News Briefs

**TCU 380A effective for 10 years**

A widely-used intrauterine device (IUD), the TCU 380A, has been rated as providing effective contraception for up to 10 years, based on continuing studies by the World Health Organization and the New York-based Population Council.

The TCU 380A IUD was previously considered effective for up to eight years. The U.S. Food and Drug Administration (FDA) in May approved the extension to a decade, according to an FDA spokesperson.

"The longer period of effective contraception is particularly important for women who want to limit births without undergoing sterilization," says Gaston Farr, associate director of FHI's Division of Clinical Trials, which has helped introduce IUDs in several countries. A longer period of effectiveness will also reduce the need to replace the devices, Farr says.

**RU 486 trials in the U.S.**

Clinical trials of RU 486, an abortifacient pill also known by its generic name, mifepristone, are expected to begin this fall at 12 U.S. centers, involving at least 2,000 women volunteers.

The drug's French manufacturer, Roussel Uclaf, has donated U.S. patent rights for mifepristone to the Population Council, a New York-based non-profit research group. If trials are successful, the council plans to apply to the U.S. Food and Drug Administration (FDA) for permission to market the pill. If approved, the drug may be available as soon as 1996 to U.S. women as an alternative to surgical abortion.

"The Council has sought to bring mifepristone to the United States, not to increase the incidence of abortion, but to provide a choice of safe abortion methods," says Margaret Catley-Carlson, council president. "We support giving women contraceptive options; with mifepristone, women also will have a choice of abortion methods."

The drug works by blocking the action of the natural hormone progesterone, which prepares the lining of the uterus for a fertilized egg and then sustains the pregnancy. About 150,000 women have used the drug in France, Great Britain and Sweden, where it has been approved by government regulatory agencies.

**Dr. Willard Cates joins FHI**

Dr. Willard (Ward) Cates, Jr., M.D.-M.P.H., an epidemiologist who directed the Division of Sexually Transmitted Diseases at the U.S. Centers for Disease Control and Prevention (CDC) for many years, has been named Corporate Director for Medical Affairs at Family Health International, effective October 1.

An internationally known expert in the field of contraception and sexually transmitted diseases, Dr. Cates is currently director of the Division of Training in CDC's Epidemiology Program Office in Atlanta.

"We are indeed fortunate to have attracted a medical director of Dr. Cates' stature and impressive background," Dr. Theodore M. King, M.D., Ph.D., FHI's president, said in announcing the appointment. "Dr. Cates will enhance our expertise in reproductive health, especially in such fields as epidemiology and sexually transmitted infections, and strengthen our capacity to serve the international reproductive health community."

For 11 years, Dr. Cates served on FHI's Technical Advisory Committee for contraceptive research, a panel of experts that provides guidance. He joined CDC in 1974, heading CDC's programs for sexually transmitted diseases (STDs) from 1982 to 1991. During his leadership, the division integrated HIV prevention activities into STD control programs and tripled in size.

Dr. Cates has authored or co-authored more than 300 scientific publications and has co-edited two widely-used textbooks on reproductive health — Contraceptive Technology and Sexually Transmitted Diseases.

**Lea's Shield, VCF and plastic condom trials**

If HI will soon start contraceptive effectiveness trials of three barrier contraceptive methods — Lea's Shield, Vaginal Contraceptive Film (VCF) and a polyurethane male condom.

A study at several U.S. sites will compare the effectiveness of Lea's Shield with the diaphragm. Lea's Shield is a vaginal barrier device that resembles a loose-fitting cervical cap, covering the vaginal opening to keep sperm out. A one-way valve allows cervical secretions to escape and maintains suction. The U.S. Food and Drug Administration (FDA) will use results of this trial to decide whether Lea's Shield can be marketed in the United States.

Another U.S. trial will compare a polyurethane male condom with latex condoms. The polyurethane condom may be more appealing to users and the material may be less susceptible to deterioration. The trial will document the effectiveness of the condom in preventing pregnancy. Data will be submitted to the FDA to consider in its deliberations on whether the new condom can be sold in the United States.

An international trial will compare VCF to foaming spermicidal tablets. VCF, a thin sheet of film containing nonoxynol-9 (N-9), is a fast-dissolving spermicide that can be inserted without an applicator. Some women find it more convenient to use than foaming tablets. VCF is already sold as an over-the-counter contraceptive in the United States. The clinical trial is being conducted to document the contraceptive effectiveness of the film form of N-9.

**Clarification**

In a chart on page 17 of the May issue of Network, "infertility" was listed as a potential side effect of IUD use. Scientific studies have not shown infertility to be a side effect of any currently available IUD.

Infertility can be caused by untreated pelvic inflammatory disease (PID). PID is usually associated with sexually transmitted diseases (STDs) and rarely with IUD use. The Dalkon shield, an IUD model that was discontinued more than a decade ago, was found to be associated with a high rate of pelvic infections.

Since IUDs have not been shown to protect against STDs, women at risk of STDs are not good candidates for IUD use.
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Network has been named “Best Population Journal” in the 1994 Global Media Awards, sponsored by the Washington-based Population Institute, scheduled to be presented in September during the International Conference on Population and Development in Cairo.

Cover photo by Sean Sprague/Impact Visuals of Ethiopian women making mats for a maternal and child health clinic crafts project.
INTRODUCTION

Women and Family Planning

This issue of Network focuses on one aspect of women's reproductive health needs — family planning. Increasingly, women do not simply use contraceptive methods, but participate in the design and implementation of family planning services and policies. At the same time, family planning is being viewed not as an isolated medical service, but as a component of women's larger reproductive health needs, which also include pregnancy-related care, prevention and treatment of STDs, including HIV, prevention and treatment of reproductive cancers, treatment of infertility, and postpartum and postabortion care.

Providing access to safe, affordable contraceptive services, which enable women to determine the number and spacing of pregnancies, is one way to help improve the health and status of women. Improvements in education, economic opportunities, and public policies are equally important.

"The crucial factor shaping the relationship between reproductive choice and other rights is the structure of opportunities that girls and women face," explains Dr. Ruth Dixon-Mueller, who has written and worked widely in this field. "It makes little sense to promote policies encouraging contraceptive use and smaller families without simultaneously addressing other legal, social and economic constraints on women's rights."

To understand women's needs and perspectives on family planning better, FHI is implementing the Women's Studies Project, a five-year research effort funded by the U.S. Agency for International Development. The project uses qualitative and quantitative research to determine how women have benefited or not benefited from use of family planning methods and services. Findings of these FHI studies will be widely disseminated, including through future issues of Network.

FOOTNOTE

Increasing contraceptive choices and expanding services are among ways to meet the needs of underserved groups.

In recent decades, family planning programs have helped increase contraceptive use among married women of reproductive age to an overall rate of more than 50 percent in less developed countries. Yet a vast number of people still want and need good quality contraceptive services but cannot get them.

About one of every five women who want to avoid a pregnancy is not using contraception — about 120 million women, according to demographic surveys in some 50 developing countries. This is the “unmet need” for contraceptives among the traditional group examined by demographers: fecund women in union who wish to delay or avoid future pregnancies.

The actual number of people who are not adequately served, however, is probably much higher. These traditional calculations do not include sexually active and single teenagers, people who already use one method but are dissatisfied with that method or those who only have access to one or two methods. Many men are also not included.

“There is a sufficiently large amount of unmet need, and we do not need to labor over refinements of the numbers,” says Dr. John Ross of The Futures Group, a U.S.-based organization. “What should programs do about it? That is the question that needs to be addressed.”

In his analysis of demographic data, Dr. Ross has found that half of the women not using contraception in low prevalence countries lacked knowledge about contraceptives or had religious reservations about using them. In countries with high contraceptive prevalence, health concerns were the major reason for non-use (18 percent), with infrequent sex (11 percent) and lack of knowledge (10 percent) also important.

Family planning programs are seeking new ways to address the unmet need for contraceptive services. Some continue to focus on married women but are concentrating more on situations involving larger reproductive health issues, especially the prenatal and postpartum periods and the needs of isolated rural women. Many family planning programs are recognizing the connection of contraceptive needs with sexually transmitted diseases, breast-cancer screening and other reproductive health concerns of women in particular.

Other programs are trying to address the needs of those not traditionally served by family planning programs, such as men, adolescents, refugees and those who turn to abortion because of poor access to contraceptives.

Better ways to reach underserved groups are only part of the challenge. Quality care can make an important contribution toward addressing unmet needs. Focus groups and other research show that women want and need courtesy, respect, privacy, clear information and instructions regarding contraceptive use, says Dr. Elaine Murphy, senior program adviser at the U.S.-based Program for Appropriate Technology in Health. “What is needed,” she says, “are services that are user-friendly, accessible and of decent quality, and good information regarding how to obtain and use family planning methods.”
MANY WOMEN LIVE IN REMOTE AREAS HARD TO REACH WITH FAMILY PLANNING SERVICES.

POSTPARTUM WOMEN
Spacing children at least two years apart can increase the health of the mother significantly, as well as the health of the child. Hence, the postpartum period is an extremely important time for contraceptive use.

"It is wise to focus on postpartum women," says Dr. Florence Oryem-Ebanyat, director of maternal and child health and family planning in the Uganda Ministry of Health. "They need help to delay their next pregnancy, and almost all women want to do that. But they [often] cannot discuss family planning with their husbands."

