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Semiannual Report

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I. INTRODUCTION

Over the next five to eight years FHI will have the staff and necessary access to a group of highly trained and specialized clinical investigators to take several new methods of contraception through the process of FDA approval and into the marketplace. A number of promising methods are in the development pipeline and receiving support from AID, but not all are under the immediate control of FHI.

FHI is ready to expand Phase II/III clinical trials of 90-day injectable NET microcapsules, but the exact timing of this work partly depends upon initiatives currently under the control of the Program for Applied Research in Fertility Regulation (PARFR). FHI is eager to see work on subdermal NET pellets expanded and is in the process of acquiring the IND relating to this product. FHI has expanded the overseas Phase III clinical trials of NORPLANT®. A total of 1717 women have been admitted to the studies in 18 sites. The time table for the final FDA approval of NORPLANT® was recently re-evaluated by the Population Council.

The past six months have seen an expansion of FHI's work in spermicides, and FHI intends to carry an appropriate formulation of Propranolol through the initial stages of FDA approved testing. FHI believes the careful management of research at all stages of contraceptive development is essential if safe and effective new methods are to be introduced as expeditiously as possible. With this goal in mind FHI is supporting selected animal studies for the FDA

approval of the Filshie Clip, an effective and potentially partially reversible method of female sterilization, and Phase I studies on chemical sterilization and spermicides in contraceptive development. FHI has put some effort into the coordination of early studies on an anti-pregnancy vaccine.

Clinical Trials also continues a large program designed to evaluate the short and long term efficacy, safety and acceptability of established family planning methods and to increase their use. For example, clinical trials of low-dose pills and progesterone-only pills involve over 20,000 women. FHI continues to study the TCU 380A IUD.

FHI's activities have expanded to a record level in the past six months and in addition to both the growth and greater focus of Clinical Trials, an impressive program in Reproductive Epidemiology is taking off. FHI and its collaborators have contributed well documented information on maternal mortality in the Third World. In Reproductive Health, FHI is making an important contribution to the evaluation of the training and effective use of traditional birth attendants and to the role of improved family planning in bringing down the current tragic and unacceptably high death rates due to maternity and induced abortion.

FHI's Natural Family Planning Advisory Committee, the WHO and an increasing number of other agencies are coming to accept breastfeeding as an intrinsic part of NFP activities. FHI's pioneering studies on the role of breastfeeding in pregnancy spacing

and ongoing studies are moving towards producing useful guidelines to instruct women if and when they need to use additional methods of family planning. In addition, FHI is completing the first detailed analysis of the effort necessary in training, support and budgets to offer the ovulation method of natural family planning to a poor urban area in Lima, Peru. The UNFPA has agreed to fund continued services in this important program and the Peruvian Conference of Bishops has made the program the core of a nationwide training effort.

FHI's division of Field Development and Training continues to provide technical assistance to family health research centers around the world, has a heavy program of training and the transfer of contraceptive technology, and also oversees FHI's information dissemination program. The Field Development and Training division is frequently asked by AID missions to conduct specific tasks and it plays a major role in providing field support to the research divisions of FHI, particularly Clinical Trials.

FHI continues to disseminate information from its studies through published papers. The Publications List for this reporting period is found in Appendix A.

II. CONTRACEPTIVE DEVELOPMENT

FHI is largely dependent for its clinical evaluation of new contraceptive products on scientific initiatives that take place outside the organization. The timing and management of initiatives undertaken prior to FHI's involvement substantially determine when new methods of contraception become available for widespread human use. Therefore, FHI is closely concerned with the expeditious conduct of the steps necessary to move a potential product or agent along the pathway of its development. FHI has probably given more attention to the staff and management necessary to bring new methods of contraception from the laboratory to the marketplace in the shortest possible interval than any other comparable agency. FHI has been asked by the Population Council to assist in the documentation of NORPLANT® for FDA approval.

FHI has a specialized but important role in the coordination and management of laboratory work on new methods of contraception that are within range of human use. FHI sponsored a meeting of experts on spermicides in December 1985, followed by a workshop in Houston, Texas during February 1986 for researchers specializing in immunology of the zona pellucida. Research was initiated at two centers to standardize the sperm antibodies (monoclonal antibodies) derived from a large number of laboratories around the world. Results of these monoclonal antibody characterization studies will be presented in Toronto, Canada in June 1986, and will help to identify the most potent antibodies to be considered for contraceptive vaccine studies.

Using AID and Andrew W. Mellon Foundation support, FHI sponsored preclinical and Phase I clinical studies of D-propranolol as a potential vaginal contraceptive. This led to the preparation of a detailed development and evaluation plan for the product. In response, NICHD awarded FHI a contract for the formal full-scale development of this potential new advance in vaginal contraception. The D-propranolol formulation has been prepared and the initial preclinical studies will be started within the third quarter of 1986.

Until FHI's involvement no agency has tried to bring together workers in the field of immunocontraception so they could coordinate their research. FHI is working with the WHO and the Population Council to estimate the budget and time likely to be involved in bringing one or more vaccines to a "go-no-go" stage of human development.

III. CLINICAL TRIALS

During the first half of this fiscal year, the Clinical Trials Division has maintained a strong emphasis on the evaluation and development of major new contraceptive methods and techniques. Important steps were taken in three areas. Phase III NORPLANT® subdermal implant studies were initiated at nine sites in three countries. At almost all study sites, the rate of volunteer enrollment proceeded more rapidly than anticipated; a total of 1717 insertions have now been performed. Considerable progress was also made in the evaluation of other long-acting steroids. Through a joint effort PARFR, eight Phase II studies comparing 100 mg and 65 mg of NET 90-day microspheres were initiated. Thirdly, FHI has reached an agreement with Endocon Inc. and Cornell University to transfer the NET biodegradable implant IND to FHI, and the manufacturing process is about to be finalized at University of Iowa.

FHI's support of studies of the Filshie Clip for female sterilization remains consistent with the original objective of satisfying international regulatory requirements. Towards that objective, extensive multicenter Phase III clinical trials have been initiated, and a preclinical carcinogenicity study that will compare the Filshie Clip and the Falope Ring has recently begun in England.

The development of a simple method of nonsurgical female sterilization that could be safely offered by medical or paramedical personnel in large-scale programs continues to be a priority for the organization. During this reporting period, Phase I studies of

quinacrine and tetracycline have progressed slowly because of difficulty in patient enrollment associated with a very demanding clinical protocol. Additional study sites will be identified and initiated in the next two to three months to increase the rate of progress.

In parallel with the development of new contraceptive products, FHI evaluates the acceptability of established products in new cultural settings. Site selection and initiation of all studies examining the value of progestogen-only pills in breastfeeding women was recently completed, and all sites have now been identified for the planned evaluation of the TCU 380A IUD. Similarly, a variety of vaginal spermicidal products are under investigation.

As all of these clinical studies are dependent upon the collaboration of expert clinical scientists and physicians, the Division maintains a dynamic Investigator Network Needs research program for the identification and development of new investigators. A total of ten studies have been ongoing through this program.

Also during the first half of this fiscal year, the Division wrote sixteen Consultant Reports (CRs) on completed studies as a service to its investigators. A list of these is found in Appendix B. The Study Status Lists for ongoing FHI clinical trials are found in Appendix C.

A. Systemic Contraception

1. Long-acting Steroids

a) NET 90-Day Biodegradable Injectable

FDA marketing approval for an injectable contraceptive remains FHI's first priority. The 90-day injectable biodegradable formulation of norethindrone (NET) that permits the continuous low-dose administration of the progestin has entered Phase II testing. In a joint project with PARFR, eight studies comparing 100 mg and 65 mg of NET microspheres have been initiated. A single site Phase I study comparing 50 mg and 30 mg has also begun. FHI is processing and analyzing data from these trials, providing regular monitoring of the studies, and working closely with Stolle R&D Corporation and Ortho Pharmaceutical on planning the Phase III clinical trial program that will lead to FDA marketing approval for the product. FHI continues to support work at Stolle R&D to scale-up the production of the formulation in preparation for the Phase III trials.

b) NORPLANT® Implants

FHI has undertaken a number of pre-introductory clinical trials of the NORPLANT® contraceptive subdermal implant system. The objective of these studies is to introduce the NORPLANT® system into countries that have no previous experience with the method, to provide proper training to physicians in the insertion and removal techniques and to determine overall acceptability of the implants in different

populations. Pregnancy rates, rates of removal for menstrual problems, side effects or other medical reasons, and continuation rates will be used to evaluate safety, efficacy and acceptability.

Bringing together an in-house team representing various disciplines, FHI also will attempt to identify some of the sociodemographic characteristics and culture-specific factors that may affect widespread acceptability of NORPLANT® implants. The clinical trials provide the opportunity to administer interview questionnaires to potential acceptors in selected centers. The purpose of these questionnaires is to assess how much appeal the method may have among potential users, to explore reasons why potential users would be willing or unwilling to use the method and to compare characteristics of acceptors with those of women opting not to use the method.

In addition to the Acceptability Surveys administered to all potential acceptors, actual acceptors and providers participating in the clinical trials are asked their subjective opinions about the method at the six-month follow-up visits.

All investigators participating in the clinical trials receive standardized training in the proper insertion and removal techniques at a regional training site. To date, 11 investigators from Asia have been trained at Raden Saleh Clinic in Jakarta, Indonesia, and 13 investigators from West Africa, Haiti and Venezuela have been trained in Santo Domingo, Dominican Republic. Additional investigators from Peru may be trained in the spring of 1986 at the Santo Domingo site,

and three to four physicians from Pakistan will be trained in Jakarta by mid-summer 1986.

Clinical trials were initiated during this reporting period in Ghana (1 center), Haiti (3 centers) and Nigeria (5 centers), bringing the total number of centers actively participating in NORPLANT® clinical trials to 18 sites in 7 countries. A summary of admissions is presented in Table 1.

Insertions have been performed in 1717 women to date. There have been a total of 35 removals, 5 due to pregnancy, 13 for menstrual problems, 10 for medical reasons and 7 for personal reasons. Of the five pregnancies, only one is a possible method failure; in the others, the women were likely pregnant at admission. All five pregnancies were intrauterine.

Of the 10 removals for medical reasons other than menstrual-related problems, half were due to infection at the insertion site. Two removals occurred in women who had respiratory problems, one woman contracted tuberculosis, one became jaundiced and one removal was in a woman who complained of depression.

A summary of cumulative lifetable event rates across all study sites is presented in Table 2. The pooled continuation rates are 99.9, 99.0 and 96.9, respectively, after 1, 3 and 6 months follow-up. The corresponding follow-up rates are 83.7, 62.3 and 33.1. Center-specific results vary greatly depending upon the time elapsed since initiation of each study.

