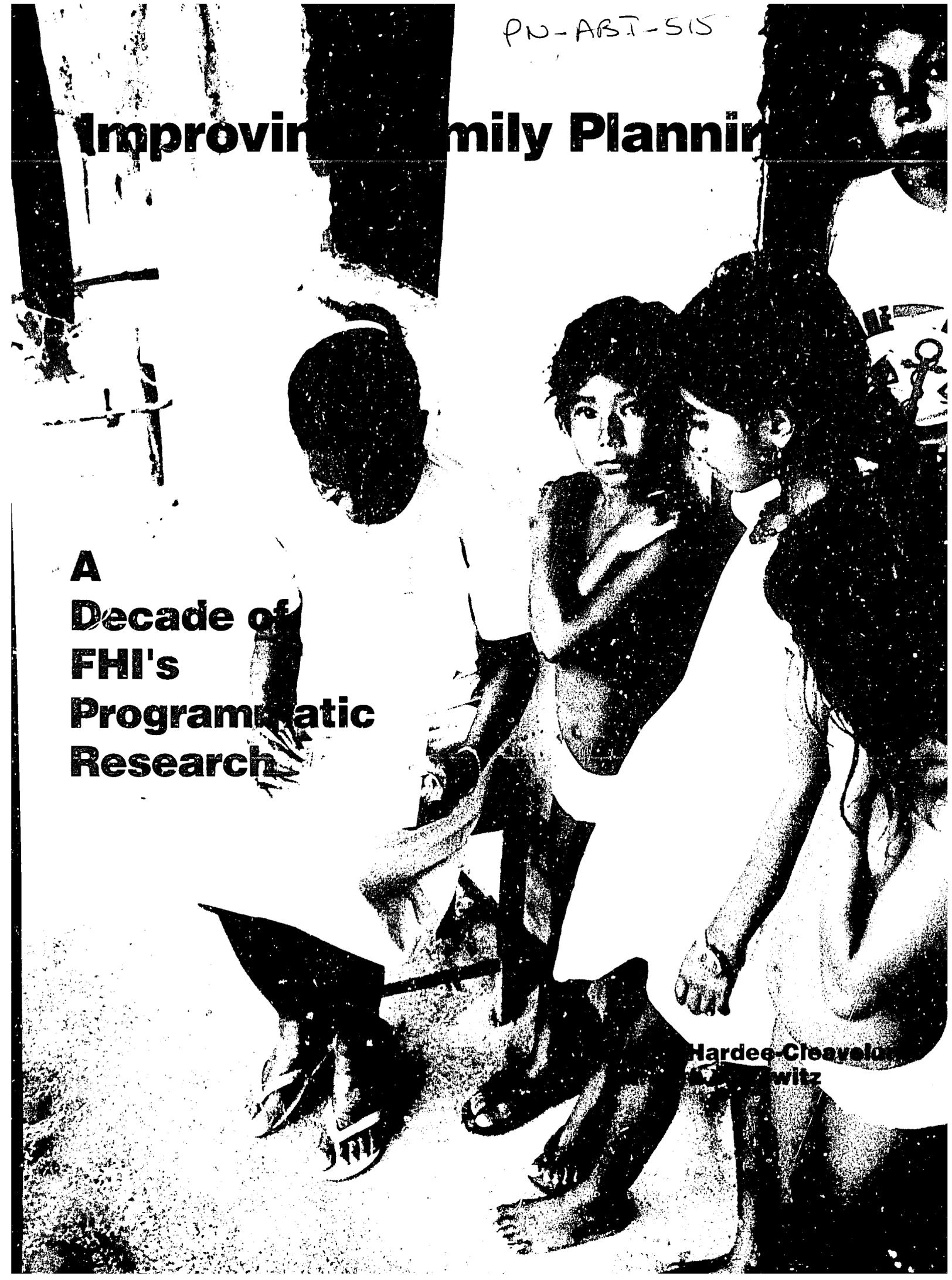


PN-ABT-515

Improving Family Planning

**A
Decade of
FHI's
Programmatic
Research**

**Hardee-Cleaveland
K. J. Switz**



**Improving Family Planning:
A Decade of FHI's Programmatic Research**

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EXECUTIVE SUMMARY



C. Stauffer/WHO

Among the many benefits of breastfeeding is its contraceptive effect.

Contraceptive technologies are effective only to the extent that they are used by men and women. Programmatic research that studies family planning programs can help to determine how to promote and provide different contraceptive technologies in diverse cultures and program settings. Programmatic research can also help to assure that contraceptive technologies are properly introduced and appropriately provided to family planning users. While operations research generally focuses on testing solutions to operational constraints in family planning programs, programmatic research — as conducted by Family Health International (FHI) — identifies and addresses obstacles to the provision and better use of contraceptive technology.

Family Health International's goal is to improve the health of mothers and their children by expanding the provision of safe, effective and acceptable forms of contraception worldwide. To this end, FHI conducts international contraceptive clinical trials which are important not only in testing new family planning methods but in demonstrating the effectiveness and safety of currently available technology.

The organization's programmatic research complements this work in clinical trials. Over the past decade, FHI's programmatic research has looked at the acceptability of contraceptive methods; perceptions of methods; the quality and cost of family planning services — including accessibility and barriers to service

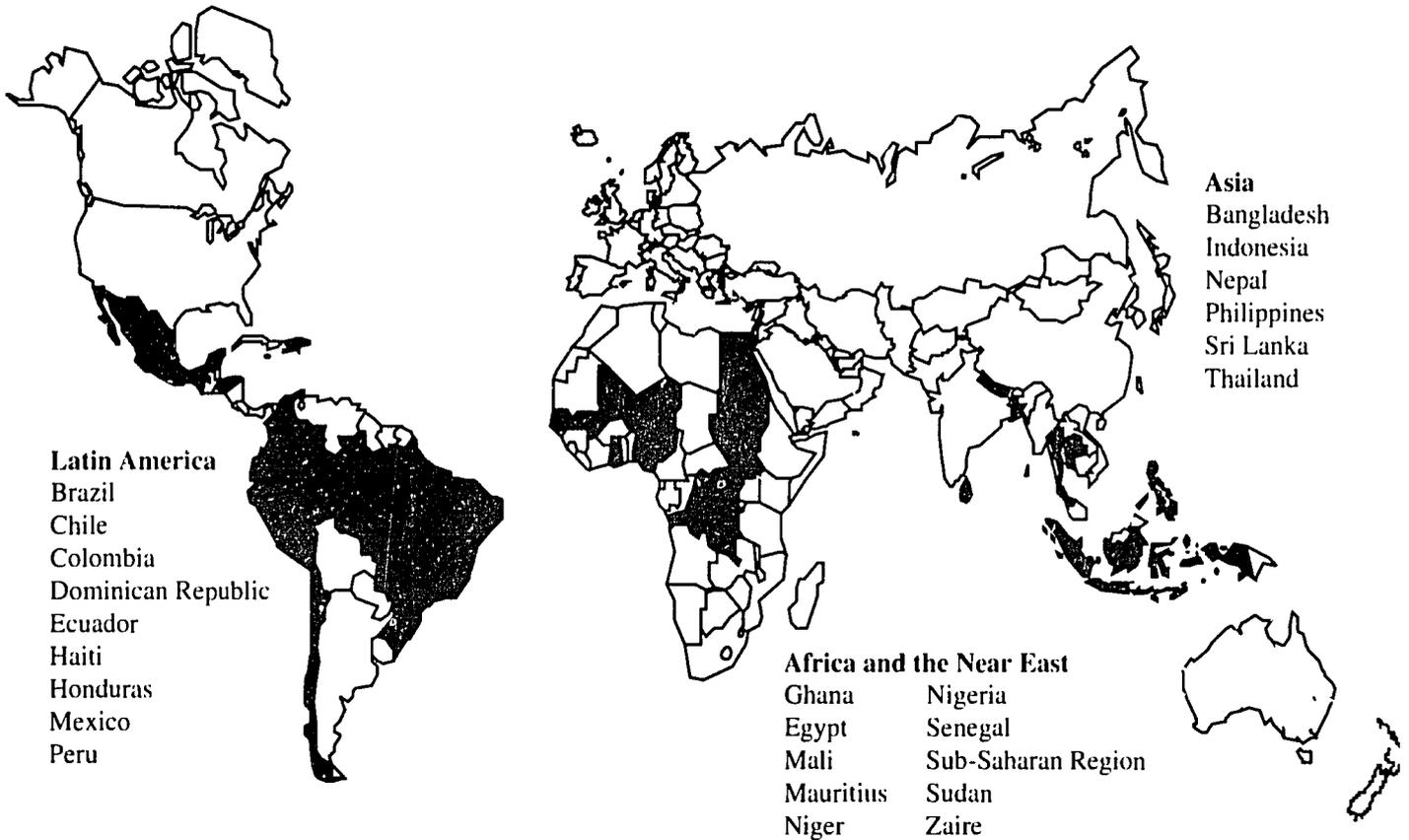
delivery — and compliance with guidelines on use of contraceptives. FHI has also conducted many programmatic studies at the request of local governments and A.I.D. missions to answer questions raised by local family planning providers or ministries of health.

FHI has made a long-term commitment to increased institutional capacity for research through work with Family Health Research Centers (FHRCs) in nine countries: Kenya, Mali, Egypt, Sri Lanka, Bangladesh, Thailand, Indonesia and Mexico. These FHRCs are involved primarily in biomedical research, but most are moving toward more programmatic research. FHI has also worked intensively with a network of research investigators in more than 80 other countries in Asia, Latin America, the Near East and Africa. Without their assistance much of the research described here would not have been possible.

FHI's programmatic research aims to provide important information to policy makers and program managers. Examples include:

- FHI's work in oral contraceptive compliance has revealed the need for standard guidelines on how to take the pill. This work culminated in a United States Food and Drug Administration (FDA) meeting in 1991 which recommended that pharmaceutical companies develop standardized and simplified instructions for oral contraceptive use to include in patient package inserts.
- Acceptability research has shown that NORPLANT[®], the new subdermal contraceptive implant, is a highly acceptable method of contraception worldwide.
- In an effort to increase the shelf life of condoms in various climate and storage conditions, FHI is working to develop a plastic condom for men. Studies indicate that the plastic condom will be acceptable among users.
- FHI's work in breastfeeding resulted in the "Bellagio Consensus." These guidelines state that women who fully breastfeed and do not supplement feeding are protected from pregnancy for six months or until first menses, whichever is sooner.
- Studies on sterilization have identified barriers to sterilization, including difficulty in obtaining a sterilization for other than medical reasons, lack of facilities, arduous administrative requirements, difficulty in leaving family, costs, and husband's objection.
- FHI has confirmed to A.I.D. that switching brands from the standard dose Norinyl 1/50 to the low dose Lo-Ovral (Lo-Femenal) has neither increased side effects nor reduced acceptability among users.
- Following a study of laboratory requirements for oral contraceptive use, policy makers in Senegal abolished certain requirements, making pills more available to women there.
- Side effects of contraceptives can have a significant influence on the decision to continue their use. Health care providers should be prepared to offer advice on management of contraceptive side effects or to offer other contraceptive alternatives.

Countries in which FHI has conducted programmatic research: 1980 to 1990



- The risks of oral contraceptive use are not increased by the distribution of oral contraceptives by non-medical personnel through community-based distribution (CBD) systems. Medical exams are not necessary for safe distribution of the pill; preconditions that preclude pill use can be determined by simple questionnaires.
- Using a methodology developed at FHI, we have calculated the costs of family planning into the next century. Funding shortages suggest that increased efforts will be necessary by donors and country program managers to improve efficiency of service delivery and to achieve cost recovery.
- During the past three years, FHI has been working intensively in two countries, Kenya and Egypt, to institutionalize the capability to conduct programmatic research. This process has included workshops to teach programmatic research methodology and assistance in all phases of study implementation.