It is important to provide information about contraceptive options during the prenatal period, so that a woman will not have to make a rushed decision immediately after giving birth. Involving husbands can also help, since that gives women a chance to discuss family planning with their spouses.

In a series of studies, researchers for the Association for Voluntary Surgical Contraception (AVSC) asked pregnant and postpartum women what kind of family planning information and services they want, when they want to use them, and whether these services were provided before they left the hospital. The studies also asked service providers about their opinions on the provision of postpartum family planning services.

At two general service hospitals in Kenya, an AVSC survey found that more than 90 percent of postpartum women wanted to use contraception, but only 2 percent left the hospital with a method. "The study demonstrates massive missed opportunities for family planning information and services," concluded the AVSC team.

A multi-country study at institutions providing maternal care found substantial unmet need for contraceptive information during the prenatal period and for services during the postpartum period. The unmet need was greatest in three of the countries, Colombia, India and Turkey, where those services are limited or did not exist, explains Evelyn Landry, AVSC's director of evaluation and research. By contrast, hospitals in Mali and Kenya clearly met the demand for postpartum IUD insertions. AVSC and FHI had conducted a postpartum IUD introduction project at these hospitals. In a Kenyan hospital, for example, about one of every four mothers interviewed (30 of 109) left the hospital with an IUD.

To help make such services available elsewhere, FHI has recently produced a training module on postpartum contraception for health-care providers. Using slides, a suggested narrative and handout materials, one health professional can use the module to train others in postpartum services. Funding from the U.S. Agency for International Development (USAID) paid for the module, which is being field-tested in Turkey, Uganda and other countries.

"We need to improve the knowledge of the health-care person," says Dr. Oryem-Ebanyat of the Ugandan ministry. "First, you need to win their confidence about the value of family planning. Then, with proper training, they will be able to discuss contraceptives knowledgeably with potential clients. Nurses, midwives and even physicians often have only an elementary knowledge about family planning methods."

The New York-based AVSC has begun a pilot project in Kenya that provides hospital staff with family planning orientations. Educational materials are made available for clients, and family planning committees have been formed with nurses from surgery, gynecology, outpatient and other wards.

Like the prenatal and postpartum period, the post-abortion period is an important opportunity to counsel women about contraceptive use. Abortion is often used as a way to cope with an unwanted pregnancy, making the postabortion period particularly critical for discussing contraceptive use with women.

SERVING RURAL AREAS
As challenging as it is to meet the contraceptive needs of women in hospitals and other urban settings, it is even more complex in rural areas, where most women in developing countries live and give birth. Rural women often live far from health or family planning services.

In several developing countries, where services have been taken beyond clinics, fertility rates have declined substantially. In Indonesia, for example, with about 400,000 providers working in villages, the average number of live births per woman during her lifetime, called the "total fertility rate" (TFR) is down to 3.1, from 6.0 a generation ago in 1961. The TFR of Thailand,
with 80,000 community-based contraceptive distributors, has declined to 2.2 from 6.0 in 1969. These lower rates are near the replacement level of about 2.0, the level at which births should gradually reach equilibrium with deaths, which eventually would result in a stable population.

"Women in Bangladesh want contraception available that they can use on their own," says Mustari Khan of Concerned Women for Family Planning in Bangladesh. "They don't have to go to a clinic or depend on their husbands." In the rural areas of this predominantly Muslim country, a woman often cannot walk in public, much less travel to a clinic, without her husband. Hence, a woman is far more likely to use services brought to her.

In Bangladesh, the nationally endorsed "woman-to-woman" fieldworker system has contributed to what Khan sees as "meeting the initial unmet need." But an in-depth study of fieldworkers in the country's Matlab subdistrict concluded that expanding the impact of the fieldworkers requires greater attention at the national policy level. The study found that fieldworkers, themselves rural women, generally could not provide both maternal/child health and family planning services competently, as called for in the national program strategy. Problems included too many households to cover, low staff motivation, poor supervision and a lack of supplies and technical competence. Recent efforts have addressed these problems by sharing the workload between new regional satellite clinics and the fieldworkers, and by focusing on planning and training.

More support at the national level for traditional medical practitioners could also help meet unmet need in rural areas. In India alone, an estimated half million practitioners are trained in indigenous medicine systems involving herbs, minerals, diet and other techniques.

A three-year pilot project in the north Indian state of Uttar Pradesh, coordinated by the Indian Council of Medical Research, trained traditional practitioners in 20 villages to provide information and contraceptives to potential users, comparing results with data collected in 17 non-intervention villages. In the intervention area, contraceptive use almost doubled (34 percent to 64 percent), with pill use going from 1 percent to 16 percent. Only new female sterilizations caused prevalence to increase at all in the comparison villages (from 36 to 49 percent).

The sharp increase in contraception by couples under age 25 that occurred only in the intervention area is noteworthy. "Accessibility increases acceptability," the researchers concluded, indicating the power of the traditional practitioner to influence groups with high need for, and low acceptance of, contraceptives. However, the researchers found that both vasectomy and condom use decreased in the intervention area, prompting them to call for a component on male responsibility in the family planning training curriculum, "in terms of supporting the wife's use of contraceptives and in promoting the husband's acceptance of a method."

IN VOLVING MEN

More male involvement with family planning is one way to help meet the reproductive health needs of women. The 1993 Women's Declaration on Population Policies, signed by thousands of people and organizations worldwide, supports policies to "encourage and support parenting and household maintenance by men." Serving as the secretariat for the declaration, the International Women's Health Coalition calls on individual men "to take responsibility for the children they father, their sexual behavior, and their partners' health and well-being."

But in order to take responsibility, men need services. Until recently, research in the family planning field seldom included men. The large-scale demographic surveys are now asking men questions as well as women. And in 1993, the first survey to calculate men's unmet need was carried out in Jamaica. Unmet contraceptive need among men is 20 percent, compared to 15 percent for Jamaican women, according to preliminary findings.

This unmet need calculation is most revealing when viewed together with other data in these surveys. The 1993 Jamaican survey, for example, found a high contraceptive prevalence rate among women in union, 62 percent, but also found that 75 percent of births to these women in the last five years were unintended — one of the highest rates in the world. "This suggests an unmet need for better information and counseling for more correct use of contraceptives," says Dr. Leo Morris of the U.S. Centers for Disease Control and Prevention, which provided technical assistance for the Jamaican survey. The most widely used methods were oral contraceptives and condoms, both of which require regular user involvement.

Modern male methods are limited to sterilization (vasectomy) or condom use. Contraceptive research is not expected to produce a reversible hormonal method for men in the reasonably near future, or any other new male method. Consequently, creative ways are needed to encourage men to support the use of female methods by their partners, as well as to encourage men to use existing male methods.

For example, an information campaign in Kenya sought to dispel myths and misinformation about vasectomy, using scientific facts as well as first-hand accounts of vasectomies from African men. Following this effort, many men indicated a willingness to use the method, contradicting the long-held conventional wisdom that African men will not have vasectomies. The next step is to train more providers and expand vasectomy services, which will take a strong commitment of both resources and effort.

Changing men's attitudes toward women's use of contraceptives will take even more commitment because of strong cultural obstacles. "We have concentrated on women," says Khan of Concerned Women for Family Planning in Bangladesh. "We did not consider the male that much. But we have to talk to the male sometime. Male involvement is an important area."

TOMORROW'S PARENTS

About one of every three persons in developing countries is younger than 15 years, and many will soon need contraception. Among the consequences of not serving adolescents are teenage pregnancy and unsafe abortion.

Teenage women are twice as likely to die in pregnancy or childbirth, compared to women 20 to 34 years old. At least one of every three women seeking hospital care for abortion complications is under age 20, estimates the World Health Organization.

Often in youth, patterns of behavior are formed that may last a lifetime. Yet in most countries, policies or practices discourage frank education about sexuality and ready access to contraceptives for unmarried adolescents.

A few pilot projects have begun to address these needs, which usually involve listening to the questions teenagers have. A family life-skills education project in Bucharest, Romania, is working with teenagers in the schools with...
permission of government authorities and parents. "The young people have a lot of myths and false beliefs," says Dr. Anemona Munteanu, a physician with the program. "They ask, 'Is it true that you cannot get pregnant the first time?' About masturbation, 'If you start, will you be less clever?'

Yes, you can get pregnant the first time; no, masturbation does not affect cleverness, Dr. Munteanu and her volunteers tell youth.

In a separate project in Rumania, in studying unmet contraceptive needs in five Rumanian hospitals, researchers found that "both women's and men's perceptions about, and use of, modern contraception could be positively affected through sexual education started in secondary school."10

Evea harder than getting accurate information is obtaining quality contraceptive services. A study in Ghana found that while trained providers gave better counseling in most cases, "both trained and untrained counselors often treated younger clients with disrespect or refused to give them the information they requested.11

In a study in Durban, South Africa, each of four teenage field-workers (two male and two female) visited 12 different clinics, a total of 48 visits. They reported being intimidated by clinic staff and encountering resistance to their requests for condoms. While they did sometimes obtain condoms, they had no privacy and received no counseling on either proper use or STD prevention. The authors reported that "nurses did not expect women to come to the clinic for condoms." The study recommended that clinics minimize obstacles to obtaining services, maintain adequate condom stocks and take advantage of opportunities for STD education when teenagers seek condoms.12

Meeting the unmet contraceptive needs of adolescents, say experts, requires parental involvement as well as an emphasis on counseling in the context of sexuality and overall reproductive health. Programs must also make services available, not just educational materials. Adolescent projects in particular require monitoring and evaluation, because small-scale service delivery projects have not generally been replicated on a large scale.