As a result of the recent initiation of many trials the long term experience with the method is still limited. Of all the insertions made only 83.7, 67.3 and 33.1% have been followed up at the respective 1, 3 and 6 month return visits.

Table 1
Status of Ongoing NORPLANT® Clinical Trials

	Initiation Date	Planned Caseload	Insertions Performed
Bangladesh			
Center 704	Feb. 1985	200	177
Center 718	Feb. 1985	200	188
Center 721	Feb. 1985	200	147
Ghana			
Center 041	Oct. 1985	100	0
Haiti			
Center 8017	Nov. 1985	100	51
Center 8331	Nov. 1985	100	60
Center 8332	Nov. 1985	50	48
Nepal			
Center 729	Feb. 1985	300	304
Center 731	May 1985	100	47
Nigeria			
Center 040	Oct. 1985	70	55
Center 042	Oct. 1985	50	28
Center 435	Jan. 1986	50	31
Center 437	Oct. 1985	50	38
Center 453	Nov. 1985	50	0
Philippines			
Center 600	Feb. 1986	100	21
Sri Lanka			
Center 703	May 1985	200	200
Center 749	May 1985	200	122
Center 758	May 1985	200	200
Total		2320	1717

TABLE 2
 NORPLANT® Clinical Trials
 Cumulative Lifetable Event Rates

Event	Rate per 100 users
Removal for menstrual problems	
1 month	0.0
3 months	0.3
6 months	0.6
Removal for medical problems	
1 month	0.1
3 months	0.3
6 months	0.7
Continuation	
1 month	99.9
3 months	99.0
6 months	96.9
Follow-up (returned at cut-off date)	
1 month	63.7
3 months	62.3
6 months	33.1

c) Other Injectables

An evaluation of continuation rates for injectables and oral contraceptives that have been supplied by agencies other than FHI has been conducted in Egypt, Mexico, Sri Lanka and Thailand. Final analysis of these studies is presented in Table 3. Three year cumulative life table continuation rates were 46.9 for injectable users compared with 54.6 for oral contraceptive users. About 86% of the women have been followed up. Injectable users had significantly higher discontinuation rates for menstrual problems and "method unrelated" reasons. The most frequently reported menstrual problem causing discontinuation was amenorrhea for women in the injectable group. Moving/travel was the most frequently reported reason in the method unrelated category. Oral contraceptive users had a significantly higher discontinuation rate for planned pregnancy.

TABLE 3

Cumulative Life Table Rates for Retrospective Studies
of Depo Provera Users Versus Oral Contraceptive Users

	Depo Provera (N=747)	Oral Contraceptives (N=746)
Accidental Pregnancy		
12 months	0.0	0.0
24 months	0.2	0.9
36 months	0.2	0.9
Menstrual Problems*		
12 months	5.2	1.2
24 months	9.9	1.9
36 months	14.7	2.7
Side Effects		
12 months	0.8	2.6
24 months	2.3	3.9
36 months	3.8	5.0
Other Medical Reasons		
12 months	1.0	1.2
24 months	2.7	1.9
36 months	4.4	2.4
Planned Pregnancy*		
12 months	2.2	6.2
24 months	6.4	12.2
36 months	13.2	21.5
Other Personal Reasons		
12 months	4.8	6.2
24 months	8.3	10.3
36 months	19.3	15.6
Method Unrelated*		
12 months	4.2	4.1
24 months	10.8	5.6
36 months	14.3	7.7
Continuation		
12 months	83.1	80.2
24 months	65.5	68.2
36 months	46.9	54.6
Follow Ups		
12 months	85.9	79.1
24 months	76.3	74.1
36 months	46.0	57.6

* There was a significant difference ($p < 0.01$) in life table rates for reported problems between the two groups using the Mantel-Cox chi-square test.

Future Plans

Interim analysis will be performed midway in the NET 90-day injectable Phase II trial to make a decision on the dose for Phase III studies. A meeting with the FDA will be held to determine if Phase III studies can begin before completion of the one-year Phase II study.

The NET 30-day injectable is being tested in baboons and will enter Phase I study by May 1986. FHI will continue support with study monitoring, data collection and analysis and will design and implement Phase II and III clinical trials when appropriate.

NET biodegradable implants are being formulated at the University of Iowa. Endocon has provided funding and raw materials for the pellet production. Preclinical studies will be conducted to assure product quality. FHI will assume responsibility for the IND and for communications with the FDA. FHI plans to conduct Phase I evaluation of the NET pellets to ensure bioequivalence to previously studied pellets, and then initiate and conduct Phase III trials in preparation for the submission of an NDA.

By the end of 1986, introductory clinical trials of NORPLANT® subdermal implants are expected to begin in Pakistan, Peru and Venezuela. Training of investigators from Venezuela is complete, whereas those from the other countries will be trained by Summer

1986. Other countries being explored as possible study sites include El Salvador, Panama, Senegal, Sudan and Zimbabwe.

Due to the seemingly universal demand for the NORPLANT® technology, a comprehensive proposal has been prepared for expanded clinical trials in countries having prior introductory experience with the NORPLANT® system. One key component of the proposal is the establishment of in-country training centers and training of physicians at rural clinics who will conduct small-scale acceptability studies. Another major component of the proposal is the development of user-oriented materials tailored to the cultural and educational characteristics of the client populations in each of the countries. The proposal is designed such that FHI will help coordinate the interagency efforts of several organizations, for example the Association for Voluntary Sterilization (AVS) in the development of a standardized training curriculum and the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT) for technical assistance in the preparation of user-oriented materials. The proposal is expected to be finalized and submitted for funding during Spring 1986.

The expanded strategy will provide an opportunity to begin introduction of NORPLANT®-2 covered rods. Select centers will be asked to undertake clinical trials of NORPLANT®-2 rods either exclusively or comparatively with standard NORPLANT® capsules.

2. Oral Contraceptives

FHI has continued to compare the efficacy, safety and acceptability of oral contraceptive formulations. In past years, the evaluation of the safety and efficacy of low estrogen dose pills and their acceptability in the developing world has been the major focus; new trials are evaluating progestogen-only pills in breastfeeding women, oral contraceptive regimes with and without iron, triphasic pills, and crossover from standard to low-dose products.

a) Norinyl 1/35

Norinyl 1/35 is being evaluated in a 15-center clinical trial in comparison with Brevicon or Lo-Ovral, two other low-dose pills, and Norinyl 1/50, a standard dose pill. Acceptability is being measured by continuation rates at one year. Analysis of these studies is presented in the three tables found at the end of this section.

Table 4 shows data from the four centers in the Norinyl 1/35 versus Brevicon trial. Brevicon users have significantly higher discontinuation rates for menstrual problems and side effects, resulting in a significantly lower 12-month continuation rate, 35.3 compared with 48.2 for Norinyl 1/35 users. The most frequently reported side effect causing discontinuation for Brevicon users is headaches. Breakthrough bleeding is the most commonly reported menstrual problem causing pill discontinuation in the Brevicon group.

A Norinyl 1/35 versus Lo-Ovral comparison is being conducted at six centers. Norinyl 1/35 has a significantly higher 12-month termination rate for menstrual problems (Table 5). Breakthrough bleeding is the most frequently reported menstrual problem for Norinyl 1/35 users. Cumulative life table continuation rates at 12 months are 78.6 in the Norinyl 1/35 group and 81.6 in the Lo-Ovral group.

Five centers are participating in the Norinyl 1/35 versus Norinyl 1/50 trial. There have been no differences between the two pill groups with respect to event or continuation rates (Table 6). Continuation rates at 12 months are 75.0 for Norinyl 1/35 and 77.0 for Norinyl 1/50.

TABLE 4
 Cumulative Life Table Rates for Comparative Studies
 of Norinyl 1/35 versus Brevicon

	Norinyl 1/35 (N=493)	Brevicon (N=495)
Accidental Pregnancy		
1 month	0.2	0.2
4 months	0.5	0.5
8 months	0.9	0.5
12 months	0.9	0.5
Menstrual Problems		
1 month	2.0	4.4
4 months**	8.6	17.1
8 months**	14.1	29.3
12 months**	21.7	36.6
Side Effects		
1 month*	1.3	4.2
4 months**	2.2	8.2
8 months**	5.8	11.2
12 months**	6.7	12.4
Other Medical Reasons		
1 month	0.9	2.5
4 months	4.1	4.8
8 months	5.6	8.7
12 months	5.6	8.7
Planned Pregnancy		
1 month	0.7	0.7
4 months	2.6	2.5
8 months	5.9	8.5
12 months	7.8	9.1
Other Personal Reasons		
1 month	2.8	2.2
4 months	8.2	9.3
8 months	13.2	13.3
12 months	16.2	17.8
Continuation		
1 month*	89.9	84.7
4 months**	72.8	60.5
8 months**	58.4	42.4
12 months**	48.2	35.3
Follow Ups		
1 month	95.9	95.2
4 months	91.4	90.8
8 months	83.0	82.4
12 months	61.7	61.2

*p<0.05
 **p<0.01

TABLE 5
 Cumulative Life Table Rates for Comparative Studies
 of Norinyl 1/35 versus Lo-Ovral

	Norinyl 1/35 (N=651)	Lo-Ovral (N=647)
Accidental Pregnancy		
1 month	0.0	0.0
4 months	0.6	0.0
8 months	0.6	0.0
12 months	0.9	1.0
Menstrual Problems		
1 month	1.2	0.5
4 months	2.7	1.3
8 months*	3.6	1.3
12 months*	4.1	1.3
Side Effects		
1 month	0.5	0.7
4 months	2.1	1.6
8 months	3.0	2.7
12 months	3.8	3.2
Other Medical Reasons		
1 month	0.3	0.3
4 months	0.7	1.5
8 months	1.6	1.7
12 months	1.6	2.6
Planned Pregnancy		
1 month	0.0	0.3
4 months*	0.0	1.3
8 months	0.9	1.9
12 months	1.5	2.4
Other Personal Reasons		
1 month*	1.6	0.3
4 months	3.5	3.1
8 months	6.6	4.4
12 months	8.0	4.6
Continuation		
1 month	95.9	97.4
4 months	88.7	88.9
8 months	82.2	84.8
12 months	78.6	81.6
Follow Ups		
1 month	91.6	94.3
4 months	83.6	86.5
8 months	75.6	78.3
12 months	62.9	63.8

*p<0.05

TABLE 6
 Cumulative Life Table Rates for Comparative Studies
 of Norinyl 1/35 versus Norinyl 1/50

	Norinyl 1/35 (N=769)	Norinyl 1/50 (N=763)
Accidental Pregnancy		
1 month	0.0	0.0
4 months	0.2	0.0
8 months	0.3	0.2
12 months	0.3	0.2
Menstrual Problems		
1 month	1.1	0.8
4 months	2.6	3.4
8 months	4.2	4.6
12 months	4.9	5.3
Side effects		
1 month	0.8	1.3
4 months	2.2	2.8
8 months	3.0	3.7
12 months	3.5	4.3
Other Medical Reasons		
1 month	0.0	0.4
4 months	0.5	1.1
8 months	1.2	1.9
12 months	2.0	2.2
Planned Pregnancy		
1 month	0.3	0.1
4 months	0.9	0.5
8 months	2.5	1.0
12 months	3.8	2.0
Other Personal Reasons		
1 month	0.8	0.6
4 months	3.6	3.1
8 months	6.0	4.5
12 months	7.6	5.9
Continuation		
1 month	96.5	95.7
4 months	88.2	87.5
8 months	80.2	81.4
12 months	75.0	77.0
Follow-ups		
1 month	94.0	93.6
4 months	87.9	87.6
8 months	83.7	83.8
12 months	79.8	80.7

b) Progestogen-only Oral Contraceptives

FHI continues to introduce progestogen-only pills around the world. A 4,000 case, 20 center noncomparative clinical trial of the progestogen-only oral contraceptive, Ovrette, is ongoing. The trial has been designed to evaluate the acceptability, safety and effectiveness of this minipill among breastfeeding women.