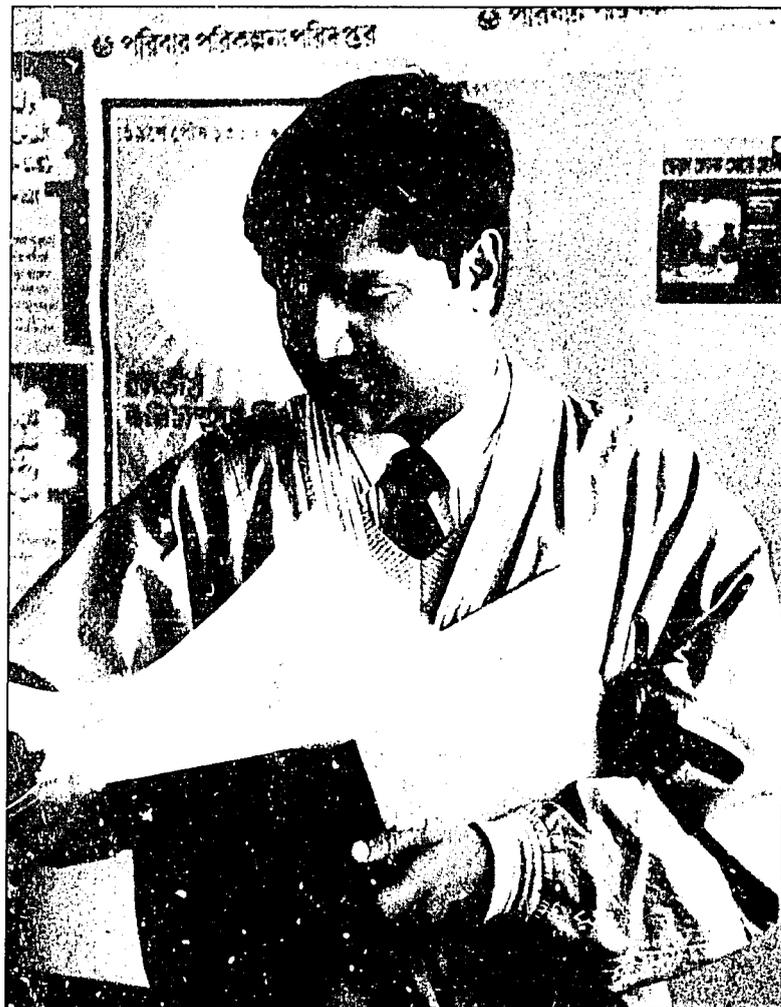
Such programmatic research will continue to play a key role in family planning programs, particularly as the demand for family planning expands more rapidly than available resources. Policy makers and program managers around the world will have to make difficult choices on expansion of services, to decide which service delivery modes to promote, to improve the quality of services provided, and to assure that contraceptives are provided in the safest, most efficient and acceptable means possible. Information about contraceptive safety and user satisfaction will play an increasingly important role in family planning program and policy development in the coming years.

TYPES OF PROGRAMMATIC STUDIES

In the past decade, FHI has conducted programmatic research in over 25 countries throughout the world (see map, page 4). Some studies have dealt with programmatic issues common to all contraceptive technologies, while others can be classified by method, including oral contraceptives, NORPLANT[®], male and female sterilization, male and female condoms, breastfeeding and natural family planning. Study topics have included: acceptability of contraceptive methods, including new product testing; contraceptive compliance and guidelines for pill distribution; acceptance of and barriers to use of sterilization; clinic practices and procedures as barriers to family planning provision; the role of health care providers in expanding or restricting contraceptive choices; method and brand switching; and the costs of family planning. Table 1 reviews the types of studies carried out, by country, and Table 2 shows the types of studies conducted by the method of contraception included in the study.

FHI has completed contraceptive acceptability studies on all methods except the Lactational Amenorrhea Method (LAM), which is currently under study by FHI. The role of health care providers has also been widely studied, particularly in Asia and Latin America. FHI is now increasing programmatic research in Africa, as family planning programs are initiated and expanded, concentrating on acceptability of contraceptive methods and improving clinic practices and procedures. Costing issues are also being addressed in Africa.

In Chapter 1 we briefly discuss FHI's perspective on the various topics and our reasons for conducting programmatic research in each area. For method-specific studies in this paper, the topics are arranged within methods in Chapter 2. For studies that focus on family planning more generally, the material is organized



Karen Hardee-Cleaveland/FHI

A physician in Bangladesh inspects NORPLANT[®] forms.

Table 1

Family Health International programmatic research, by country and study topic

Country	Acceptability	Compliance	Acceptance of & Barriers to Use	Clinic Practices and Procedures	Role of Health Care Providers	Method / Brand Switching	Cost of Family Planning
Africa							
Ghana	●						
Mali	●						
Mauritius					●		
Niger	●			●			
Nigeria	●			●	●		
Senegal	●			●	●		
Sub-Saharan Region			●				
Zaire	●			●			
Asia							
Bangladesh	●						
Indonesia	●				●		
Nepal	●						
Philippines	●		●		●		
Sri Lanka	●		●		●	●	
Thailand	●		●		●		●
Central & South America							
Brazil	●		●		●		
Chile	●						
Colombia		●		●	●		
Dominican Republic	●						
Ecuador	●						
Haiti	●						
Honduras	●		●			●	●
Mexico	●		●		●		●
Peru					●		
Near East							
Egypt	●	●	●	●	●		●
Sudan						●	

according to topic in Chapter 3. Chapter 4 discusses FHI's work in institutionalizing the capability within developing countries to conduct programmatic research. Chapter 5 outlines FHI's future directions in programmatic research.

This monograph highlights those programmatic studies that emphasize the provision of contraceptive services. Complementary work that has been done to show the need for instituting or expanding service delivery programs has been excluded. This work excludes surveys of special groups including young adults and men, as well as women hospitalized for complications of illegally induced abortions. The monograph also excludes studies of women receiving obstetric care, many of whom have had many closely spaced births. Finally, much of the national survey work that FHI has done in Honduras and statewide surveys in Brazil have been excluded, although some aspects of this work that are especially concerned with family planning service provision are included in this monograph.

Acceptability

While some contraceptive methods are widely used in some countries, they fail to gain popularity in others. For example, in the geographically disparate countries of Ecuador in South America and Sri Lanka in South Asia, pill prevalence is low. Acceptability research can help determine the reasons why widely available methods succeed or fail to gain popularity in each country. When a new method is introduced into a family planning program, acceptability research has been useful

Table 2

Family Health International programmatic research, by contraceptive method and study topic

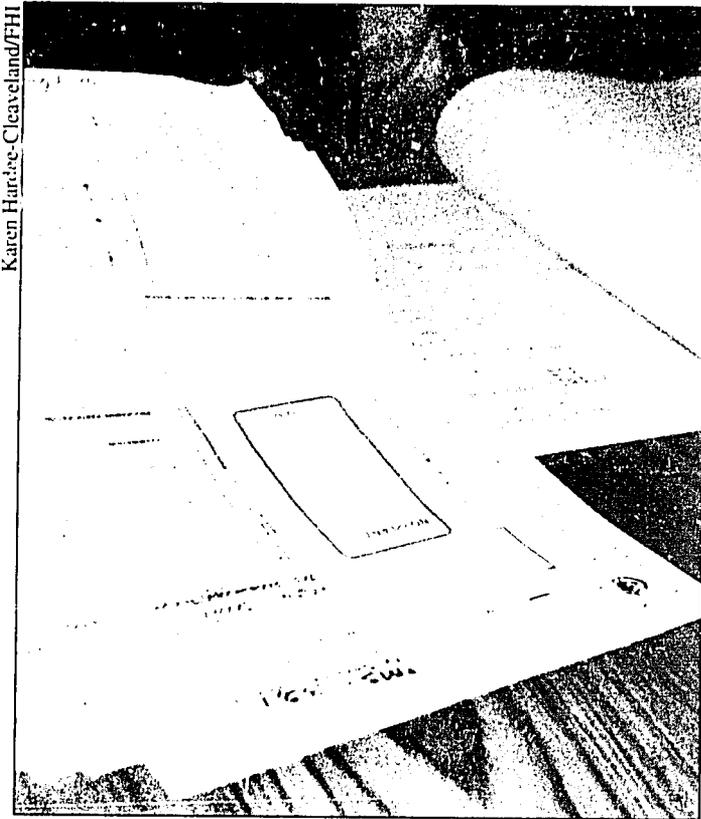
Method	Acceptability	Compliance	Acceptance of & Barriers to Use	Clinic Practices and Procedures	Role of Health Care Providers	Method / Brand Switching	Cost of Family Planning
Pill	●	●		●	●	●	
Implants	●						
Sterilization	●		●				
Condoms: Male	●						
Female	●						
Breastfeeding & Family Planning			●		●		
Natural Family Planning (NFP)	●				●		
General Family Planning			●	●	●		●

in planning information, education and communication (IEC) programs to combat fears and to emphasize the positive feelings potential users have about the method. Acceptability research is also useful at the early stage of product development. A method may be safe and effective but if it is not acceptable it may not be used.

Development of new methods is costly; by carrying out acceptability research, the pitfall of developing a method no one will use can be avoided. FHI has conducted acceptability studies on oral contraceptives, NORPLANT[®] and condoms.

Pill Compliance

Under ideal conditions, oral contraceptives (OCs) have a failure rate of less than one percent. In actual use, however, failure rates of up to 20 percent are found in some developing countries. Failure rates may be high because women stop taking the pill without substituting another effective contraceptive method or because they take the pill incorrectly, thereby reducing its effectiveness. Incorrect pill taking may also result in method failure if poor compliance leads to side effects and discontinuation. Little information is available on the knowledge of clients or providers about how to take the pill or on actual compliance patterns. If continuation rates of oral contraceptives are to be high and unwanted pregnancies low, women must receive correct and adequate counseling at the time of acceptance to impress upon them the need to take the pill correctly and consistently, even if they experience common side effects.



Women desiring NORPLANT[®] are carefully screened.

Acceptance of and Barriers to Sterilization

Sterilization is one of the most cost-effective means of providing protection against the risk of pregnancy. Because it is a permanent method, care should be taken to ensure that the level of regret is minimal, while at the same time keeping barriers to obtaining the method at a reasonable level. Over the years, FHI has carried out a number of studies focusing on barriers to and regret from sterilization, including the effect of compensatory payments.

Clinic Practices and Procedures

Policies and practices adopted by programs and clinics may intentionally or inadvertently limit access to family planning. Stringent guidelines may discourage individuals from seeking family planning by requiring unnecessary tests or signatures, by making services too expensive, time consuming, or otherwise too difficult to obtain.

The Role of Health Care Providers

The promotion of any method of family planning can be greatly influenced by the attitudes and knowledge of the health care providers. Health care providers influence both clients in their choice of methods, and family planning programs in

the methods that are available for distribution. If providers, particularly physicians, are not convinced of the safety and efficacy of a contraceptive method, it will likely be underutilized by clients. Health care providers are the link between programs and clients. The information they dispense and the attitude they project to clients can have an important effect on acceptance and continuation of family planning.

Method, Dose, and Brand Switching

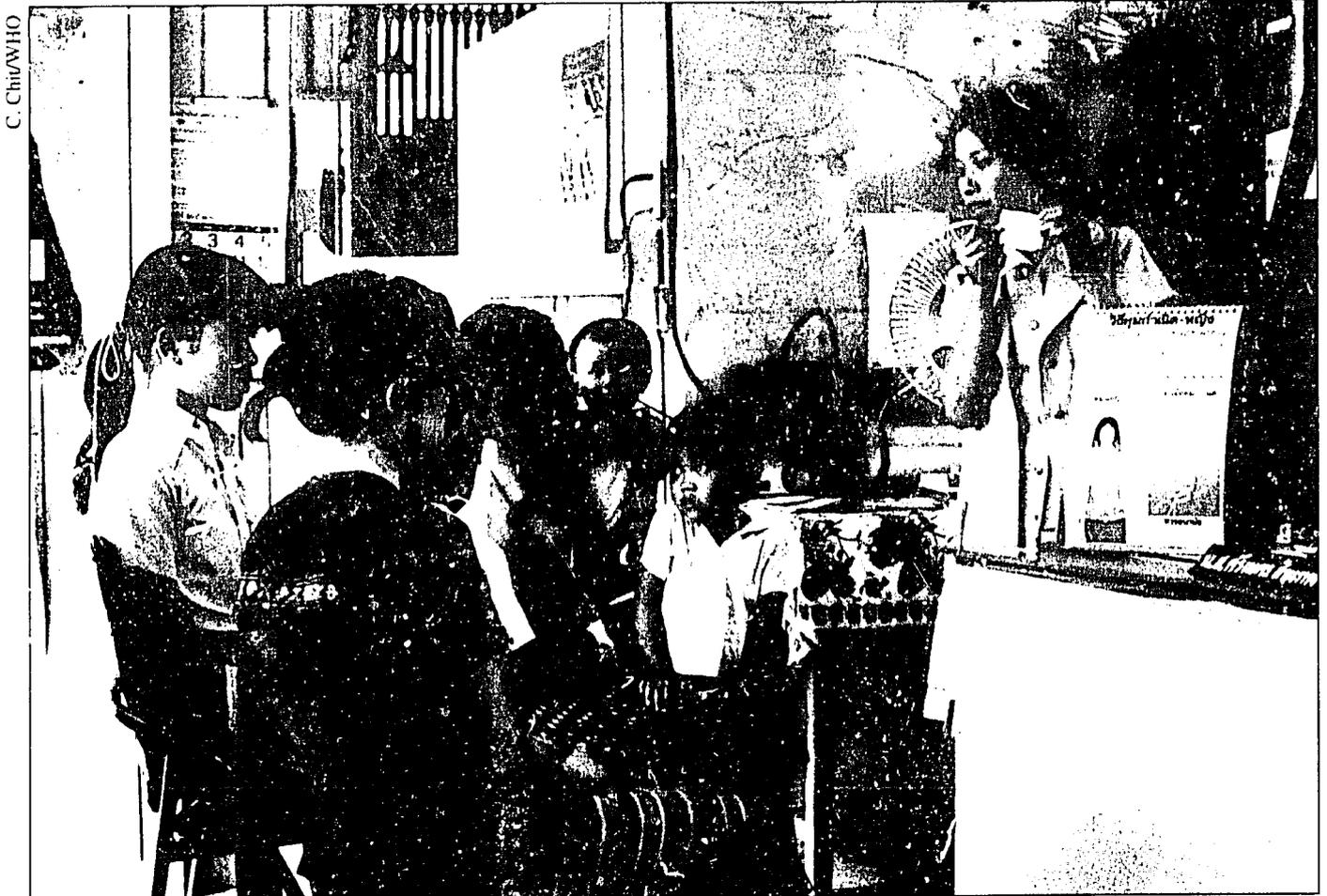
Because of procurement decisions made by international organizations, women who obtain their oral contraceptives from publicly funded programs may be required to switch from one brand or dose to another. For example, in the early 1980s A.I.D. changed its procurement of combined oral contraceptives (COC) from Norinyl 1/50, a standard estrogen-dose COC, to Lo-Ovral, a low-estrogen dose COC. What are the consequences of these procurement decisions? Do women experience side effects? Does this experience lead to discontinuation? Is special counseling required to deal with women's concerns about the change in the oral contraceptive provided?