Involving youth themselves in program planning is important, because youth are more likely to understand how to motivate and reach their peers with services. Finally, the larger community is particularly impor-

Footnotes

Family Planning and Development

“If a woman is hungry, you cannot talk to her about family planning.”

In their efforts to enhance the overall quality of people’s lives, some family planning programs and economic development programs are working together to link contraceptive services with broader efforts to improve health, education and employment.

Partnerships between the two activities are logical, say managers of both types of programs. Contraceptive use is influenced not only by the availability of methods and services but by cultural and economic factors as well. Programs that combine family planning and development seek to address some of the underlying causes of high fertility, such as poverty, women’s low social status and low survival rates for their children.

“If a woman is hungry, you cannot talk to her about family planning. If her child is dying, you cannot talk to her about family planning,” says Chief Bisi Ogunleye, national coordinator of the Country Women Association of Nigeria (COWAN), a development organization that offers family planning services. “If she has no money to buy food, she has no money to buy family planning.”

There is a direct relationship between women’s poverty, their lack of autonomy and high fertility, says Sônia Correa of the Instituto Brasileiro de Análises Sociais e Econômicas in Rio de Janeiro.

“Lack of economic resources and inequality in gender relations make having children a strategy for survival,” she says. “That is one reason why it is so critical to address [the complete range of] women’s reproductive needs instead of focusing narrowly on distribution of contraceptives.”

Children can be a source of labor to gather fuel, cook, fetch water or perform other necessary chores. For women who cannot own land, children — especially sons — may be a source of power. In areas where child mortality is high, having many children may offer the hope that some will survive.

“Twelve of my children have died,” explains a woman in the Okhuesan village in rural Nigeria. “If I did not have many children, I would be left with none.”

Merging Programs

Decisions to link family planning and development services have been prompted by community need. In many cases, managers say they did not create new services but found ways to merge existing family planning and development programs.

In West Africa, two family planning programs began development activities in response to low contraceptive prevalence.
Contraceptive use is influenced not only by availability of methods but by cultural and economic factors, such as access to jobs and income. This woman works in a clothing factory in Port-au-Prince, Haiti.

rates (about 7 percent in the region). When workers questioned women about their reluctance to use contraception, their answers revealed economic and cultural barriers.

The Family Planning Association of Sierra Leone, an affiliate of the International Planned Parenthood Federation (IPPF), began its first development program in 1982, with three-year grants to income-generation projects in several northern villages.

“We found that family planning and no income do not go together well in rural areas,” says Fatmata Kassim, a program officer. “We went into these communities in which our family planning programs were operating and found the response wasn’t very good. We saw that women had to ask their husbands when they wanted something, and in the end they didn’t get what they asked for,” including money for family planning. “We said, ‘Why don’t you begin an income-generation project? Then you won’t have to ask your husband when you need to buy something.’”

Women participating in the income-generation project learn how to dye fabric and make soap, which they then sell to local residents to supplement family income. Women who participate also receive information about contraceptives from community-based workers, who distribute pills, condoms and spermicides and refer women wanting other methods to local clinics.

The income-generation effort initially experienced problems. The family planning association had difficulty establishing a system of accountability to determine how funds were spent. Also, membership in programs dropped as families moved from one village to another. Five programs have been started. Two programs in the north, Gbonkobana and Kamahai villages, with a combined membership of more than 130 women, are now self-sustaining.

Some 500 miles to the north, The Gambian Family Planning Association (GFPA), also an IPPF affiliate, runs an income-generation project in which women are taught about vegetable gardening, sewing and soap-making, along with contraceptive use. The first project began 20 years ago, when family planning workers met with development field workers to discuss common concerns and problems.

Women who participate in the projects attend weekly meetings where they learn and practice job skills. They are trained by a development field worker, hired temporarily by the GFPA. Family planning workers attend the meetings, providing education on contraceptive methods and supplying methods to women who request them. Workers also provide information about AIDS and sexually transmitted diseases.

One of the most difficult aspects of the program has been cultural barriers, says Buba Joff, project manager. Because large families are a sign of wealth and status, motivating men and women to have smaller families is not an easy task. “We have created awareness, but now we must get clients to come (for services),” he says.

Recently, with funding from the Japanese Organization for International Cooperation in Family Planning, The GFPA began pilot development projects in two villages. Project staff, in cooperation with the Ministry of Health, identify children who are malnourished, then provide mothers with information on proper nutrition and diet. Women receive training in income-generating activities, which in turn can help buy food for the family. Also, workers provide information on hygiene and sanitation as well as family planning.

ADOPTING VILLAGES

One of the largest development efforts by a family planning program can be found in southeast Asia, where the Population and Community Development Association (PDA) operates a diverse development program for residents of rural Thailand.

Established in 1974, PDA was founded to support nationwide government family planning efforts. Since then, PDA has trained more than 10,000 men and women to work as family planning educators in rural villages throughout the country. The villagers, whose activities are supervised by health workers at the PDA office in Bangkok, educate their neighbors about contraception and dispense condoms and oral contraceptives.

In 1979, PDA expanded its services by establishing Community-Based Integrated Rural Development (CBIRD), which offered residents in the country’s northern region information about health-related services and development activities. The CBIRD program, which operates from nine centers throughout Thailand, offers small loans and job training for rural villagers. Among PDA’s on-going efforts are programs to prevent parasitic infections and tetanus; to promote breastfeeding; to encourage and provide prenatal care; and to build water, sanitation and irrigation systems.

“We introduce new development activities always in a link with family planning,” says Dr. Apichart Niraphampongorn.
director of PDA's medical and nursing bureau. Villagers who are convinced of the benefits of family planning are likely to be receptive to development activities.

With the help of the Ford Foundation, five years ago PDA began the Thai Business Initiative in Rural Development (TBIRD), which has the dual purpose of providing jobs for rural villagers and slowing the trend of urban migration.

In the TBIRD project, PDA matches rural villages in need of jobs with area businesses in need of employees. More than 40 businesses, including an auto manufacturer, a bank and a glass company, have "adopted" a village and provide training and education to local residents, who then produce goods in their homes. For example, the Singer Company offers sewing classes in one village, where local women now help the company fill orders for uniforms. Some villagers grow flowers and plants that are shipped to Bangkok, where they decorate offices and hotels.

Dr. Apichart sees a long-term benefit for Thailand, a country in which many unskilled illiterate young women migrate from rural areas to cities in search of jobs. There, without job skills, the women may be forced into prostitution to survive. The impact of the program, he says, is that it provides job opportunities in the villages for girls and women who want to remain in their home communities.

The project, administered by CARE-Peru and funded by CARE International and the U.S. Agency for International Development, began in July 1993. It is active in five regions: Piura and Chimbote on the coast, Cajamarca and Ayacucho in the mountains, and Iquitos in the jungle. During the first nine months, MSPP trained more than 950 women and men to serve as community-based family planning promoters, who distribute condoms, pills and spermicides. Some provide injectable contraceptives as well. More than 10,000 people living in rural communities and in areas near the cities have chosen to use contraceptives.

The MSPP uses existing CARE development activities as a foundation for family planning programs. For example, CARE supports community soup kitchens run by women's groups in urban shanty towns. Volunteers working in the kitchens help identify neighbors who are potential family planning promoters. Another project designed to help rural communities build and run potable water systems has trained health-care extension workers to provide contraceptive education and to refer potential clients to family planning services. Agriculture extension workers play a similar role.

The MSPP faced several obstacles in establishing family planning services. One was cultural barriers. "There are a lot of myths and rumors surrounding contraceptive use," says Thorndahl. "Most people have heard of modern contraceptive methods, but very few have used them. Fears of cancer, effects on libido and effects on the developing fetus are widespread. In addition, many women indicate that their husbands won't let them use a contraceptive."

Medical barriers were a problem as well. Health professionals at government clinics were concerned about quality of services and possible loss of clients to community-based distributors. Today, community-based workers and government health professionals work cooperatively. Health ministry staff train and supervise family planning promoters, and promoters refer family planning clients who want provider-dependent contraceptive methods, such as an intrauterine device or sterilization, to government clinics.

A NATURAL EXTENSION

For many development programs, the decision to offer family planning services came after discussions with community members about their health-care needs. Projects in Peru, Nigeria and India illustrate this.

"We had people working in the field, saying, 'What you've done is very good, but can you help us with family planning?"' says Reed Thorndahl, project manager of the Multi-Sectoral Population Project (MSPP) in Peru. "Family planning was a natural extension, particularly of health services, but of just about any area we work in."

A woman in Thailand sells food on a busy street.

Steve Cagan/Impact Visuals
nationwide, and most women used sterilization to end their childbearing after having large families. Few saw contraception as a way to space births or limit family size during their childbearing years.

The trust offered contraceptive information through existing trust activities, including adult education programs and child day-care centers. Also, trust workers visited women in their homes — a “woman-to-woman” approach that contributed to the project’s success.