Preliminary data on 2,983 women from 19 centers in Latin America and Africa show a 6-month continuation rate of 74.9. Most discontinuations were for "other personal reasons", such as the women desired a change, forgetfulness or the pill was no longer needed. Fifty percent of the women have returned for the 6 month visit.

In order to establish the acceptability of the progestogen-only pill in a large population of breastfeeding women, a 10,000 case expanded strategy has been developed to distribute and evaluate Ovrette in several countries, often through a community-based or health post system. Six studies have begun in Mali, Ghana and Brazil.

Preliminary data on 456 women show a 2-month continuation rate of 81.0. The majority of discontinuations were for the same "other personal reasons" as described above; 40.7 percent of the women have returned for the 2-month visit. In Thailand a 1,000 case multicenter introduction of progestogen-only pills has been initiated by the Thailand Fertility Research Association. The study will evaluate overall acceptability and efficacy of progestogen-only oral contraceptives, examine the contraceptive practices of breastfeeding

women and assess the attitudes of health personnel to the introduction of the progestogen-only pill.

A 600 case comparative study of progestogen-only oral contraceptives versus nonhormonal methods in lactating women is being conducted at two centers located in Egypt and Argentina. In addition to evaluating acceptance and side effects of this pill among breast-feeding women, the differences over time in the weight of breast-fed infants for both groups will be compared. To date, 81 women have been admitted to the study.

c) Oral Contraceptives With and Without Iron

FHI will initiate a double-blind placebo controlled trial to study the effects of iron supplement tablets on the reported side effects, the acceptability of oral contraceptives and their effect on iron levels in the blood. FHI has obtained drug supplies for this study from Kimia Farma of Indonesia. A 1,280 case comparison will be conducted at four centers. Three locations have been selected in Thailand, Indonesia and Mexico. Study initiation is planned for Spring 1986.

d) Triquilar versus Lo-Femenal

A study has been designed for an evaluation of a triphasic formulation compared with Lo-Femenal. Triphasic formulations vary the ratio of progestogen and estrogen to simulate natural hormonal changes in the menstrual cycle. A 1,500 case comparison of the

effectiveness, side effects and acceptability of the Triphasic oral contraceptive, Triquilar (Schering), and the low-dose contraceptive, Lo-Femenal (Wyeth), will be conducted at five centers. Center selection has been completed with locations in Brazil, the Dominican Republic, Chile, Sri Lanka and the Sudan. Study initiation is planned for Spring 1986.

e) Loestrin versus Lo-Femenal

FHI will conduct a comparative evaluation of two low-dose oral contraceptives, Loestrin (Parke-Davis) and Lo-Femenal (Wyeth). Low estrogen dose oral contraceptives are being introduced in government programs throughout the world in an attempt to reduce long- and short-term side effects. A 1,500 case comparison will be conducted at five centers to evaluate the effectiveness, side effects and acceptability of the oral contraceptives and to determine their effects on blood lipids. Three centers, located in Mexico, Egypt and Colombia have been selected with study initiation planned for Spring 1986.

f) Crossover Pill Studies

FHI is evaluating the acceptability of switching from a standard to a low-dose estrogen pill. Concern has been expressed that a switch from one oral contraceptive formulation to another may result in an increase or change in side effects that will lead to discontinuation. Of particular concern is the change from a standard to low estrogen dose. The objective of the study is to determine the acceptability

of switching from Norinyl 1/50 (Syntex) to Lo-Femenal (Wyeth) in comparison with switching from Lo-Femenal to Norinyl 1/50. The 1,200 case trial will be conducted at four centers located in Yugoslavia, the Philippines, Mexico and Brazil. Three of the centers are active and 172 women have been admitted, 95 of whom have completed their one month follow-up visit. The fourth center is currently being supplied with study product.

Future Plans

FHI plans to develop three additional studies of oral contraceptives: 1) an evaluation of the influence of in-depth counseling on the acceptability of switching from a standard to a low-dose estrogen pill, 2) an evaluation of the metabolism of estrogen in different races, and 3) an assessment of the effect of progestogen-only oral contraceptives on milk yield during lactation.

B. Vaginal Contraceptives

1. Barriers and Spermicides

FHI has proceeded with its evaluation of a number of vaginal contraceptives in the past six months including: the diaphragm with and without spermicide; spermicidal foam; Neo Sampoo foaming vaginal tablets containing the spermicide, menfegol; Ortho (OVT) vaginal tablets containing the spermicide, nonoxynol-9; and Ortho vaginal tablets containing menfegol (Neo Sampoo repackaged). There are four strategies for comparative trials of these products ongoing at seven

sites. Patient recruitment has continued at four sites during this reporting period.

Table 7 summarizes the results of the active comparative trials evaluating foaming tablets. The number of observed pregnancies continues to be high in most studies, although more than half have been attributed by the physician to user failure. Results, as in previous studies, continue to be country-specific. In Yugoslavia (Study 785), itching is the single most common method-related complaint and reason for discontinuation of both foam and Neo Sampoo. Tablets are most acceptable in Ghana (Study 7798), where a burning sensation is the most frequent use-related complaint. Recruitment continues to be extremely difficult at U.S. sites (Study 7799), and lost-to-followup rates in excess of 40% support the view that foaming tablets remain an unacceptable contraceptive option to American women.

TABLE 7
Reasons for Discontinuation and Primary Method-related Complaints
for FHI Comparative Vaginal Contraceptive Studies of Foaming Tablets

	Study 785 Yugoslavia		Study 7798 Ghana		Study 7799 United States	
	Foam (N=130)	NeoSampoon (N=135)	OVT-n* (N=81)	OVT-m* (N=80)	OVT-n* (N=23)	OVT-m* (N=26)
<u>Reasons for Discontinuation</u>						
Accidental pregnancy	15	11	7	2	2	3
Planned pregnancy	7	5	0	1	1	0
Medical	0	0	0	3	0	0
Discomfort						
Burning	0	0	3	0	0	0
Itching	15	11	0	0	0	0
Penile irritation	2	1	0	0	1	1
Other	18	16	0	0	0	0
Product-related						
Messy, inconvenient	1	1	0	0	1	1
Failure to dissolve	0	0	1	0	0	0
Other personal	20	19	4	5	3	2
<u>Primary Method-related Complaints**</u>						
Itching	34	47	0	0	0	0
Messy, inconvenient	5	5	3	1	3	0
Burning	2	1	3	5	1	5
Difficulty with placement	0	0	0	0	1	4
Foam runs out	0	0	0	0	3	3
<u>Woman Months of Use</u>	885	962	418	387	56	97

* OVT-n = OVT with nonoxynol-9

OVT-m = OVT with menfegol

** Ever reported during product use.

FHI is conducting a study comparing the fitted diaphragm with spermicide, the fitted diaphragm without spermicide, and spermicide alone (foam) at the Margaret Pyke Center in London (Study 7788). To date, 39 cases have been recruited. One pregnancy has been reported in the diaphragm without spermicide group.

FHI is evaluating the bacteriocide/fungicide, tioconazole, for its potential protective effect against STDs such as chlamydia and gonorrhea in a group of sexually active, high risk women in Costa Rica (Study 7800). (Tioconazole is expected to have spermicidal activity and will be studied as a potential vaginal contraceptive pending successful completion of this study.)

2. Development of D-propranolol as a Spermicide

Since approval by NICHD of the proposal for development of D-propranolol as a spermicide, work has begun in several areas according to the original workplan. The stereospecific synthesis of optically-pure D(+)-propranolol hydrochloride is being carried out by Synthon Laboratories. Problems in scaling up the synthesis, that resulted in the delay of delivery of the initial 200-gram sample of the compound, are expected to be overcome shortly. Delivery of a 50 gm sample was made during the third week in March and the remaining 150 gm delivery is expected by May 12. An additional 800 grams were scheduled originally for delivery in June, however in order to meet this date, the scale up problems must be overcome. When the 1000 gm

1000 gm of D-propranolol is received, it is expected to be sufficient material for completion of preclinical and early clinical studies.

Preliminary formulation studies, using racemic D,L-propranolol, were initiated under the direction of Dr. James Swarbrick at the University of North Carolina. Two prototypes, one cream and one gel, have been shown to have acceptable in vitro release profiles and will be submitted to Dr. Patricia Saling at Duke University for in vitro screening tests.

In vitro evaluations will include assessment of spermicidal activity and measurement of the ability of D-propranolol (in pure form as well as in formulation) to impede the penetration of sperm into cervical mucus.

Since November 1985, D. Maynard, PhD, a pharmaceutical consultant, has been retained by FHI to manage the preparation of the IND for D-propranolol as a vaginal spermicide. He has completed an extensive review of the preclinical and clinical literature on D-propranolol and has prepared the clinical investigator's brochure for the compound. Assembly of related material pertaining to the synthesis, formulation, manufacturing and clinical investigation of D-propranolol is continuing.