An important question for donors and program planners is what happens to contraceptive use when a new distribution system or a new product is introduced. Many countries have introduced social marketing programs and there is interest in determining the impact of such programs on total use of contraception and on use of the social marketing methods. Finally, it is important to know the characteristics of users of the new system, including those of women who have switched from other systems, in order to determine if the program is reaching the appropriate target groups.

The Cost of Family Planning

Projections show that the demand for family planning will increase into the next century, while donor resources may increase only slightly, if at all. If more couples and individuals are to be reached with family planning services, governments and the private sector will need to invest more resources in family planning, more of the burden must be shifted to the consumers of services, and services will need to be provided more efficiently. FHI has conducted economic analyses to determine current and projected costs of providing family planning into the next century. FHI is also undertaking innovative studies to reduce the costs of service provision, without compromising high quality services.

METHOD-SPECIFIC STUDIES



C. Chit/WHO

Women in Thailand receive instructions on pill taking.

Oral Contraceptives

For the past 30 years, oral contraceptives, or pills, have played a major role in family planning programs worldwide. Together with IUDs and sterilization, they have been a centerpiece of most family planning programs. According to the United Nations (UN, 1989), there were 10 countries in which at least half of the current contraceptive users in 1988 were using the pill, and there were another 22 countries in which the pill accounted for at least 20 percent of contraceptive use.

Despite such widespread use, rumors abound regarding the safety of the pill. A 1985 Gallup Poll in the United States found that 75 percent of U.S. women believed that there were substantial health risks associated with taking the pill, and only 16 percent thought that having a child posed more of a health risk than taking the pill.

As a follow-up to the Gallup Poll, FHI worked with investigators in Egypt, Thailand, Sri Lanka, Senegal, Nigeria, Chile, Mexico and the Philippines to gain a better understanding of women's perceptions of the pill (Grubb, et al., 1987). The results of the 1986 study suggest the need for better information and education about the pill. Among the 100-150 urban, middle class women interviewed in each country, the perceptions of the health effects of the pill were very consistent. Taking the pill was considered to have substantial health risks by 50-75 percent and was thought to be more dangerous than childbearing by over 40 percent of respondents (except those in the African samples). Table 3 shows general perceptions of the safety of the pill in selected countries.

Women who had used the pill were as likely as those who had not to be unaware of possible serious cardiovascular effects (10-35 percent). More than one-quarter of the women were aware that the pill may be associated with heart disease, 15-25 percent strokes, and 50-65 percent severe headaches. Contrary to scientific evidence, many women thought that the pill caused sterility and birth defects. Between 20-50 percent of the women thought that the pill could cause breast, uterine or stomach cancer, although the latter has never been associated

Table 3

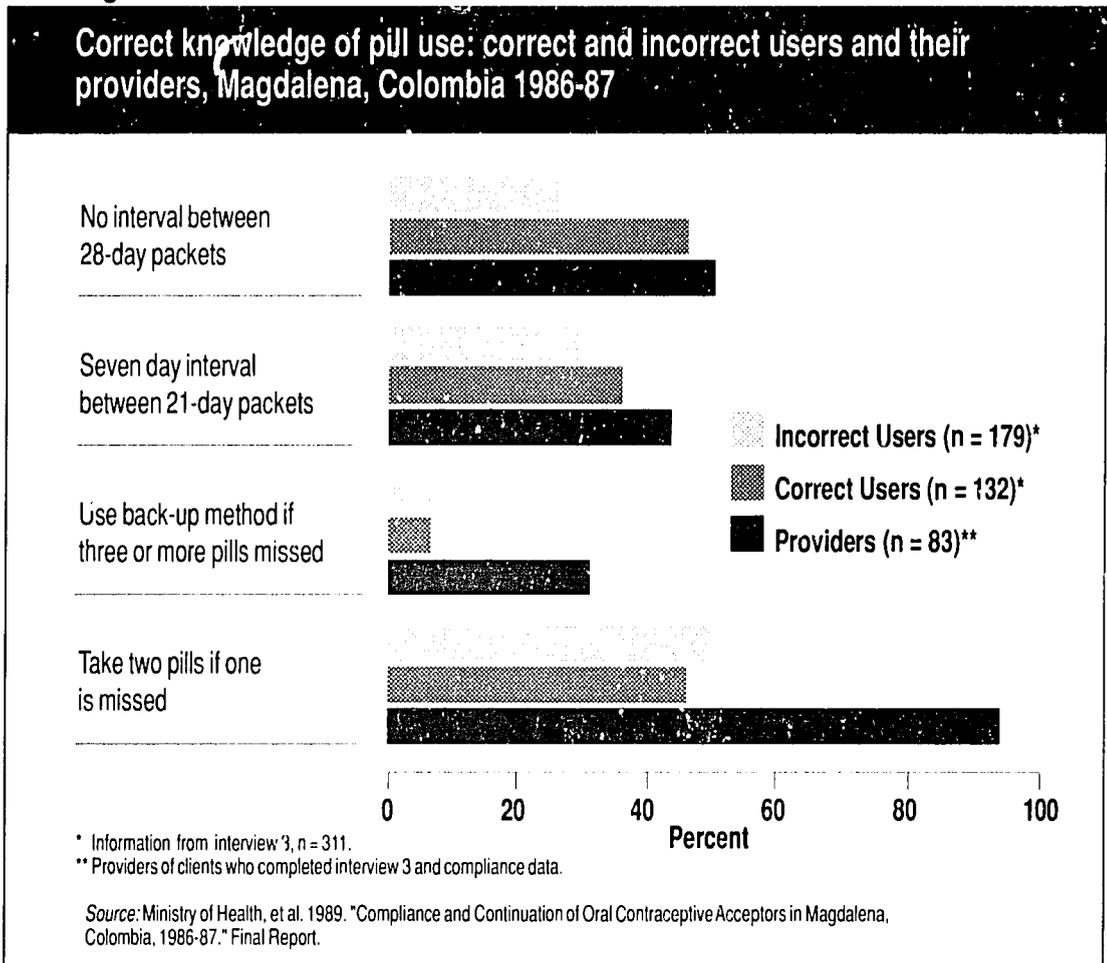
General perceptions of the pill's safety, among women, for selected countries: 1986 (in percent)

Country	Pill Use Has Substantial Health Risks			Compared with Childbearing Pill Use Is:			
	Yes	No	Don't Know	More Risky	Equally Risky	Less Risky	Don't Know
Thailand	61	33	6	48	8	22	22
Sri Lanka	51	40	9	40	21	12	27
Egypt:							
Urban	57	36	7	2	27	61	10
Rural	52	42	4	3	21	70	6
Senegal	69	28	3	2	38	40	20
Nigeria	66	24	10	27	9	59	5
Costa Rica	75	25	0	47	19	30	4
Chile	74	16	10	50	23	24	3
Mexico	61	37	2	48	21	29	2
United States*	76	22	3	46	18	16	20

*Source: Gallup Poll, January, 1985.

Source: Grubb G, et al. 1987. "Women's Perception of the Safety of the Pill: A Survey in Eight Developing Countries." *Journal of Biosocial Science*. Vol. 19.

Figure 1



with the pill. The protective effects of the pill, on the other hand, were virtually unknown; for example, very few women knew that the pill provided protection against anemia.

Pill Compliance

To further understand pill compliance, FHI collaborated with the Ministry of Health in Bogotá and the Health Services of Magdalena in 1986 to conduct a study in Magdalena, Colombia (Potter, et al., 1988). Of 341 current users, fewer than half (42 percent) took the pill correctly during the two-week study period. Ten percent of the women ran out of pills; another 43 percent had missed taking at least one pill during the cycle (and had not made it up). Many had done so on purpose, due to the absence of their partner, irregular sexual activity, an attempt to reduce side effects or to make their supplies last longer. Nearly half of incorrect users made errors in transition from one cycle to the next, either by waiting too long or not long enough between packets.

The study in Magdalena also measured knowledge of the pill. While 80 percent knew that the pill is highly effective, only 17 percent knew that it works by preventing ovulation and 33 percent knew that they should continue taking the pill even if mid-cycle bleeding occurs. Only 5 percent knew that a back-up method should be used if three or more pills are missed (Figure 1).

In 1988-1989 in Egypt, FHI worked with the Social Planning, Analysis and

Administrative Consultants (SPAAC) to conduct 12 focus group discussions with a total of 96 women to explore factors associated with pill compliance (Loza and Potter, 1990). Thirty-four providers were also interviewed individually. These providers included physicians, nurses, social workers, outreach workers and pharmacists in public and private sector organizations.

The Egyptian pill users were clear that they did not want more children and yet compliance errors made accidental pregnancy a strong possibility. Women in Egypt are taught to start the new cycle of pills on the fifth day of the menses; the need to wait no more than seven days between 21-day packets and to start the 28-day packet immediately were virtually unknown. A complementary demographic health survey (DHS) found that just over 10 percent of the women knew how long to wait between the 21- and 28-day packets. Pill use is perceived as being harmful to the health of a woman, and is thus interrupted in some cases because of perceived side effects, temporary absence of sexual relations, intermenstrual bleeding, and the perceived need to “rest” from taking the pill. Egyptian women generally do not use a back-up method when “resting” or after pills are missed. The reasons for errors in pill use are varied, including incorrect folk wisdom, the lack of contact between physicians or other health care providers and clients, and lack of strong or accurate counseling.

Most service providers also had gaps or inconsistencies in their knowledge of pill-taking practice. Most did not know how long to wait between 21- and 28-day pill packets, how to compensate for missed pills, and when back-up methods are necessary.

There was agreement among users and discontinuers that better care, education and counseling would reduce their anxiety and help them continue using the pill. Information, education and counseling activities should address a number of issues related to pill use. The study generated recommendations to help users take oral contraceptives effectively (see sidebar, right).

Misinformation is not particular to Colombia and Egypt, or to certain distribution systems. Knowledge of specific errors in pill use makes it easier to design training for service providers to help clients use the pill more effectively.

As a result of FHI’s work on pill compliance and a meeting held at the Food and Drug Administration (FDA), the FDA will recommend to pharmaceutical companies that manufacture oral contraceptives that they develop standardized and simplified instructions for OC use to include in patient package inserts. As part of a broad pill compliance strategy, FHI is currently designing programmatic research studies to test the effect of proper counseling on how to take the pill and the use of

Focus on five basic messages to improve pill use:

1. The pill is safe and effective if taken every day.
2. Taking the pill every day means taking it even with discomfort or when the husband is away.
3. Wait 7 days between 21-day packets but continue 28-day packets without interruption.
4. Know when and how to use a back-up method, and what back-up method to use, such as condoms or foam.
5. Know which side effects are transient and minor, and which require medical attention.



Good counseling can increase the acceptability of NORPLANT.*

NORPLANT®

Acceptability

Together with the Population Council, FHI has conducted pre-introductory clinical and programmatic studies of NORPLANT*. The method has been found to be highly effective and acceptable, particularly among couples who want to limit, but are not necessarily ready to stop, childbearing. Among 2,500 potential users of NORPLANT* in family planning clinics in Bangladesh, Haiti, Nepal and Nigeria, initial interest in trying NORPLANT* was high (Kane, et al., 1990). Between 48 and 67 percent of respondents who had gone to the clinics to either start or switch their contraceptive method expressed interest in NORPLANT*. The women identified effectiveness, reversibility, and convenience of use as the attractive features of NORPLANT*. However, women's fears sometimes limited interest, suggesting the need for strong counseling to reduce fears about side effects of the method.