At the end of three years, contraceptive prevalence among younger women increased from 12 percent to 61 percent, and more than 9,000 women had chosen to use family planning. The most popular methods of contraception were pills (56 percent), followed by female sterilization (19 percent), IUDs (13 percent), male condoms (12 percent) and male sterilization (0.2 percent).

“I think one of the successful elements of the program was the way [community health workers] were able to link family planning with other programs that are empowering women,” says Dr. Lily P. Kak, one of the project researchers and a senior program adviser with the Centre for Development and Population Activities (CEDPA) in India. “It is all seen as a package — improving economic status and improving health status as well.”

When the program began, field-workers encountered community resistance. “When we would approach the houses to talk about family planning, men would slam the doors on our faces, shouting that we were giving their wives immoral ideas,” Kak says.

In Nigeria, COWAN began offering family planning services to village women in 1984, two years after its development program was established. In the first training session, 20 villagers were educated to be community-based family planning workers. Today, there are 350 community-based workers who provide education and contraceptive methods to COWAN’s 38,000 members. Ten supervisors monitor the community workers, and workers are part of a formal health-care network that allows them to refer complicated cases to physicians or nurses.

COWAN’s Chief Ogunleye says there is a necessary link between development and family planning. “When you talk about family planning, it does not mean just how many children you should have or how to space the number of children,” she says. “It also means talking about how much are we going to eat? Who is going to do this task or that? It is talking about each individual’s functions and responsibilities within the family.”

In addition to family planning, COWAN offers other health services. Six “visiting nurses” travel to rural areas to work with traditional birth attendants in an effort to improve maternal and infant health. COWAN also has established its own health insurance program, which helps members obtain care at hospitals or clinics. Women who cannot pay all their health-care costs can obtain a COWAN loan, which is interest-free for the first three months.

COWAN has credit programs for members who want to start their own businesses, including “mini-pharmacies” from which to distribute contraceptives to rural neighbors.

When India’s Gujarat State Crime Prevention Trust began its family planning program in 1987, it emphasized temporary methods for younger, low-parity women. Researchers had discovered that sterilization was the most commonly used contraceptive method nationwide, and most women used sterilization to end their childbearing after having large families. Few saw contraception as a way to space births or limit family size during their childbearing years.

The trust offered contraceptive information through existing trust activities, including adult education programs and child day-care centers. Also, trust workers visited women in their homes — a “woman-to-woman” approach that contributed to the project’s success.

At the end of three years, contraceptive prevalence among younger women increased from 12 percent to 61 percent, and more than 9,000 women had chosen to use family planning. The most popular methods of contraception were pills (56 percent), followed by female sterilization (19 percent), IUDs (13 percent), male condoms (12 percent) and male sterilization (0.2 percent).

“I think one of the successful elements of the program was the way [community health workers] were able to link family planning with other programs that are empowering women,” says Dr. Lily P. Kak, one of the project researchers and a senior program adviser with the Centre for Development and Population Activities (CEDPA) in India. “It is all seen as a package — improving economic status and improving health status as well.”

When the program began, field-workers encountered community resistance. “When we would approach the houses to talk about family planning, men would slam the doors on our faces, shouting that we were giving their wives immoral ideas,” Kak says.
says. "Mothers-in-law ... would say how weak and lazy modern girls were because they could not take care of many children."

Attitudes are different today. "When I heard Rakshaben [a field-worker] talk about the benefits of a small family, I instructed all my daughters and daughters-in-law to use the medicines [oral contraceptives]," said one woman.3

QUALITY CONSIDERATIONS

Integration of family planning into development programs raises some concerns about quality of services. Quality can suffer, health providers say, if those monitoring family planning services are not adequately trained and supervised. Quality also may suffer if family planning funds are diverted to other types of development services.

"There are questions about which stages of development family planning programs should be integrated with other programs, what kinds of integration make sense and whether such programs are cost-effective," says Dr. Nancy Williamson, director of the Women's Studies Division at Family Health International. "There also are questions of ethics — for example, if family planning services are part of a feeding program and use of family planning is tied to getting food for your children."

Cooperative efforts between family planning and development programs reflect changing views of how best to balance population growth with economic and environmental resources.

Since the 1980s, many feminist groups noted that strategies to reduce population growth were targeted toward women but questioned whether family planning programs helped improve the overall well-being of women. Development efforts to promote family planning did not take into account other areas of women's lives, such as education, work, income, or health care, they said. Feminists suggested that family planning be viewed as one component of reproductive health.

Dr. Elaine Murphy of the U.S.-based Program for Appropriate Technology in Health says that development efforts should encompass more than income-generation and family planning. "Basic and profound changes in women's status in developing countries are needed — access to education, women's power in relation to men, rights to jobs, rights to own property and rights to control their fertility," she says.

The Rio Statement on Reproductive Health and Justice, a document prepared early in 1994 by more than 200 women's rights advocates attending the International Women's Health Conference for Cairo 1994, strongly urges policy-makers to incorporate reproductive health in development strategies. "Quality reproductive health services are a key right for women," says the statement. Services should include safe contraception and abortion; prenatal, maternity and postpartum care; and services to prevent, diagnose and treat sexually transmitted diseases, cancers, HIV and AIDS. The statement also asked that more research be conducted on barrier contraceptive methods, which are user-controlled and prevent both pregnancy and STDs.4

"Family planning should be part of development activity," says Salina Mumbungegwi of the Women's Action Group in Harare, Zimbabwe, an advocacy organization that works to improve women's health and legal status. "These programs should complement each other, and one shouldn't occur at the expense of the other. They are both there to improve the quality of life."

— Barbara Barnett

FOOTNOTES

"Empowering" Women

In discussing ways to improve access to family planning services, researchers frequently talk about "empowerment" of women as a key factor. Yet, the term has caused much confusion for health-care providers and policy-makers. Following are two complementary perspectives on empowerment and how it affects women's use of family planning, written by two experts on women's health.

Allowing all voices to be heard

In exploring the relationship between women's empowerment and their use of family planning, it is important to view empowerment as a process, not a single event. Empowerment is a series of steps by which individuals gain access to critical economic and educational resources, such as information, assets, cash and skills. Then, individuals use those resources to bring about changes in their environment and to influence other persons and institutions with competing or conflicting interests.

One view of empowerment is that it encourages all voices to be heard so that mutually beneficial solutions to problems can be reached. It does not mean wresting power from one group or individual and giving it to another.

The relationship between empowerment and women's use of family planning is a complex and problematic one. Although family planning programs typically are targeted toward women, women often lack the autonomy to make decisions about contraceptive use. Spouses, partners or mothers-in-law may make those choices and decisions. Women also may lack the economic resources to obtain the health care they need, including family planning services, or the health care their children need.

In her extensive research on reproductive health and population policy, Dr. Ruth Dixon-Mueller sees comprehensive reproductive health programs as a vehicle for women's empowerment.

"The low status of women has been identified as a root cause of maternal deaths, poor health and high fertility in many societies," she writes. "A reproductive health program forms one component of a comprehensive effort to transform power relations in the family, the community and the society. It challenges female subordination in the sexual and reproductive spheres, as well as in other spheres of women's lives."

In exploring the relationship between family planning, reproductive health and empowerment, researchers may want to consider three spheres or dimensions of women's lives:

Nepalese women learn to read and write. Education is a vital step in the process of "empowering" women.
• The political dimension, where women learn that they can influence others through collective action, such as participation in a political campaign or a voluntary organization.

• The economic dimension, which involves control over land or business, control over the labor of others, economic security, autonomy in the workplace, and gaining access to credit or markets through collective actions, such as credit programs.

• The household dimension. In this dimension women can gain autonomy; they learn to obtain critical resources (information, education, income, financial assets and family planning) and use them to influence decisions that affect themselves and their dependents. Also, women can learn to obtain critical resources and use them to influence decisions affecting the entire household, such as inheritance of property.

While changes in any of these dimensions could be viewed as beneficial to women, there are also questions about whether changes may have negative consequences for women in some settings. In the economic dimension, how can employment be viewed as empowering if it leads women into jobs that are oppressive? In the household dimension, if men view women's autonomy as threatening could there be increases in divorce and domestic violence? Efforts to empower women must also acknowledge men's concerns, so men can be supportive, not antagonistic to the empowerment process.

**Mixed results**

In the economic dimension, at least one study has shown mixed results as to whether access to employment empowers women. This cross-sectional study, based on early data from the Cebu Longitudinal Health and Nutrition Survey in the Philippines, addressed the relationship between smaller families and women's work. The study, which included data from 3,000 households collected over a 10-year period, found that women with fewer young children were more likely to hold an economically secure job, a result suggesting that lower fertility or spacing births may improve women's chances of obtaining and keeping jobs that offer economic security. This depends, of course, on the country's national economy and the availability of jobs for women with children.

The impact of education, which has been associated with use of family planning and smaller families, varied. Mothers with an elementary or secondary education were more likely to work outside the home than mothers with no education or a post-secondary education. Women with several preschool children were more likely to do some kind of work outside the home, presumably to provide for the children's needs.

**Women's Empowerment and Contraceptive Use**

Women who are empowered (through mobility, economic security and other variables) are more likely to use contraception than women who are not empowered.