Supporting studies of D-propranolol continue as well. A study measuring the concentration of D,L-propranolol in serum and cervico-vaginal mucus following insertion of the 80 mg tablet vaginally was completed in the United Kingdom. Concentrations of propranolol in

the cervical mucus were several times higher than those in the plasma during the first 24 hours following the 80 mg oral dose. Also, a pilot study of changes in seminal parameters in men who have been on a DL-propranolol regimen for at least six months is being conducted in Minnesota.

All AID-supported work involving D-propranolol is being carefully coordinated with that sponsored by NICHD.

Future Plans

FHI plans to continue comparative trials of foaming tablets, although limiting emphasis to conducting high quality studies in regions of the world where tablets have previously been used successfully. Both the diaphragm study at the Margaret Pyke Center in London and the tioconazole fungicide study in Costa Rica will continue. Pending successful results of the Costa Rica study, a study evaluating the spermicidal potential of tioconazole will be undertaken.

During the next six months, emphasis will be placed on initiation of additional D-propranolol preclinical studies. Projects expected to be completed during this period include the preformulation studies and in vitro evaluations of prototype formulations. Those studies scheduled to begin include primate postcoital efficacy studies (including pharmacokinetic evaluation), rabbit vaginal irritation and pharmacokinetic studies, and preclinical pharmacology. Submission of the IND for D-propranolol is scheduled for the fourth quarter of 1986.

C. Surgical Sterilization

1. Female Sterilization

The primary emphasis in female sterilization strategies has been on the evaluation of the Filshie Clip. This device is being compared with the tubal ring, the Wolf Clip, the Secuclip or the Pomeroy method of tubal occlusion in 24 centers.

The Filshie Clip is being compared with the Wolf Clip in minilaparotomy procedures in interval women in Panama and in the Dominican Republic. To date 279 procedures have been performed. There have been no technical failures. The following table (Table 8) details the surgical difficulties.

Two women (2.1%) in the Wolf Clip group were reported as having a major complication from sterilization to discharge. Early follow-up (<30 days post-sterilization) visits have occurred for more than 75% of the cases. Fourteen Wolf Clip cases (12.0%) and 18 Filshie Clip cases (15.3%) reported one or more complications at early follow-up. One luteal phase pregnancy was reported in the Filshie group. Long term follow-up visits are just beginning. Two more centers are being sought for this comparison.

TABLE 8

Filshie Clip versus Wolf Clip
via Minilaparotomy

	Filshie Clip (N=139)		Wolf Clip (N=140)	
	No.	%	No.	%
A. Events at Surgery				
<u>Surgical difficulties</u>				
With equipment	0	-	1	0.7
Entering the peritoneum	1	0.7	4	2.9
Visualizing/grasping tubes	2	1.4	3	2.1
Occluding tubes	0	-	1	0.7
<u>Surgical Injuries</u>				
Tubal injury without bleeding	0	-	1	0.7
Tubal bleeding	0	-	2	1.4
Cornual lesion	1	0.7	0	-
Uterine tear	0	-	1	0.7
Apnea	0	-	1	0.7
Total women with 1+ surgical injuries/ complications	1	0.7	5	3.6
B. Events Reported at Early Follow-up				
Women returning for early follow-up	118	76.6	117	75.5
Readmissions	1	0.8	1	0.9
<u>Complications</u>				
Serous discharge	5	4.2	7	6.0
Hematoma	5	4.2	1	0.9
Inflammation at incision	5	4.2	3	2.6
Abscess	3	2.5	2	1.7
Perineo-plastic surgery	0	-	1	0.9
Women reporting 1+ complications at early follow-up	18	15.3	14	12.0

The two clips are also being compared in laparoscopic procedures. Four sites are now active, one in Haiti and three in Latin America. Interval sterilizations have been performed on 162 patients; one technical failure has been reported in a case (Wolf) where only one tube was found. Surgical difficulties, injuries and complications are detailed in the following Table 9. The only major recovery period complication was one case of hematoma in a Wolf Clip patient. About half of the women in both groups have returned for early follow-up visits (<30 days post-sterilization). Only three complications, one case of serous discharge, one case of hematoma and one urinary tract infection were reported; all were Wolf Clip cases. At this time, only two patients have returned for their 6 month follow-up visit.

TABLE 9
 Filshie Clip versus Wolf Clip
 via Laparoscopy

	Filshie Clip (N=80)		Wolf Clip (N=82)	
	No.	%	No.	%
A. Events at Surgery				
<u>Surgical difficulties</u>				
With equipment	0	-	2	2.4
Entering peritoneum	0	-	1	1.2
Visualizing the tubes	1	1.3	4	4.9
Grasping the tubes	1	1.3	1	1.2
Occluding the tubes	1	1.3	3	3.7
<u>Surgical injuries</u>				
Cervical laceration	0	-	1	1.2
Tubal bleeding	1	1.3	0	-
Clip left in pelvis	0	-	1	1.2
Total women with 1+ surgical injuries or complications	1	1.3	2	2.4
B. Events Reported at Early Follow-up				
Women returning for early follow-up visits*	42	52.5	40	49.4
Total women with 1+ complications at early follow-up	0	-	3	7.5

* technical failure cases are excluded from follow-up analysis.

A comparison of the Filshie Clip and the Tubal Ring via laparoscopy is underway in Panama. Data have not yet arrived from two centers in Indonesia and one center in Mexico. Admission should begin at a center in the Dominican Republic this summer. To date 300 procedures have been performed. There have been seven technical failures (Table 10). Surgical difficulties, injuries and complications are also detailed in the table. Surgical injuries and complications were reported in 14 (9.3%) of the ring patients and 12 (8.0%) of the clip patients.

The only major complications or complaints reported during recovery were two cases of vaginal bleeding in ring patients. About 70% of the women in each group have returned for early (<30 days post-sterilization) and 6 month follow-up visits. One luteal phase pregnancy was reported.

TABLE 10
 Filshie Clip versus Tubal Ring
 Via Laparoscopy

	Filshie Clip (N=150)		Tubal Ring (N=150)	
	No.	%	No.	%
A. Events at Surgery				
<u>Technical Failures</u>				
Change in approach	2	1.3	0	-
Change in technique	0	-	2	1.3
Two techniques used	0	-	3	2.0
Total	2	1.3	5	3.3
<u>Surgical Difficulties</u>				
Entering the peritoneum	3	2.0	1	0.7
Visualizing/grasping the tubes	2	1.3	8	5.3
Occluding tubes	2	1.3	3	2.0
Other	2	1.3	0	-
<u>Surgical injuries/complications</u>				
Cervical laceration	5	3.3	3	2.0
Uterine perforation	1	0.7	1	0.7
Tubal bleeding	1	0.7	8	5.3
Bladder injury	1	0.7	0	-
Other injury	0	-	1	0.7
Soft tissue emphysema	5	3.3	2	1.3
Blood loss > 100 ml	0	-	1	0.7
Total women with 1+ injuries/complications	12	8.0	14	9.3
B. Events Reported at Early Follow-up				
Women reporting for early follow-up*	102	68.9	111	76.5
Readmissions	1	1.0	1	0.9
Total women with 1+ complications at early follow-up	14	13.7	10	9.0

TABLE 10 (continued)
 Filshie Clip versus Tubal Ring
 Via Laparoscopy

	Filshie Clip (N=150)		Tubal Ring (N=150)	
	No.	%	No.	%
C. Events Reported at Long Term Follow-up				
Women reporting for 6 month follow-up*	110	74.3	107	73.8
Readmissions	1	0.9	2	1.8
Pregnancies	1	0.9	0	-
Total women with 1+ complications at long-term follow-up	12	10.9	6	5.6

* excludes technical failures

Three centers in Latin America have been equipped to undertake the comparative study of the Filshie Clip and Tubal Ring via minilaparotomy. One center in Africa will begin admissions in May. Of the 340 procedures performed this far, (Table 11) eight have resulted in technical failures. These failures were evenly divided between the two techniques. Surgical difficulties occurred in 17.9% of the ring procedures and 9.3% of the clip procedures. Surgical injuries and complications were reported for 25 (14.0%) of the ring procedures and for 19 (11.8%) of the clip procedures. Nearly 90% of women have reported for their early follow-up visit (<30 days post-sterilization). The percentage of women reporting one or more complications at the early follow-up visit was 15.9% in the ring group and 20.7% in the clip group. Six month follow-up exams have been completed for more than 60% of the patients; the rate of complications reported at this follow-up visit was 3.9% in the clip group and 9.3% in the ring group. One center has begun 12 month follow-up visits; 62 women have returned. No pregnancies have occurred.

TABLE 11
 Filshie Clip versus Tubal Ring Via Minilaparotomy

	Filshie Clip (N=161)		Tubal Ring (N=179)	
	No.	%	No.	%
A. Events at Surgery				
<u>Technical Failures</u>				
Change in approach	2	1.2	2	1.1
Two techniques used	2	1.2	2	1.1
Total	4	2.5	4	2.2
<u>Surgical Difficulties</u>				
With equipment	0	-	2	1.1
Visualizing and/or grasping tubes	12	7.5	20	11.2
Occluding tubes	1	0.6	5	2.8
Entering peritoneum	0	-	2	1.1
Closing incision	0	-	1	0.6
Spasm	0	-	1	0.6
Varicosities, ovarian cyst	2	1.2	2	1.1
Total	15	9.3	32	17.9
<u>Surgical Injuries/Complications</u>				
Tubal injury without bleeding	7	4.3	7	3.9
Tubal injury with bleeding	4	2.5	10	5.6
Uterine perforation	4	2.5	1	0.6
Cervical laceration	0	-	3	1.7
Spasm of larynx	0	-	2	1.1
Blood loss > 100 ml	1	0.6	0	-
Vasovagal reaction	1	0.6	0	-
Other injury/complication	3	1.9	3	1.7
Total women with surgical injuries/complications	19	11.8	25	14.0
Total women reporting major complications during recovery	3	1.9	4	2.3

TABLE 11 (continued)
 Filshie Clip versus Tubal Ring Via Minilaparotomy

	Filshie Clip (N=161)		Tubal Ring (N=179)	
	No.	%	No.	%
B. Events Reported at Early Follow-up				
Women returning for early follow-up*	144	89.4	161	89.9
Readmission to the hospital	1	0.7	2	1.3
Total women reporting 1+ complication at early follow-up visit	29	20.7	25	15.9
C. Events Reported at Long Term Follow-up				
Women returning for 6 month follow-up*	101	62.7	119	66.5
Women returning for 12 month follow-up*	23	14.3	39	21.8
Total women reporting 1+ complication at long term follow-up**	4	3.9	11	9.3
Hospitalizations reported at long term follow-up**	0	-	1	0.8

* excludes technical failures

**includes 6- and 12-month follow-up visits

A comparison of the Filshie Clip with the modified Pomeroy method via minilaparotomy in postpartum women is underway in four centers in Thailand, the Philippines, Taiwan and Panama. A total of 866 procedures have been performed to date. Table 12 details the technical failures, surgical difficulties and surgical injuries and complications that occurred. One case of bleeding, one case of complete dehiscence and a case of postpartum anemia occurred during the recovery period in Filshie Clip patients. A Pomeroy patient had a urinary tract infection during recovery. Early follow-up (<30 days post-sterilization) is now complete for more than 80% of the women.