A study based on the first year of the FHI-sponsored clinical trials conducted by the Family Planning Association of Sri Lanka similarly found that acceptability of NORPLANT* among 400 acceptors in two centers was very high (Basnayake, et al., 1988). Factors most important to NORPLANT*'s acceptability were the low risk of pregnancy, the long duration of contraceptive coverage, and the convenience of use. Table 4 shows acceptors'

assessment of satisfaction with NORPLANT* in Colombo and Kandy, Sri Lanka.

NORPLANT* is an ideal method for a country such as Egypt, in which childbearing begins early and women face many years at the end of their reproductive lives in which they want no more children. Women ready to stop childbearing may have up to ten years in which they require contraception. Acceptability of NORPLANT* is high in Egypt, both among service providers and clients, according to the results of focus group discussions. Results from Egypt also suggest the need for strong counseling to allay the fears of potential users.

Male Condoms

In 1982, an estimated 40 million people worldwide were using condoms. Of those, 14 million were from developing countries (Population Reports, 1982). Despite such widespread use and relative benefits of the condom — that no medical supervision is needed, and that it is a key method to help reduce the spread of AIDS and other sexually transmitted diseases (STDs) — there has been little research on its acceptability, continuation or use-effectiveness.

Acceptability

A 1986 study by FHI and the Centres Pour Le Développement et la Santé in Haiti found little interest in condom use among men in the Cité Soleil suburb of Port-au-Prince (Boulos, et al., 1989). The study sampled male partners of recent

Table 4

Acceptors' assessment of satisfaction with NORPLANT[®] at six months of use, Colombo and Kandy, Sri Lanka: 1985-1987 (in percent)

Assessment Variable	Percent*			Total Number
	Colombo	Kandy	Both	
Most Liked Aspect				
Lasts for several years	58.6	21.9	40.6	152
Easy to use	25.7	4.9	15.5	58
Low risk of pregnancy	14.7	71.0	42.2	158
Fewer side effects/other	1.0	2.2	1.7	6
Least Liked Aspect				
Menstrual changes	19.4	4.4	12.0	45
Side effects	1.0	0.5	0.8	3
The way they look	0.5	0.0	0.3	1
Other	4.2	0.0	2.1	8
None	74.9	95.1	84.8	317
Intends to use a second set	36.1	85.8	60.4	226
Does not intend to use a second set	30.4	12.0	21.4	80
Reasons for Not Wanting				
Wants another child	23.0	0.5	12.0	45
Wants sterilization	6.3	8.2	7.2	27
Weight increase/menstrual changes/ infection	0.5	2.1	1.3	5
Planning to go abroad	0.5	0.0	0.3	1
No specific reason	0.0	1.1	0.5	2
Not sure of intention	33.5	2.2	18.2	68
Received Adequate Information				
Yes	99.0	96.7	97.9	366
No	1.0	3.3	2.1	8
Recommends to Another Person				
Yes	97.4	97.3	97.9	364
No	0.5	1.6	1.1	4
Not sure	2.1	1.1	1.6	6
Number	191	183	374	374

*Sum of percent distribution for each question equals 100. Some percentages may not add to the total because of rounding.

Source: Basnayake S, S Thapa and SA Balogh. 1988. "Evaluation of Safety, Efficacy, and Acceptability of NORPLANT[®] Implants in Sri Lanka." *Studies in Family Planning*. Vol. 19, No. 1. Jan/Feb.

family planning acceptors at the USAID-funded Family Planning Center in Cité Soleil, as well as sexually active males in the community. Although knowledge of condoms was nearly universal in Cité Soleil, few men currently used them. The low usage was not due to supply constraints or to general opposition to family planning, but to a lack of interest among males in practicing family planning. Obtaining condoms was considered a woman's domain. Over half of those who had tried condoms had stopped using them because they or their partners "did not like them" (Table 5). Another 28 percent reported experiencing method failure (unplanned pregnancy). Condoms were generally considered less effective than other methods of family planning. However, of the men who had stopped using condoms, 70 percent were not using another method of family planning.

Condoms are currently the most effective means, other than abstinence, of slowing the spread of AIDS and other STDs, and they continue to play an important role in family planning. It is vital that condom breakage be reduced to a minimum.

In addition to its condom testing lab, used to identify means of reducing condom wastage from storage under adverse conditions and to identify ways to reduce breakage, FHI has conducted acceptability studies of thicker, stronger condoms. One study carried out in 1989 in Mali, the Dominican Republic and Sri Lanka compared a 3.4 mils (1000/inch or 25 microns) thick condom to a standard 2.6 mils condom (Cordero, et al., 1989). Fifty-seven participants from Santo Domingo and 64 from Bamako completed the study in which the men compared the standard and thick condoms.

Almost 75 percent of the men in the Dominican Republic and 91 percent in Mali reacted favorably to the stronger condom. Only six percent of the sample thought the condom was too thick. The stronger condom was perceived to be more comfortable and sensitivity was comparable to the standard condom. When asked which condom they would purchase in the future, 78 percent said they would buy the stronger condom, and of those, virtually all said they would be willing to pay more for it, particularly if it provided added protection against pregnancy, AIDS and other

STDs. Breakage rates of the stronger condom were, unfortunately, similar to those of the regular condom. Given the acceptability of the stronger condom in these study populations, FHI continues to evaluate the acceptability of this device in other countries and is currently developing a comprehensive study of the breakage rates of the standard versus the stronger condom.

FHI also conducted a five-country study to assess the acceptability of spermicidally lubricated condoms, which may reduce risk of pregnancy and the transmission of AIDS and other STDs when condoms break. This study was conducted with counterparts in Bangladesh, Honduras, Ghana, Mali and Egypt in



Condoms are laboratory tested for strength.

Table 5

Characteristics of former condom users, Cité Soleil, Haiti, 1986

Characteristics	Percent
Reasons for Discontinuing Condom Use	
Respondent or partner didn't like method	53
Method failure resulting in pregnancy	28
No longer available	2
Pregnancy desired	1
Not specified	16
Total	100
Currently Using Another Family Planning Method	
Yes	30
- Oral contraceptives	12
- Injectables	11
- Rhythm	4
- Other	2
No	70
Total	100
Plan to Use Condoms Again	
No	79
Yes	21
Total	100
Number	123

Source: Boulos ML, R Boulos, and DJ Nichols. 1989. "Perceptions and Practices Relating to Condom Use Among Men in Cité Soleil, Haiti." FHI Final Report.

1987-1988 (Potter and Clarke, 1988). Participants were given a choice of a one-month supply of either the Prime (single dose of nonoxynol-9) or the Double-S (a double dose condom). Reaction to the spermicidally lubricated condoms among the 633 men who completed the study was favorable: 86 percent liked the condom, particularly because the spermicide added extra protection against pregnancy. Most of the negative comments referred to the Double-S, and focused on the excessive amount of lubricant. Two-thirds of the men said they would be even more favorable toward the spermicidally lubricated condoms if they were sure that the condoms provided added protection against pregnancy, STDs and AIDS. More than 75 percent said they would prefer to purchase the spermicidally lubricated condom in the future, even if it cost more. Given the acceptability of the spermicidally lubricated condoms, more research should be conducted regarding the protection provided against pregnancy and STDs, including AIDS.

New Product Market Testing

In an effort to increase the shelf life of condoms in various climate and storage conditions, FHI is working to develop a male condom constructed of plastic rather

than latex. Thus far, function tests of use and acceptability have been conducted on several prototype models of the plastic condom.

Female Condoms

Acceptability

In 1989 in Khon Kaen, Thailand, the Khon Kaen University and FHI tested the female condom, recently named "Reality," to determine its acceptability as a method of protection against STDs for high-risk women (Sakondhavat and Potter, 1990). The female condom is made of a thicker, more durable material than the male condom and covers more surface area, thereby possibly increasing protection against STDs and decreasing risk of breakage. Twenty commercial sex workers in Khon Kaen tested the female condom for one month. The main opposition to it came from the partners of the women; two-thirds of the women reported no aversion to the female condom, while the attitude of their partners was generally negative. Eighteen of the twenty women said they would recommend the female condom to other commercial sex workers.

A follow-up study is currently being conducted in Thailand, again with commercial sex workers. Preliminary results indicate that male partners still have negative reactions to the female condom.

Sterilization

Acceptance and Regret of Sterilization

Because of concern that compensatory payments may cause men and women to accept a permanent method that they would not have accepted in the absence of such payments, FHI has undertaken research to determine the impact of compensation on acceptance of and regret from sterilization (Thapa, et al., 1987; de Silva, et al., 1988; and Hapugalle, et al., 1989).

In Sri Lanka, FHI worked with Community Development Services (CDS) to conduct a survey of women who had been sterilized in order to determine the correlates of regret, including the amount of the compensatory payment. Sri Lanka has provided compensatory payments to both tubal ligation and vasectomy acceptors. The compensatory payments are implemented with the objective of reaching those who want to regulate their fertility but cannot afford to do so. The study found that regret in Sri Lanka is affected by the number and sex distribution of the children and by whether the spouse supports the decision to be sterilized (Hapugalle, et al., 1989). Compensatory payments may cause some couples to seek sterilization earlier than they had previously planned, but these payments do not cause couples to make a contraceptive decision that they later come to regret. Table 6 shows that compensatory payments are not associated with regret.

A related study of vasectomy acceptors was carried out by the Family Planning Association of Sri Lanka (Thapa, et al., 1987). The purpose of the study was to determine whether compensatory payments had negative impacts on the lower economic status acceptors compared to acceptors of higher economic status. Stepwise discriminant analysis was used to identify the relative importance of a series of independent variables in distinguishing lower- from higher-income acceptors of vasectomy. Results showed that respondents' education and "improving family economic opportunities" were the two most powerful variables in explaining differences. The third was the compensatory payment. Among both high and low income acceptors, there was a high level of satisfaction regarding the

Table 6

Percentage of women who regretted their sterilization*, by site of the procedure, payment period and amount of payment, for Sri Lanka: 1983

Site, Payment Period and Amount of Payment	%	N
Total	14.3	817
Colombo	12.8	297
(3) Rs 200	14.1	99
(4) Rs 300	10.2	98
(5) Rs 500	14.0	100
Tea Estates**	15.4	169
(3) Rs 500	13.0	77
(4) Rs 500	17.4	92
Rural District	15.1	351
(1) Rs 100	13.0	46
(2) Rs 500	14.3	91
(3) Rs 200	20.6	97
(4) Rs 300	12.0	117

*In this and subsequent tables, women who wanted another child and women who wished they had been sterilized later or not at all.

**The sterilization of women from the tea estates was subsidized by the estates at a level of Rs 500 from 1980 to 1983.

NOTE: None of the associations between regret and amount of payment reached statistical significance.

Source: Hapugalle D. B. Janowitz, S. Weir, D. Covington, L. Wilkens and C. Aluvihare. 1989. "Sterilization Regret in Sri Lanka: A Retrospective Study." *International Family Planning Perspectives*, Vol. 15, No. 1.

decision to have a vasectomy. Overall, the level of payments was not found to have consistent negative consequences on the two types of acceptors.

In Africa, sterilization is not a widely used method of contraception. In order to promote contraceptive use, and sterilization in particular, a counseling program was introduced at the University of Benin Teaching Hospital for women with at least four previous deliveries who received prenatal care during their fifth or higher order pregnancy (Omu, et al., 1989). Results of the counseling program showed that contraceptive acceptance and use, including sterilization, were higher among the group that received special counseling than among the group that received the usual counseling (Table 7).

However, costs could be reduced significantly with only a small decline in the number of contraceptive and sterilization acceptors if more restrictive selection criteria for counseling were employed. Very few women who had fewer than five or six children (not including the current delivery) were sterilized, indicating that even the better educated, urban Nigerian women who frequent the clinic were not interested in sterilization until they had at least six children.

Results of this study indicate that barriers to sterilization can be overcome in

sub-Saharan Africa but that this method is not likely to be important until women are older and already have large families; thus, its potential to reduce fertility is lower in Africa than in Asia and in Latin America.