**Areas of empowerment**

- Mobility
  - Ability to travel outside the home

- Economic security
  - Ownership of property, cash savings

- Purchasing
  - Ability to make purchases, including household items, clothing, food

- Non-violent home
  - Freedom from domination and violence within the home

- Politics
  - Knowledge of government and marriage and inheritance laws, participation in political campaigns

Based upon research on women's empowerment and contraceptive use conducted in rural Bangladesh by John Snow, Inc. Research and Training Institute in the United States and the Development Research Centre in Bangladesh.
The study suggests that work alone may not be a vehicle for women's empowerment. Poor women with several preschool children and no hired worker or female relative to help with child care may be forced to take jobs that allow them flexibility to balance employment and domestic responsibilities — for example, work that is paid by the piece rather than the hour; work that allows them to combine domestic and employment responsibilities, such as tending to a small store; or work that they can take on and quit easily to accommodate family needs and crises. These jobs may not pay well enough to help the women attain any level of economic stability or empowerment.1

Types of employment, women's reasons for seeking employment, and women's ability to determine how their wages are spent should be considered in future research on women's empowerment.

One of the tasks of the Women's Studies Project at Family Health International is to gain new understanding about the relationships among employment, empowerment and women's contraceptive use. FHI plans to analyze existing data from the Cebu Longitudinal Study to explore the relationship between women's work histories, fertility and contraceptive use. Another study, which will collect new qualitative and quantitative data in the Philippines, will explore both short- and long-term impacts of family planning on a number of areas of women's lives, including health, work, status and self-esteem.

By studying the issue of empowerment and identifying factors that can limit or encourage women's use of family planning, researchers, program managers and policymakers will gain important information that ultimately may help them design methods and services that best meet women's contraceptive needs.

— Dr. Rebecca Miles-Doan

Dr. Rebecca Miles-Doan is a research associate at the Center for the Study of Population at Florida State University. She works as a collaborator with FHI's Women's Studies Project on research in the Philippines.

FOOTNOTES


In exploring the relationship of empowerment and contraceptive use, researchers listed six “domains” of empowerment and developed indicators of empowerment in each domain.

**Mobility.** Women were asked about their ability to travel outside their homes to the market, clinic, movies, or other settings.

**Economic security.** Women were asked if they owned a house or land; if they had cash savings; if they used savings for business or loans.

**Ability to make purchases.** This includes the ability to buy pots and pans, children’s clothing, their own clothing and food.

**Freedom from domination and violence within the family.** Respondents were asked if, within the past year, they had been beaten by their husbands, had money taken from them against their will, had property taken against their will, had been prevented from visiting relatives, or had been prevented from working outside the home.

**Political and legal awareness.** Women were questioned about their knowledge of local and national government, plus their knowledge of marriage and inheritance laws.

**Participation.** Women were asked about their participation in public protests and political campaigns, including campaigns for candidates seeking public office or protests against domestic violence or unfair wages.

In late 1992, researchers conducted a survey of more than 1,500 women, including 1,300 married women under age 50. The survey included members of the Grameen Bank and the Bangladesh Rural Advancement Committee (BRAC), two non-governmental programs that provide small loans (an average of U.S. $65 to $75) for women who are self-employed in activities such as craft production, poultry farming, livestock raising or small trade.

For comparison, researchers interviewed women who were eligible to participate in programs but lived in villages not served by programs. Additionally, they interviewed women who were not members of either program but lived in villages served by the Grameen Bank.

Grameen Bank membership had a significant effect on use of contraception. Fifty-nine percent of bank members used contraception, compared with 48 percent of non-members in bank villages, and 43 percent of women living in villages with neither credit program.

The study also showed the level of contraceptive use was increasing at a faster rate among Grameen bank members than non-members. And Grameen Bank members tended to have higher rates of contraceptive use whether or not they had been visited by a family planning worker. A greater percent of the bank’s members get loans, have independent incomes and contribute to their family incomes. Researchers believe this economic security leads to greater contraceptive use.

However, economics appeared to be only one factor influencing contraceptive use. The Grameen Bank promotes small families as the norm, and as a requirement for receiving credit, women must recite “16 decisions,” including the decision to have a small family. Researchers believe this and other membership rituals help women develop an identity outside the home and reinforce the messages of birth spacing that family planning workers promote.

In rural Bangladesh, where the custom of purdah or seclusion is practiced, women typically remain in their homes and villages. They have little opportunity for education and employment and, consequently, few opportunities to earn income. In summary, the Grameen Bank program helps empower women, in part, by strengthening their economic roles, allowing them to contribute to their families’ support, and helping women develop an identity outside the family. The study shows it is possible to help women achieve their fertility goals through programs that decrease women’s isolation and their economic dependence on men. Programs similar to the Grameen Bank can help women overcome obstacles to contraceptive use, such as lack of mobility, lack of cash, lack of information about contraceptive methods and services, and opposition or lack of cooperation from their husbands and other family members.

— Dr. Sidney R. Schuler

Dr. Sidney R. Schuler is the director of the Empowerment of Women Research Program at the JSI Research and Training Institute in Arlington, VA, USA. PHI's Women's Studies Project is planning to support secondary analysis of the studies Dr. Schuler has been directing in Bangladesh.

**FOOTNOTE**

1. In the study methodology, the possibility of selection bias was addressed in several ways. For more information see: Schuler SR, Hashemi SM. Increasing use of contraception by decreasing women’s dependence and isolation: credit programs and family planning outreach in Bangladesh. JSI Working Paper No. 7. (Arlington, VA; JSI) 1994. Also see: Schuler SR, Hashemi SM. Credit programs, women’s empowerment and contraceptive use in rural Bangladesh. Stud Fam Plann 1994; 25(2): 65-76.

*Family planning workers in Dhaka, Bangladesh visit homes. The ability to travel outside the home is one aspect of empowerment for women.*
Long-acting Methods Require Special Care

IUDs, implants and sterilization are very effective and convenient, but proper service delivery is essential.

Long-acting contraceptive methods, including intrauterine devices (IUDs), Norplant and sterilization, are among the most effective, convenient methods available for preventing unwanted pregnancy. They require little or no effort on the part of the user after initial service delivery, which should be done by trained health-care providers.

Because these methods must be delivered and removed by providers, women may have less control over use than with other contraceptives. This situation leads to the potential for inappropriate method use, which can include providing a method without a woman's fully informed choice, blocking access to removal, or providing a method to an inappropriate client. Such problems have led some women's advocates to protest the development and use of provider-dependent contraceptive methods.

But making a contraceptive method unavailable because of potential abuse can restrict women's reproductive choices. "Abuse generally comes from the legal or delivery system — it is not an integral part of a method itself," says Susan Palmore, director of FHI's Division of Policy and Research Utilization. "If something is highly useful, you have to think of ways to avoid abuse rather than throwing the method out. There should be standard norms for performance and no targets for specific methods. Satisfied users should be the goal."

Good service delivery can help prevent inappropriate method use and ensure that women receive adequate information and counseling to help them make reproductive choices without undue influence. Revising approaches to contraceptive introduction and program evaluation can also reduce the potential for method abuse.

While the types of provider-dependent methods vary from IUDs, Norplant and sterilization to injectable forms such as DMPA, many of the service delivery issues are similar. These methods require trained providers, specialized supplies or equipment and proper conditions for delivery. Improved training, counseling, supervision, access to removal for some methods, and other good service delivery practices can prevent method abuse and upgrade the quality of care, experts say.

Norplant Delivery

Norplant, a subdermal implant made up of six capsules that release progestin, prevents pregnancy for five years. Many women choose it because it does not require daily effort, is highly effective and is reversible.

Norplant capsules must be inserted and removed by trained providers. As with other relatively new methods, there may not be enough providers trained in Norplant delivery, even in areas with widely available family planning services.

Norplant implants were developed by the New York-based Population Council, an international nonprofit research organization that has made clear recommendations concerning its delivery and use. "[S]ervices must be available for a client to have the method removed on request, for whatever reason," the council recommends. "Several factors affect accessibility: trained providers, convenient clinic hours, sensitive counseling, and a follow-up system to remind women at five years that the method should be removed."
There is debate about whether access to removal services is adequate to meet Norplant users' needs. An FHI study of Norplant service provision in Bangladesh, where the method was introduced in 1985, illustrates some of the strengths and weaknesses in service delivery. The 1990 study focused on 1,151 women enrolled in clinical trials of the contraceptive implants.

While an earlier study concluded that a majority of users in Bangladesh found Norplant acceptable because of its convenience, effectiveness and long duration, one-third of the women surveyed in the FHI study had requested removal of the implants, primarily because of menstrual disturbances.

Seventy-six percent of these women were able to get Norplant removed at the clinic where it was inserted, but 9 percent went elsewhere and 15 percent still had the implants in place, according to the FHI study. Some women were refused removal more than once, often because side effects were being treated. However, in other cases, clients were told the physician was too busy to remove the implants or that the implants must remain in place for five years.

While most of the centers provided Norplant delivery and removal on request, and most users were satisfied with the method, interviewing clients and providers helped pinpoint problems with removal at a couple of the centers, says Dr. Karen Hardee, an FHI researcher and the study's principal author.

Because few providers in Bangladesh are trained to remove Norplant, some women turned to untrained people to remove the capsules, which led to complications, such as excessive bleeding at the incision site in their arms. Training more providers in Norplant delivery and removal would give women more options for removal, experts say.

