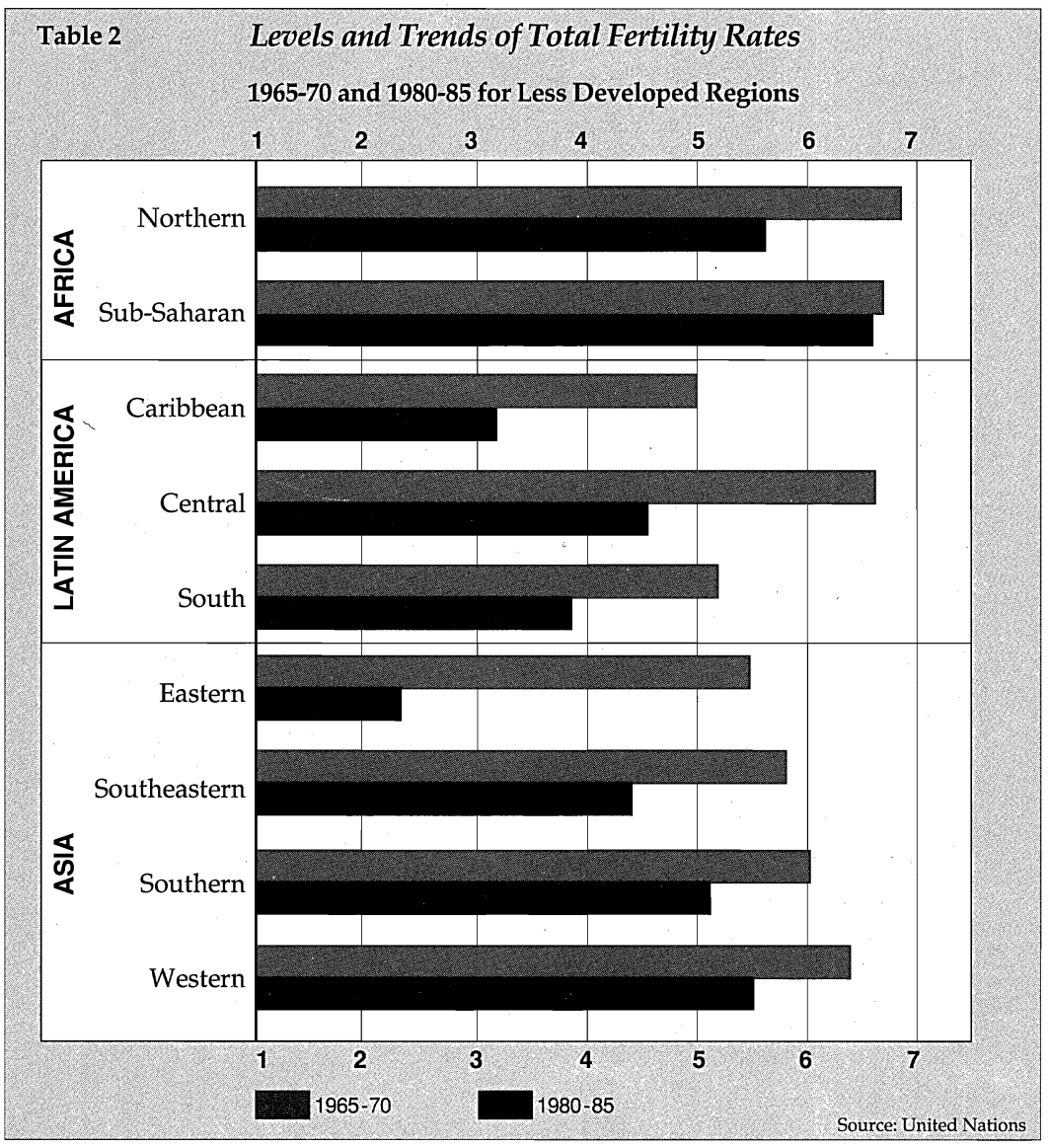
One DHS objective is to continue monitoring the role and impact of family planning programs in bringing about changes in fertility levels. From 1965 to 1990, the percentage of couples of childbearing age using contraception increased from 10 to 48 percent, reported Mary Beth Weinberger of the U.N. Population Division in a plenary paper at the conference.[3] "Rising use of contraception is indisputably the main proximate determinant of the ongoing fertility decline in developing countries," she explained.

The factors affecting fertility levels directly — known as "proximate determinants" by demographers — include contraceptive use, age at marriage, breastfeeding and abortion. Socioeconomic factors such as education and income affect fertility indirectly as they interact with the primary determinants.

In a major new finding, DHS showed that three countries in sub-Saharan Africa had significant declines in the total fertility rate — Botswana, Kenya and Zimbabwe.[4] In just four years, the Zimbabwe total fertility rate dropped 19 percent, from 6.6 to 5.3 children born per woman, and Botswana showed a 14 percent decline, from 5.6 to 4.8. While Kenya still has one of the world's highest fertility rates, its total fertility rate declined 9 percent, from 7.1 to 6.5. DHS conducted these three surveys in 1988-89, comparing the fertility rate during the period 0-3 years prior to the survey and the rate during the period 4-7 years prior to the survey.

The new DHS reports make possible more thorough analysis of trends in sub-Saharan Africa. "One important feature of the DHS surveys for countries with insufficient or deficient data on fertility is that, because full birth histories are incorporated in the questionnaire, the data can be used to estimate trends over time," explain Freedman and Blanc.[5]

Despite the remarkable progress in the fertility declines, many experts also point out the sobering challenge ahead. While the fertility rate is declining, record numbers of



young girls born *before the declines* are moving into childbearing age. In addition, there has been a welcome decline in mortality which offsets some of the impact of declining fertility in total population figures. The world's population will at least double in the next 30 years, from 5.4 billion to more than 10 billion. The increase could be much higher if the replacement fertility goal of 2.1 is not reached.

"It's easy to get euphoric, to say we're doing great things, and that's true," says Cornelius. "But it is helpful to remember that we're only halfway towards achieving fertility declines that will assure replacement levels," he cautions. "All of this is uncharted territory. We don't know how easy or hard it will be to sustain those reduced fertility levels and how fast the rates can continue to decline."

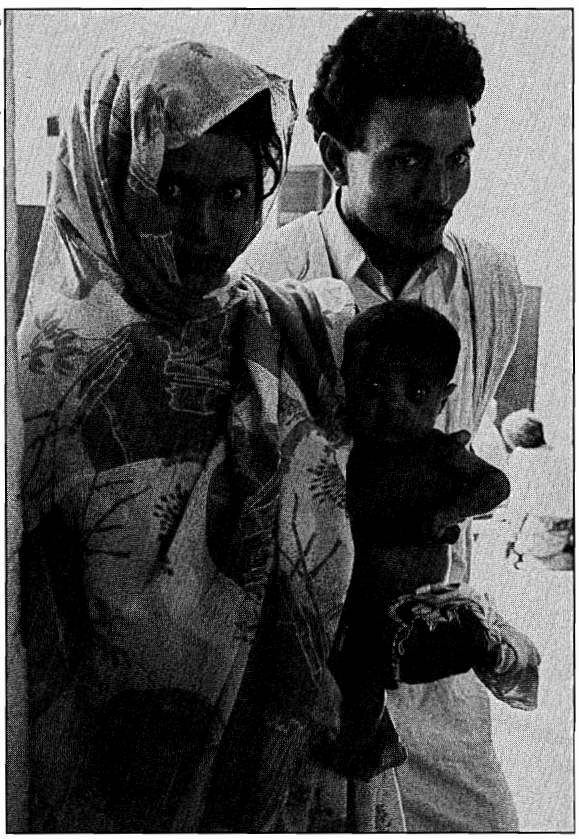
A careful examination of the developing nations with the largest populations shows other challenges. The 14 less developed countries (LDCs) with populations of more than 45 million account for 78 percent of the LDC population. They range from China, with 1.1 billion people, to Egypt, with 48 million. In these countries, the fertility rate declined 40 percent in 15 years — substantially better than the worldwide decline of 30 percent, called "extraordinary" by experts.

However, these figures are heavily weighted by China, which went from a total fertility rate of 6.0 to 2.3, 95 percent of the way to the replacement figure. "Omitting China, the weighted average decline for the other countries was 27 percent, or 41 percent of the way to the 2.1 [replacement level]," reported Freedman and Blanc.[6]

The news can look even more discouraging with a regional review. Over the last 15 years, the worldwide LDC fertility rate declined to 4.2, but the rate is substantially higher in Southern Asia (5.1), Western Asia

(5.4), and Northern Africa (5.7). The biggest challenge is the 6.6 fertility rate for sub-Saharan Africa, which is "not reliably below the estimated levels for 15 years earlier" (see Table 2).[7]

There is an intermediate ground between the remarkable declines in fertility rates and the discouraging aspects of the future. "I believe we have to be optimistic about it," says Vaessen. "In the early 1970s, you couldn't even talk about family planning in Latin America, for example. Change can occur very, very fast. Things can go fast now in countries where the government is encouraging more attention to family planning."



Beryl Goldberg

This Mauritanian couple visits a family planning clinic in Dakar, Senegal.

In addition to findings on family planning and fertility, the DHS studies provide important new information on many related subjects. The data are particularly important for understanding child health. "One exciting thing that makes the DHS work unique is the substantial emphasis on maternal and child health," says Cornelius.

These surveys exposed the very strong linkages between family planning and infant and child health issues, adds Vaessen.

"DHS gives us for the first time extremely useful information about things such as the incidence and treatment of diarrhea, acute respiratory infections, immunization, and nutritional status of children," says Cornelius. This kind of information, along with the basic family planning and fertility data, is invaluable to policy makers. "If we didn't have these surveys, then we would be relying predominantly on family planning service statistics, which are notoriously weak in most developing countries."

The 1991 World Conference and the DHS comparative studies report series have elevated the base of information on worldwide reproductive health issues to a major new plateau. The trends point to extraordinary gains, yet to large unmet needs as well.

"The truly exciting thing that's coming out is that the developing world has really embarked on a path toward sustained fertility decline and increased contraceptive use," says Cornelius. "The exceptions are becoming fewer and fewer." ■

— *William R. Finger*

Footnotes

1. R Freedman, A Blanc. Fertility Transition: An Update. Presented at the Demographic and Health Surveys World Conference. August 5-7, 1991; Washington, D.C.
2. The 16 countries included four in sub-Saharan Africa (Ghana, Kenya, Senegal and Sudan), three in North Africa (Egypt, Morocco and Tunisia), three in Asia (Indonesia, Sri Lanka and Thailand), and six in Latin America and the Caribbean (Colombia, Dominican Republic, Ecuador, Mexico, Peru and Trinidad/Tobago).
3. MB Weinberger. Recent Trends in Contraceptive Use. Presented at the Demographic and Health Surveys World Conference. August 5-7, 1991; Washington, D.C.
4. F Arnold, A Blanc. Fertility Levels and Trends. Demographic and Health Surveys Comparative Studies 2. Columbia, MD.: Institute for Resource Development/Macro Systems Inc. October 1990. The report found a statistically significant decline in fertility rates in 22 of the 26 countries where data analysis was completed in 1990, although those in Burundi, Mali, Senegal and Togo were statistically inconclusive (Table 4.1).
5. Freedman and Blanc, page 9.
6. Freedman and Blanc, page 6.
7. Freedman and Blanc, page 6.

Information Available from DHS

Demographic and Health Surveys (DHS) is funded by the U.S. Agency for International Development and administered by IRD/Macro International Inc., Columbia, MD, USA. DHS publications are available free of charge, including the DHS newsletter (published twice a year) and summary reports from many DHS surveys. DHS plans to publish 17 reports in its "Comparative Studies" series; six have been released thus far. For further information on DHS publications, write to Sidney Moore, Editor, IRD/Macro, 8850 Stanford Blvd., Suite 4000, Columbia, MD 21045, USA.

Spermicides for Family Planning and Disease Protection: An Update

For many women around the world, negotiating condom use is not possible. Vaginal spermicide, a chemical barrier contraceptive method which can be used by women without a partner's involvement, offers protection against both pregnancy and some sexually transmitted diseases (STDs). And, in the era of the human immunodeficiency virus (HIV), protection against STDs may mean the difference between life and death.

"The growing STD/HIV epidemic makes it more urgent than ever to give women some control over their reproductive health," says Dr. David Heymann, Chief of Research for the World Health Organization's Global Programme on AIDS. "Any sexually active woman who may be at risk for STDs needs to use a method for disease control regardless of what contraceptive she chooses."

Latex condoms should be the first choice for protection against HIV infection. But the use of a condom requires the cooperation of both partners. Spermicides offer an alternative for women whose partners refuse to use condoms.

Traditionally, spermicides have been used primarily in conjunction with other barrier contraceptive methods — condoms, diaphragms and cervical caps. Hence, little research has focused on spermicides used alone, but knowledge of spermicides is rapidly increasing.

Researchers have no conclusive data on whether spermicides, used alone or in combination with condoms, protect against HIV and other viral STDs. Also, some concerns are now emerging about the safety of using multiple doses of spermicide per day. Nevertheless, women appear to like using spermicides for disease protection, especially when counseling about spermicide use is available.