Approximately 60% of the women in each group have also returned for their six-month follow-up visit. During the early follow-up period, complications were reported for a total of 51 (13.8%) Filshie Clip patients and 54 (15.0%) Pomeroy patients. Only two of the complications required hospitalization for overnight observation. During the six-month follow-up interval seven women, six in the Pomeroy group and one in the Filshie Clip group, were re-admitted to the hospital. Only one of these readmissions, a hernia operation at the incision site (Pomeroy group), was considered by the investigator to be a complication related to the sterilization.

More than half of the women in both groups have returned for their one year follow-up visit. Although almost 20% of them have reported complications at this visit, most of these are reports of keloids at one center. Two year follow-up visits are just beginning at two centers.

TABLE 12

Filshie Clip and Modified Pomeroy

	Filshie Clip (N=426)		Modified Pomeroy (N=440)	
	No.	%	No.	%
A. Events at Surgery				
<u>Technical Failures</u>				
Change in approach due to adhesions	0	-	1	0.2
Two techniques used due to:				
Obesity	0	-	1	0.2
Tumors	1	0.2	0	-
Difficulty in application	1	0.2	0	-
Only one tube	0	-	1	0.2
Total	2	0.5	3	0.7
<u>Surgical Difficulties</u>				
Entering peritoneum	2	0.5	0	-
Visualizing tube	7	1.6	13	3.0
Grasping tubes	9	2.1	12	2.7
Occluding tubes	2	0.5	0	-
Uterine involution	0	-	2	0.5
Obesity	1	0.2	0	-
Mesosalpinx varicose	0	-	1	0.2
PID complicated by incision	1	0.2	0	-
Total	22	5.2	28	6.4
<u>Surgical injuries/complications</u>				
Tubal/mesosalpinx injury without bleeding	1	0.2	1	0.2
Tubal/mesosalpinx injury with bleeding	5	1.2	5	1.1
Soft tissue emphysema	0	-	1	0.2
Total	6	1.4	7	1.6

TABLE 12 (continued)
 Filshie Clip and Modified Pomeroy

	Filshie Clip (N=426)		Modified Pomeroy (N=440)	
	No.	%	No.	%
B. Events Reported at Early Follow-up				
Women returning for early follow-up*	372	87.3	363	82.5
Readmission to the hospital at early follow-up	1	0.3	1	0.3
<u>Incision Complications</u>				
Serous discharge	26	7.0	22	6.1
Inflammation	14	3.8	16	4.4
Abscess	5	1.4	6	1.7
Bleeding	1	0.3	1	0.3
Incomplete dehiscence	3	0.8	8	2.8
Other	1	0.3	0	-
Total women with 1+ complications*	51	13.8	54	15.0
C. Events Reported at Long Term Follow-up				
Women returning for 6-month follow-up visit*	257	60.3	279	63.4
Women returning for 12-month follow-up visit*	238	55.9	253	57.5
Total women with 1+ complications at long term follow-up**	59	19.7	65	20.2
Re-admission to the hospital at long term follow-up**	1	0.4	6	2.2

*excludes technical failures

**includes 6- and 12-month follow up

A comparative evaluation of the Filshie Clip and the Secuclip via minilaparotomy in interval women has been completed at three centers in Latin America. A total of 184 procedures were performed. There were three technical failures, all in the Filshie Clip group. In two cases, obesity necessitated a change in approach; one case of adhesions was encountered at the time of the procedure. Surgical difficulty rates were 7.0% and 8.3% for the Filshie Clip and Secuclip, respectively. Rates of surgical injuries/complications were 6.0% for the Filshie Clip groups and 2.4% for the Secuclip group. Few major complications occurred during the recovery period; nine (0.3%) Filshie Clip patients and six (7.1%) Secuclip patients developed problems at that time. Most of these complications were related to the surgical incision.

Early follow-up visits were completed for 80 (80.0%) of the women in the Filshie Clip group and 69 (82.1%) of the women in the Secuclip group. Complications were noted for 20 (25.0%) of the Filshie Clip patients and 14 (20.3%) of the Secuclip patients at the early follow-up visit. The majority of these complications were incision related. There was one readmission of a patient for hematoma drainage. There was also surgical management, resuturing of the wound, for two Filshie Clip patients and another case of draining a hematoma in a Secuclip patient.

Six month follow-up data were collected for 78 (92.9%) of the Secuclip group and 90 (90.0%) of the Filshie Clip group. Three pregnancies were reported among Secuclip patients and two luteal

phase pregnancies, one in each group. At long term follow-up visits 13 Secuclip patients (16.3%) and 14 Filshie Clip patients (15.2%) reported complications. Most of these were tender or enlarged adnexa. One Filshie Clip patient required surgical intervention to drain an abscess. More than half (55%) of the Filshie Clip patients and 70.2% of the Secuclip patients have returned for one year follow-up visits.

One investigator in Brazil is undertaking a comparison of the minilaparotomy and laparoscopic techniques using the Filshie Clip. Minilaparotomies were performed on 96 interval patients and 94 interval patients had laparoscopic sterilizations. There was one technical failure in the minilaparotomy group in which a salpingectomy was performed on one tube. There were no surgical difficulties reported with the laparoscopic approach. Three cases of difficulty entering the peritoneum and one case of difficulty occluding the tubes were reported with the minilaparotomy technique. There were two cases of surgical injuries in the minilap group, one case of tubal injury without bleeding and one case of a severed anomalous vein. The rate of injuries/complications was 2.1% for the minilap group, 0% for the laparoscopic group. There was one case (1.1%) of vaginal bleeding prior to discharge in the minilap group.

All minilap patients and 98.9% of the laparoscopic patients have returned for early follow-up visits. Uterine infections were reported for two minilap patients (2.2%).

Six month follow-up visits have been completed for all patients. No pregnancies, rehospitalizations or subsequent surgeries have been reported. However, a surprisingly high rate of uterine infections, 53.2% in the minilap group and 30.9% in the laparoscopic group, were reported. A monitoring visit has been scheduled to verify the accuracy of this diagnosis and some inconsistencies in the center's data.

A noncomparative trial of the Filshie clip applied via laparoscopy is underway in one Canadian center and four centers in England. Two additional centers in Canada and one each in Scotland and England are expected to start in early summer. One Canadian center has withdrawn from the study because of difficulty in obtaining approved consent forms from study participants. The consent forms are those approved by the FHI Protection of Human Subjects Committee. Sterilization procedures have been completed on 58 interval patients. Surgical difficulties have included: two cases of difficulty with the equipment, three cases of difficulty entering the peritoneum and four cases of difficulty occluding the tubes. The rate of surgical injuries/complications is 6.9%. There were two cases of tubal or mesosalpingeal bleeding, one case of a ruptured ovarian cyst and one case of vasovagal reaction. There were no reports of major complications from sterilization to discharge. At the early follow-up visit 11.6% of the 43 women returning reported one or more complications. There were two cases of bleeding at the incision and three cases of vaginal bleeding. Endometrial aspiration was performed for one of these cases.

FHI has also been assessing the long-term effect of surgical female sterilization at two sites, one in Thailand and one in Bangladesh. In Thailand, 453 women have returned for a long-term follow-up visit five years post-sterilization. These women were sterilized as part of three previous clinical trials, one noncomparative study of the Hulka Clip, one comparative trial of the Hulka clip vs. electrocoagulation and another comparative study of the tubal ring and electrocoagulation. A total of 13 (3.3%) post-sterilization pelvic surgeries have been reported. Six of these surgeries were performed on women sterilized with the Hulka Clip, including three hysterectomies, one diagnostic laparoscopy and one colpoperineorrhaphy and one salpingectomy oophorectomy. Six surgeries were reported for women sterilized by electrocoagulation. These surgeries included two hysterectomies, two cases of dilatation and curettage, one case of severe dysplasia resulting in a hysterectomy, and one unspecified procedure. One ring patient also had a hysterectomy. One ectopic pregnancy was reported in the electrocoagulation group; a right tubectomy was performed. Most women (99.7%) have indicated satisfaction with their decision concerning sterilization.

Long term follow-up data is also being collected at an additional site in Bangladesh where a comparative evaluation of the Tubal Ring and the Pomeroy method was done in 1978. To date 60 women have returned for a long-term follow-up visit. No pregnancies, surgeries or complications have been reported.

The first phase of data collection for the Thailand nurse-midwife study has been completed. Between June and December 1985 data on more than 5000 sterilization procedures by nurse-midwives and physicians was collected. A sample of 900 cases has been selected for follow-up with the attitudinal questionnaire developed by Program Evaluation. The first 4000 sterilization cases are being followed up at 1 to 3 months and 12 months post-sterilization. Data will be analyzed by the TFRA in Bangkok.

A pilot study of the Femtest device for determining tubal patency is underway in Chile. If initial results are encouraging, the study will be expanded to one additional site. To date results using the Femtest device have been compared with results from a hysterosalpingography in 69 women undergoing testing before sterilization and in 29 (42%) of them after sterilization. There was agreement in 97.1% of the cases before sterilization and in 100% of the cases after sterilization.

FHI is collaborating with PARFR to evaluate the Intratubal Device, a nylon plug inserted at the tubal ostia that may be removed to restore fecundity. All scheduled 100 procedures have been performed. There were five technical difficulties; three required that the procedure be discontinued, whereas in two cases only one tube was plugged. Insertion difficulties, due primarily to difficulty finding the tubal ostia, were reported for 16 procedures. The rate of injuries or complications at insertion was 6.0%. The injuries included two cases of tubal bleeding; other major complications included three cases of

vasovagal reaction and one case of blood loss greater than 100 ml. No major complications were reported from sterilization to discharge.

Thirty-two women returned for early follow-up examination. Infection prompted an exploratory laparoscopy in one case and the device was removed. Two cases of vaginal bleeding were reported. One device had been displaced in two cases. More than 60% of the women returned for the 6 month follow-up visit. In three cases the devices were removed; in one case both devices were displaced and in nine cases one device was displaced. One pregnancy was reported at this time. One case of infection and five cases of tender or enlarged adnexa were reported. An exploratory laparoscopy was performed for one of these cases; the device had expelled. Only 24% of the women returned for their 12 month follow-up visit. In five cases, one device had been displaced. This study has been closed and a final report is being prepared.