Using data collected in Honduras in the late 1970s through FHI's Maternity Care Monitoring (MCM) system, we found that the rate of sterilization among women hospitalized for delivery at two large public hospitals and who did not want any more children was very low (Janowitz and Núñez, 1981). Lack of facilities was the apparent reason for this finding. In order to determine how well the demand for sterilization was being met at these two public hospitals, a special study was carried out (Janowitz, et al., 1983). The study obtained information on

Table 7

Percentage of women who underwent sterilization, by various characteristics, according to study group, Benin City, Nigeria, 1984-1986

Characteristics	Treatment (Special Counseling)		Control	
	%	N	%	N
Total	13.0	509	3.4	503
Age				
< 30	3.5	173	1.7	180
30-34	11.8	203	1.1	180
≥ 35	27.5	131	8.8	136
Unknown	0.0	2	0.0	7
Living Children				
0-3	4.3	47	4.0	50
4	5.8	173	0.0	160
5	8.7	149	5.7	158
6	20.9	91	4.2	72
≥ 7	45.8	48	4.8	63
Unknown	0.0	1	0.0	0
Contraceptive Plan at Admission				
Sterilization	79.2	48	42.9	35
Pills, injectables, IUD	4.1	317	0.3	312
Other/unknown	14.3	98	0.0	82
None	2.2	46	1.4	74
Family Limitation Desires				
Didn't want pregnancy/ didn't want more	38.8	49	10.8	65
Wanted pregnancy/ didn't want more	23.4	154	6.0	150
Wanted pregnancy/ wanted more	3.1	290	0.4	264
Unknown	12.5	16	0.0	24

Source: Omu AE, S Weir, B Janowitz, DL Covington, and P Lamptey. 1989. "The Effect of Counseling on Sterilization Acceptance by High Parity Women in Nigeria." *International Family Planning Perspectives*. Vol. 15, No. 2.

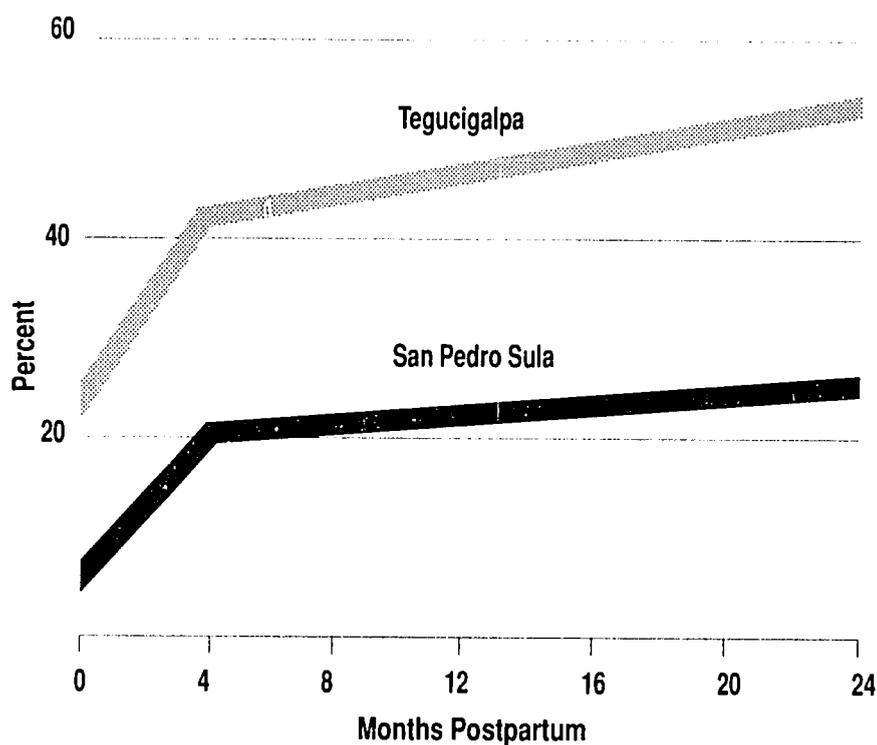
sterilizations performed at the time of hospitalization for delivery and, for women not sterilized, on the reasons why sterilization was not performed. It also collected information on interval sterilizations for women desiring but not receiving sterilizations during hospitalization for delivery. In both hospitals it was difficult for a woman to obtain a sterilization at delivery for any reason except medical grounds.

Although many women did get sterilized after hospitalization for delivery and within four months of delivery, a high percentage did not. Important reasons for not having done so included difficulty in leaving family, cost, and husband's objection. These reasons might indicate that some women were not fully committed to getting sterilized, but that other women who genuinely wanted sterilization found that accessibility factors prevented them from following through with their decision.

Two years following delivery, unsterilized but interested women were again contacted to determine whether or not they had gotten sterilized, and if not, why not (Janowitz, et al., 1985). The cumulative percent sterilized was much higher for women delivering in the hospital in Tegucigalpa than in the hospital in San Pedro Sula (see Figure 2). These differences may be explained by variations in steriliza-

Figure 2

Cumulative percent sterilized among women interested in sterilization, from baseline study through two-year follow-up, Honduras



NOTE: The baseline study was conducted during October-December 1980, and the two-year follow-up (24 months) was conducted September-December 1982. Zero months postpartum indicates immediately postpartum.

Source: Janowitz B, J Núñez, D Covington, and C Colven. 1985. "Why Women Don't Get Sterilized: A Follow-up of Women in Honduras." *Studies in Family Planning*. Vol. 16, No. 2.

tion facilities. We found that among women interested but unsterilized two years following delivery, the same percentage had become pregnant as had been sterilized since the baseline study. Among the barriers to obtaining a sterilization are difficulties in meeting the administrative and medical requirements for sterilization (Table 8). Moreover, time and family problems and economic limitations were major reasons for not getting sterilized.

It is now widely known that postpartum sterilization is strongly associated with cesarean delivery in Brazil. These findings were first documented in a series of studies carried out by FHI. In an initial analysis of data from FHI's Maternity Care Monitoring (MCM) system, we found that at hospitals in a large city in the south-east of Brazil, the rate of sterilization among women who did not want any more children was far higher among those with a cesarean than with a vaginal delivery (Janowitz, et al., 1982a).

FHI followed up this finding by carrying out a more detailed study in one of the Brazilian hospitals (Janowitz, et al., 1982b). Results showed that the method of payment for care substantially influenced whether a woman was sterilized. Wealthier women who paid for their care with their own funds or with private insurance were more likely to get sterilized than were poorer women whose care was financed through government insurance or who were indigent. In addition, women sterilized postpartum almost always had a cesarean delivery, and cesarean

Table 8

Percentage of unsterilized women meeting specified requirements for sterilization at time of survey: Honduras, 1982

Requirement	Percent Meeting Requirement	
	Tegucigalpa	San Pedro Sula
Specific Requirement Met		
Husband's consent	32.1	37.9
Social worker interview	32.1	14.3
Medical examination	23.1	5.4
Pap smear	15.7	9.4
Lab test	13.4	12.3
Number of Requirements Met (Summary Measure)		
0	50.7	57.6
1	21.6	25.1
2-4	21.6	14.7
All	6.0	2.5
Total	100.0	100.0
Number	134	203

NOTE: Percentages may not equal 100% due to rounding.

Source: Janowitz B, J Núñez, D Covington, and C Colven. 1985. "Why Women Don't Get Sterilized: A Follow-up of Women in Honduras." *Studies in Family Planning*. Vol. 16, No. 2. Mar/Apr.

delivery was more prevalent as the socioeconomic status of the woman rose.

As a result of these early studies, greater attention has been paid to obtaining countrywide information on sterilization and cesarean section not only in Brazil but in other countries. The link between cesarean section and sterilization also serves to focus attention on the need to increase access to sterilization for those women who do not have cesarean section deliveries or who want to get sterilized sometime after delivery (interval sterilization).

Although sterilization is a very prevalent method in Brazil, there is limited access to interval sterilization. One of the main providers of interval sterilization in Brazil is the Center for Research on Mothers and Children (CPAIMEC), headquartered in Rio de Janeiro. The Center requested assistance from FHI to obtain information on why a significant proportion of women approved for interval sterilization did not follow through with the procedure. We found significant barriers to obtaining interval sterilizations (Lassner, et al., 1986). The number of steps that a woman had to complete to obtain sterilization was an important determinant in whether she was actually sterilized. In order to satisfy the requirements (obtaining documents, lab work, consent forms), additional clinic visits were necessary. As a result of this study, the clinic has changed its procedures for scheduling sterilization surgery.

Breastfeeding and Family Planning

Breastfeeding is the oldest contraceptive, yet it is not generally recognized or promoted by family planning providers as an effective means of family planning. FHI has played a leading role in conducting research on the contraceptive effect of breastfeeding, and continues to take a lead in promoting programmatic research to increase the use of breastfeeding for family planning (Kennedy, 1989). FHI has worked with investigators in Mexico, Egypt, Pakistan and Thailand to study intensively the breastfeeding patterns of small numbers of volunteers in order to generate guidelines to help women know how long breastfeeding will protect them from pregnancy (Figure 3)

(Rivera, et al., 1988; Israngkura, et al., 1989; Shaaban, et al., 1989; and Khan, et al., 1989).

The striking results of the FHI studies and others conducted in eight countries led FHI to assemble a group of experts to form a consensus on breastfeeding. The Bellagio Consensus, as it became known, has been widely disseminated throughout the world.



The Bellagio conference generated a list of research priorities, including programmatic research. FHI is currently testing programmatic aspects of the consensus statement.

A 1986-1988 study in the Philippines assessed the effect of an education program on breastfeeding patterns (Savina and Kennedy, 1989). Women who received the educational program introduced supplements later and almost all gave colostrum to the infant. There was no difference, however, in return of menses (a proxy for return of fertility), probably because levels of breastfeeding were high even among women in the control group. The study showed, however, that the educational program had a positive effect on the health of the breastfed babies in that the incidence of infant illness was lower in the educational than the control group (Nakao, Kennedy and Savina, 1990).

The Bellagio conference concluded that:

1. Breastfeeding should be regarded as a potential family planning method in all maternal and child health programs in developing and developed countries.
2. Postpartum women should be offered a choice of using breastfeeding as a means of family planning, either to help achieve optimal birth spacing of at least two years, or as a way of delaying the introduction of other contraceptives. They should be told how to maximize the antifertility effects of breastfeeding to prevent pregnancy.
3. Breastfeeding provides more than 98 percent protection from pregnancy during the first six months postpartum if the mother is "fully" or nearly fully breastfeeding and has not experienced vaginal bleeding after the 56th day postpartum.
4. Guidelines specific to a particular country or population for using breastfeeding as a postpartum family planning method can be developed based on this consensus. Local infant feeding practices, the average duration of amenorrhea and the ongoing changes in women's status and health practices should be considered in adapting these general guidelines.

Source: FHI, Lancet 11(8621): 1204-1205, 1988. (Kennedy, et al., 1989)

Natural Family Planning

Natural family planning (NFP) is not an insignificant method of family planning throughout the world. FHI worked with A.I.D. and the Institute for Resource Development at Westinghouse to compile a monograph on use of periodic abstinence in developing countries (Hermann, et al., 1986). This and other work by FHI on NFP indicate the need for continued programmatic research on topics such as cost-effectiveness, counseling and other educational techniques, providers' training, effective means of recruiting users, and the characteristics of more versus less successful users.

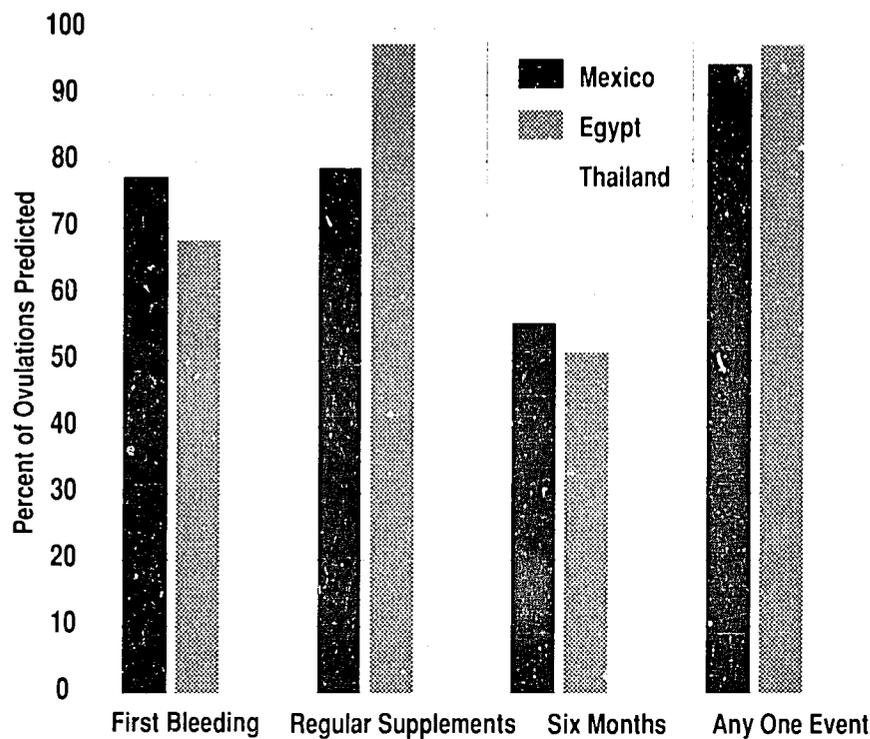
In Egypt, only four percent of women currently use the "safe period" method of family planning. A study was conducted in 1985-86 of 203 persons who had attended an Egyptian program on the Billings Ovulation Method. The women who had completed the natural family planning training and were either motivated to avoid or delay pregnancy were generally successful. Of the 182 women whose pregnancy status was determined at the follow-up interview, only 7 percent of the avoiders and 14 percent of the spacers had had unplanned pregnancies. While these data show that natural family planning could play a larger role in the Egyptian family planning program,

the data from the study were insufficient to calculate use-effectiveness rates and costs per couple of teaching natural family planning. More research is needed to answer those questions.