Spermicides Used for Family Planning

Spermicides offer a readily reversible form of contraception that requires no medical supervision. Unlike the pill, spermicides are only used at the time of sexual intercourse and cause virtually no side effects. Most family planning programs recommend spermicides to supplement natural family planning or breastfeeding, or as an adjunct to condoms, diaphragms or cervical caps. Spermicides are also easily available in pharmacies and are especially suitable for women who experience adverse effects from hormonal methods or IUDs.

Despite these advantages, however, less than 3 percent of contraceptive users worldwide rely on spermicides as their primary method. This is in part a reflection of the fact that both couples and family planners have thought of spermicides as an only moderately reliable contraceptive when used alone.

Researchers estimate that spermicides have a theoretical contraceptive effectiveness of about 97 percent, but have only a 79 percent efficacy rate among typical users.[1] This actual use effectiveness is much lower than that estimated for intrauterine devices (IUDs) and Norplant (97 percent), and lower than that estimated for oral contraceptives (80 to 94 percent) and condoms (88 percent).[2]

Inconsistent use is likely a major factor in the relatively low contraceptive efficacy of spermicides. Other factors may involve the method itself. Spermicides can be difficult to use correctly and have a tendency to leak out unless a woman is lying flat. Also, some sperm swim directly into the opening of the cervical canal and hence avoid contact with spermicide. Laboratory tests show nonoxynol-9 (N-9), the active ingredient in most spermicides today, cannot penetrate cervical mucus.[3]

Spermicides are valuable for family

Spermicides are available in several forms, need be used only at the time of sex, and require no prescription.

Julia Beamish/FHI

planning and they offer protection against infection with bacteria responsible for pelvic inflammatory disease (PID). Clinical data suggest that spermicides provide substantial protection from gonorrhea and chlamydial infection.[4] These infections can lead to PID and infertility and can increase a woman's risk of HIV infection.

"Family planning is not just preventing pregnancy," says Ron Roddy, Associate Medical Director of FHI's Reproductive Epidemiology Division. "It is also protecting and maintaining fertility and future *wanted* pregnancies."

Experts estimate the efficacy rates for spermicides could be significantly higher under optimal use (that is, when women use it every time and correctly) than rates reported for "typical" use. By implication, the protection they offer against STDs could be higher than is now reported.

For the first time, researchers hope to assess how effective spermicides may be among optimal users. A large U.S. study is now under way to determine the maximum protection that spermicides, both used alone and used together with condoms, can offer women at risk of bacterial STDs and herpes. At the University of Alabama in Birmingham, researchers are studying 1,200 women attending an STD clinic. The project features monthly group and individual counseling sessions to motivate women by emphasizing the need to use spermicides consistently.

Spermicides offer an alternative for women whose partners refuse to use condoms.

Spermicide Use for STD Protection

Sexually transmitted diseases can be bacterial, such as gonorrhea or chlamydial infection, or viral, such as infection with HIV or genital herpes. The transmission of STD bacteria or viruses occurs by direct contact with infectious lesions or body fluids. Spermicides place a chemical barrier between infected fluids and vulnerable tissue.

Specific STDs tend to infect different sites of the female genitalia, hence the location of the spermicide inside the woman is critical to the effectiveness of spermicides against various STDs. Gonorrhea is a cervical infection, so a spermicide which covers the cervix may be most effective in preventing this disease. HIV may infect women by entering through the cervix, or it may travel through the vaginal wall, especially in the presence of tissue ulceration, so women need a method that protects them from HIV transmission through both cervical and vaginal routes.

Since the 1970s, numerous laboratory studies have shown that spermicides inactivate most STD pathogens, including HIV. In

What Are Spermicides?

For the past 5,000 years, women have tried to prevent conception by inserting into their vaginas various mixtures of fruit and herb juices, honey, cedar gum, and even crocodile dung. These substances are strongly alkaline or acid, environments hostile to sperm. Today's spermicides control fertility in the same way — by creating an environment hostile to sperm.

Spermicides create a chemical barrier that stops sperm before it reaches a woman's cervical canal. Spermicides consist of two components: an inactive base or carrier, which carries the active agent and tends to hold it in the vagina; and the spermicidal agent or active chemical ingredient which kills sperm.

The most commonly used spermicides today contain chemicals that destroy the surface or membrane of sperm cells and immobilize them. The most widely used spermicides contain nonoxynol-9 (N-9) or menfegol (sold under the brand name NeoSampoon in some areas). Similarly, these spermicides have been shown to kill bacteria and viruses that cause some sexually transmitted diseases by breaking bacterial cell membranes and viral envelopes.

Spermicides can be used in conjunction with condoms or vaginal physical barrier methods, either applied to the devices during the manufacturing and packaging process or inserted manually at the time of sexual intercourse. Four types of spermicides are used vaginally: creams and gels squeezed from a tube; water-soluble tablets or capsules that dissolve at body temperature; foam, in pressurized containers or tablets that disperse when in contact with vaginal secretions; and a water-soluble paper-thin contraceptive film, a two-inch square sheet that is folded and placed at the cervix.

Some of these products are designed to be used in conjunction with a diaphragm or cervical cap. Spermicidal foam, cream or gel can be used alone or added to the diaphragm or cap. Melting gel suppositories, foaming tablets, and contraceptive film are designed for women to use without a physical barrier method.

— *Sara Townsend*

human use, the evidence is more limited but data are accumulating.

FHI and researchers in Thailand measured the effect of using spermicidal film among 343 women working in massage parlors in Bangkok. They found that consistent use of spermicides reduced the risk of gonorrhea and chlamydial infection among these women by 40 percent.[5]

Laboratory data have shown that nonoxynol-9 destroys both cell-free HIV and the virus lodged in white cells, where most HIV in semen is contained. This *in vitro* evidence was first demonstrated in 1985, and based on these laboratory findings, N-9 has been incorporated into HIV prevention recommendations as possibly offering extra protection in conjunction with condoms.

Conclusive epidemiological data showing protection against HIV transmission are lacking, however. To date, there are no published reports on whether spermicide use protects women from HIV infection.

Some anecdotal reports and unpublished findings presented at scientific meetings suggest that in actual use spermicides may not protect sufficiently against HIV infection. According to a presentation at the Fifth International Conference on AIDS in 1989, a clinical trial study of Nairobi prostitutes showed no protective effect for women using a spermicide-impregnated sponge.[6]

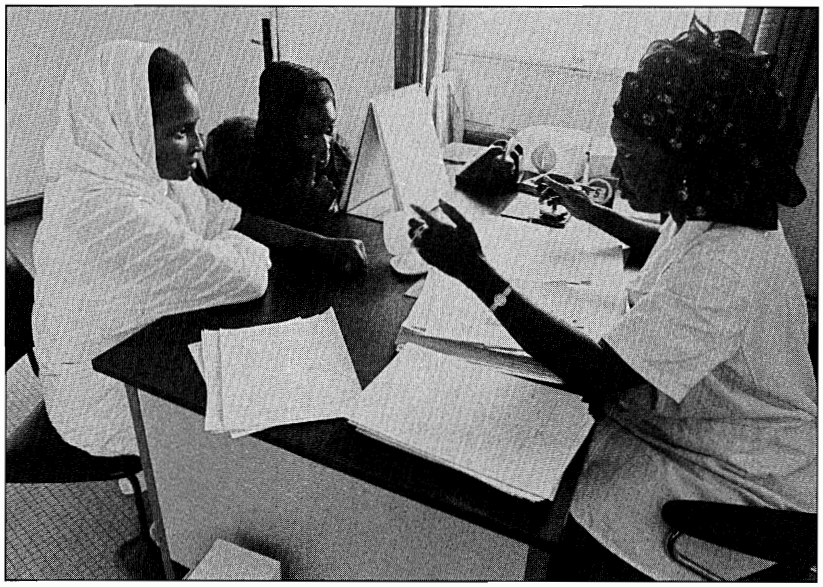
Likewise, a prospective study in Kigali, Rwanda, of discordant couples (couples in which only one partner is infected with HIV) failed to find that spermicides provided any protective benefit against HIV, although spermicide use was rare in this cohort.[7]

So far, results from two FHI studies assessing spermicidal efficacy against HIV transmission in Africa are ambiguous. In Cameroon, preliminary results indicate consistent spermicide use substantially reduces the rate of HIV infection. In a study in Zambia, however, preliminary data show no protective effect for spermicide users.

The Cameroon study, conducted in Yaounde in collaboration with the National AIDS Control Service, is studying the effect of spermicide and condom use on the rate of HIV seroconversion. Researchers are examining the degree to which spermicide use decreased the risk of HIV transmission among 274 women at high risk for HIV infection. So far, data show that consistent spermicide users had an 80 percent reduction in the rate of HIV infection.[8]

In Lusaka, Zambia, among 112 HIV-discordant couples, researchers are measuring the seroconversion rate of uninfected partners. Among consistent users of spermicides, no reduction in HIV infection rates has been noted. Results are preliminary, however, and because they are based on a small number of seroconversions, statistical analysis is imprecise.[9]

The issue of spermicide use and HIV protection may be complicated by growing concerns about safety. Studies have found a possible link between the frequent use of spermicides and damage to genital tissue. This may suggest that frequent use of spermicides — several times a day — could lead to irritation and abrasion of women's genital tissue and hence make women more susceptible to HIV.[10] Research is now under way to see if changes in cervical and vaginal tissue occur with use as infrequent as every other day (see box on page 27).



Beryl Goldberg

Family planning clinics often recommend spermicides as an adjunct to condoms, diaphragms or cervical caps.

Do Women Like Spermicides?

No matter how effective spermicides may be in protecting against STDs or pregnancy, there will be little benefit unless women use them and use them correctly. Many factors, ranging from ease of use and access to cost, affect the acceptability of any contraceptive or disease prophylaxis.

Inconsistent or incorrect use may stem from confusing instructions about how to use spermicides. For example, women may not understand the need to allow time for the product to dissolve or disperse. Some spermicidal products, such as capsules and tablets, require a period of at least ten minutes to dissolve or melt after placement in the vagina before sexual intercourse. No waiting period is necessary for creams, jellies or aerosol foam.

User acceptability research suggests that spermicides are not very acceptable to women uncomfortable with touching their genitalia, as is required for inserting most

spermicides. Some users complain that some spermicide products do not dissolve, melt or disperse entirely.

Another common complaint about spermicides is irritation of the vulva or penis, although for two of the newer products, the gel capsule and the film, some acceptability research suggests irritation is not a problem.

Women reported liking contraceptive film because it dissolved in only five minutes. FHI studies in Colombia and the Dominican Republic have compared women's reactions to spermicides carried in capsules, gel and foam. Among 165 women studied, researchers noted high acceptability for all the spermicide products, but especially for capsules and gel.[11]

An FHI study now under way in Bogota, Colombia, is measuring the acceptability of spermicides among women at high risk for STDs, comparing whether women will use *both* condoms and spermicides together or one alone to protect against STDs.

The ongoing FHI study of HIV-discordant couples in Zambia yielded data on the acceptability of three spermicidal products — gel in an applicator, suppository tablets and film. Both men and women were enthusiastic about spermicides and reported consistent use, says Paul Feldblum, Acting Director of FHI's Division of Reproductive Epidemiology and Sexually Transmitted Diseases. Of the three products, film has been the most popular.

"Effective counseling is key to consistent use of spermicides," says Feldblum. Joint counseling of the couples seemed to be far more effective than recommendations made to one member of the couple alone. Also, having a choice between spermicides and condoms may have enhanced the acceptance of both methods. This study has led to plans by Zambia's National STD Control Program to provide a spermicide product at STD clinics nationwide.

In the FHI study of prostitutes in Cameroon, FHI researchers reported a high level of acceptability for spermicide. Among this group, spermicide use was initially low, but with regular access to and instruction in the use of spermicides, a majority showed frequent and consistent use of spermicides over an extended period of time.[12]

Effective counseling is key to consistent use of spermicides.

Conclusion

Spermicides fill a contraceptive need among a wide range of women, especially those with irregular sexual activity, those whose partners refuse to wear condoms, and those with contraindications to other methods.

Researchers must clarify the degree of protection offered by existing spermicides, while new active ingredients currently under study may offer greater efficacy and less irritation to the vaginal and penile tissue.

The use of a spermicide alone will not offer as much protection as a condom or a spermicide with a condom, but it may be more useful to some women (and men). Even if moderately effective, spermicides could offer a more significant impact on the incidence of HIV than a more effective but less acceptable method.

"We still do not have answers to whether or to what extent spermicides protect against HIV in actual use, and we need to learn more about their effect on vaginal tissue," says Feldblum. "But spermicides clearly have a place in the family planning community both for contraception and STD control."■

— *Sara Townsend*

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Researchers Studying Frequent Use of N-9

Despite some complaints over the years about local irritation and burning sensation by both men and women when using spermicides, extensive safety testing of spermicides in the past 30 years has shown no harmful effects to users. However, recent research has found that women who use spermicides several times a day can develop genital tract irritation.[1]

A possible link between irritation, ulcers and frequent use of spermicides first surfaced in the late 1980s in anecdotal and unpublished reports. This evidence is now gaining support from a published report on local toxicity of spermicides to female genitalia.

Concerned about potential adverse effects on vaginal and cervical tissue of frequent users of nonoxynol-9 (N-9), the active ingredient in most spermicides today, FHI is conducting a series of studies on this issue. The results thus far indicate irritation can occur but frequency and manner of use greatly affect the risks.