2. Male Sterilization

Improvements in vasectomy techniques have been rare. However, the possibility of occluding the vas without a surgical incision in the scrotum is a potentially significant step forward.

Admissions are complete for a comparative study of percutaneous occlusion of the vas by diathermy and the standard incision with diathermy. The study is taking place at one center in England. A total of 51 percutaneous procedures and 50 standard incision procedures were performed. The percutaneous cases also had an

incision to verify occlusion. One surgical difficulty was reported in which there was a problem with verification of the occlusion site in the first percutaneous procedure. A case of excessive bleeding was reported in the incision group. Early follow-up evaluations (within 15 days) have been completed for 96% of the patients. The most common complaint at the early follow-up contact was serous discharge reported for 6.3% of the incision group and 24.5% of the percutaneous group. Hematomas were reported for 18.4% of the percutaneous patients and 10.4% of the incision patients. Six percutaneous patients (12.2%) complained that the wound was not healing. Incision infection was reported in three (6.3%) incision patients and four (8.2%) of the percutaneous patients. Almost all (98%) of the percutaneous group have completed three or more long term (>15 days poststerilization) follow-up contacts; 42% of the incision group have completed two or more follow-up contacts. Complaints at long term follow-up have included three cases of pain or tenderness in the incision group and two cases in the percutaneous group, one case of granuloma, one case of discharge and one case of adhesions in the percutaneous group and one case of infection and one case of swelling in the incision group. There has been one case in each group that has been declared a sterilization failure.

Future Plans

A new strategy to compare the Filshie Clip and bipolar electrocoagulation has been approved. These studies will be conducted primarily at centers in Europe and Canada.

Other plans include:

- A comparison of open versus closed laparoscopy.
- A retrospective evaluation of Filshie Clip procedures done over 5 years in Malaysia.
- Comparative trials of incision and ligation vs puncture and ligation techniques.
- Comparative trials of chemical male sterilization via a puncture vs incision and ligation technique.

D. Nonsurgical Female Sterilization

FHI continues to work on the development of a rapid, effective and safe nonsurgical method that can be performed by paramedical personnel.

1. Quinacrine Hydrochloride

Long-term follow-up of 151 women who have been sterilized by three transcervical administrations of quinacrine hydrochloride pellets has been completed in Chile. The 60-month cumulative life table pregnancy rate is 4.8 per 100 women.

A Phase I study conducted under an IND to determine the effect of intrauterine insertion of 250 mg of 10-minute releasing quinacrine hydrochloride pellets in 10 women one month before hysterectomy has been initiated at the University of Texas Health Sciences Center in San Antonio. This study includes histological evaluation of uterine

and fallopian tube tissue in addition to a determination of quinacrine pharmacokinetics.

An independent study conducted by Dr. J. Zipper has provided preliminary evidence that 100-minute releasing quinacrine pellets may be as effective as the 10-minute releasing product when given with only one or two insertions rather than with three. Two insertions in 107 women have resulted in a 12-month pregnancy rate of 2.0 per 100 women. Two-thirds of the women have completed 12 month follow-up. A Phase I 30-day pre hysterectomy study of this slower releasing formulation is being conducted at the University of Southern California.

2. Tetracycline Hydrochloride

The Phase I Study of the transcervical insertion of 1 gram of tetracycline hydrochloride pellets 24 hours before hysterectomy has been initiated at the University of North Carolina in Chapel Hill. The study will evaluate tetracycline pharmacokinetics and include histological examinations of uterine and fallopian tube tissues.

A Phase I study comparing the sclerosing activity of quinacrine and tetracycline when pellets are placed directly into the Fallopian tubes one month before hysterectomy is being conducted in Mexico with the aim of providing an objective comparison of the effect of the two chemicals. All of the 15 planned cases will be completed by May 1986. The Hospital General de Seguridad Social y Asistencia, where

the hysterectomies are performed, was completely destroyed in the earthquake in August 1985. Records for four patients were lost.

FHI has continued interest in identifying new uterine sclerosing agents that might provide better efficacy and improved safety. Preclinical studies are being conducted on quinacrine hydrochloride, tetracycline hydrochloride, lysine and glutamic acid hydrochloride. LD50 and Ames test data will be obtained for each of the compounds. Breeding tests in rats and histological evaluation of exposed tissues are being carried out in Aberdeen, Scotland and Dayton, Ohio, USA. The animal work is complete and reports are expected by May 1986.

Future plans

During the next quarter, a study will be designed to determine the capability of adjunctive therapies to prevent fallopian tube spasm upon intrauterine quinacrine insertion in the interest of improving the sclerosing activity of quinacrine. In addition, upon successful completion of the 30-day pre hysterectomy studies of quinacrine hydrochloride, FHI will meet with the FDA to discuss initiation of a small scale Phase II study to evaluate the safety and efficacy of the method.

Evaluations of the safety and sclerosing effect of tetracycline pellets (1000 mg) on uterine and fallopian tube tissue when administered 30 days before a scheduled hysterectomy will be initiated after the 24-hour pre hysterectomy study is underway.

While attempting to devise a method with the highest possible effectiveness, FHI also intends to develop a strategy to explore the service potential. Acceptability and safety of current chemical sterilization methods can be combined with post procedure testing for tubal patency. Treated women will be divided into those who may rely on the method, and those (with evidence of tubal patency) who will need referral for an alternative family planning method.

E. Intrauterine Devices

FHI continues to conduct studies to evaluate the acceptability of newly approved IUDs in various geographical locations and to explore possible ways of decreasing side effects associated with IUD use.

1. Long Term Evaluation of the TCU380Ag

Twelve-month follow-up has been completed for studies comparing the TCU380Ag with either the Multiload Cu375 or Copper 7 IUD. Continuation rates at 12 months were comparable for the TCU380Ag and each of the comparison devices. Because the TCU380Ag was developed as a long term device, investigators in Panama, Yugoslavia and the Philippines are collecting three year follow-up data on women enrolled in this evaluation. Among the centers participating in this long term follow-up, the TCU380Ag and Multiload Cu375 or Cu7 are comparable in terms of efficacy and complications and complaints according to data received thus far. All follow-up data will be collected by the end of this fiscal year.

2. Copper T IUD With and Without Strings

A clinical trial comparing TCU200 IUDs with and without marker strings to determine the possible role of strings in the etiology of pelvic inflammatory disease (PID) has progressed well during the past year. Preliminary analyses of 934 women from four centers, with an overall 12 month follow-up rate of 67%, reveal no difference between the two groups with respect to the incidence of infection and inflammation. There is, however, a significant difference between the two groups in the removal rates for bleeding and pain. The 12 month removal rate is 6.1 for the strings group and 1.6 for the without string group ($p < 0.01$). Because the number of women in each group reporting bleeding/pain complaints are comparable, this difference may be due to the relative ease of removing an IUD with attached strings compared to removing an IUD without strings.

An additional center in the Dominican Republic began admitting women into this trial in December 1986. Expected completion date for all the studies under this strategy is December 1988.

3. Evaluation of the TCU380A

A multi-center trial of the TCU380A IUD has been designed to assess acceptability of the FDA-approved device by comparing it to locally used IUDs throughout the world.

The most common comparison under this strategy is between the TCU380A and the TCU200 or TCU220. Data have been received from Egypt, Brazil

and Mexico. Studies comparing these devices have also been recently initiated or will be initiated in the next six months in Chile, Costa Rica, El Salvador, Honduras, Pakistan, the Philippines and the Sudan. The EFCS is also coordinating a multicenter trial in Egypt and will analyze the data with their computer facilities.

A study designed to compare the TCu380A with the LLD has begun in Peru, and additional studies are planned in Cameroon and Nigeria. One study has begun in Venezuela in which the TCu380A is being compared to the Nova T. Sufficient data have not been received to report any results from these studies at this time.

A large 1400 case multicenter study comparing the TCu380A with the Multiload Cu250 is being conducted in Thailand. To date, 991 cases have been admitted. With a 60% follow-up rate at 1 month and a 30% follow-up rate at 3 months, no differences between the devices are evident at this time. Two studies in Sri Lanka also comparing these two devices were initiated in February 1986.

A 3000 case multicenter study comparing the TCu380A with the MLCu375 and the LLD is being conducted by the BKS PENFIN in Indonesia. As with the EFCS study, the data will be analyzed in-country with the BKS PENFIN computer facilities. For both the BKS PENFIN and EFCS studies, data on printouts and disks will be made available to FHI periodically.

All studies under this strategy are expected to be initiated during this fiscal year. All admissions should be complete by October 1987; all follow-ups should be complete by October 1988.

4. Adapted T versus TCU200

The technique of trimming the horizontal arms of the TCU200 to fit the width of a woman's uterus is being evaluated in a study comparing the trimmed or adapted T to an untrimmed or standard TCU200.

Measurements of the fundal width are determined by the use of the Cavimeter II, an instrument designed for this purpose.

A small pilot study was initiated in Thailand in May 1985. A total of 82 women have been enrolled to date. With a one-month follow-up rate of 60%, no difference between the devices is apparent at this time.

Future Plans

Under the supervision of the Clinical Trials Division, a site in Nigeria will be added to the trial comparing groups of women who have IUDs inserted with or without the administration of a single dose of the prophylactic antibiotic doxycycline. This trial was originally conducted under the supervision of the Reproductive Epidemiology Division at one site in Kenya. Results from the initial study indicated that the infection rate was lower than expected when the sample size was originally determined; the site in Nigeria will be

included in order to provide an adequate sample size to detect a significant difference between the two groups.

The IUD String Retriever (formerly named the Brush Retriever), a device developed at FHI to retrieve IUD strings that have retracted into the uterine cavity, will be evaluated initially at one or two sites in the US or Europe in a small pilot study, pending approval of an application for Investigational Device Exemption (IDE) by the FDA.

IUDs placed in the uterus through the incision immediately following cesarean section continue to be a topic of interest to many FHI investigators. A study to evaluate the safety and expulsion rates of post-C-section IUD insertions is now scheduled to begin this spring in Mexico.

A proposal is also being developed for a retrospective study to determine whether there is a relationship between side effects experienced by women wearing IUDs and subsequent fertility. Three groups of women will be studied, including those who have their IUDs removed for (1) pain and bleeding, (2) other medical reasons and (3) planned pregnancy. Contraception rates calculated by the lifetable method will be compared for these three groups, controlling for possibly relevant factors such as age, parity, type of IUD, duration of use and number of sexual partners. Sites in Taiwan, Korea and Yugoslavia are being considered for this study.