In Indonesia, FHI worked with the National Family Program (BKKBN) in 1986-1987 to test the efficacy of three alternative methods of periodic abstinence based on the cervical mucus symptom: the Billings Ovulation Method; the

Figure 3

Event that predicted ovulation, from selected studies



Source: Kathy I. Kennedy: Lactation and Contraception. *Ginecología y Obstétrica de México*. 58(1): 25-35, 1990.

Dorairaj modified mucus method; and a local version of the mucus method (Thapa, et al., 1989). The purpose of the study was to provide information to determine whether to include one or more of these methods in the national family planning program.

The study, carried out in five centers in Indonesia, included a three-month learning phase and a twelve-month effectiveness phase. Of the three methods, only the Billings method showed low termination and pregnancy rates during the learning and effectiveness phases. Factors associated with discontinuation were young age, low parity and desire for more children. More discontinuers wanted to space rather than limit childbearing.

The results of this study suggest that periodic abstinence is not necessarily easy to practice. Couples must remain highly motivated to conform to strict rules for abstinence and to observe and chart mucus patterns. The Billings Method appeared to be superior to the other methods studied, therefore the national program should consider including it rather than the modified mucus method or the indigenous method. The results of the study also show the need for systematic evaluation before including contraceptive methods in national family planning programs.

POLICY AND PROGRAMMATIC ISSUES

Clinic Practices and Procedures

One factor that may limit use of family planning is the failure of some country programs to provide a wide choice of contraceptive options; the result is that many women must accept a method other than the one they prefer. In a project carried out at three clinics in Dakar, Senegal, FHI found that the clinic itself was an important determinant of the type of contraceptive method used (Nichols, et al., 1985). At two clinics virtually all the women were given IUDs, regardless of whether they wanted to space or limit their families (Table 9). At a third clinic which had supplies of other methods, there was a better match between the contraceptive provided and the desire for spacing or limiting births. At that clinic, a higher percentage of spacers than of limiters received oral contraceptives.

In a second project carried out at the first family planning clinic in Niamey, Niger (Hogle, et al., 1990), FHI looked at how the availability of family planning services affected the methods provided. Due to scarcity of supplies, many women did not receive the methods that they wanted. Consequently methods were rationed based on ability to pay. Scarce clinic supplies were reserved for the poorest women, while higher income women generally received prescriptions to be filled at the pharmacy.

When women do not get the method that they want, they may not only discontinue using the method that they do get, they may stop contracepting. To determine what factors explain the high discontinuation rate among contraceptive acceptors, FHI is



John Stanback/FHI

Some countries require laboratory testing for prescriptions of oral contraceptives.

carrying out a number of follow-up surveys of acceptors of contraceptives in Africa (including Niger, Zaire and Senegal). Results of these studies will provide important information to determine how to help users continue their method. Possible improvements might include removal of age-parity guidelines for provision of spacing methods, and provision of oral contraceptives on an initial visit even if the woman is not at the appropriate stage of the menstrual cycle to begin use. Instructions on when to begin use, of course, would have to be provided.

FHI recently carried out a study in Senegal to determine the impact of removing laboratory test requirements for the provision of OCs (Université Cheikh Anta Diop de Dakar, 1990). Information on sociodemographic characteristics and medical history for 500 new OC acceptors was obtained, and a physical exam and laboratory tests were carried out. Laboratory test results must be interpreted with care. The cost of identifying women with contraindications (even assuming that the test results are accurate) was high. The combination of low specificity and sensitivity combined with problems in interpreting test results made the tests of little use under the best of circumstances. Based on the study results, policy makers decided to drop the laboratory test requirements. Elimination of laboratory tests will reduce an economic and logistical barrier to the provision of hormonal methods in Senegal.

The Role of Health Care Providers

Physicians form an elite group in most societies; their opinions are respected and their instructions are rarely questioned. A 1986 study of the attitudes of Nigerian physicians regarding family planning found that the demographic and family planning characteristics of the 681 physicians interviewed differed from

Table 9

Contraceptive method provided at clinic visit by desire for additional children, for Senegal: 1983 (in percent)

Method	Additional Children Wanted					
	ASBEF		PMI de Medina		Croix Bleue	
	Yes	No	Yes	No	Yes	No
IUD	84	87	20	33	100	99
Pills	9	6	40	20	0	1
Barrier methods	4	2	31	41	0	0
None	3	5	9	6	0	0
Total	100	100	100	100	100	100
Number of Clients	196	85	482	227	133	88

NOTE: Excludes cases where data not reported.

Source: Nichols D, S Ndiaye, N Burton, B Janowitz, I Gueye and M Gueye. 1985. "Vanguard Family Planning Acceptors in Senegal." *Studies in Family Planning*, Vol. 16, No. 5. Sep/Oct.

those of the general population (Covington, et al., 1986). Almost half used family planning themselves, compared to six percent of the general population. Desired family size among the physicians was four children, compared to a national average of eight children.

Despite the widespread use of family planning among Nigerian physicians, they seemed reluctant to approve large-scale promotion of family planning, particularly sterilization. Most disapproved of non-physicians providing many of the modern methods of contraceptives (Table 10), an attitude that prevails in much of the region. Interestingly, more of the Nigerian physicians approved of non-physician insertion of IUDs than of distribution of oral contraceptives, even though IUD insertion is a more complicated clinical task. More than one-quarter did not even approve of non-physicians providing barrier methods, such as the condom.

This study points to the need for programmatic research to convince doctors of the ability of non-physicians to provide family planning services. A community-based distribution (CBD) system in Oyo State in Nigeria, which utilizes non-physicians for distribution of contraceptives, shows that such activities do have the potential for the widespread success in Nigeria and other countries in the region (Horn and Seidman, 1989).

A 1984 study in São Paulo, Brazil (Bailey, et al., 1985), investigated the role of physicians in providing vasectomy services and focused on whether or not physicians would advise their patients to have surgical sterilization, particularly vasc-

Table 10

Percent of respondents who approve of non-physicians providing various methods of family planning, by medical specialty, for Nigeria: 1984

Method	Total (681)	Percent Who Approve of Non-Physicians Providing Family Planning Methods			
		OB/Gyn (140)	GP ^a (173)	Other Specialist (125)	House Officer (243)
Barrier	67.5	73.6	66.5	67.2	65.0
IUD	37.7	42.9	31.8	36.0	39.9
Orals	26.6	36.4	25.4	29.6	20.2
Injectables	18.6	27.1	13.9	20.8	16.0
Vasectomy	1.6	0.7	2.3	1.6	1.6
Tubal ligation	1.0	0.7	0.6	1.6	1.2

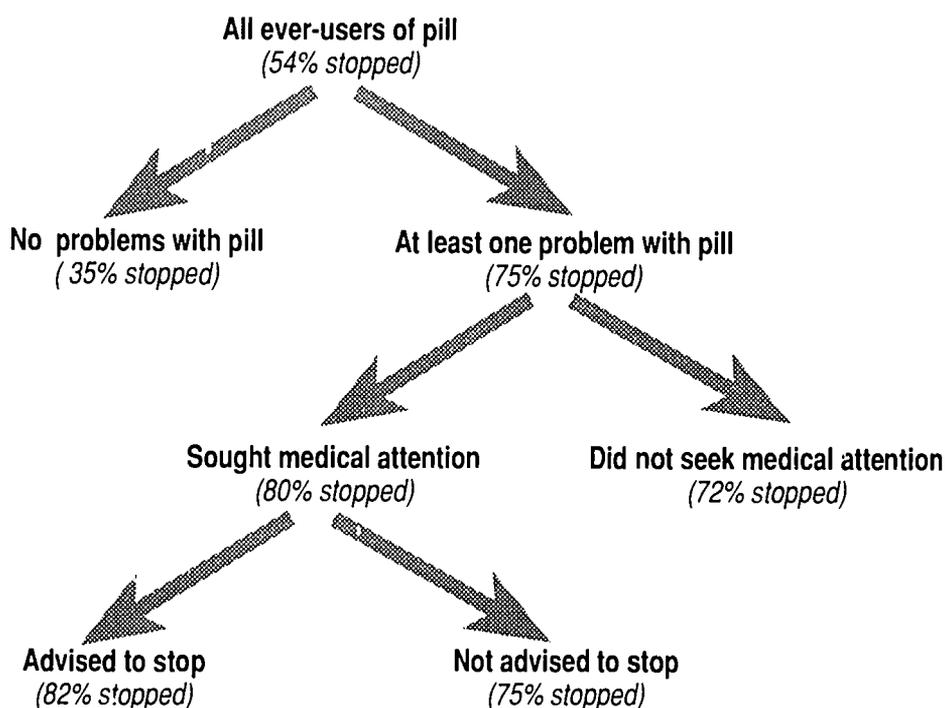
NOTE: Number of cases shown in parentheses.

^aGeneral practitioner.

Source: Covington D, EO Olorin, B Janowitz, D Gates, P Lamptey and OA Ladipo. 1986. "Physicians' Attitudes and Family Planning in Nigeria." *Studies in Family Planning*. Vol. 17, No. 4.

Figure 4

Percentage of women discontinuing use of oral contraceptives for southern Brazil: 1981



Source: Janowitz B, TT Kane, JM Arruda, D Covington and L Morris. 1986. "Side Effects and Discontinuation of Oral Contraceptive use in Southern Brazil." *Journal of Biosocial Science*. Vol. 18.

tomy. The study found that most physicians had positive attitudes regarding vasectomy and that the physicians were less of a barrier than had been anticipated. Among the male physicians, 38 percent had been sterilized (or their wives had); of those about one-third had chosen vasectomy. Eleven percent of the male doctors were vasectomized in a state where sterilization prevalence was 2.6 percent in 1986.

In a study of discontinuation of pill use in Brazil using data from statewide surveys of contraceptive use conducted in 1981 (Janowitz, et al., 1986), FHI found that while the main factor affecting discontinuation was the reported experience of a problem (Figure 4), women with problems who sought medical attention were more likely to discontinue (80 percent) than were those who did not (72 percent). Over 54 percent of women who had ever used the pill stopped using it; of those with no problems, 35 percent discontinued compared to 75 percent of those who had experienced a problem. It is not clear from this data why physicians recommended that such a high percentage of women discontinue. While the pill is not suited for certain women, many side effects, if properly explained and managed, can be tolerated or alleviated.

In a clinical trial of oral contraceptives in Sri Lanka conducted between 1977 and 1981, FHI and the Sri Lanka Family Planning Association found that field workers exercised more influence than had been anticipated (Miller, et al., 1985).



Home visits by a public health nurse are good opportunities for discussing family planning needs.

In Colombo, field workers were responsible for following up women who missed clinic visits and making house visits to women who were between clinic visits. In the urban study, continuation rates were significantly associated with the work performance, including diligence and persuasiveness, of the field workers. The results emphasize that differences in procedures and personnel can have as important an impact on program effectiveness as the contraceptive methods themselves.

Non-physicians provide oral contraceptives both in pharmacies and in community-based distribution (CBD) outlets. In CBD programs, standard checklists are often used to identify women with contraindications – women who should see a doctor before receiving OCs. An FHI study of the reproductive risks in a CBD in Mexico in 1982 found that the risks of oral contraceptive use were not increased by the distribution of the pill by non-professionals (Zavala, et al., 1987).

The study, conducted with the Centro de Orientación Familiar in Matamoros, Mexico, attempted to quantify the effectiveness of the checklists. The purpose of the study was to determine whether screening is necessary before women start to use OCs and what role, if any, physicians should play in their distribution. The health profile of the 102 screened program users was similar to that of the 135 non-CBD program users. These latter women had never had an examination either by a doctor or nurse to determine whether they had contraindications to pill use. Results indicate that screening for pill use may not be necessary. It adds to costs and accomplishes very little, if anything. It may detract from a program's ability to expand provision of OCs by using resources to screen rather than promote additional use. However, a modified checklist, which focuses on easily identifiable risk factors, may be an efficient use of scarce resources while still effectively identifying those women truly at risk of problems related to the pill.

In 1985, FHI collaborated with the Indonesian Society for Perinatology to study the knowledge, attitudes and practices of health care professionals in eight urban hospitals regarding breastfeeding management (Hull, Thapa and Wiknjosastro, 1989). The doctors, nurses and midwives interviewed generally had positive attitudes towards breastfeeding; however there was wide variation in the knowledge of correct breastfeeding practices and in the advice given to breastfeeding women.

For example, although most respondents provided advice on breastfeeding, information given was not always sound. Less than half thought that breastfeeding should be initiated immediately after delivery and nearly twenty percent thought that breastfeeding should follow a fixed schedule. Support for the concept of rooming-in was strong, although one-third of the respondents did not think that the mother and infant should be together for the full 24 hours implied by rooming-in. Some expressed fears that rooming-in would increase the risk of infection.