In a 1990 pilot study with the Thai Red Cross Society, FHI researchers instructed 14 women to insert spermicidal suppositories once an hour for four successive hours, each day for two weeks. These women did not have sexual intercourse during the study, washed their genitals one hour after inserting the last suppository for the day, but did not wash between suppositories. Then, each woman was examined with a colposcope, which allows direct observation of the vagina and cervix, for any tissue disruption, bleeding, inflammation and swelling. Six of the 14 spermicide users showed cervical or vaginal tissue ulcers, breaks and bleeding.

"Some evidence of local toxicity is suggested by this research," says Ron Roddy, Associate Medical Director of FHI's Division of Reproductive Epidemiology and Sexually Transmitted Diseases.

A more extensive study of 190 women in the Dominican Republic is intended to evaluate the irritant effect of various doses of N-9 on the genital tract. To determine doses of N-9 that women can safely use, researchers are examining the effects of varying frequencies, from every other day to four times a day.

In another investigation, following 186 women using N-9 under conditions more likely to occur than those in the published pilot study, researchers noted no greater risk for genital ulcers.

"Because most of these women washed their vaginas between sexual partners, the dose of spermicide did not accumulate as it did in the pilot study," explains Roddy. The study found no increase in the rate of genital ulcers among the women who used spermicide frequently, but women using spermicide did report more symptoms of irritation than did the placebo users."[2]

"Theoretically, it is possible that irritation caused by spermicide may increase the risk of HIV among women already at high risk because genital lesions make women more susceptible to infection. But there are no data to confirm this," says Roddy. "We need to learn what a safe dose is. Is it every other day? Every day? At this point, we do not know at what frequency spermicide use may cause ulceration."

Until research establishes the safety of N-9 with regard to frequent use, the potential benefit of spermicides in HIV prevention for women who have sex multiple times per day may not outweigh the potential risks, says Roddy. There is no indication or research to suggest that any of these problems apply to women who use N-9 *infrequently*.

— *Sara Townsend*

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Managing STDs in the AIDS Era

In Burkina Faso, efforts have begun to organize the diagnosis of sexually transmitted diseases (STDs) based on symptoms when expensive laboratory testing is not available. In the Dominican Republic, comic books are helping to explain ways to prevent transmission of these diseases. In Cameroon, pharmacies are preparing to sell treatment kits for male urethritis without requiring a doctor's prescription.

These programs, with funding and technical assistance from FHI/AIDSTECH, reflect the new emphasis in AIDS prevention on managing STDs other than HIV, the AIDS-causing infection. The presence of STDs such as genital ulcers may enhance the transmission of HIV by as much as fiftyfold in a single act of intercourse.

Bacterial STDs such as gonorrhea, chancroid, syphilis and chlamydial infection can be cured. Diagnosis and treatment, as well as prevention, are important goals for controlling bacterial STDs, both as an AIDS-prevention strategy and in their own right. These infections can lead to such reproductive health problems as pelvic inflammatory disease, infertility in women and blindness in children born to infected women. There is no cure available for viral STDs such as HIV, so managing viral STDs depends on prevention.

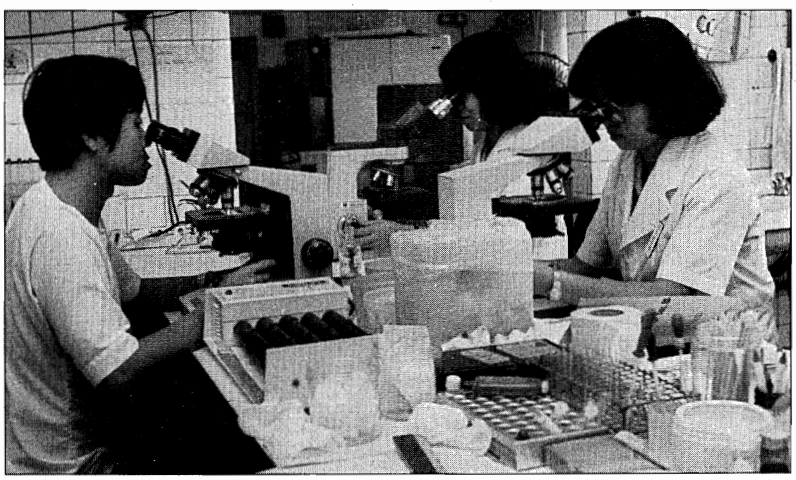
This issue of *network* focuses on strategies to diagnose and treat bacterial STDs as an AIDS-prevention strategy. Articles also describe two innovative ideas for managing STDs, known as mass treatment and social marketing, and important issues related to preventing STDs.

"STD management is much more in the limelight due to HIV," says Dr. Andre Meheus, program manager for STDs at the World Health Organization/Global Programme on AIDS. "Now, due to HIV, resources are there for STD patient management."

The term "STD management" refers to a range of efforts designed to diagnose, treat and prevent sexually transmitted infections. They include the four "c's," a phrase coined by experts including Dr. King Holmes, STD specialist from the University of Washington (U.S.) who is making major contributions to FHI's AIDS prevention programs. The four "c's" are *counseling* patients about behaviors that cause STDs, promoting the use of *condoms*, using antibiotics *correctly*, and notifying and treating sexual *contacts* of the STD patients seeking treatment.

While it is important to focus on treating and preventing STDs as an AIDS-prevention strategy, the fundamental need is to alter sexual behavior that puts people at high risk for HIV transmission.

Dr. Peter Lamptey, FHI vice president for AIDS programs, explains that five broad strategies are needed to manage STDs for AIDS prevention. "These five are the diagnosis and treatment of STDs, behavioral interventions, condom promotion and distribution, intervention-linked STD-related research, and policy reform," he says. "The five must be integrated and are mutually reinforcing." ■



T. Farkas/WHO

What Should You Know About STDs?

Research shows that the presence of sexually transmitted diseases (STDs), especially those causing genital ulcers, may enhance the chance of HIV transmission by as much as fiftyfold in a single act of intercourse.

Chancroid and syphilis are the primary bacterial STDs causing genital ulcers. In most populations, STDs which do not cause genital ulcers – especially chlamydial infection, gonorrhea and trichomoniasis – are much more common than are chancroid and syphilis.

"Data on non-ulcerative STDs and [their relation to] HIV infection are far more limited," reports Dr. Judith Wasserheit of the U.S. Centers for Disease Control.[1] However, if these non-ulcerative STDs are shown to enhance HIV transmission significantly, they could be more important in terms of AIDS prevention.

As studies on STDs and their relationship with HIV increase, so does attention to the management of STDs. "A consensus has emerged that the prevention of sexually transmitted HIV infection, as well as the prevention of the major sequelae of STDs in women and infants, mandate a global initiative for the prevention and control of STDs," explains a report from an interagency group of STD experts led by the U.S. National Institutes of Health.[2]

With such initiatives under way, the once highly technical world of management of STDs is slowly shifting from special treatment and referral centers to primary health-care clinics and health education efforts. This means that health-care workers at the grassroots level now need better information and more practical strategies for controlling STDs.

The range of information is intimidating. The primary STD reference book runs 1115 pages, in 95 chapters.[3] More than 20 pathogens are known to be spread by sexual contact, including 11 bacterial, six viral, three protozoan, one fungal and two ectoparasitic.[4] The recently released World Health Organization (WHO) guidebook, *Management of Patients with Sexually Transmitted Diseases*, describes 15 separate treatment approaches in developing countries at the primary health-care level. These approaches are based on groups of signs and symptoms, known as syndromes, rather than on the causative agents involved.[5]

The so-called "syndrome-based" approach to diagnosis and treatment of STDs is the basis for attempting to treat large numbers of people with limited resources (see article on page 4). Resources do not exist in developing countries to allow for large-scale treatment based on laboratory diagnosis, which determines the causative agent for each person's STD.

Ideally, for a syndrome-based treatment to work, local health-care providers would know which STDs are present in the country or region and how the STDs respond to various treatment regimens. This requires research, ideally from an STD reference center in each country, because few generalizations can be made.

"In East Africa, 50 percent to 70 percent of the genital ulcers are due to chancroid, and 10 percent to 25 percent, to syphilis," explains Dr. Andre Meheus, program manager for sexually transmitted diseases at the World Health Organization's Global Programme on AIDS. "In West Africa, genital ulcer diseases are much less common; about 50 percent is syphilis, maybe 10 percent to 20 percent chancroid. But we don't have good surveillance data that would allow developing countries to have an idea of the amount of sexually transmitted diseases occurring each year."

In many developing countries, STDs rank among the top five diseases for which health-care services are sought. If age-specific consultation rates were available for the age group 15 to 44 years, the most sexually active segment of the population, STDs would probably rank number one or two, explains Dr. Meheus.

Researchers have relied primarily on ad hoc surveys for STD data, often done in family planning or antenatal clinics or within selected groups, such as prostitutes, who practice sexual behaviors likely to transmit STDs. Known as "cross-sectional" or "prevalence" data, this information shows the mixture of various STDs present at a specific point in time.

The prevalence data vary widely, depending upon the country. For example, testing for syphilis at antenatal clinics in 19 developing countries indicated prevalence levels as high as 20 percent in Zaire and 19 percent in Tanzania. The prevalence of syphilis among prostitutes ranged from 31 percent in Kenya to 71 percent in The Gambia.[6]

"Syphilis, which causes genital ulcers, can be easily treated with benzathine penicillin," says Dr. David Sokal, epidemiologist at FHI's AIDSTECH Division. "Other antibiotics may be used for those allergic to penicillin. Gonorrhea and chancroid can also be

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treated with antibiotics."

Increasingly, however, gonorrheal strains are resistant to penicillin-based antibiotics; from 30 percent to 70 percent of strains are resistant in many African and Asian countries. In Nigeria, for example, the portion of gonorrhea cases caused by resistant strains increased from none to 70 percent in just five years.[7] Chancroid is also becoming more difficult to treat, especially in HIV-positive patients.

Meanwhile, a newer group of causative agents, known as the second generation of STDs, has been identified over the last 10 to 20 years. These are much more difficult to diagnose, especially in women, and include chlamydial infection and viral infections such as HIV and herpes. Viral agents currently cannot be cured with drug treatments.

— *William R. Finger*

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Condoms Prevent HIV Transmission

Condoms are very effective in preventing HIV transmission, according to an FHI analysis of studies involving couples who continued having sex even after one partner had contracted the HIV infection.

One of every four partners contracted HIV from their mates among couples not using condoms while only one of every 40 became infected among couples who used condoms regularly, according to an analysis by Paul Feldblum of FHI's Division of Reproductive Epidemiology and STDs. His assessment of the studies was published in the October 1991 issue of *AIDS*, a medical journal.

"The most notable finding of these prospective couples studies is the consistency of protection among condom users," Feldblum wrote. "Condom use is believed to be the most effective prophylactic measure to prevent sexual acquisition of HIV, and that assertion seems borne out by these data."

Feldblum cited five studies published since 1987 that provide separate HIV cumulative incidences for condom-using couples and non-users. In four of the five studies, not one infection was transmitted among condom-using couples. In one study, no transmissions occurred irrespective of condom use.

In addition, unpublished data from the University Teaching Hospital in Lusaka, Zambia, show an HIV-infection rate of 3.5 per 100 couple-years among couples who reported using condoms at every intercourse. Among less consistent condom users, the infection rate was 10.1 per 100.

Pooling data from the five studies and the unpublished data from the Zambia study shows four new infections among 172 condom-using couples (2.3 percent). For couples not using condoms regularly, there were 37 new infections among 145 couples (25.5 percent).

The available data had limited interpretive value, Feldblum says. For example, the studies were generally small, prohibiting complex analysis. Consistency of condom use was not well-defined and the follow-up period was variable, often of short duration.

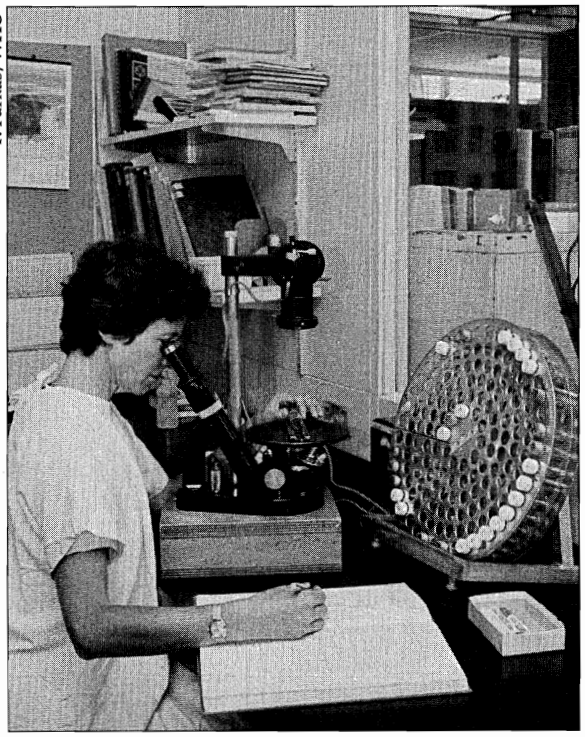
Also, the couples studied came from diverse backgrounds. Some were African, whose only known risk behavior was heterosexual intercourse. Others were European, of whom some HIV-positive partners were exposed to a number of high-risk behaviors. ■

For a copy of the article described here, please write to the Publications Assistant, FHI, and request reprint number 91-36.