FHI's interest in conducting clinical trials of the levonorgestrel-releasing IUDs in developing countries continues.

F. Investigator Network Needs

There have been ten studies conducted under FHI's Investigator Network Needs Strategy during the past six months; two of these studies are now complete. These studies encompass a variety of contraceptive methods and according to the objectives of the strategy, all of these studies address special research interests of the investigators. They are reported here by study area.

1. IUD Studies

Two non-randomized studies were conducted that compare the TCu200 and the LLD IUDs. In the study in Egypt, now complete, the 12 month follow-up is 60%. The TCu200 appears to be performing better than the LLD in terms of expulsion rates and rates of removal for bleeding and pain ($P < 0.05$). The other study is in Nigeria. One hundred forty-eight of a proposed 150 women have been enrolled and the follow-up rate at 6 months is 54%. No differences between the devices are yet apparent.

In Thailand a randomized study comparing the MLCu250 and the TCu200 inserted immediately postpartum (via forceps) is now in progress. All of the proposed 300 women have been admitted and the follow-up rate at six months is about 60%. The expulsion rate for both devices

is approximately 25%; high expulsion rates are not unusual in a postpartum study. The Multiload Cu250 is the copper IUD provided by Thailand's national family planning program. This study will provide the government with important information concerning its use during the immediate postpartum period.

Another study being conducted in Nigeria is a surveillance study of interval women using Lippes Loop IUDs. All 150 women have been admitted and the follow-up rate at six months is about 60%.

2. Sterilization Studies

In Kenya, 500 women were enrolled in a female sterilization surveillance study. The procedures used primarily in this study have been the Pomeroy technique via puerperal laparotomy (N=153) and via minilaparotomy (N=229), and tubal ring via laparoscopy (N=53). One technical failure occurred in the study; a change in approach was made because of obesity. One surgical injury was reported in the laparoscopy group (1.8%). Incision infections and complications have been the most common problem in each of the groups at the early follow-up visit; at the three month follow-up visit PID has been diagnosed for one woman in the minilaparotomy group. This study is now complete.

3. Systemics Studies

Data have been collected from two retrospective studies designed to evaluate the safety and acceptability of Depo-Provera (DMPA) supplied

by other agencies. One in Brazil compares two groups of women, both of whom have been using DMPA for at least a year before study entry, but at two different dosages and intervals: 25 mg once a month versus 150 mg once every three months. The data for 3 cases indicate that more women receiving 150 mg of DMPA every three months experience amenorrhea (60.4%) than do women receiving 25 mg of DMPA monthly (15.4%). The 12 month continuation rate is higher (though not significantly higher) at 72.9% for the 150 mg group than for the 25 mg group at 58.6%. No more cases will be included in this study. Follow-up is continuing slowly; the twelve month rates are 67.6 for the 150 mg group and 37.5 for the 25 mg group.

In the other Depo-Provera study, the Gambia Family Planning Association is conducting a retrospective study comparing women who have used DMPA with women who have used oral contraceptives. Retrospective admission forms were completed for two hundred women who began using each method prior to June 1981. With follow-up complete for only about 25% of the women, no differences in continuation or termination rates have been demonstrated. These women are now being followed up and data are awaited for final analysis.

Another systemic study is in progress in Mali, at the Maternal and Child Health Center associated with the Ministry of Health. This study compares Noriday and Lo-Femenal, two locally available oral contraceptives. One hundred forty-eight women have been admitted into this study. With about 50% follow-up at four months for these

women, there appear to be no differences between the pills in terms of reasons for discontinuation or side effects.

A study designed to compare two types of progestogen-only oral contraceptives, Micronovum and Ovrette, was recently begun in Zimbabwe. Fourteen hundred women will be admitted to this study; the type of pill received by each woman will be randomly assigned. There are not sufficient data to report at this time.

An additional systemic study was initiated in Malaysia in January 1986. This study was designed to compare the triphasic Triquilar with the low-dose combination pill, Marvelon. The investigator in this study was a participant in the 1985 Clinical Trials workshop in Singapore. No data for this study have been received.

Future Plans

FHI's policy continues to be to attempt, whenever possible, to meet local needs, as brought out by AID Missions and/or local investigators. In addition to answering locally defined questions, investigator needs studies also assist FHI in continuing to recruit proven investigators for new studies.

Initiation of several systemic studies to be conducted by Clinical Trials Workshop participants have been planned for the second half of 1986. Two investigators from the Philippines will compare two oral contraceptive preparations: Nordette (Wyeth) a low-dose combination pill currently available in the Philippines, and Trinordial (Wyeth),

a triphasic pill that the manufacturer will begin marketing in the Philippines this year. Another systemic study will be initiated in March 1986. Two oral contraceptive preparations currently manufactured and marketed in Nepal, Gulaf and Nilocon, will be compared in a randomized trial. Gulaf is a standard-dose preparation equivalent to Norinyl 1/50 and Nilocon is a low-dose preparation equivalent to Brevicon.

An additional surveillance systemics study has been proposed in Mali. Data will be collected on the use of two pills available there: Stediril and Minidril.

Two female sterilization studies are also planned. One in the Ivory Coast is designed to collect programmatic data for the AVS. In Nigeria, a surveillance study will be conducted by an investigator who has been identified as a potential Filshie clip investigator.

G. Other Studies

1. World Pill Survey

A 1985 ACOG-sponsored Gallup poll showed that 75% of American women thought there were substantial health risks associated with using oral contraceptives. To see if there are similar concerns about the safety of pill use in the developing world, FHI has conducted a survey of 100 urban, middle class women in each of eight countries.

Preliminary information from the surveys suggest that concern about the safety of the pill is as great as in the US. Cancer remains a prime concern and most women consider childbearing equally or less risky than OC use. These safety concerns may be hindering the acceptability of pill use in developing nations. The information from the survey can help family planning educators and counselors address specific concerns.

2. Egypt: Introduction of Long-Acting Steroids in Egypt

A major, interdepartmental project involving the introduction of long-acting steroids in Egypt has been implemented with the support an in-country FHI field office and staff member. The project is designed to evaluate the performance of NORPLANT® subdermal implants in a broad population and is being conducted jointly with the National Population Council of Egypt. The initial objectives of the project are: 1) to identify and follow-up the acceptors who participated in the original NORPLANT® field trials in Egypt, 2) to establish at least two in-country training centers (Assiut and Alexandria), and 3) to initiate a multi-center university-based 1200-case clinical trial of NORPLANT® capsules and rods.

IV. REPRODUCTIVE EPIDEMIOLOGY

The work of the Reproductive Epidemiology Division focuses on factors that affect reproductive health, with an emphasis on contraception. The division researches the long-term indications and consequences of contraceptive use, including sexually transmitted diseases and cardiovascular disease. A major emphasis over the past year has been integrating the benefits and risks of contraception in order to allow policy decisions that compare the use of contraceptives against its alternative, pregnancy.

A. Completed Projects

Breast and Cervical Cancer and DMPA in Costa Rica

Concern for reproductive cancers was the primary reason for the US Food and Drug Administration's (FDA) failure to approve DMPA for contraceptive use in the United States. Animal studies suggest that DMPA might increase the risk of breast cancer, but no human study has shown this. Animal studies also suggest increased risk for cervical cancer, and data from a WHO collaborative study show a slight increase in risk for women who used DMPA for more than four years. FHI, in collaboration with the Centers for Disease Control (CDC), the Costa Rican Demographic Association and the Social Security Administration of Costa Rica, has completed a case-control study of cervical and breast cancers and their relationship with contraceptive history. The study included 171 cases of breast cancer, 415 cases of cervical cancer and 149 cases of invasive cancer. The 770 controls were drawn

at random from the nation's population. Data are presently being analyzed. Preliminary results, presented at the Annual Meeting of the Association of Planned Parenthood Professionals in October 1985, reflect no increased risk of cervical cancer among DMPA users. In collaboration with the CDC, preparation of papers for submission to journals will take place during March-July of 1986.

Reproductive Age Mortality Survey (RAMOS)

The RAMOS studies conducted in Egypt and Indonesia were designed to provide information on the causes of death to women of reproductive age, in particular, to determine the proportion of deaths that are due to pregnancy, childbirth, abortion and contraception.

Maternal mortality was the leading cause of death to women of reproductive age in Bali, and the second cause in Menoufia (after deaths from diseases of the circulatory system). Among the maternal deaths, hemorrhage accounted for one third in Menoufia and almost one half in Bali. It is estimated that about two thirds of maternal deaths could be prevented if women over 30 and who had three or more children chose to have no more children and understood that the risks of uncontrolled childbearing greatly outweigh any risk attributable to contraceptive use. These data were presented at the WHO in November 1985. In a recent review of maternal mortality by the WHO, drawing in all available research data bases, the RAMOS studies provided the largest series available for study and helped to formulate international policymaking in the area of maternal mortality.

In both countries, reproductive mortality was dominated by maternal mortality which accounted for one quarter of all deaths to women of reproductive age. Maternal mortality accounted for 98% of all reproductive deaths. The rates were 1.9 per 1000 live births or 44.9 per 100,000 married women 15-49 in Menoufia, and 2.4 per 1000 live births or 67.2 per 100,000 married women 15-49 in Bali. They represent the first significant large scale efforts anywhere in the world to obtain data on causes of death to women in a traditional society, and their findings have policy implications for family planning and for public health in general. These data were published by the American Journal of Public Health (with an accompanying editorial) in February 1986.

Balancing the Risks and Benefits of Contraception

A great deal of information is now available from many sources on immediate and long-term benefits and risks of oral contraceptive use. FHI has developed a method to display various aspects of this accumulation of data in a readily understood way using estimates of expectation of life for users and non-users.

For women under 30 who use oral contraceptives, there is a very slight **increase** in life expectancy as compared with nonusers; for women over 30, there is a small decrease in life expectancy. In both cases the changes are small (+12 days and -88 days respectively in developed countries) and trivial besides such things as smoking (-4 years or more). However, the demonstration that the protection offered against

malignancy later in life more than outweighs the risks of cardiovascular disease among women under age 30 is most important, as most users in the United States are under 30 years old. A paper describing this analysis will appear in the May 1986 issue of Studies in Family Planning.

Fertility and its control continue to be increasingly safe in the United States. Between 1975 and 1982, the number of deaths attributable to pregnancy and childbirth, abortion, and contraception declined from 1083 to 732. The mortality rates for each of these components also decreased, by 38%, 89% and 35%, respectively, and the overall reproductive mortality rate dropped by 38%. A paper documenting these changes has been submitted to the Journal of the American Medical Association.