Worldwide, family planning providers face a difficult task: They must provide contraception to large numbers of women, while working with scarce resources. "Norplant is expensive and providers are getting double messages," Dr. Hardee says. "Program managers tell them on one hand to make sure Norplant is not removed too early. On the other hand, consumer advocates tell them women must have access to removal. It is a fine line between counseling to keep a method and refusing to remove it."

Some providers did not take women's concerns about side effects seriously, the study says. But side effects are often very important to clients, says Nasreen Huq, a member of Naripokkho, a women's advocacy group in Bangladesh. Worldwide, scrutiny from groups such as Naripokkho has brought to public attention concerns about inappropriate use of long-acting methods. "Taking time to go to a clinic is a considerable commitment," Huq says. "A woman may have gone when she could not cope with [the side effects] anymore. What happens very often is that people coming in for service may not be educated, and they may be poor and powerless. They are not taken very seriously and not treated with respect."

To make providers more aware of these kinds of concerns, clients' comments from the study were used during subsequent provider training for Norplant delivery, says Dr. Hardee.

The study's authors recommended strengthening the service delivery system in order to prevent future difficulties. They suggested improving counseling, insertion services, training and supervision. Better counseling, for example, can prepare women for a method's possible side effects.

Keeping good records and monitoring the process of Norplant delivery and removal can also prevent difficulties by highlighting how clients are treated, Dr. Hardee says. While special vigilance is required during clinical trials, these efforts should be carried over into service delivery, she says.

PROVIDING IUDS

IUDs, when inserted properly by a trained provider, can offer safe, effective, inexpensive contraception for up to 10 years, depending on the model used. More than 100 million women use IUDs worldwide. Providers can ensure successful IUD use by offering the method to appropriate clients, inserting IUDs properly under aseptic conditions, and following up with clients, among other efforts.

Good service delivery involves deciding whether an IUD is an appropriate method, in light of a woman's overall reproductive health. A Population Council study of 509 women in two villages in rural Giza, Egypt found that of 113 women using IUDs, 60 percent had reproductive tract infections, a contraindication for IUD use. Substantial numbers of users also had other conditions that could be problematic for IUD use.

Like many other contraceptive methods, IUDs offer no protection against sexually transmitted diseases (STDs). If left untreated, STDs can lead to pelvic inflammatory disease and infertility. Women who have sexually transmitted diseases, or are at risk of them, should be advised to use condoms or other protective measures. They are not good candidates for IUD use.

Screening and treating for disease is very important, but it generally is not budgeted for, emphasized or monitored in programs, the study's authors wrote. "The use of acceptors may even be creating pressure on program staff that leads to avoidance of the screening requirement," they wrote. "[Family planning policy cannot ignore the health dimension. To do so imperils both the effectiveness of family planning programs and the health and well-being of women.]"
Offering Sterilization

Sterilization provides permanent contraceptive protection that is safe and more than 99 percent effective. It is the world’s most widely used contraceptive method.

One of the most important aspects of good service delivery for sterilization is ensuring that clients have freely chosen the method. Clients interested in sterilization should be counseled on their contraceptive options and given complete information about sterilization, including its risks, benefits, and permanence. Then they should be free to make a decision about the procedure and give their informed consent.

Good counseling can ensure that women are appropriate candidates for sterilization and are aware of the consequences of their choice. It also can reduce the potential for sterilization regret or reversal requests. This conclusion is borne out by a study of 432 women in Brazil who were sterilized between 1971 and 1990.

Women were less likely to request reversal if they were informed that: they would be unable to bear other children; they could change their minds anytime before the procedure; sterilization was a surgical procedure; it carried risks; and there was a possibility of method failure.

Women who knew about more than one method of contraception were less likely to request sterilization reversal than those who had less information. Women who were older than 30 at the time of surgery also requested reversals less frequently. Providers may be able to use this information in order to counsel clients properly for sterilization.

“Women have less regret if there is better counseling,” says Dr. Ellen Hardy, an assistant professor in the Department of Obstetrics and Gynecology at the Universidade Estadual de Campinas in the state of São Paulo, Brazil and the study’s principal author. “If you did really good counseling, many of these women would never have been sterilized.”

However, staff who do counseling sometimes find it difficult to convey the permanence of the procedure and other information to clients, Dr. Hardy says. “The nurses want to know ‘How do you get women to realize that what we are telling them is for their own benefit and is true?’,” she says.

Women who do not control their own decisions about sterilization face a higher chance of regret, which is generally more prevalent than requests for reversal. An FHI retrospective study of 817 women in Sri Lanka who had undergone sterilization found that women who felt pressured by others to get sterilized were almost four times as likely to regret the decision as those who did not feel pressured.

Providers also should consider timing when discussing long-acting methods and other contraceptive choices with clients, experts say. Women should not be asked to make major contraceptive decisions during labor, immediately postpartum, immediately postabortion or at other times when their ability to make a choice is impaired.

Ensuring that policies do not threaten a client’s right to choose, doing away with method targets, ensuring that any existing compensation does not serve as an excessive incentive, providing quality services and other factors also are essential in preventing abuse of sterilization, says Cynthia Steele Verme, director of special programs at the Association for Voluntary Surgical Contraception, a New York-based organization that works to improve access, quality and choice of clinical contraceptive methods worldwide. Programs have shifted from approaches built on incentives and other potentially compelling elements to programs emphasizing a woman’s right to choose her own contraceptive method, Verme says.

Protecting against abuse is still necessary, but service delivery improvements have reduced the use of inappropriate tactics. “Public outcry, the availability of different kinds of methods, more patient advocacy and changes in client-provider interactions have made problems less prevalent,” Verme says. “Also, it does not work to be coercive. It backfires. A program can only achieve success if it is voluntary.”

Improving Access

While inappropriate method use occurs, many women are affected by another factor that reduces their contraceptive choices — lack of availability of and access to contraceptives, including provider-dependent methods. Providers need training in good counseling procedures, insertion and removal techniques, and other areas to ensure both access and good quality care.
Part of broadening a woman's reproductive choices is ensuring that health systems can offer good quality care covering a wide range of methods. Evaluating needs and services before introducing new technologies can help prevent inappropriate method use. Proper training, follow-up and other procedures should be included in the effort to introduce a new method.1

As part of its revised introduction strategy, the World Health Organization (WHO) is working with local teams in several countries, including Brazil, South Africa and Vietnam, to evaluate the need for contraceptive introduction, based on existing resources and conditions. In Brazil, a team of representatives from the Ministry of Health, the scientific community, WHO, and women's groups recently conducted an assessment of method mix, service-delivery capabilities, user and provider perspectives and needs, government policies, and program constraints in the public sector. The team concluded that priority should be given to improving the use of existing contraceptives rather than introducing new ones. In stage two of this effort, WHO will fund a pilot research project in Santa Barbara d'Oeste, a small municipality in the state of São Paulo. In the third stage, a plan for implementing research findings will be developed.1

Other researchers have suggested new ways to focus program planning and evaluation on the needs and preferences of clients. One example is a new evaluation method based on the proportion of women who meet their reproductive goals. Known as the Helping Individuals Achieve their Reproductive Intentions (HARI) index, the system counts as a success any client who avoids an unwanted pregnancy, using whatever contraceptives and service delivery point she chooses.2

—Carol Lynn Blaney

FOOTNOTES
Informed Consent
Plays Key Role

Informing and protecting volunteers in contraceptive studies is vitally important.

Family planning research lays the groundwork for greater contraceptive choice and offers new ways to deliver services. Its benefits include safer and more acceptable contraceptive methods and improved family planning programs.

Both biomedical and social science research in family planning involve some risk to participants, because some of the effects of new drugs, devices or programs are unknown. Unlike most drugs and devices, contraceptives are used by healthy people, sometimes for long periods of time, so contraceptive development studies typically focus on healthy, fertile individuals — usually women. Such studies must protect the health, safety and well-being of participants. Organizations sponsoring research are responsible for guarding these rights, plus privacy and confidentiality.

Contraceptive research is carried out in both developed and developing countries. Trials conducted in developing countries have sometimes raised concerns that new devices and drugs are tested primarily on poor or illiterate people without their consent.

Several safeguards protect against taking advantage of research participants. International ethical guidelines developed by the Council for International Organizations of Medical Sciences in collaboration with the World Health Organization (WHO) state that an investigator must ensure that “persons in underdeveloped communities will not ordinarily be involved in research that could be carried out reasonably well in developed communities,” among other recommendations. The international Declaration of Helsinki, revised in 1989, explicitly directs researchers to design studies in order to protect all volunteers in research.

Health research supported by U.S. government funding, including that conducted in developing countries, must conform to strict regulations protecting participants. Violations can result in civil liability, professional sanctions, loss of financial support for the work or other negative consequences.

“The only way to do ethical research is by using ethical investigators,” says Dr. Roberto Rivera, FHI's corporate director of international medical affairs. “The commitment of the investigator is the most essential element.”

Communicating all necessary information about the research to participants and obtaining their voluntary informed consent is an essential way to protect them, experts say. In addition, ethical review before research and communication between investigators and staff who conduct studies are also important.
CONTRACEPTIVE RESEARCH

Contraceptive development research is regulated so that human participants are protected at each step of the research process. Before human studies begin, laboratory and animal tests must rule out any method that appears to pose an unacceptable risk. Results from animal studies and plans for human studies must be reviewed by ethical review boards and, in many countries, by regulatory agencies before research involving humans can begin.