Treating STD Syndromes Gains New Attention

A 29-year-old taxi driver had hoped the yellow and orange capsules from the street vendor's jar would help his problem. But now he sits waiting to see the nurse at a clinic in Bobo Dioulasso, the second-largest city in Burkina Faso. The situation is typical in this West African city. The man's name might be Mamadou.

Like most persons with sexually transmitted diseases (STDs) in the developing world, Mamadou is seeking formal health care only as a last resort. Usually, people first try herbs and topical ointments from traditional healers or antibiotics from street vendors or pharmacies. Often the drugs are not correct for the infection, are already expired or are sold in too small a dose. The outcome is often no better at local health clinics in many developing countries which, with some notable exceptions, lack laboratory facilities, effective drugs and staff trained to manage STD patients.



T. Farkas/WHO

This laboratory in Australia produces drugs for treating STDs.

Like thousands more men and women in Burkina Faso, however, Mamadou now has a better chance of getting his STD correctly treated. Health-care providers in public and private-sector clinics will be trained to manage STD patients in Bobo Dioulasso based on groups of signs and symptoms, called syndromes. A regional center for public health research and training, the Centre Muraz, is coordinating the project in conjunction with FHI's AIDSTECH Division and with funds from the U.S. Agency for International Development.

The terms used in connection with the Burkina Faso project include "syndrome-based" and "patient management." The flowchart that guides diagnosis and treatment has various names as well, including "algorithm." The flowcharts for syndromes that are relatively easy to diagnose, such as urethral discharge in men, are easy to follow with little training.

"It is almost misleading to call them algorithms," says Dr. King Holmes, director of the University of Washington (U.S.) Center for AIDS and STD and a leading writer and adviser on STDs worldwide. "Treatment plans need to be so simple that a health worker with no training in STDs can recognize the syndrome and treat it."

The Burkina Faso project reflects a growing interest around the world in using a syndrome-based treatment approach. Countries as diverse as Kenya, Thailand and St. Lucia are at various stages of considering this approach, and a few — notably Zambia and Zimbabwe — have been working with it for nearly a decade.

In the late 1970s, the World Health Organization (WHO) began field testing this approach to STD treatment but met resistance. "Some specialists in the medical community felt that using simplified treatment strategies without a laboratory would lower patient management standards," explains Dr. Andre Meheus, Program Manager for STDs at the WHO's Global Programme on AIDS (WHO/GPA).

Another criticism of syndrome-based treatment surfaced as well. "Many countries didn't want to go into it because they would have to say, 'Who is going to supply the drugs?' It was a period of very low resources for STDs, and a systematic approach to patient management would quickly create the demand for better services," adds Dr. Meheus. "No government could answer that demand. But this has changed with HIV. There are more resources around."

Syndromes Determine Treatments

"The cornerstone of STD control must be adequate management of STD patients," says Dr. Franklyn Judson, director of Denver Public Health and Hospitals in Denver, Colorado (U.S.) who recently worked with the STD program at WHO/GPA. "Having standardized treatment plans based on syndromes allows STD patients to be managed effectively by nonspecialist clinicians who have little or no access to laboratory diagnostic tests."

Dr. Judson worked with the WHO Study Group that produced the recently published STD management guidelines. The heart of the publication is entitled "STD Management Protocols at the PHC [Primary Health Care] Level." It describes syndromes and treatment strategies and includes flowcharts designed for different levels of clinic and laboratory sophistication, ranging from sim-

ple two-step plans to detailed algorithms. The guidelines emphasize integrating STD services into primary care clinics.

In settings with no laboratory facilities, flowcharts are particularly useful for two syndromes: urethral discharge in men and genital ulcer disease in men and women. For urethral discharge, patients are treated for gonorrhea and/or chlamydial infection. For genital ulcer disease, they are treated for syphilis and/or chancroid. Even in such clinics, knowing the prevalence of STDs provides more precise diagnosis as well as cost-effective treatment, as the project in Burkina Faso illustrates.

At the clinic, Mamadou reported pus dripping from his penis and a burning sensation when he urinated, classic symptoms for urethritis. Research in this project has shown gonorrhea strains resistant to penicillin to cause most urethral discharge. Chlamydial infection is not currently common among male STD patients attending the clinics in Bobo Dioulasso. Hence, the nurse would likely recommend a single injection of ceftriaxone, an antibiotic effective against such gonococcal strains.

Following the flowchart's instructions, the nurse would tell Mamadou to return in three to five days if his symptoms persisted. If he did return with symptoms, the nurse would then treat for chlamydial infection, another possible cause of urethral discharge syndrome. If resources permitted, the nurse would have treated initially for both gonorrhea and chlamydial infection, with the injection of ceftriaxone and a seven-day oral course of doxycycline.

While the local etiology – or cause – of the syndrome adds valuable knowledge in refining a general flowchart, general information may be sufficient. "The value of this approach is that we can treat STDs now," says Dr. Holmes. "We have enough prevalence information for effective syndrome-based diagnosis now. There isn't time to fine-tune these flowcharts before we start using them."

In settings where some laboratory tests are available, treatment can be more specific and less expensive. For genital ulcer disease, the patient could be treated for chancroid rather than both syphilis and chancroid, for instance, if a special syphilis microscope test were negative. For urethral discharge, the patient could be treated for non-gonococcal urethritis, rather than both gonorrhea and chlamydial infection, if a Gram stain were negative.

This treatment approach appears to be far less effective for treating STDs in women, particularly vaginal discharge syndrome, because of the wide range of possible infections. Women complaining of abnormal vaginal discharge, for example, could be suffering from at least one of five common infections: cervical infections such as gonorrhea and chlamydial infection as well as vaginal infections such as trichomoniasis, bacterial vaginosis or candidiasis.

"There is no substitute for at least elementary laboratory testing to manage STDs in women adequately," says Dr. Judson. "Without laboratory tests, flowcharts for vaginal discharge are not cost-effective and can lead to bad medicine."

However, laboratory facilities are usually not available in primary health-care clinics in most developing countries. Hence, Kenya has prepared a flowchart for vaginal discharge designed for such clinics. Based on the appearance of the discharge, the flowchart recommends treating initially for candidiasis or candidiasis plus trichomoniasis, and if the infection persists, for gonorrhea and chlamydial infection. If a woman still does not respond, she is then referred to an STD clinic, which has more diagnostic capacity.

The flowcharts might vary, even in the same geographical area, depending upon the population being served. For example, the flowchart for vaginal discharge might be altered for use among groups where there are high prevalence levels of gonorrhea and chlamydial infection, such as prostitutes.

The quality and availability of such referral clinics depend upon the level of commitment to a national STD control program, which is essential for widespread use of syndrome-based diagnoses, says Dr. Holmes. In addition to district-level STD clinics with some laboratory diagnostic capacity and trained staff, a country should have an STD referral center, usually in the largest city at a major teaching hospital. That center would treat people whose cases have not responded to treatment at smaller hospitals and primary care clinics, provide training in STD management, and conduct STD research and prevalence studies that could be used for periodic revisions of flowcharts used at the local level.

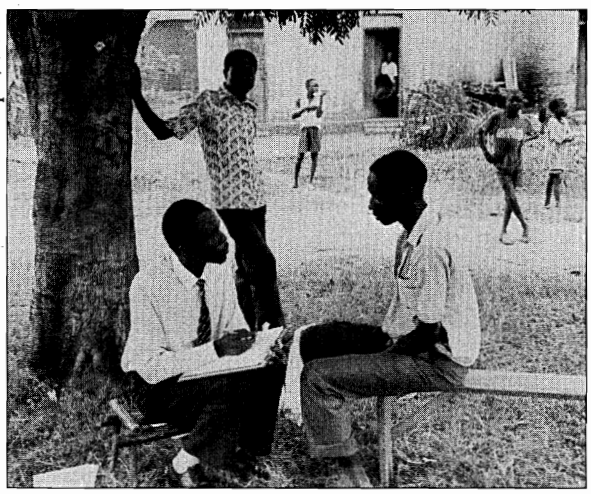
The experience of Zambia, in Central Africa, illustrates how this overall system can work. With scarce resources and an STD problem of huge proportions in the early 1980s, Zambia launched a comprehensive STD control program with a syndrome-based treatment plan and a national system of STD referral clinics at district hospitals.

"This simple treatment approach has decreased the STD reservoir in Zambia," says Dr. Subhash Hira, director of the National STD Control Program in Zambia, currently on leave. "More STD cases are being

"The value of this approach is that we can treat STDs now."

treated at an early stage and more are being cured at primary care clinics."

Updating flowcharts tracks a program's success, allows more effective treatment and streamlines costs. The flowcharts used in Zambia have been revised several times as the proportion of penicillin-resistant gonorrhea changed. From a high of about 55 percent in the mid-1980s, the proportion dropped to 30 percent by 1990 as a result of flowchart recommendations for the use of other antibiotics against the resistant strains, according to Dr. Hira. As penicillin-resistant strains decrease, it may eventually be possible to return to the use of less expensive antibiotics.



E. Hooper/WHO

Learning about people's concerns about AIDS is an important step in planning AIDS-prevention efforts.

Even at clinics with access to laboratory testing, the scarcity of drugs is a major obstacle to STD treatment in the developing world. The spread of resistant strains of STD organisms has made the most common drugs useless, and many of the newer drugs are prohibitively expensive. However, ensuring a steady supply of effective antibiotics to areas of the world where they are needed is crucial to STD control. "It is a particularly bad situation in Africa," says Dr. Meheus of WHO/GPA. "Without drugs, the best algorithm becomes a theoretical proposition."

As Dr. Holmes puts it, "There is no point in training clinicians to be accurate marksmen if you're not going to give them any ammunition."

Moving Beyond Treatment of Syndromes

National STD control programs have other challenges that go beyond diagnosis and treatment systems. "Patient management involves a comprehensive system, based on a systematic approach to the problem," says Dr. Meheus. "This includes counseling the patient on STDs and HIV. Also, you must introduce the idea of partner notification." This term refers to contacting the sexual partners of the patient treated. Usually, this involves having the patient notify his or her sexual partners of the infection and encourage the partners to seek treatment.

STD experts have begun to refer to these additional aspects of an STD control program with the phrase, the "four c's," coined by experts including Dr. Holmes. The four c's refer to: *counseling* patients about behaviors that cause STDs, promoting the use of *condoms*, encouraging the treatment of sexual partners of infected persons through *contact* tracing, and promoting *correct* use of antibiotics (or *compliance*).

Another important aspect of STD control is the need to develop better clinical facilities, as discussed in the article on page 8. "In the long run, the health system's infrastructure needs to be strengthened," says Dr. Doris Mugrditchian, STD specialist at AIDSTECH. "But upgrading STD services takes time and enormous financial and human investment." Zambia, for example, has taken more than a decade to develop its basic STD service network, which is now adding to its emphasis on treatment the important elements of preventive education, counseling and condom distribution.

In addition to the "four c's" and developing an STD treatment infrastructure, Dr. Meheus and others point out that countries must at least attempt the more difficult step of outreach for people with asymptomatic STDs. Without serious symptoms, many men and women will not seek treatment. The best ways to identify such infected persons routinely is through partner notification and screening of selected population groups. Screening could be done at clinics for pregnant women or among groups practicing behaviors with a high risk of STD transmission, such as prostitutes and their clients.

The current strategies for controlling the spread of AIDS provide opportunities for tackling the long-standing STD management problem. Various approaches can be used simultaneously for a problem of this magnitude.

"At the rate at which the AIDS epidemic is raging through the developing world, we cannot afford to wait for 6 to 10 years for the establishment of a functional STD infrastructure," says Dr. Mugrditchian of AIDSTECH. "While long-term efforts are needed to strengthen STD management, from primary health clinics to central referral hospitals, innovative approaches might also help. Two such efforts that can draw on syndrome-based treatment are social marketing of STD treatments and mass treatment of STDs." (See articles on pages 14 and 12.)

— *Sara Townsend*

Using Syndrome-Based STD Treatment

When physicians, nurses and pharmacists from eastern Caribbean islands met recently to discuss sexually transmitted diseases (STDs), they examined the merits of treating STDs based upon a patient's symptoms. Symptoms are grouped into treatment categories called "clinical syndromes."

FHI's AIDSTECH co-sponsored the seminars in St. Lucia and Dominica, along with each country's Ministry of Health and the Caribbean Epidemiology Center. AIDSTECH has since encouraged several island nations to consider adopting the approach as one way to expand treatment without the expensive burden of diagnostic laboratory testing.

In a syndrome-based treatment, health workers rely on directions called a "flowchart" or "algorithm." These are based on the prevalence of STDs in the area where the flowchart is used. Chlamydial infection and gonorrhea, prevalent STDs in the eastern Caribbean, are considered likely targets for syndrome-based treatment in these areas.

AIDSTECH is also planning to train health workers in Guatemala in this treatment approach, as part of a broader effort to upgrade STD management in conjunction with the Guatemalan Association of Family Welfare.

Syndrome-based treatment is already being used in Kenya, where health-care workers use a one-page management sheet to diagnose and treat patients. The sheet summarizes treatments for four syndromes: genital ulcer disease in men and women, urethral discharge in men, vaginal discharge in women and lower abdominal pain in women. It also contains guidelines for patient counseling, partner notification and treatment, record keeping and basic drug dosages.