Health care professionals can play an important role in ensuring long durations of breastfeeding. This study indicates that a strong training program is needed to equip health care providers with the knowledge and skills they will need to carry out the important task of promotion of breastfeeding.

A study of the knowledge and perceptions (including behavioral intentions) of 375 physicians regarding periodic abstinence (PA) was undertaken by FHI and a number of other international organizations and universities in collaboration with investigators from Mauritius, Peru, the Philippines and Sri Lanka in 1984-1985 (Snowden, et al., 1988). The periodic abstinence method providers were older, and more likely to be female and be general practitioners than were those who provide other family planning services. They were also more likely to hold strong Catholic beliefs, although some Catholic physicians did provide other family planning services. Whether or not a physician would recommend periodic abstinence to a client depended on whether that physician considered himself or herself a provider of periodic abstinence methods, and what country he or she was from (Table 11). Many who did provide periodic abstinence methods did not have detailed knowledge of the methods, or had knowledge of one periodic abstinence method to the exclusion of others. Although a majority of the physicians expressed interest in receiving more information about periodic abstinence methods, only 10 percent were receptive to receiving training for the methods.

Method and Brand Switching

To assist A.I.D. in determining the expected consequences of changing contraceptive procurement decisions, FHI has carried out a number of studies comparing the side effects and continuation rates associated with a switch among Norinyl 1/35, Norinyl 1/50 and Lo-Femenal, as well as the acceptability of Lo-Femenal among women switching to this method from Noriday 1/50. Results indicated that Lo-Femenal had favorable rates of side effects and continuation compared to the other COCs (Gerais and Rushwan, 1985).

In a study in Sri Lanka, FHI found that many women switch from oral contraceptives to traditional methods of contraception because of side effects of OCs (Kane, Gaminiratne and Stephen, 1988). Proper counseling could have allayed the fears of the users, and the anticipated result would have been fewer unwanted pregnancies.

Social marketing provides a delivery system that allows contraceptives to be sold through the commercial sector at subsidized prices. FHI carried out an intercept survey of buyers of oral contraceptives at pharmacies in Honduras, comparing buyers of the brand provided by the social marketing program and all brands available through the commercial sector. Buyers of the pill from the social marketing program in Honduras were of lower socioeconomic status than were buyers of commercially priced pills (Bailey, et al., 1989). However, many buyers had switched from commercially priced pills to the social marketing pill (thereby increasing the subsidy to the provision of pills). In addition, many had switched from the Community Based Distribution program to the social marketing pill, perhaps reducing the subsidy to provision of pills (Table 12). Women switching to the social marketing product from commercial products had characteristics similar to those of women who switched from one commercial pill to another. However, women switching to the social marketing product from the non-commercial sector appeared to be of the lowest socioeconomic status. The determination of whether

Table 11

Percent of physicians who would recommend or would like to see their patients use any periodic abstinence method (PA), by PA-provider status for selected countries: selected years, 1984-1985 (in percent)

Recommend Any PA Method	Mauritius		Peru		Philippines		Sri Lanka		All Sites	
	Non- provider	Provider								
No/uncertain	65	39	65	46	21	4	69	55	59	32
Yes	35	61	35	54	79	96	31	45	41	68
Total	100	100	100	100	100	100	100	100	100	100
Number	52	18	66	39	34	66	51	49	203	172

NOTE: PA = periodic abstinence. In this table, PA method providers are those physicians who have provided at least one PA method to their patients.

Source: Snowden R, et al. 1988. "Physicians' Views of Periodic Abstinence Methods: A Study in Four Countries." *Studies in Family Planning*. Vol. 19, No. 4.

Table 12

Characteristics of previous pill users, by source of previous pill and brand purchased, for Honduras: 1986

Reason	Currently Using Perla		Currently Using Other Brands	
	Previous Source Noncommercial	Previous Source Commercial	Previous Source Noncommercial	Previous Source Commercial
Mean age	39.4 (5.6)	28.4 (5.2)	27.5 (5.6)	27.1 (6.3)
Mean number of living children	3.6 (1.6)	2.6 (1.8)	2.8 (1.6)	2.2 (1.5)
Mean number of years of schooling	4.4 (2.5)	7.7 (3.7)	5.9 (4.0)	8.1 (4.1)
Electricity (%)				
Yes	62.6	73.9	60.6	78.3
No	37.4	26.1	39.4	21.7
Sanitation (%)				
Inside toilet	8.0	46.0	31.5	48.6
Outside toilet	17.8	14.4	18.7	14.9
Latrine	56.6	26.5	45.0	27.5
None	17.6	13.1	6.9	9.0
Number of Cases (unweighted)	107	106	101	158

NOTE: Numbers in parentheses are standard deviations. The comparison of continuous variables was done with t-tests. Commercial versus noncommercial groups were compared separately for both Perla users and users of other brands. The *nonsignificant* comparisons were: age for noncommercial versus commercial among users of other brands, and all three mean comparisons of commercial versus commercial between the two current pill groups. The remaining comparisons were significant at $p < 0.05$.

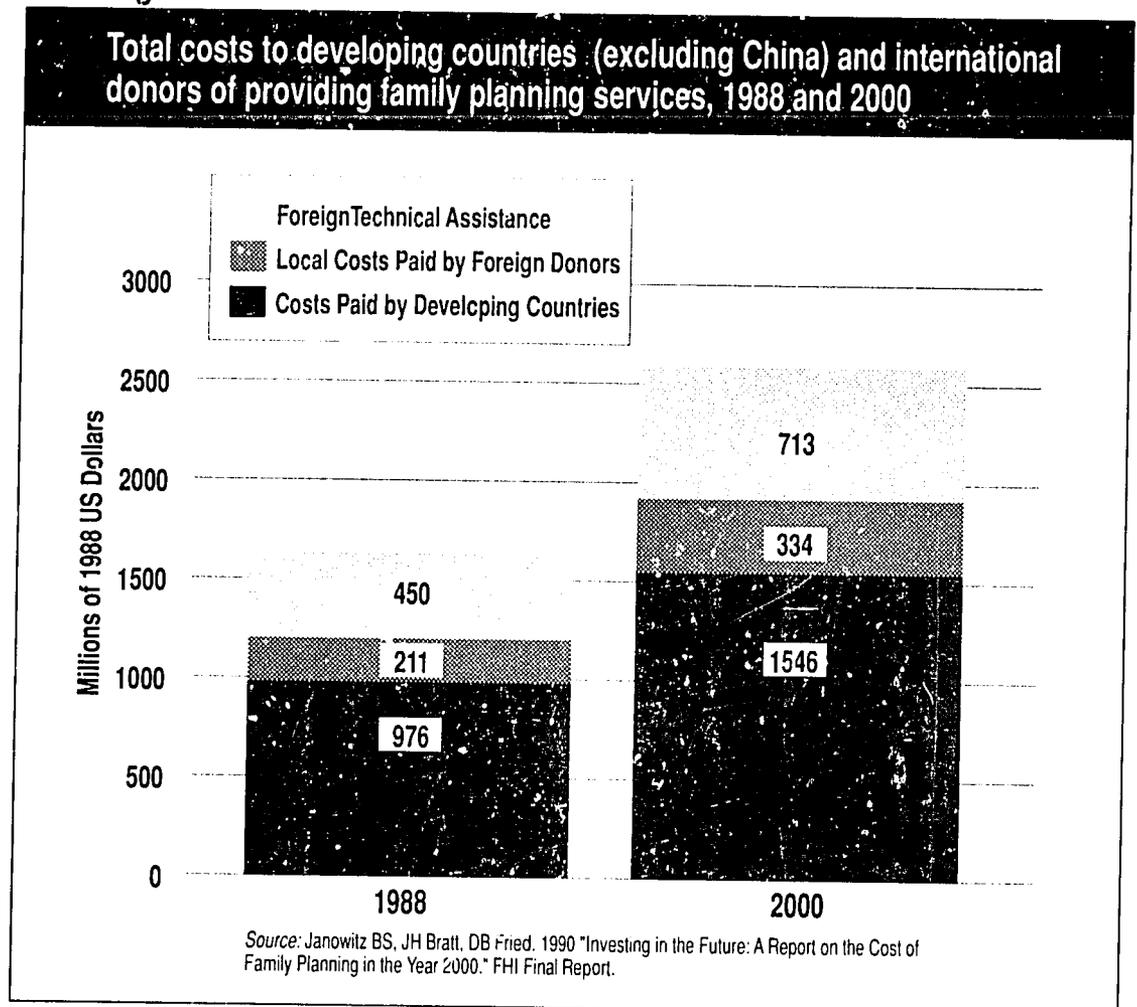
Source: Bailey PE, et al. 1983. "Consumers of Oral Contraceptives in a Social Marketing Program in Honduras." *Studies in Family Planning*, Vol. 20, No. 1. Jan/Feb.

or not the program actually increased contraceptive use will require comparison of household survey results obtained over time. Our results confirm that the program did reach the more disadvantaged groups, but more work is needed to assess the impact on contraceptive use and subsidization of family planning.

The Cost of Providing Family Planning

During the 1990s, contraceptive use is expected to continue to increase in developing countries. However, this increase will require additional resources from both governments of developing countries and from donor organizations. FHI has estimated the costs of providing family planning in less developed countries (LDCs) in the year 2000, assuming that the medium variant population projections of the United Nations are met (Janowitz, Bratt and Fried, 1989) (Figure 5). The cost in real terms of providing family planning services in public and

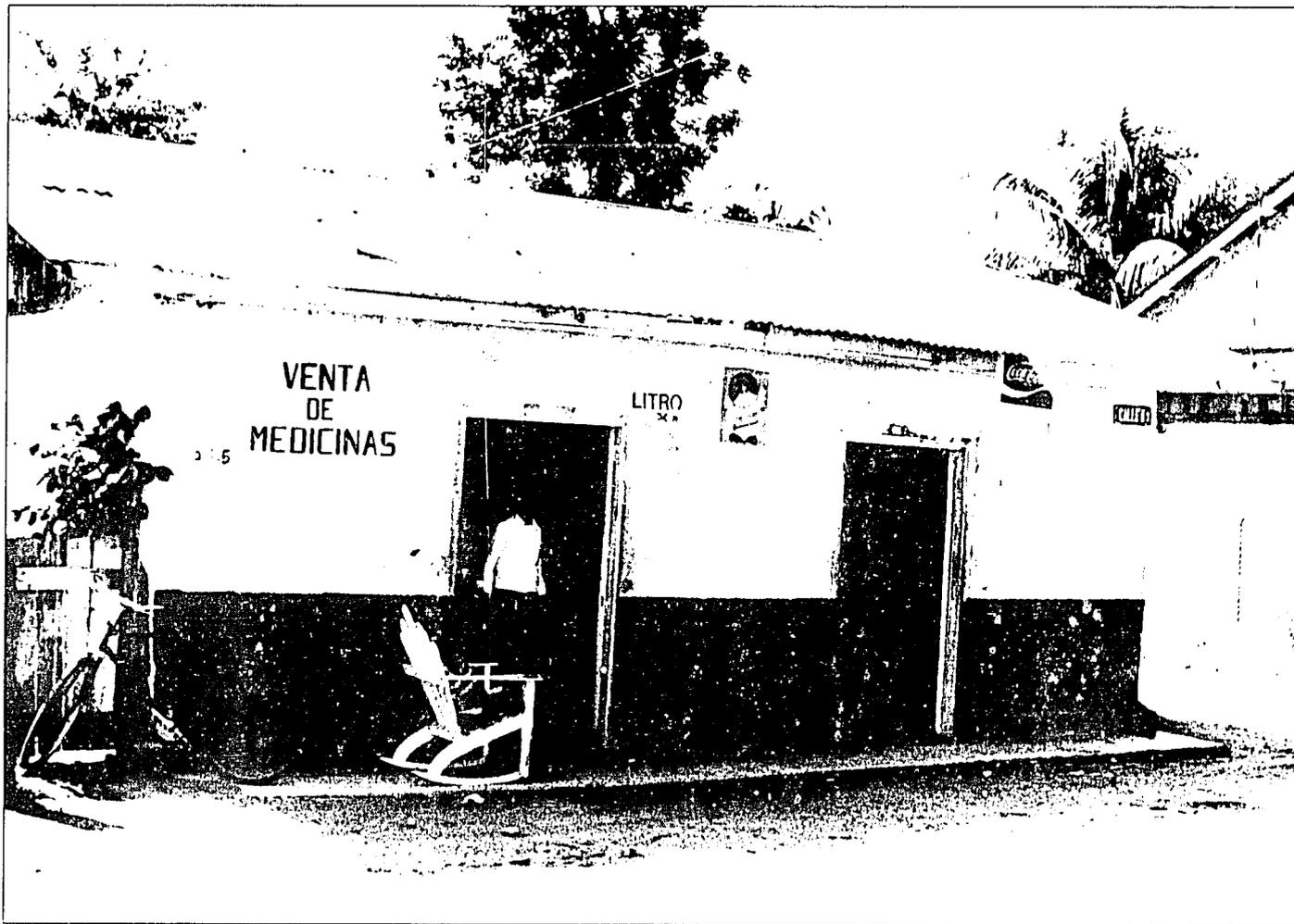
Figure 5



private voluntary organization (PVO) programs, and the cost of related population services in developing countries (excluding the People's Republic of China) will be approximately U.S. \$2.6 billion in the year 2000. The share of these costs borne by developing country governments and foreign donors will depend on income generated through user fees and donations. This figure, while considerably lower than previous projections, represents a nearly 60% increase over current estimated levels of spending on family planning. The largest percentage increases in cost will be in sub-Saharan Africa and the Near East, where use will likely increase the most. The largest absolute increase in costs will be in Asia, where the largest number of people live, and where the largest increase in population is predicted. These estimates suggest that, if the targets are to be achieved, the United States and other developed countries must increase their assistance to developing country family planning programs.