For contraceptive drug development, human studies are generally split into consecutive phases. Research on contraceptive devices follows a similar sequence, although the terminology may differ.

- Phase I trials are the first safety trials in humans. They last up to a year and use small numbers of volunteers — between 20 and 100. Early contraceptive safety trials are generally done in industrialized countries or other locations where participants can be monitored closely and treated quickly if problems arise.
- Phase II tests for effectiveness and safety; contraceptive trials last up to two years and may involve several hundred volunteers. Phase II trials, which also are often done in industrialized countries, are initiated after Phase I trials have demonstrated safety in the smaller groups of volunteers.
- Phase III trials examine the acceptability, safety and effectiveness of new methods and compare them with methods already available. Contraceptive trials may involve thousands of participants at varied sites around the world and may last several years.

Before studies begin, ethical review boards at many international research institutions examine proposed studies and protocols, their potential effects on volunteers, informed consent documents, and other issues. These boards also address proposed reimbursements to cover study participants' travel or other costs. This area is sensitive, because high reimbursements or other excessive incentives can be considered coercive, but offering no reimbursement for expenses can put a financial burden on participants.

Among other duties, ethical review boards also consider whether the populations represented in studies will be able to reap benefits from the research findings, a particularly difficult question with expensive drugs, treatments or vaccines.

FHI has helped establish and has worked with ethical review boards in many countries where it collaborates on research.3 FHI's review board for its own work is composed of outside experts and consumer representatives. Known as the Protection of Human Subjects Committee, the board has 10 members, including a divinity school dean, a social scientist, an attorney, two consumer representatives, an obstetrician-gynecologist, and one FHI employee — a registered nurse — who is a non-voting member.

While recruiting participants for research, investigators obtain informed consent from participants: Investigators or their representatives give volunteers complete information about the study, allow them to make a free decision about participating and ask them to sign a document to that effect.

During research, sponsoring organizations monitor studies to ensure that procedures are being followed and that volunteers are adequately protected. FHI has made significant efforts to increase the protection of study participants by enhancing the review process for research and improving the clarity of informed consent documents.

INFORMED CONSENT

In recruiting volunteers for research, investigators should establish that a person has the capacity to understand the research and give consent. Obtaining informed consent should be treated as a human rights issue, says Dr. Juan Díaz, who directs the New York-based Population Council's contraceptive research in Latin America and the Caribbean.

In order to obtain informed consent, investigators or appropriate staff members must be thoroughly familiar with the study, so they can describe it to potential participants. Investigators or their representatives typically explain the purpose and methods of the study, how long it will take, what is expected of participants, the procedures involved, the risks and benefits of the research, and whom to contact if a problem occurs, among other information. They also assure study participants they will not be denied health services or face other retribution if they decide not to participate or if the trial is discontinued.

"We emphasize that women have a choice and there is no penalty if they do not go into the study," says Ron Roddy, an FHI epidemiologist who does spermicide research in Cameroon, Thailand and the Dominican Republic. "I keep a count of how many people do not go into the study. If there are many people, it indicates that we did not have coercion, because they feel comfortable enough to say 'no.'"

The process of obtaining informed consent for research is similar to that for sterilizations and other medical procedures. However, for informed consent before research, investigators discuss an experimental procedure with volunteers; for informed consent before sterilizations, providers discuss an established medical procedure with their clients. Sometimes the roles of investigator and provider are played by the same individuals.

Informed consent shares some similarities with informed choice, including the need to provide clients with relevant information. However, informed choice involves offering information about reproductive choices and access to contraceptive methods, and allowing a client to choose freely among them, if desired. Informed choice involves a provider-client relationship.

After having the research explained to them, volunteers usually are asked to sign informed consent documents stating that they have received the information and have agreed to participate. In signing informed consent documents, participants do not waive their legal rights.

"Informed consent should not be considered a document to protect funding agencies, institutions or the investigator from legal liability," says Dr. Rivera of FHI. "The reason for informed consent is to protect the volunteer."

FHI has strived to make its consent forms for research easy to understand. The organization requires its researchers to provide explanations in short sentences, short paragraphs and non-technical words.4 For example, "hypertension" can be rephrased as "high blood pressure," and "upper extremities" become "arms." FHI also has consulted with experts in readability to be sure the forms are simple and understandable for clients. All FHI informed consent documents are designed so they can be read by someone with no more than six years of schooling.

Educational and cultural differences are considered in the informed consent process. For example, FHI and other research groups translate documents into the appropriate languages and then check the translations to be sure they have retained their original meaning.

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INFORMED CONSENT

For each potential participant in biomedical research, investigators' responsibilities include the following:

**Inform**
Before seeking consent, provide necessary information in clear language:
- aims, methods, risks and benefits of research
- expected duration of participation
- alternative treatments available
- extent of confidentiality protection
- description of any compensation for ill-effects of research
- extent of investigator's responsibility for medical care
- provision that individual can refuse to participate or withdraw at any time without retribution
- person to contact in case of problems

**Discuss**
Offer opportunity to ask questions

**Choice**
Allow individual to choose participation

**Consent**
Obtain a signed informed consent form

**Reimburse**
Offer only suitable payments or reimbursements

**Honesty**
Use no deception or undue influence

**Update**
Renew informed consent after major changes in study conditions or procedures

Researchers also should safeguard confidentiality, ensure that the research receives appropriate scientific and ethical review, and meet other requirements outlined in international guidelines.


For illiterate participants, verbal consent may be used. But verbal consent requires additional safeguards to protect participants, such as having a witness present. Witnessing a volunteer's informed consent is a role that women's health advocates can play.

Researchers should verify all participants' understanding of the study before asking them to sign an informed consent document, perhaps by asking them to paraphrase the information. "Showing a piece of paper does not indicate whether people had concepts explained to them," says Nasreen Huq, a member of Naripokkho, a women's advocacy organization in Bangladesh. "We should budget the time to explain concepts. If it means we have to spend two hours explaining something, we should do it."

**HISTORY OF CONSENT**

Many countries require informed consent for medical procedures, and international research agencies generally require informed consent for research, whether or not a country has such regulations.

Still, the concept and formal process of informed consent have developed relatively recently—over the past few decades. Previously, biomedical researchers often experimented on themselves, on people they knew, or on people who had no choice, such as prisoners. A few studies done in the United States before ethical guidelines were well-established involved using radiation on the mentally retarded, reporting illegal behavior without subjects' knowledge and consent, and withholding medical care from men known to have syphilis.

Other problems have led to international rules protecting study participants. The first set of these guidelines was the Nuremberg Code, a response to Nazi experimentation on prisoners in concentration camps during World War II.

More recent guidelines, including the Declaration of Helsinki and detailed U.S. regulations, also require researchers to protect research participants. "The right of the research subject to safeguard his or her integrity must always be respected," reads the Declaration of Helsinki. "The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent."

Informed consent is a dynamic process that is evolving through time. "Standards of informed consent are getting higher as we learn more about people's experiences with research," says Dr. Nancy Williamson, director of FHI's Women's Studies Division. "Thus, we must continuously evaluate our procedures and not be complacent."

**FROM IDEAL TO PRACTICE**

While little research has been done to determine whether clients understand and remember the information they were given during the informed consent process, one study suggests that at least some clients do not remember. More than one-quarter of 156 subjects of medical research at Veteran's Administration Hospitals in the United States did not realize they were participating, even though they had signed consent forms. They were more likely to be unaware
some observers point out that problems occur because ideas about informed consent may not be translated into action. “My major concern is that ‘informed consent’ differs in practice,” says Dr. Carmen Barroso, director of the population program at the MacArthur Foundation in Chicago, and a former professor of the University of São Paulo in Brazil. “[This is] not because of any ill intention, but because of social conditions around the process of research,” she says.

An extreme difference of power and status between an investigator, who is often a physician, and a research participant, who may be uneducated and poor, can influence whether the client feels she can make a free choice. Some participants in research are not given complete information about studies or do not understand the information given.

Concepts of research or disease may not be familiar to potential study participants, Dr. Barroso says. "Research is something that is not in the everyday life of a poor woman in the Third World,” she says.

Because they may be less intimidating than physicians, trained counselors or other staff who do not have a vested interest in the research may be good candidates for offering information about research and obtaining voluntary consent. Teaching women about their rights and giving them all the information necessary to make a decision can improve the informed consent process, Dr. Barroso says, adding that political will is a necessary ingredient for bringing about these changes.

Legal experts and women’s advocates have asked to be more involved in research, as another means of protecting participants. “Organizations doing research should be forthcoming in providing answers to observers’ questions about it,” says Tahmina Rahman, a Bangladeshi lawyer and a research fellow at the Harvard Center for Population and Development Studies, in Cambridge, MA, USA. “There is too much mystique about this whole issue.”

FHI and other international organizations are responding to these requests. For example, FHI has invited the participation of women’s groups to outline research questions for its new Division of Women’s Studies, which is examining the effect of family planning on women’s lives. WHO and the Population Council have played pivotal roles in the process of beginning to include women’s health advocates in decision-making about contraceptive research at early stages.8

Dr. Elaine Murphy, senior program advisor at the U.S.-based Program for Appropriate Technology in Health, recommends that women’s groups should play an important part in explaining and obtaining informed consent. Involvement of these health advocates can help assure a volunteer’s comprehension of the study and develop trust, she says.