The Kenyan Ministry of Health, in collaboration with the University of Nairobi Medical School, developed the treatment approach with technical assistance from the University of Manitoba, Canada, and the Government of Belgium.

The flowcharts were developed with data gathered at a central STD treatment center in Nairobi, the capital of Kenya. "We know [from the data] that in men with urethral discharge, about 60 percent is caused by gonorrhea and 10 percent to 15 percent by chlamydia," says Dr. Stephen Moses, director of the University of Manitoba team. "We also know that more than half of the gonorrhea is resistant to penicillin alone."

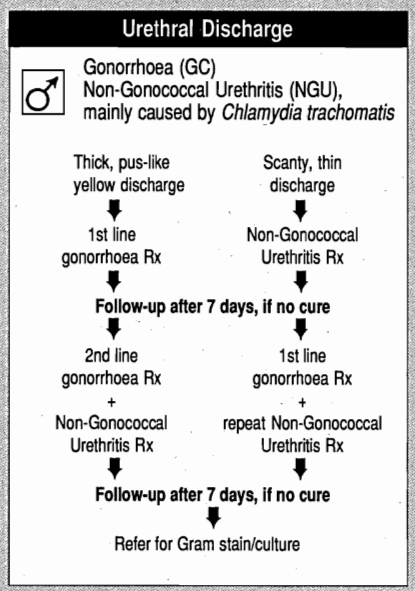
The flowchart for urethral discharge (shown below) is based on this data. Men with thick, copious urethral discharge are likely to have gonorrhea.

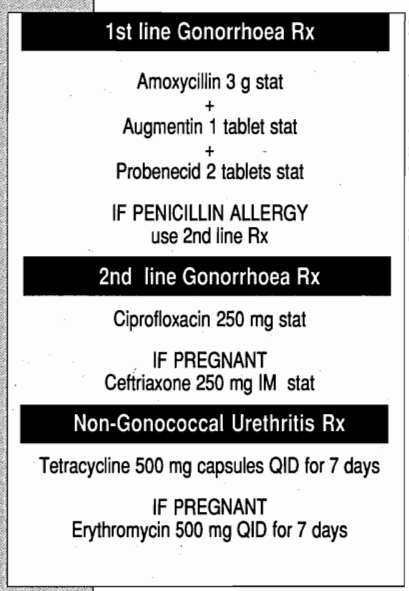
The flowchart recommends that all men with this symptom receive amoxycillin, a penicillin-based drug; Augmentin, whose active ingredient, clavulanic acid, makes the resistant gonococcal organism sensitive to penicillin; and probenecid, which makes the amoxycillin last longer in the bloodstream. While the treatment may seem cumbersome, says Dr. Moses, it is the cheapest effective regimen for penicillin-resistant gonorrhea. It is a one-time treatment.

Since the flowchart approach was introduced into three Nairobi clinics in 1991, 1,500 patients per month have been treated for STDs. The project also serves patients in the western Kenyan town of Nakuru and may soon expand to other clinics in the country.

"These algorithms could be used anywhere in Kenya where there is a health worker," says Dr. Moses.

— *William R. Finger*





Kenyan Ministry of Health

In primary health-care clinics in Kenya, health-care workers are using the flowchart above, left, to diagnose urethral discharge in men. The treatment regimens used with the flowchart appear at right.

Primary Elements for STD Clinical Treatment

Health professionals need four basic elements to treat people with sexually transmitted diseases (STDs): diagnostic tools, training, well-run clinics and antibiotics.

In many countries, primary health-care (PHC) centers, which see all types of patients, are expected to provide initial preventive and curative services for STDs. "Ten percent or more of their daily workload may be related to STDs and their complications," explains the latest report from the World Health Organization (WHO) on STD management. "However, diagnostic facilities at the PHC level are often either limited (microscopes only) or nonexistent."[1] Ideally, primary health clinics can refer patients if necessary to a network of STD clinics with laboratory support and staff trained in STD diagnosis.

Diagnostic Tools. Primary care clinics ideally need tables for pelvic examinations, lamps, reliable supplies of water and electricity, instruments such as specula for pelvic exams, sterilization equipment, gloves, microscopes that work and blood-taking equipment. Physical examination of women, for example, helps distinguish among several vaginal infections. If a pelvic examination with a speculum is possible, one can better decide whether a vaginal discharge is caused by a vaginal infection such as trichomoniasis or a cervical infection such as gonorrhea.

W. Stone/WHO

Primary health care clinics, such as this one in Tanzania, provide important STD control services.

WHO recommends that these clinics be able to perform two simple microscopic tests. One, a "wet-mount" test, places a sample of vaginal or urethral discharge on a glass slide with a solution of sodium chloride (salt). The other, a Gram stain, uses blue and red dyes as reagents for staining a sample on a slide. These tests are possible even in rural areas without a reliable source of electricity for incubators or refrigerators. A Gram stain can detect gonorrhea in men, which reduces the uncertainty of a syndrome-based treatment. A wet-mount can diagnose trichomoniasis, candidiasis or bacterial vaginosis in women.

Syndrome-based treatments, which can function without microscopes, are now being used in primary care clinics in Kenya (see article, page 7). "We would be more accurate in our diagnosis if we had Gram stains available, and where feasible, they should be introduced," says Dr. Stephen Moses, who works with the Kenya project. "But the reality is that in most places in Africa, it could be a long time before this will happen."

Questions of diagnostic capacity become more complex when moving from primary health centers to district STD referral clinics, often based in hospitals. One country that has worked to introduce microscopes to its system of STD referral clinics is Zambia. Each of the 45 regional government STD clinics nationwide now can perform basic laboratory tests, says Dr. Subhash Hira, who directed these efforts. "Now they can diagnose more precisely and more accurately."

More sophisticated laboratory tests are needed to detect gonorrhea and chlamydial infection in women, as these infections are often asymptomatic. Yet, ideally, a diagnosis needs to be made during the patient's first clinic visit. Learning the results of more complicated diagnostic tests requires a return visit, never made by many patients. The basic technology is available for on-the-spot diagnosis of chlamydial infection and gonorrhea, but the high cost of such tests (US $4 to $7 per person) limits their use in settings with scarce resources.

In 1990, an international "STD Diagnostics Initiative" was formed to develop and evaluate new technologies that would be appropriate for use in resource-limited settings. These diagnostics need to be inexpensive, yield results before the patient leaves the clinic, have a long shelf-life and require no refrigeration. Tests for cervical infections (gonorrhea and chlamydial infection) are a top priority for this group. Other major priorities include simplification of methods for syphilis serology and diagnostics for genital ulcer disease. The Initiative has resulted, for example, in a coordinated effort by WHO, the U.S. Centers for Disease Control and the Program for Appropriate Technology in Health to evaluate and field-test kits for di-

agnosis of chlamydial infection.

Training. Effective STD patient management requires clinic staff trained in a variety of skills, from STD clinical diagnosis to counseling about condoms and partner notification.

As with diagnostic capacity, the level of expertise required for STD clinic staff varies with the type of clinic. At primary care clinics in Nairobi, Kenya, for example, health-care providers receive just two days of training on how to read syndrome-based treatment charts, with in-service training on a periodic basis. Two thousand kilometers south in Lusaka, the Zambian government focuses its limited resources on creating a cadre of skilled trainers at the district hospital level who can subsequently train health-care workers at the primary care level. Clinicians at the district hospital level spend three months training at the national STD center in Lusaka.

Increased attention to STD treatment has also generated plans for more training in Latin America. In Haiti, the Pan American Health Organization (PAHO) AIDS control project, affiliated with WHO, had plans for a two-week training program for doctors, nurses and labor technicians in syndrome-based treatment until political unrest forced its delay in 1991.

The Guatemalan Association of Family Welfare (APROFAM) plans to strengthen STD services at its STD treatment, family planning, prenatal and adolescent clinics, all in Guatemala City. With assistance from FHI/AIDSTECH, clinical and laboratory staff were trained in a four-day workshop in such tests as wet mounts, Gram stains, more complex microscopy for syphilis, gonorrhea culture tests and rapid tests for chlamydial infection. They will also learn to use STD syndrome treatment flowcharts and conduct physical examinations, with ongoing updates on local STD prevalence, diagnostic techniques and drug treatment regimens.

Well-run Clinics. In addition to trained clinicians, effective clinics need staff trained in program administration. "Deficiencies in management are a major reason for ineffective programs," says Dr. Doris Mugrditchian, STD specialist for AIDSTECH, working closely with STD projects in Africa and Central America. "There is a need for trained program managers who can plan and implement activities, including procurement, storage and distribution of condoms, drugs and STD diagnostic materials."

Upgrading STD care, whether through special STD clinics or primary health centers, also involves improving the facility itself. In the past decade, FHI has examined STD clinics around the world to identify factors that contribute to effective STD patient management.

STD care often can be improved significantly with minimal changes in clinic operations, explains Ron Roddy, associate medical director of FHI's Division of Reproductive Epidemiology and Sexually Transmitted Diseases, who has assessed clinics in seven countries. Below is a checklist FHI researchers use to assess how well these facilities operate:

- convenient location,
- clearly displayed signs directing patients to the clinic,
- convenient operating hours for persons likely to use the clinic, including evening hours,
- privacy while waiting and during intake and examination,
- comfortable waiting areas, which are supplied with STD educational materials, and
- patient flow requiring minimal waiting time and allowing efficient use of existing staff resources.

"These operational criteria, while not unique to STD clinic services, are particularly relevant to STD services because of the social stigma often attached to STD problems and patients," explains Roddy.

Antibiotics. Recommending the right type and dosage of a drug is crucial because inappropriate dosages can often increase the resistance of some STDs, particularly gonorrhea and chancroid, to traditional treatments. WHO guidelines call a drug effective if it cures a particular infection in 95 out of 100 cases. In many developing countries, STD clinics provide free diagnosis and drugs, but clinics often run out of supplies of effective drugs.

The principal obstacle to availability of effective drugs is cost. New drugs are continually being developed but are not affordable to most of the world. For example, the U.S. Food and Drug Administration recently approved the first single-dose oral treatment for chlamydial infection, called azythromycin.

Treating chlamydial infection is difficult. Currently, the recommended treatment is a seven-day regimen of either tetracycline (four times a day) or doxycycline (twice a day). These cumbersome dosages are not conducive to patient compliance and are not recommended for pregnant women. Furthermore, the simpler of the two, doxycycline, is not available in generic form in many developing countries, which makes it prohibitively expensive.

Azythromycin could help with treating chlamydial infection, and it can also be used as a single-dose treatment for chancroid. Yet it may be too expensive for public clinics to stock — even though reducing the prevalence of chancroid may be one of the most effective measures that a country could take to reduce the rate of HIV transmission.

Drugs for gonorrhea pose another significant problem because of the rapid increase in strains resistant to many antibiotics. "Inexpensive oral antibiotics able to cure gonorrhea caused by multiresistant strains when given in a single dose are urgently needed, and may become available," wrote Dr. Mead Over of The World Bank and Dr. Peter Piot of the Institute of Tropical Medicine in Antwerp.[2]

"Today," says Dr. Mugrditchian, "an injectable antibiotic such as ceftriaxone or spectinomycin may be the recommended treatment for gonorrhea, but we hope that these can be replaced by newer drugs such as cefixime that are just as effective, safe during pregnancy, cost less and can be taken orally."

Cost and availability are constantly changing and vary widely, so decisions about flowchart recommendations and procurements of particular drugs must be made nationally or even locally. In Singapore and Bangkok, for example, kanamycin is cheaper than spectinomycin. In Africa, the reverse may be true.

In light of cost, many health authorities reserve some drugs for the referral hospitals and provide the primary care clinics only with penicillin for gonorrhea. But when the prevalence of strains resistant to penicillin is high, this leads to high treatment failure rates and gives clinic care a bad reputation.

Leading STD experts are concerned about the cost and availability of drugs. Ideas for addressing the problem include international donor agencies supplying some portion of the drugs and various cost-recovery methods.

"Donors now realize that with HIV around, they will have to come up with at

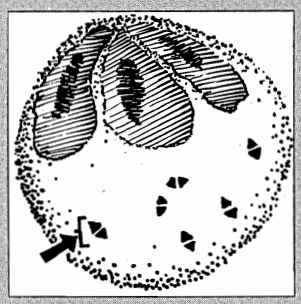
Drawings by Lance Kozlowski

Five Common STDs That Can Be Cured

More than 20 organisms are transmitted through sexual contact. Below are the five most common sexually transmitted diseases that can be cured with antibiotics. The Latin names are the causative agents; all of those shown below are bacteria except *Trichomonas vaginalis*, which is a protozoan.

Chancroid, *Hemophilus ducreyi*, usually causes a painful, purulent grey ulcer or ulcers located on the external genitals and sometimes enlarged lymph nodes in the groin (called bubos). Ulcers may also be severely eroded with a ragged border and bleed easily when handled. The bubo may rupture in many cases. Diagnosis rests primarily on clinical features. Dark-field microscopy or blood tests to eliminate the possibility of syphilis are useful. Definitive diagnosis requires culture. Resistance to the traditional drug treatments — tetracyclines and sulphonamides — is growing, but ceftriaxone, erythromycin, ciprofloxacin and a new drug named azythromycin are effective in many areas.