If contraceptive use is to rise significantly, not only must there be additional resources for family planning, but additional concern must be paid to using resources more efficiently. How can services be increased without compromising their quality?

A recent FHI study in Thailand showed that nurse-midwives could deliver postpartum sterilization services without incurring any more complications than did physicians while at the same time providing counseling that was superior to that of



Social marketing promotes a variety of family planning methods in Honduras.

physicians (Kanchanasinith, et al., 1990). Similar projects could be conducted by other countries to demonstrate locally that contraceptive clinical services of high quality could be provided by nurses and at significantly lower cost than services provided by physicians.

Other innovative ways of providing family planning services need to be tested to determine if costs can be decreased and quality of services can be improved. Currently, FHI is carrying out another project in Thailand to determine the feasibility of using nurses to insert NORPLANT[®].

Results will show whether nurses can provide this method as safely as physicians. In addition, we are planning to carry out other activities to determine the potential impact of NORPLANT[®] on contraceptive use and on costs of family planning provision. Results of these studies will be useful in helping countries make decisions about the relative importance of NORPLANT[®] in their family planning programs. FHI is now instituting such a study in Egypt; the Thai study will provide comparable information for Thailand.

INSTITUTIONALIZING PROGRAMMATIC RESEARCH

Over the past several years, FHI's approach to programmatic research has come to focus on the process of capacity building and the transfer of research skills. In the past, research topics were often generated by collaborating investigators in the field, usually with data from studies sent to FHI for analysis, and reports drafted by FHI staff. Recently, FHI has encouraged an increasing number of organizations in the field to implement studies themselves, with technical assistance from FHI as needed. The local organizations identify the topics, write the proposals, design the data collection instruments, conduct the field work, design the data analysis plan, carry out the data analysis, draft the final report, and disseminate the findings from the studies. FHI is there at each stage of the process to provide assistance as needed.

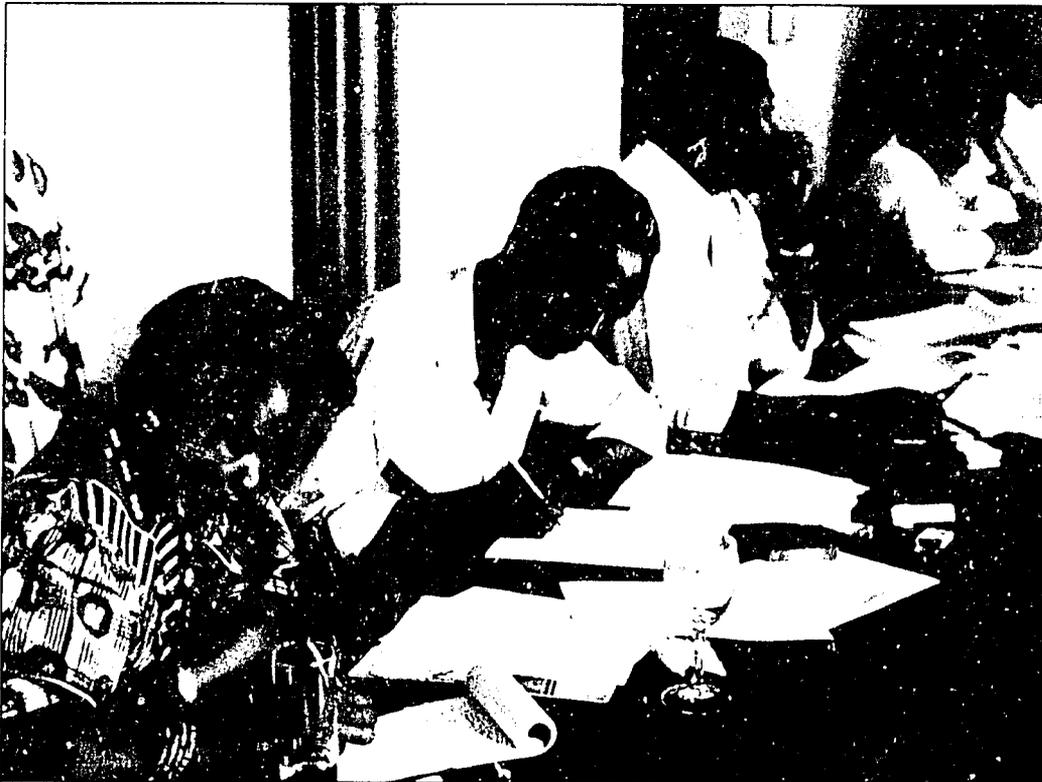
During the past three years, FHI has been working intensively in two countries, Kenya and Egypt, to institutionalize the capability to conduct programmatic research. This process has included workshops to teach programmatic research methodology and assistance in all phases of study implementation.

In Kenya, FHI is providing technical and financial support to the Department of Obstetrics and Gynaecology of the Kenyatta National Hospital to develop, implement and evaluate field studies in the areas of reproductive health research. In addition to providing support to the Department for

salaries, provision of microcomputers and related software, and training, FHI is collaborating with the Department on three programmatic research studies. Proposals for the studies were developed at a workshop on research methods.

The first study, a self-administered mail-out survey of approximately 900 physicians, was conducted in 1989-1991. The study was designed to measure the

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knowledge, attitudes and practice of family planning and the provision of family planning services by Kenyan physicians. Following two reminders, a response rate of 43 percent was achieved. A report on the survey's findings is currently in preparation. It is expected that the study will point out ways to improve family planning services by the physicians, particularly through the provision of better information.

A second study is looking at barriers to contraceptive use among Kenyan couples who want to space or limit births. This investigation constitutes the first (diagnostic) phase of a programmatic research project designed to understand why many Kenyan couples who are not seeking pregnancy are not using contraception. The study population will be drawn from areas identified as having low contraceptive prevalence and high fertility, yet where family planning services are available. Obstacles to family planning will be identified by a descriptive study through use of focus-group discussions and in-depth interviewing. Findings of the study will be discussed with policy makers in order to plan for a second (intervention) phase of the research project.

The third study, a one-year study, will assess the acceptability of three contraceptive methods in Kenya: the TCU 380A IUD, injectable Depo provera, and low-dose combined oral contraceptive pills. All three methods are currently available in government family planning clinics. Acceptability will be measured by continuation rates, reported user satisfaction and the types and frequency of side effects. Fifteen hundred volunteers will be followed up for one year or until discontinuation. Results of this study, which began in June 1990, will provide valuable information on user satisfaction and reasons leading to discontinuation, and should contribute to the improvement of contraceptive service delivery in Kenya.

In Egypt, FHI works through the National Population Council to develop the capability within family planning organizations to conduct all phases of programmatic research. Program managers from 10 organizations have been oriented to the uses of programmatic research (Hardee-Cleaveland and Kafafi, 1989). Study topics have been selected in consultation with the program managers. FHI conducted two workshops at which 34 participants from six organizations produced 10 programmatic research proposals.



Training is an integral part of institutionalizing programmatic research.

Of the nine on-going studies, two have completed data collection and analysis and final reports have been drafted. The rest are still in the data collection stage. One study was not implemented. Topics of the nine studies reflect the perceived problems faced by each organization.

The Ministry of Health, the principal organization in Egypt involved in programmatic research, is conducting four studies. Two of the studies are related to the reorganization of the training system in the MOH family planning program. One study is evaluating the impact of training on work performance of physicians working in family planning units of the MOH in Ismailia Governorate. A second study is looking at the effect of nurses' training on their provision of services, particularly counseling. The MOH in 1989 instituted a system of incentives for workers to try to improve their work performance. The third study is testing the impact of worker incentives on contraceptive prevalence rates. The fourth study is testing the impact of client materials (an IUD booklet) and related counseling on IUD knowledge and use in MOH family planning centers.

The Clinical Services Improvement Project (CSI) of the Egyptian Family Planning Association, operating since 1988, is designed to provide high quality family planning services to clients. One CSI study is looking at reasons why some clinics met their targets while others did not. A second study is analyzing patient flow at clinics to try to reduce waiting time for clients.

The National Population Council operates a cadre of female community workers, called Raidat Riefiat, who reside in their own communities and motivate local residents to accept family planning. The NPC is concerned about the uneven performance among the Raidat Riefiat and is looking at the effect of a new training system for Raidat Riefiat (female community workers) on promoting their role in family planning within the National Population Council program.

The Teaching Hospitals Organization (THO) has been operating a family planning clinic in the Al Galaa teaching hospital for a few years. As they expand services to seven other clinics they are concerned about maintaining a high quality of services. Their topic, therefore, is testing the impact of a new family planning management information system (MIS) on assessing the quality of services at the family planning units of the THO. Results from this study will be used to improve the MIS system at THO family planning units.

The Regional Center for Training (RCT) has developed training curricula for clinical training of health care providers. They train not only clinicians but also trainers to teach in the Satellite Training Centers (STC). RCT would like to know how best to provide follow-up to its trainees. Their study is testing the cost-effectiveness of three alternate teams in implementing the RCT follow-up system.

No programmatic research study is beneficial unless the results are used by program managers to improve services. Dissemination of findings is an integral component of the process of developing the capability to conduct programmatic research. In addition to final reports for each study, one or two dissemination workshops will be held to discuss the results from each of the studies. Program managers and policy makers will be invited to hear the results and recommendations from the studies. In addition, working sessions will be held with the practitioners who conducted the studies to discuss the process of conducting programmatic research and to share lessons learned.

NEW DIRECTIONS

FHI's priority contraceptive research areas continue to be the development, testing and introduction of new and existing contraceptive methods into family planning programs. Consequently, much of FHI's programmatic research is related to contraceptive technology, although, as this paper has indicated, FHI conducts programmatic research on a broad range of issues. While the emphasis of FHI's clinical trials focuses on clinical populations, our programmatic research emphasizes understanding factors associated with contraceptive acceptance, correct use, and continuation in the general population.



FHI now focuses its programmatic research in five priority areas, while maintaining the flexibility to respond to requests for assistance in other types of programmatic research. The five priority areas are as follows:

1. **Acceptability/Demand of New and Developed Methods:** Research in this area emphasizes male and female condoms, including both latex and plastic condoms. Other new methods like injections or biodegradable implants are likely areas for study as well.
2. **Improving Contraceptive Use:** Research in this area focuses on compliance and informed choice. Emphasis is given to impact and intervention studies to improve pill compliance. In the area of informed choice, we plan to test various interventions to improve informed choice and raise the quality of service provision.
3. **Improving Program Effectiveness:** This area includes studies on the reasons for continuation and discontinuation, evaluation of social marketing, assessing the impact of family planning and health programs and cost analysis. New studies include research to determine how continuation rates can be improved (with emphasis on sub-Saharan Africa), an evaluation of the use of the concept of reproductive risk to provide family planning services (Brazil), studies to determine the cost and impact of adding new methods to the existing method mix (NORPLANT[®]), and studies to determine the impact of cost recovery policies.
4. **Breastfeeding and Postpartum Contraception:** Studies in this area will include testing of the Bellagio Consensus and support of programmatic research on postpartum programs. Research will be directed toward determining how the Bellagio guidelines can be implemented and whether pregnancies can remain as low as under conditions prevailing in clinical trials. Research on postpartum contraception will complement research carried out in FHI's other divisions.
5. **AIDS and Family Planning.** Research will emphasize the feasibility of adding HIV risk assessment to family planning programs (including the testing of alternative counseling strategies) and exploring the impact of the HIV epidemic on family planning programs. Research will also focus on the acceptability of contraceptive methods, including condoms and spermicides, which may reduce the transmission of HIV.

In addition, FHI will place emphasis on continuing to support more field-based studies, in which FHI provides assistance to local organizations to implement all phases of programmatic research studies, from proposal and protocol development, data collection, instrument designs, analysis, report writing and dissemination.

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