**IMPROVING VOLUNTEER PROTECTION**

Researchers in developing countries may be unfamiliar with the concept of informed consent,4 and they may be reluctant to tell participants the details of studies for fear of turning them away or frightening them with the idea of being experimented on. They also may feel pressure to recruit large numbers of research participants.

Despite any misgivings, researchers must communicate clearly and in a non-coercive way with potential participants to be sure they have understood and can make a free choice, experts say. Organizations supporting research also should make careful estimates of how many clients are to be recruited by a given center, says Dr. William of FHI’s Women’s Studies Division. “Abuses may occur if a center is overloaded with work or gets behind in recruitment,” she says.

In addition, safeguarding privacy and confidentiality is important during research. Investigators typically lock or encode participants’ medical files, which are available primarily to the study team, and participants’ names generally are not included in research reports, among other protective measures.

During social science research, which often requires asking personal questions of research volunteers, privacy also must be carefully guarded. For example, a woman participating in family planning research could be at risk if her husband does not know she is using contraceptives. “You may have to time interviews in the home so you are talking to that person alone,” says Dr. Karen Hardee, an FHI researcher who specializes in quality of care issues.

Protecting participants also requires follow-up during research. “We require that during follow-up in Norplant studies researchers ask specifically ‘Do you want to continue using this method?’,” says Dr. Díaz of the Population Council, a non-profit research organization that developed the contraceptive implant. “The questions have to be objective and not meant to induce a certain answer.”

Educating investigators about research ethics and volunteers about their rights can improve participant protection, which is not only morally but scientifically sound. “Investigators compete in having better results, and their first fear is that continuation rates will be low and the studies will be bad if clients make a free choice about participating,” Dr. Díaz says. But good counseling for participants before research can improve continuation rates and the quality of studies, he says.

— Carol Lynn Blaney

**FOOTNOTES**

“Now I Will Tell my Daughters”

Some women who lack contraceptive services or the power to negotiate contraceptive use turn to unsafe abortions to deal with an unwanted pregnancy. A Bolivian woman describes her experience with such an abortion to Susanna Range of International Projects Assistance Services (IPAS), a U.S.-based organization that concentrates on abortion-related research.

LA PAZ, Bolivia — If I have sexual relations six days before and six days after my period, nothing will happen. That was my rule during the last seven years since I had my last child. But this time it failed me. I already had three daughters. It had been five days and my period hadn’t come. I got desperate because usually my period is early. It never comes late. I said to myself, I’ll just have to do something.

So I went where I could. Here comes this lady wearing this nurse’s outfit, although she did not seem to be a nurse. She said, “I guarantee they will do it well in this place.” I told my husband. We decided to do it.

They got me all ready and then did that treatment to me. I was there from 8:00 to 11:00 and got out feeling dizzy. They did a scraping or general cleaning, as they would call it. Then they told me, now you can go home and you’ll feel better. By Saturday, I was feeling okay, just resting. On Sunday night, I started feeling bad, I had a fever, pain around the waist, and on Monday I went to work and I just couldn’t do my job as usual. I was sick by then, I was beginning to sweat and all that.

I wondered what was going on. Was I supposed to rest for a longer time? My stomach was swollen. I looked as if I was pregnant again. But I just couldn’t stand the pain anymore. So my husband said, “Let’s go see a doctor, maybe they did something wrong.”

So, we went to the hospital and the doctor said, “It’s possible that there has been a perforation in the uterus. We have to do surgery right away.” I had surgery that same night.

I regret everything that I did and that I shouldn’t have done. There was no other alternative for me. I had talked to my husband. He doesn’t have a job. I work but my salary is 200 Bs a month (U.S. $45). I work from 6:00 in the morning to 11:00 at night. I work hard, very hard. If I get pregnant I won’t be able to go to work. And then what will happen to my husband, who will provide food for our children? There are no jobs for men.

We wanted to have one more child, but we needed to make sure we had enough money to support it. Unfortunately, now it doesn’t matter.

My daughters came to see me. They brought me a rose and said, “Get well soon, Mommy.” They understood what went on. If we had enough money, they would be looking forward to a new baby. But that’s not possible. My ten-year-old says to me, “I’m going to school because one of these days I’m going to help the poor by providing jobs for everyone.”

If I could go back in time, I would do what the doctors told me to do, I would probably use the “copper T” [intrauterine device] to prevent pregnancies and when I was ready to have a child I’d just have it removed. Now, I will tell my daughters everything about my life experience. About the things they can do, all the things doctors can tell you to solve problems. I think it will be different for them. I think it will be better.
"In Talking to People, Simplicity is Best"

Determining ways to meet women's needs has been the driving motivation of dedicated health-care providers throughout the world — people such as Grace Duano of Nigeria. Trained as a nurse and midwife, she worked many years with the University College Hospital in Ibadan and co-founded the Association for Reproductive and Family Health in Nigeria. She is on the Technical Advisory Committee for FHI's Women's Studies Project.

IBADAN, Nigeria — When I began introducing modern contraceptive methods in my territory in Nigeria, I quickly realized that when you talk of overpopulation, families do not understand what you are talking about. They have food to grow and need children to help them. But when you talk in terms of wanting the woman to survive, they understand.

In talking to people, simplicity is best. I try to use words that they will understand — not just telling them that they must do something. If women understand how their reproductive organs work and the consequences of repeated childbirth on these organs, they will understand the need to space births. Hence, I talk about menstruation and pregnancy, and the importance of antenatal care, postnatal care and infant welfare.

My mother had a big impact on me. She did not have a child until my brother was born in 1925. Between my brother and myself, she had about four or five babies who all died. If my mother had gotten help, the babies would most likely have survived. The babies died because of ignorance, and a lack of health care and quick intervention.

My mother taught herself to read and write and was highly interested in helping people measure up to their expectations and prove to themselves that when you talk of overpopulation, families do not understand what you are talking about. They have food to grow and need children to help them. But when you talk in terms of wanting the woman to survive, they understand.

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Market-based delivery of services is an important opportunity. The Committee on Women and Development (COWAD) of Nigeria wanted clinics in the market places to prevent maternal mortality and provide other services. In 1985, we trained 264 women and men in Oyo State who sell their wares in 39 markets. They provide family planning education, treatment of common illnesses, oral contraceptives, condoms, foam and referral for other methods. The U.S. Agency for International Development funded this through Columbia University. In 1989, the local government took over this work.
Resources

Unmet needs in women's reproductive health

Challenges, Unmet Needs describes the concept of unmet need in family planning. The booklet details women's health perspectives on unmet need, particular needs in several countries, current and anticipated unmet needs, and approaches that have been tested, such as contraceptive social marketing and reaching poor and rural people. There is also a list of recommended further reading on the topic of unmet need.

The booklet is available at no cost to family planning workers and associated individuals and organizations from: Public Affairs Department, International Planned Parenthood Federation, Regent's College, Inner Circle, Regent's Park, London NW1 4NS, UK.

Bibliography lists publications on abortion

Abortion and Health, a List of Selected Resources, is a bibliography of materials published since 1980 that provide information on the impact of induced abortion on women's lives and health, the extent of illegal and unsafe abortion around the world, and what measures can be taken to ensure that women have access to safe abortion services. Articles cover general topics, law and policy, abortion and physical health, abortion and mental health, and regional and country information.

The free listing is available from Public Affairs Department, International Planned Parenthood Federation, Regent's College, Inner Circle, Regent's Park, London NW1 4NS, UK.

Training module on postpartum contraception

Postpartum Contraception, the second training module in FHI's Contraceptive Technology Update Series, is available from FHI. The slide presentation provides an overview of contraceptive concerns and needs of women during the postpartum period, features of successful postpartum programs, and contraceptive methods appropriate for postpartum use. The presentation targets a broad audience, including physicians, nurses, administrators, policy-makers and other health professionals, and can be adapted to suit particular audiences. The module contains 35mm color slides, a suggested narrative, a reference list and reprints of selected journal articles and book chapters.

Single copies of the module are available at no charge to family planning trainers in developing countries upon written explanation of need, and available to others for a modest fee. To obtain a copy, or information about other modules in the series, contact: Vana Prewitt, Senior Health Communication and Training Coordinator, Family Health International, P.O. Box 13950, Research Triangle Park, NC, 27709, USA.

Norplant and IUD updates

New publications on Norplant and the copper T IUD are available from the Population Council. Norplant, Guide to Effective Counseling, has been revised and conforms to U.S. Food and Drug Administration labeling. The Copper T 380 Intrauterine Device: A Summary of Scientific Data contains data on the copper T IUD, and studies of Copper T 380Ag and Slimline.

These publications are available at no cost to readers in developing countries. There is a small cost for readers from developed countries. Contact: The Population Council, Office of Communications, One Dag Hammarskjold Plaza, New York, NY 10017, USA.

Proceedings of Helsinki conference

The proceedings of a conference, International Symposium on the Recent Advances in Female Reproductive Health Care, contain information on recent contraceptive research. The 1992 conference, held in Helsinki, Finland, addressed population trends; hormones, family planning and health; long-acting contraceptive methods; postpartum contraception; anti-progestins; and new trends in contraception.

The proceedings are free by writing to: Publications Coordinator, Family Health International, PO Box 13950, Research Triangle Park, NC 27709 USA.