Chlamydial infection, *Chlamydia trachomatis*, produces symptoms similar to gonorrhea. In men, it is the most common cause of nongonococcal urethritis. Men may have a thin, watery urethral discharge, dysuria (pain when urinating) or painful swelling in the testicles. Women have fewer symptoms but may have unusual vaginal discharge, dysuria or lower abdominal pain. If left untreated, it can damage reproductive organs, causing chronic pain, infertility, sterility and an increased risk of ectopic pregnancy. Chlamydial infection is asymptomatic in 75 percent of infected women and 25 percent of infected men. Reliable diagnostic tests exist but often are not available. On exam, the cervix may appear red and bleed easily. Another chlamydial infection is *Lymphogranuloma venereum* (LGV), a disease causing genital ulcers and swollen lymph nodes (bubos). Chlamydial urethritis and cervicitis are treated with a seven-day regimen of tetracycline, doxycycline, erythromycin or a sulfa drug, while LGV requires 14 days of treatment. Azythromycin, a newly developed relative of erythromycin, was licensed recently in the United States as a single-dose treatment.



Gonorrhea, *Neisseria gonorrhoeae*, usually produces symptoms in men such as dysuria and purulent (containing pus) urethral discharge. Gonorrhea may cause abnormal vaginal discharge, dysuria, and lower abdominal pain in women. About 70 percent of women and 10 percent of men will not report symptoms when infected with gonorrhea. Untreated infection can lead to pelvic inflammatory disease, infertility, increased risk of ectopic pregnancy, sterility, arthritis, and heart problems. Diagnosis can be made by

least a start towards providing drugs," says Dr. Andre Meheus, program manager for STDs, WHO/Global Programme on AIDS. "I've seen this change in the last several years. Donors should not provide all of the drugs, of course. We need to have sustainable programs."

Dr. King Holmes, a leading writer and adviser on STDs worldwide, suggests a combination of donor support and national funding is necessary for subsidizing drug treatment. "As with contraceptive programs, donor support is the only way to provide enough funding initially," he says. "But I don't agree with the common perception that supplying drugs will be like trying to fill a bottomless pit."

Providers do not have to create a market for STD treatments. "People are highly motivated to pay for getting well. The subsidy is needed to make the drugs affordable to the average person," says Dr. Holmes. He suggests providing free treatment for sexual partners of STD patients because they often are asymptomatic and perhaps less motivated to pay.

Conclusion

It is important to keep in mind that treatment of an STD infection is part of the larger goal of STD control. While the clinical treatment system depends on diagnostic tools, adequate training, well-run clinics and adequate supplies of appropriate antibiotics, the larger goal also includes testing for STDs in settings such as antenatal clinics, counseling about sexual behaviors, encouraging condom use and notifying partners of persons infected with an STD.

— Sara Townsend

Footnotes

1. *Management of Patients with Sexually Transmitted Diseases*. Report of a WHO Study Group, WHO Technical Report Series. 1991; No. 810: p. 3.

2. M Over, P Piot. HIV Infection and Sexually Transmitted Diseases. Forthcoming in DT Jamison and WH Mosley (eds), *Disease Control Priorities in Developing Countries*. New York: Oxford University Press for the World Bank. 1991; p. 50, review copy.

microscopic examination of a Gram- stained specimen of urethral or endocervical discharge. Gram stain diagnosis is effective in men, but culture of cervical discharge is a much more reliable way of diagnosing gonorrheal infection in women.

Penicillin is no longer the drug of choice for gonorrhea infection because strains of gonorrhea resistant to penicillin have become common. Recommended therapies include ceftriaxone, ciprofloxacin, spectinomycin, kanamycin and thiamphenicol.

Syphilis, *Treponema pallidum*, is a spiral-shaped bacteria that causes disease in three stages. Primary (first stage) syphilis usually involves a painless genital ulcer (chancre) and enlarged lymph nodes near the site of infection. Women may not notice the ulcer if it is in the vagina or on the cervix, and men may not notice the ulcer if it is covered by the foreskin. This may be followed months later by symptoms of secondary syphilis (second stage), a non-itchy body rash, wart-like growths in moist areas and enlarged lymph nodes at several different areas. Both primary and secondary symptoms disappear in several weeks without treatment. Untreated syphilis in pregnant women is a common cause of stillbirths in many developing countries. Tertiary syphilis (third stage), which occurs in about 25 percent of untreated cases, is an often fatal progression that may involve the heart and brain. Syphilis can be diagnosed when a sample from a primary or secondary sore is examined under a dark-field microscope or when a blood test shows the presence of syphilis. Long-acting penicillin (benzathine penicillin) remains the treatment of choice.

Trichomoniasis, *Trichomonas vaginalis*, usually causes a vaginal discharge and itching of the vagina and vulva. In men, it produces few symptoms, but may inflame the urethra and cause a watery white discharge. Many women and most men have no symptoms. Diagnosis is made by microscopic examination of a drop of saline mixed with the discharge (wet mount). It is treated with metronidazole, but a few strains have shown resistance to this drug.

– Ron Roddy and Sara Townsend

Ron Roddy is associate medical director of FHI's Division of Reproductive Epidemiology and Sexually Transmitted Diseases

Can "Mass Treatment" Work with STDs?

A promising yet little-used medical strategy for containing sexually transmitted diseases (STDs) borrows from the detective's formula of rounding up the key suspects.

Treatment is given to everyone within a group likely to be infected, whether a person shows symptoms or not. The approach goes by different names that underscore the variations in approach: mass treatment, selective periodic treatment and rapid STD reduction. It has been used in only a handful of sites around the world. Treating rural people in tropical climates for yaws and farm workers in the United States for syphilis are among the few examples within recent decades.

Treating everyone within a targeted population raises important issues to evaluate carefully. Would the strategy provide lasting results? Would it be cost-effective? Would it avoid intolerable side-effects?

"The major constraint in the past has been intellectual," says Dr. Francis A. Plummer of the Department of Medical Microbiology, University of Manitoba, Canada. "This idea goes, to a large extent, counter to much of the training in clinical medicine. You're not treating a disease. You're treating more according to demographics."

Treating prostitutes on a regular basis, for example, may be an effective way of curtailing some STDs, Plummer and his associates concluded from their 1981-82 studies in Nairobi, Kenya. They found that prostitutes play a key role in transmitting gonococcal infections in this African city.[1]

B. Wolff/U.N.

Marketplace in Lomé, Togo.

Some diseases may be more viable targets than others in this approach to STD treatment. "For chancroid, which has the most to do with enhanced HIV transmission, you could probably eradicate it with this approach," says Dr. Plummer. Chancroid seems to enhance HIV transmission because the genital ulcers caused by the disease provide a pathway for the AIDS virus.

Dr. David Sokal, epidemiologist at FHI's AIDSTECH Division, agrees that mass treatment might offer an effective way of controlling chancroid. "Give it a big kick within a defined geographic area, and chancroid might just go away," Dr. Sokal says. He chaired a workshop on such treatment strategies during a 1991 international research conference in the United States.

Mass treatment campaigns are rare, but not new. The World Health Organization (WHO) and United Nations Children's Fund (UNICEF) waged global campaigns between 1952 and 1969 against yaws, a once-common skin disease caused by the spiral-shaped bacterium *Treponema pertenue*. Treating 50 million infected people in 45 countries with single doses of penicillin nearly eradicated the disease, although it has resurfaced in recent years.[2]

"The idea was that if we treated everybody, moving on a systematic basis from village to village, we would reduce the reservoir of infected people" until the disease was virtually conquered, said Dr. Peter L. Perine, a tropical disease expert at Uniformed Services University of the Health Sciences in Maryland (U.S.), who took part in the treatment campaigns.

It was an expensive project, financed by the countries involved and assisted with U.S. $7 million in supplies and technical assistance from WHO and UNICEF.[3] Dr. Perine believes the cost was justified in many ways, even when strictly viewed as a monetary investment. "People simply couldn't plant their fields or harvest their crops, it was so bad," he says. While rarely fatal, the disease produced debilitating lesions on hands and feet, sometimes crippling its victims.

Another successful campaign focused upon a few hundred California (U.S.) migrant farm workers and prostitutes during 1976 and 1977, resulting in a 27 percent decline in reported syphilis among the farm workers and a 51 percent decline among prostitutes from one year to the next. Fewer cases were reported despite more diligent efforts during the second year to locate infected people.[4]

But a small-scale mass treatment effort had mixed results in treating people for gonorrhea during the 1960s in southern Greenland. At issue was whether the treatment provided lasting results. Gonorrhea declined considerably during the years of the Greenland campaign — 10 percent of all people examined at the beginning of one effort had the disease, for example, while only 1 percent were infected six months later. Anyone in south coastal towns and settlements who had been treated for gonorrhea within recent months was required to take penicillin and probenecid, while all unmarried people between 15 and 30 were urged to receive treatment. The beneficial effects, however, seemed to fade soon after the program ended in 1968.[5]

"This is one of the two biggest questions: Is this going to have any real, long-term effectiveness?" says Dr. John S. Moran of the Division of STD/HIV Prevention, U.S. Centers for Disease Control. Mass treatment in Greenland did reduce gonorrhea levels, he acknowledges, "but for less than a year."

The other big issue in Dr. Moran's mind is cost. For treating chancroid, a single injection of the drug ceftriaxone may cost more than U.S. $7, he notes. It is difficult enough to get money for drugs to treat people whose illness has been verified, says Dr. Moran.

Yet another factor worthy of scrutiny, Moran and others say, is the side effects of a mass treatment approach. The drugs themselves can have side effects, and widespread use of drugs could lead to more drug-resistant forms of a disease. Use of antibiotics can also mean an increased susceptibility to other infections.

For Dr. King Holmes, a University of Washington expert in sexually transmitted diseases, the treatment's name carries important distinctions about how the procedure is carried out.

The term "mass treatment," he says, suggests that everyone within a targeted population would be treated at the same time. Actual campaigns would more likely treat individuals at different times and more than once.

"The term I prefer is selective periodic treatment, which means providing treatment on a periodic basis selectively to those members of a population who have a high prevalence of STD and are frequent transmitters of STD. And it may be selective, too, in selecting only some of the STDs to treat," he says.

Administering penicillin at regular intervals to groups of prostitutes with a high risk of syphilis exposure is not uncommon, Holmes says, although careful analysis of the effectiveness of such programs has not been conducted. In some areas of Indonesia, for example, prostitutes receive regular penicillin treatments.

As for the UNICEF and WHO efforts to treat yaws, Dr. Holmes notes that success hinged in part on the fact that medical teams could find people afflicted with the disease without difficulty because symptoms were easily recognizable. Unless a target population were defined purely by demographics — treating all prostitutes, for example — identifying the right people to treat for a disease with less-apparent symptoms may not be easy, he says.

Sean Sprague/Impact Visuals

Women in Dhaka, Bangladesh, line up for immunization. Mass treatment for an STD might be conducted similarly.

The fact that they show clearcut symptoms is among the reasons Dr. Sokal of FHI believes chancroid and syphilis are the most promising candidates for testing and evaluating some form of selective mass treatment. Other important factors to consider for testing the approach, he says, are the degree of a disease's infectiousness and the ability to control it by a single-dose treatment.

— *Nash Herndon*

Footnotes

1. LJ D'Costa, FA Plummer, I Bowmer, et al. Prostitutes Are a Major Reservoir of Sexually Transmitted Diseases in Nairobi, Kenya. *Sexually Transmitted Diseases*. 1985; 12(2): 64-67.

2. GT Noordhoek, JDA van Embden. Yaws, an Endemic Treponematosis Reconsidered in the HIV Era. *European Journal of Clinical Microbiology and Infectious Diseases*. 1991; 10(1): 4-5; GM Antal, G Causse. The Control of Endemic Treponematoses. *Reviews of Infectious Diseases*. 1985; 7(2): S220.

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4. HW Jaffe, DT Rice, R Voigt, et al. Selective Mass Treatment in a Venereal Disease Control Program. *American Journal of Public Health*. 1979; 69(11): 1181-82.

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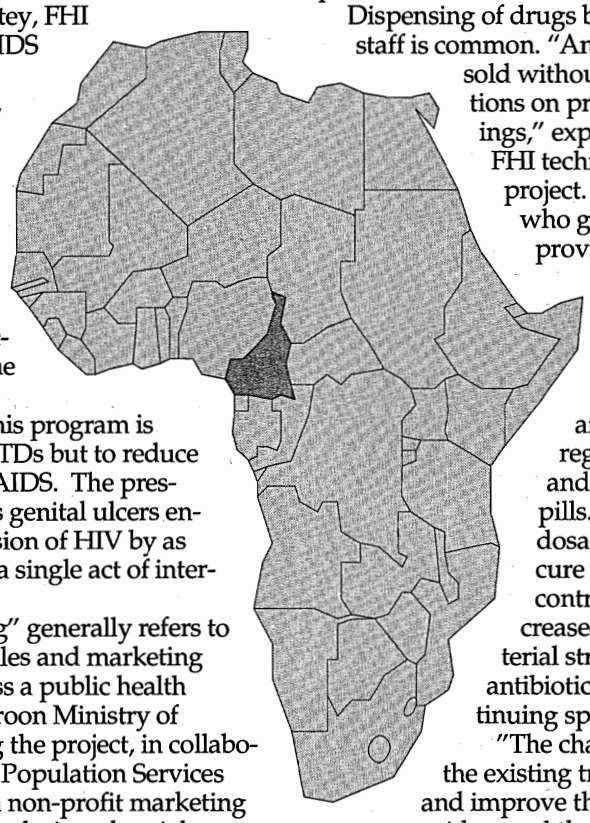
Cameroon Launches Social Marketing of Antibiotics

This summer, nearly 100 pharmacies in the West African country of Cameroon will begin selling antibiotics in a treatment kit for a sexually transmitted disease (STD). This pilot project, being watched closely by experts, is the first attempt anywhere to treat STDs through an approach called social marketing.

"We have had good success with social marketing of contraceptives, and we want to try the same approach with STD treatment," says Dr. Peter Lamptey, FHI Vice President for AIDS Programs. "This approach, if successful, would provide an inexpensive and standardized treatment, accessible to those people who cannot afford expensive treatment and now buy ineffective drugs outside the health-care system."



The purpose of this program is not only to control STDs but to reduce the transmission of AIDS. The presence of STDs such as genital ulcers enhances the transmission of HIV by as much as fiftyfold in a single act of intercourse.

"Social marketing" generally refers to using commercial sales and marketing techniques to address a public health problem. The Cameroon Ministry of Health is sponsoring the project, in collaboration with FHI and Population Services International (PSI), a non-profit marketing organization that has designed social marketing campaigns in Asia and Africa. This project is funded by the U.S. Agency for International Development.

As with other social marketing strategies, this project hopes to attract consumers with low prices, promotion and easy access to the product. Appealing to both the profit motive among merchants and consumer interest in good quality for a good price, the kit will be priced to be affordable to low-income consumers, and yet allow enough profit margin that pharmacists will be encouraged to stock the product. The project is subsidizing the price of the kits.

Some social marketing programs, for example those promoting condoms, seek to create the widest possible distribution of the product to increase its use. By contrast, the Cameroon project seeks to improve the *quality* of STD treatments.

"The vast majority of the world's people with STDs already go to a local healer, pharmacist, shopkeeper or trader," says Dr. Tony Klouda, AIDS prevention coordinator for the International Planned Parenthood Federation. "Perhaps 90 percent of all STDs are treated at that level, which only perpetuates the problem because people receive inadequate treatment."

Dispensing of drugs by untrained shop staff is common. "Antibiotics are often sold without labels or instructions on proper use or warnings," explains Jason Smith, FHI technical monitor for the project. "Many patients who go first to a health provider must then go to a pharmacy to buy the antibiotics."

But typically, the patients cannot afford the complete regimen of antibiotics and buy only a few pills. Taking incomplete dosages often fails to cure the infection and contributes to the increased resistance of bacterial strains to some antibiotics and thus a continuing spread of the disease.

"The challenge is to get into the existing treatment system and improve the knowledge of the providers and the treatments they are giving," says Dr. Klouda.

Marketing a prescription product to treat an infection differs significantly from promoting a non-prescription product for disease prevention, such as condoms. Traditionally, there has been a reluctance in the medical world to popularize antibiotics. The new program in Cameroon is attempting to improve the use of antibiotics, decrease their misuse and enhance quality control.

The medical community in general has begun to relax strict controls over antibiotics. In 1991, for example, the U.S. Food and Drug Administration (FDA) approved over-the-counter sale of an antibiotic that treats vaginal candidiasis. For the first time in the United States, a person can purchase an antibiotic for treating a genital infection without

a prescription from a doctor. The FDA qualified its over-the-counter recommendation, however, by advising self-diagnosis only to women with repeat infections. Television advertisements specify the antibiotic should be used only by women who have previously been medically diagnosed with candidiasis.

The Cameroon project is focusing on both treatment and prevention. The kit will include appropriate antibiotics to treat the most common strains of gonorrhea and chlamydial infection in Cameroon, along with instructions on taking the medicine. At the same time, the kit will promote correct condom use and include two packages of condoms, four condoms per package. Another important element is a "partner referral" card. This encourages sexual partners of the persons buying the kits to seek treatment and offers a coupon for purchasing a kit.

"This approach has the potential to improve the current situation, which offers ineffective treatment and no prevention," says Dr. King Holmes, director of the Center for AIDS and STD at the University of Washington. If successful, social marketing of STD treatment will make the appropriate drugs available and lower their costs. This social marketing approach could help to standardize the wide range of ineffective treatment regimens now being used. Success will also mean linking diagnosis and treatment with counseling, condom promotion and partner treatment.

Because this is a pilot project, a thorough information base is needed at the outset to know how well it is working over the coming months and years. This requires significant baseline data on which to base the monitoring efforts as the project proceeds.

"We have a number of baseline studies under way," says FHI's Smith. "For example, we are doing surveillance studies among pregnant women and commercial sex workers and other prevalence studies to know as much as we can about STDs in this area. We also are researching the causes of male urethritis to be sure we have the right antibiotics in the kits." The baseline research being coordinated by AIDSTECH/FHI also includes a household survey and a study of behavioral patterns between pharmacists and consumers.

Cameroon is particularly suited for this kind of project. Cameroonians are accustomed to getting drugs and health care services through the private sector, which already has a strong private pharmacy distribution system. Also, this project follows PSI's successful condom social marketing program, still under way in Cameroon, and will benefit from its existing private distribution and sales network.

As with its condom marketing campaign, PSI plans to build awareness and demand for the STD treatment kits. The campaign will promote two messages: proper STD treatment reduces complications of STDs and lowers chances of HIV transmission. A cure should be easier to sell than a prophylactic because people infected with a disease generally are highly motivated to seek treatment.

The kit will have its own name and logo. Advertising and other promotions will link treatment with prevention and specifically with "Prudence," the name of the condom in the existing campaign.

Radio commercials, billboards, posters and leaflets will advertise the kits as an effective and affordable cure for male urethral discharge. The promotions will also direct those suffering from symptoms of urethral discharge to their local pharmacist. Male urethral discharge syndrome is the most prevalent STD problem in the two Cameroonian cities where the project is beginning.

The syndrome typically has painful symptoms that prompt most men to seek help. Yet women are often asymptomatic and may not know they have an infection until it advances to a much more serious condition, such as pelvic inflammatory disease. The partner referral card included in the kit is particularly important for reaching these women.

Most social marketing programs depend on some subsidy. National governments and international donor agencies, such as the U.S. Agency for International Development, fund most condom social marketing programs in operation today, although sales revenues recover some of the costs. Sustaining a program such as the pilot effort in Cameroon is likely to require some subsidy for antibiotic supplies, training and promotion. However, with the strong incentive consumers have for buying treatment, this type of project has the potential to pay for itself eventually.

As the project develops, its value as an STD treatment approach will become clearer. Kit sales figures, changes in knowledge about STDs, reported condom use, number of partner referral cards returned and other indicators will be monitored. "Having good baseline data is essential in order to know what the impact of the project really is," says FHI's Smith.

If successful, the project may lead to long-term programs in Cameroon and other countries offering an array of kits to treat common STD problems. This approach has the potential for expanding as well to street vendors and traditional healers.

— Sara Townsend

The new program in Cameroon is attempting to improve the use of antibiotics, decrease their misuse and enhance quality control.

Prevention of STDs — The Challenge of Changing Behaviors

An STD clinic has a captive audience of people who have an increased risk of becoming infected with HIV — because of their STD infection and because of the sexual behaviors that led to the infection. Moreover, a clinic has a built-in infrastructure, which is almost certainly more sustainable than a new type of prevention and treatment system is likely to be.

For these reasons, STD clinics provide a valuable opportunity to use the three primary STD preventive measures — counseling, condom distribution, and promoting treatment-seeking behaviors.

"People coming to a clinic with an STD infection need to hear and learn specific things," says Lynda Cole, Deputy Director of FHI's AIDSTECH Division. "First, tell them that the behaviors that they did to get an STD are the same behaviors that put them at risk of HIV infection. Second, say that if you continue to have those sexual behaviors, then use a condom."

Counseling for prevention of further STD infection is most effective with condom promotion. "After these two steps, then find out if they know how to use a condom," adds Cole. "If not, demonstrate condom use on a penis model and get the patient to practice. Finally, distribute free condoms if possible."

COIN / PROCETS

A page from "Maritza's Advice" depicts Maritza counseling a younger sex worker who has an STD she doesn't know how to treat.

Some people come to clinics on their own and hence can receive these preventive messages along with correct treatment. Reaching others with preventive techniques is more difficult.

For example, two years ago, most commercial sex workers in Santo Domingo, the capital of the Dominican Republic, thought that taking penicillin or douching regularly would protect them from sexually transmitted diseases (STDs). But a character named Maritza, in a series of colorful comic books, has begun to change these incorrect assumptions.

"Too much vaginal douching is not good," Maritza tells another sex worker in "Maritza's Advice," a pocket-sized pamphlet. "It makes the vagina too acidic or not acidic enough. Then it's too dry and susceptible to diseases. That's why douching does not protect you from sexually transmitted diseases. On the contrary, douching can allow the disease to attack frequently and stronger."

The comic book is part of the Avancemos Project, an AIDS/STD intervention project among sex workers begun in 1989 by the Dominican Republic Ministry of Health, in conjunction with FHI's AIDSTECH Division. Two non-governmental organizations, Centro de Orientación e Investigación Integral in Santo Domingo and Comite de Vigilancia Contra el SIDA in Puerto Plata, implemented the project. Through their efforts, 16 sex workers initially were trained as peer educators to promote correct condom use and distribute education materials among other sex workers. These 16 have in turn trained more than 300 others as peer health educators. They, together with local STD clinics, provide "Maritza's Advice" and condoms to some 4,500 commercial sex workers.

For every person seeking treatment for an STD, there is at least one other person infected. An STD treatment clinic provides a means of at least notifying infected people's sexual partners that they may be infected. A person receiving treatment at the clinic should be counseled to encourage these partners to seek treatment as well. Since many STDs are asymptomatic, particularly among women, people often do not even know they are infected.

Building such prevention efforts into an STD clinic from the outset is valuable. In El Salvador, for example, the Salvadoran Demographic Association is establishing STD clinical services in conjunction with the PROFAMILIA Family Planning Clinic. A social worker has begun outreach efforts among commercial sex workers, encouraging them to seek treatment and use condoms. AIDSTECH is supporting the El Salvador project with funds and technical assistance.

Experts have identified two basic groups of people as targets for STD prevention efforts. First are those at high risk for contracting or transmitting an STD, such as the commercial sex workers and their clients in the Dominican Republic. The Avancemos Project illustrates how an AIDS-prevention project has tried to prevent people at high risk for HIV transmission from getting bacterial STD infections. The El Salvador project has begun to reach into this population.

Second are those about to enter the world of STD risks — teens and children. Preventing youngsters from STD infection involves the controversial arena of sex education, including information about STDs. "Many societies have problems acknowledging sexuality, and there is a prevailing attitude that those who get STDs deserve them," says Dr. Sevgi Aral of the Division of STD/HIV Prevention, U.S. Centers for Disease Control.

Overall goals are the same for projects working with both groups. "The interventions directed at these groups should encourage beneficial behavior changes, such as using condoms, seeking medical care for STDs and decreasing the number of sex partners," explains the report of a recent meeting of some 200 specialists from 33 countries and territories of the Americas.[1] Ideally, projects "should also reduce stigmatization of STDs, eliminate myths and lead to a better overall understanding of sexuality."

But, the report added, "Public opinion and societal norms could undermine these health programs, and religious objections were a common problem in the Americas." The Pan American Health Organization (PAHO), part of the World Health Organization, sponsored the meeting.

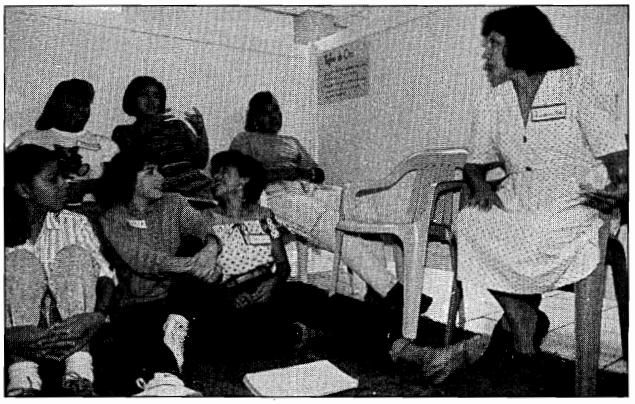
Public health professionals distinguish among primary, secondary and tertiary preventions. A study on prevention and control of STDs, coordinated by the U.S. National Institute of Allergy and Infectious Diseases (NIAID), explains the three types of prevention.[2]

"Primary prevention" refers to preventing the occurrence of a disease, such as the project in the Dominican Republic is working to do. Examples include health education and condom use.

Secondary prevention, the NIAID report explains, refers to activities attempting to detect and treat STDs so as to prevent complications from developing. Examples would be screening programs at antenatal and family planning clinics, which could help detect asymptomatic infections, and notifying the sexual partners of an infected person to be tested and possibly treated. Tertiary prevention refers to steps taken to stop an infection from causing permanent damage, such as treating pelvic inflammatory disease before it causes infertility.

The professional public health community has emphasized secondary prevention, that is, treatment, of bacterial STDs. "Hence, hardly any research exists on intervention programs for STDs," says Dr. Aral, referring to primary prevention efforts.

The Avancemos Project in the Dominican Republic grew out of the AIDS-prevention effort being managed by two local research and education groups focusing on AIDS. Dr. Ernesto Guerrero, a member of the five-member STD Advisory Group for the VII International Conference on AIDS, initiated the overall effort.



Frederick Chase/Impact Visuals

Teenage girls attend a sex education class in Mexico.

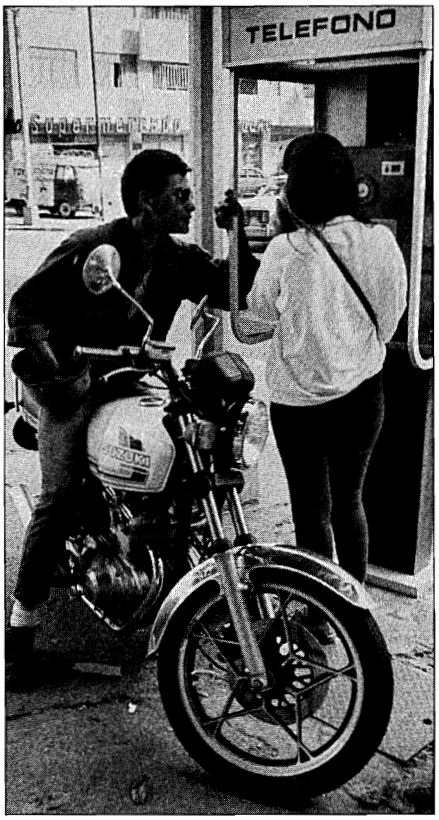
At the beginning of the project, a survey of the knowledge, attitudes and practices of the commercial sex workers revealed the many misconceptions the women had about STDs. Besides the responses about penicillin and douching, women said incorrectly, for example, that you are safe from infection if you have sex without a condom with someone you know.

The results of the survey underscored the need for educational materials to which the women could relate, and Maritza, her friends and clients were born. Maritza is a handsome, well dressed, street-wise sex worker. In "The Triumphs of Maritza," a second comic book, she tells her peers about negotiating with clients to use a condom. She deals with typical client types, from an affluent executive to the uncompromising Jaime, whose money she returns because he refuses to use condoms. AIDSCOM, an AIDS-prevention project funded by the U.S. Agency for International Development, helped develop the Maritza books.

If the savvy Maritza is ultimately successful in changing the behavior of these women in Santo Domingo and other cities in the

Dominican Republic, it is because the very women she is meant to reach have played a fundamental role in her creation and her dissemination, and because she makes those women feel that they have value.

"An excitement bordering on evangelism seems to have developed among the peer leaders," observes Tito Coleman, AIDS-TECH resident advisor in the Dominican Republic. "Not only do they see, for the first time, materials that have been created just for them, but Maritza appears to have tapped into buried feelings of self-worth among the women."



Beryl Goldberg

It is important to teach young people about safe sex before they begin their sexual lives.

This observation is consonant with theories of health behavior change, which argue that a sense of self value must precede behavior change. Individuals must believe in themselves and in their ability to affect their environment in order to make the necessary and protective changes toward better health.

"The employers and the clients of the women were the weak links in our program," Coleman says. "Therefore, we have been holding educational seminars for the owners of the bars, cafes, massage parlors, brothels and other places where the women work. Many owners have now collaborated because the prostitutes who work for them are required by the government to hold cards attesting to their freedom from disease, and because healthy women are obviously better for their businesses."

In its next stage, the Avancemos Project plans to assess the impact of its programs with a follow-up survey. It also hopes to reach some 6,000 more women by expanding into new areas of Santo Domingo and Puerto Plata, as well as into other cities in the country. Efforts are also beginning to involve the women's partners and clients through outreach into the factories and businesses where they work.

The commercial sex workers and clients in the Dominican Republic are known among specialists as a "core group." An STD epidemic spreads through a small group of high-frequency transmitters with large numbers of sexual partners, referred to as the "core." Other examples of core groups are sexually active young people and highly mobile populations such as truckers and the military.

Experts believe that focusing on core groups can be a strategic use of limited resources. "Preventing or curing an STD in a member of a core group has much more impact than doing so in a person who is unlikely to transmit the infection," write Dr. Aral and Dr. King Holmes of the University of Washington.[3]

Broad-based education among young people before they might enter such a group is also essential. "Teenagers are a critical population for AIDS prevention," says Dr. Tony Klouda, AIDS prevention coordinator for the International Planned Parenthood Federation. "A large proportion of HIV is acquired during the teen years. To address this problem means to broaden the AIDS-prevention efforts to the whole issue of sexual health."

For nearly a decade now, AIDS-prevention projects have learned what types of activities and approaches are most effective in changing sexual behaviors.[4] Now, these lessons are being applied to the task of reducing STD infection as well. Such creative approachs to preventing STD infection as using the "Maritza's Advice" comic book shows the fruits of many similar peer education projects.

"The further spread of AIDS can be minimized not only through programs specifically to prevent HIV transmission but also through programs designed to combat other STDs," reports PAHO.[5] "Conversely, the lessons learned through fighting AIDS can be adapted for the fight against STDs."

— Janel Halpern and William R. Finger

Janel Halpern is Information Dissemination Coordinator for AIDSCAP/FHI.

Footnotes

1. Regional Meeting on Behavioral Interventions for STD and AIDS Prevention. *Bulletin of PAHO*. 1991; 25(2): 186-90.
2. Report of the NIAID Study Group on Integrated Behavioral Research for Prevention and Control of Sexually Transmitted Diseases. *Sexually Transmitted Diseases*. 1990; 17(4): 205.
3. S Aral, K Holmes. Sexually Transmitted Diseases in the AIDS Era. *Scientific American*. 1991; 264(2): 62-69.
4. For a summary of lessons learned in AIDS-prevention projects targeting behavioral change issues, see *network* 12(1) 1991, especially Peer Education: Changing Behavior in Hard-to-Reach Groups.
5. *Bulletin of PAHO*, p. 187.

AIDS News

New HIV Test Available

A simple and inexpensive blood test has been developed that can identify HIV infection in babies as young as three months, much sooner than current testing allows, according to the National Institute of Allergy and Infectious Diseases.

The test currently in wide use cannot detect HIV infection in infants younger than about one year. The institute published findings on the new test in the Dec. 25, 1991 issue of the *Journal of the American Medical Association.*

The new method detects antibodies in the infant called IgA, which are stimulated by HIV infection. IgA antibodies do not travel across the mother's placenta, which means the IgA in an infant could not have come from the child's mother.

"This study demonstrates the promise of the IgA antibody test for detecting HIV in infants many months before the blood tests currently used," said Dr. Anthony S. Fauci, director of the institute based in Baltimore, MD (U.S.).

The existing method detects different antibodies, called IgG. During pregnancy, IgG antibodies cross an infected mother's placenta to her fetus and persist within the infant's bloodstream for a year to 15 months after birth, even if the child is not infected with HIV.

While an infected infant would also produce IgG antibodies, the current testing can not distinguish between IgG simply passed by the mother to a healthy infant and new IgG being stimulated by a child's own HIV infection.

The institute evaluated the new test on 320 infants born in Baltimore and Port au Prince, Haiti. Collaborators included scientists at Johns Hopkins University, Baltimore, and the Center for Development and Health, Port au Prince. ■

Worldwide HIV Infections

More than 1 million new HIV infections have occurred worldwide since the spring of 1991, for a total of at least 10 million adults infected by the virus, according to the World Health Organization's latest estimates.

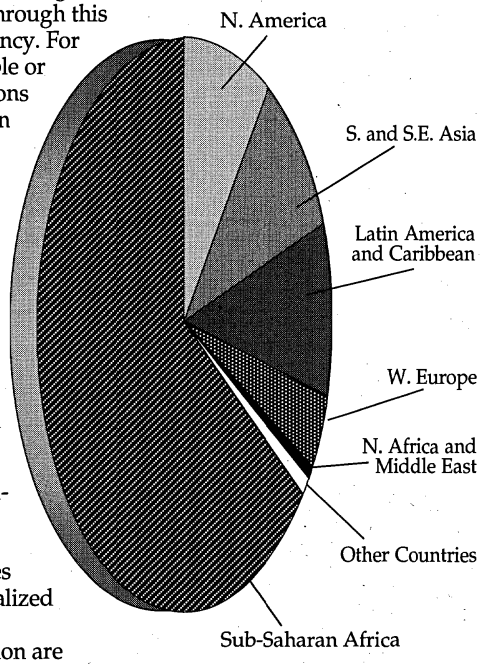
The estimates suggest an increasing number of people will become infected through this decade and beyond, said the agency. For the year 2000, WHO projects triple or quadruple the number of infections worldwide — between 30 million and 40 million people.

The agency said in a January report that nearly two out of every three infected people are living in sub-Saharan Africa. In addition to adults, about 1 million children worldwide are infected, said the Switzerland-based organization, for a total of about 11 million people.

More than 90 percent of the new infections among adults come from heterosexual intercourse. "This reflects the continuing trend toward heterosexual transmission," the agency said, "not only in developing countries but, increasingly, in the industrialized world."

WHO estimates about 2 million are in the late phases of the HIV infection, the stage known as AIDS. Of those, about 500,000 are children. ■

Ten Million Adult HIV Infections Worldwide



Source: World Health Organization, January 1992

Resources

STD Management Guidelines

"Management of Patients with Sexually Transmitted Diseases" is an easy-to-use set of guidelines for anyone involved in health care. It includes management summaries with different types of treatment flowcharts that can be used, depending upon the laboratory diagnostic capability of a clinic. Reference sections describe recommended diagnostic tests, common microscopic findings and treatment recommendations. Known as Report Number 810, copies are available from the World Health Organization, Distribution and Sales, 1211 Geneva, 27 Switzerland. FAX number [41-22] 788-0401. Cost is US $8.50 to persons in developing countries.

Films on AIDS in Africa

"Faces of AIDS" is a new 20-minute educational video produced by AIDSTECH/FHI. Through the stories of people with AIDS, the video provides a human picture of the impact of the epidemic on individuals and communities in Africa. It is designed as a training tool to complement the work of AIDS educators. Filmed in Zimbabwe and Cameroon with the assistance of African film crews and support of the USAID missions, ministries of health, and private organizations, it is available on video cassette (NTSC, PAL, and SECAM formats) in French and English. Discussion guidelines are included, also in French and English.

"Challenges in AIDS Counseling" is a 25-minute video with a 63-page training guide, produced with support from USAID/Lusaka, AIDSCOM and Johns Hopkins University. Through a dialogue among Zambian AIDS counselors, this video explores the important issues and common difficulties that arise in AIDS counseling. The video is available on cassette in English (NTSC and PAL formats).

For more information on these and other films, contact, according to your location:

United States: Development through Self-Reliance, 9650 Santiago Road, # 10, Columbia, MD 21045 USA

Zimbabwe: Media for Development Trust, P.O. Box 6755, 135 Union Ave., Harare, Zimbabwe.

Kenya: DSR/Kenya, P.O. Box 38941, Nairobi, Kenya.

Guide to Behavior Change

A special issue of *network* on behavior change (12.1, June 1991) is available free upon request to: Debbie Wade, Publications Assistant, FHI, P.O. Box 13950, Research Triangle Park, NC 27709. ■

New FHI Publications

91-34 I Chi. The Nova-T IUD— A review of the literature. *Contraception* 1991 Oct; 44(4): 341-366.

91-35 McLaurin VL; Dunson TR. A comparative study of 35 mcg and 50 mcg combined oral contraceptives: results from a multicenter clinical trial. *Contraception* 1991 Nov; 44(5): 489-503.

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91-38 Bhiwandi P; Smith JB; Potts M. Family planning for the growing cities. *Earthwatch* 1991; 438-11.

91-39 Potts M. New concepts in barrier methods of contraception. In: Runnebaum B; Rabe T; Kiesel L (Eds). *Female contraception and male fertility regulation* Vol.2. Advances in gynecological and obstetric research. Park Ridge, New Jersey, Parthenon 1991; p.103-08.

91-40 Bailey P; Dominik RC; Janowitz B; Araujo L. Assistencia obstetrica e mortalidade perinatal em uma area rural do nordeste brasileiro. *Bol Of Sanit Panam* 1991; 111(4): 306.

91-41 Malhotra A; Thapa S. Determinants of contraceptive method choice in Sri Lanka: an update of a 1987 survey. *Asia-Pacific Pop Journal* 1991; 6(3): 25.

91-42 Boulos ML; Boulos R; Nichols DJ. Perceptions and practices relating to condom use among urban men in Haiti. *Stud Fam Plann* 1991; 22(5): 318.

91-43 Bonhomme M; Potts M; Fortney JA; Allen MY. Safety of depot medroxyprogesterone acetate (letter). *Lancet* 1991; 338(8772): 942.

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91-45 I Chi. An evaluation of the levonorgestrel-releasing IUD—its advantages and disadvantages as compared to the copper-releasing IUDs. *Contraception* 1991; 44(6): 573.

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91-47 Potts M; Thapa S. *Child survival: the role of family planning* (revised edition). Family Health International 1991

91-47A Potts M; Thapa S. *La survie des enfants: le rôle de la planification familiale.* Family Health International 1991

91-47B Potts M; Thapa S. *La supervivencia infantil: el papel de la planificacion familiar.* Family Health International 1991

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