Although in the total population more women now die from fertility control (contraceptives and induced abortion) than from pregnancy and childbirth-related complications, the risk of death during a specific pregnancy and delivery is twenty-four times greater than that due to induced abortion and seven times more than contraceptive mortality. The more numerous contraceptive deaths reflect the far greater number of women who use contraceptives than those who become pregnant: nearly thirty million women used contraceptives, while slightly fewer than four million women were pregnant to term.

The decrease in the contraceptive-related mortality rate between 1975 and 1982 probably reflects a combination of safer contraceptives, notably oral contraceptives, fewer women using contraceptive methods

that may not be the safest for them, and an increasing number of sterilizations, which remove women from the group of those at highest risk of contraceptive-related mortality. Maternal mortality appears to be slowing its rate of decline, while abortion mortality is very low due to the absence of illegal procedures. A paper describing this analysis has been submitted for publication.

Work was also begun to assess the reproductive mortality rate around the world as a means of summarizing the mortality risk of fertility and its control. A first draft of the international perspective was presented as part of a Harvard School of Public Health Continuing Medical Education course on current perspectives in obstetrics.

Prostatic Cancer and Benign Prostatic Hyperplasia

In collaboration with Kaiser Permanente of California, FHI has examined the relationship between vasectomy and prostatic cancer and benign prostatic hyperplasia. Data collection began in July 1984 and was completed in March 1985. One animal study suggested that vasectomy may increase the risk of renal carcinoma, while several large follow-up studies indicate no effect on this or other cancers. However, long-term follow-up on prostatic effects is presently lacking.

Ninety cases of prostatic hypertrophy and 17 cases of cancer were identified through a computer search. This study compared medical

records of cases and controls and calculated incidence rates for men with and without vasectomy. Nonsignificant relative risks of 1.2 for prostatic cancer and 1.2 for benign prostatic hyperplasia were found. These data are currently being reviewed and organized for publication.

Contraindications to Contraceptive Methods

Few developing countries have reliable mortality and morbidity data or information on the prevalence of conditions that contraindicate use of specific contraceptive methods (especially oral contraceptives). Availability of this information is important for public health officials in making choices about contraceptive methods for country programs. In collaboration with the National Family Planning Coordinating Board of Indonesia (BKKBN), and Yayasan Kusuma Buana (YKB), FHI collected information on hospital discharge diagnoses for women of reproductive age. All teaching hospitals in Java participated. By providing data on morbidity for women in this age group, the study supplemented the RAMOS study in Indonesia (which collected data on mortality only).

Thirty-eight percent of all hospitalizations were for complications of pregnancy. The proportions of hospitalizations for cancer, respiratory and digestive diseases were also similar to the proportions dying of these disease groups in the RAMOS study; but the proportion hospitalized for infectious and parasitic diseases, and circulatory diseases was less, and the proportion hospitalized for genito-urinary conditions and "other & unknown" conditions was more.

The low prevalence of circulatory disease in Java is reassuring in the light of nonmedical distribution of oral contraceptives in Indonesia. Only three oral contraceptive users were hospitalized for a circulatory disease, but the specific condition is not known.

Surgical Contraception by Nonphysicians

To determine whether trained paramedics can perform vasectomies with safety and efficacy rates comparable to those of physicians, FHI evaluated 1500 procedures done by paramedics in a program in Indonesia. Men were visited in their homes and asked about complications experienced with the procedure. Because of recall difficulties, minor complications may have been under-reported. Data collection is complete, but analysis is delayed because of the temporary absence of one of the researchers.

Contraceptive Use and the Prevalence of Sexually Transmitted Diseases (STDs)

A cross-sectional study of the relationship between contraceptive use and the prevalence of STDs was conducted at the Margaret Sanger Center, Planned Parenthood of New York City. The study indicates that users of barrier methods and spermicides have a risk of gonorrhea 0.8 times and of chlamydia 0.6 times those of oral contraceptives users. These data are being prepared for publication.

B. Continuing Projects

Cervical Cancer and Hormonal Contraception in Jamaica

FHI is collaborating with the Jamaica Cancer Society and the University of the West Indies in a case control study of cervical cancer and hormonal contraception in Jamaica. Several factors make Jamaica an excellent site for examining this relationship:

(1) Jamaica has one of the world's highest incidence rates of cervical cancer; (2) it has a tumor registry that is relatively complete for the Kingston Corporate Area; and (3) more than half (55%) of women in union use contraception, and approximately 15% of women have used DMPA.

Study personnel were trained by staff from FHI and Survey Research Associates in October 1985. The first case was interviewed in November 1985. Interviewing is progressing slowly because of limitations on access to the Tumor Registry; to date, 24 cases and 3 controls have been interviewed. No physician has declined to participate, and the response from cases has been excellent.

Human Papillomavirus (HPV) and Cervical Cancer

Only a few of the more than 30 HPV types appear to be etiologic agents of cervical cancer. To establish a plausible relationship between HPV and cervical dysplasia, a prospective study is about to begin in

Panama and Brazil. HPV DNA typing will be done in the US. Newly available data suggest that women with cervical warts have a 10- to 20-fold increased risk of cervical dysplasia compared to women without cervical warts. A recent study implied a causal role for oral contraceptives in cervical cancer when it found long-term oral contraceptives use (>5 years) was associated with a 10-fold increased risk of having genital (not necessarily cervical) warts. The FHI study will be useful in Latin America where cervical cancer is the leading cause of death to women of reproductive age and where treatment for cervical warts is not always available.

Anovulation and Risk of Breast Cancer

Several investigators have examined the number of menstrual ovulatory cycles (MOCs) as a risk factor for breast cancer with conflicting results. Because of small sample sizes, these studies failed to separate clearly the effect of the number of MOCs from that of other risk factors. Yet, because of the significance of breast cancer in the overall pattern of female disease, it is essential to get a further insight into this important problem. FHI will use the CDC's Cancer and Steroid Hormones (CASH) case-control study to examine the association between breast cancer and MOCs. Almost 5000 cases of breast cancer in the CASH data permit simultaneous control of other risk factors. In addition, the effect of oral contraceptive use on the association between anovulation and breast cancer will be studied. Cases are women aged 20-54 with a new diagnosis of primary breast cancer. Analysis began in January 1986. Preliminary results indicate a significant trend of increasing risk associated with greater number

of ovulatory cycles after controlling for recognized risk factors for breast cancer.

Sickle Cell Disease

Many doctors consider oral contraception to be contraindicated in women with hemoglobinopathies including sickle cell disease. However, for women in many countries in the world where sickle cell disease is prevalent, childbirth is more than usually hazardous and few contraceptive alternatives are available. One study of DMPA showed that this form of contraception benefits women who are homozygous for sickle cell anemia by decreasing the frequency of sickling crises. Building on this study, FHI is conducting a study with the Medical Research Council of the University of the West Indies in Jamaica. Thirty patients will be followed through six months on oral contraceptives and six months on placebo, with a 3 month "washout" period between the two phases. To date, 15 patients have been admitted to the study and 7 have completed the first phase. Although these patients have not been free of illness, there has been no difference in either the number or the severity of complaints and complications experienced by patients taking oral contraceptives and those taking placebo tablets. Results from this study should be available by mid-1987.

Effects of in utero Steroid Exposure

Two studies are being conducted. In Thailand, approximately 1200 children have been identified who were exposed to DMPA and 200 who

were exposed to oral contraception while in utero, either because of unnoticed pregnancy at the time of the injection or because of contraceptive failure. These children are being examined to determine whether their developmental indices (including sexual maturation) differ from those of unexposed children. Interviewing began in June 1984 and is approximately three fourths complete. The study is being conducted in collaboration with the Johns Hopkins University.

A similar study, that looks at more subtle indices of development, is being conducted in Israel with children exposed to medroxyprogesterone acetate (MPA) used to treat threatened abortion. Handedness, degree of aggression, psychological factors and masculine-feminine orientation are being evaluated. The questionnaire was pretested in 1984, and data collection began in August 1985. Hebrew University in Jerusalem is the collaborating institution.

The Effect of Prophylactic Antibiotics on Post-IUD Insertion PID

The possibility of infertility following IUD use became increasingly apparent to lay and professional groups in 1985. FHI is conducting a randomized double-blind trial to study whether prophylactic antibiotics given at IUD insertion help prevent pelvic inflammatory disease (PID). The pilot study for this project was carried out in November 1984. Data from the 190 subjects in the pilot study are being analyzed. The main study began in December 1984. FHI and CDC are collaborating with Kenyatta National Hospital to conduct this study. Eighteen hundred women will be screened for gonorrhea and chlamydia before IUD insertion. They are then given a single dose of

200 mg doxycycline or placebo and the IUD inserted. Women are followed for one month to determine whether there is a lower rate of PID among women given the antibiotic than among those given the placebo. If the gonorrhea or chlamydia cultures are positive, women are treated at follow-up visits. Prevalence of gonorrhea and chlamydia infection at the time of IUD insertions can be useful in judging the background rate in asymptomatic women. By 1 March 1986, 1450 women had been followed, with a PID incidence rate of 1.2%. This rate is appreciably lower than the rate used by the government to justify their recommendation not to insert IUDs in young women with few children.

The Effect of Contraception on Sexually Transmitted Diseases (STDs)

Sexually transmitted diseases are a major cause of infertility in some parts of the world, especially parts of Africa. FHI has completed a pilot study of the prophylactic effect of the contraceptive sponge on transmission rates of gonorrhea, chlamydia, trichomonas and monilia. The study was a collaborative effort with the Venereal Disease Division of the Ministry of Public Health of Thailand. Two hundred and fifty-five women, half of whom received sponges, participated and accumulated 575 woman-weeks of observation. The sponge reduced the incidence of chlamydia by 40%, but did not affect the incidence of gonorrhea. However, these estimates form minimal estimates of risk reduction because of compliance problems among the user group. The pilot study led to many protocol revisions and improvements, and after changes were instituted, the final phase began in March 1986.

A conference of fifteen STD experts from Africa and the rest of the world will meet in The Gambia in April 1986, to establish priorities for African STD work. This workshop is expected to yield a useful list of options for FHI to pursue STD work in the future as well as to help other organizations with priorities.

Infectious Etiology of Ectopic Pregnancy

Prior infection of the fallopian tubes is an important risk factor for ectopic pregnancy. Salpingitis causes tubal scarring or dysfunction that may prevent fertilization or result in ectopic pregnancy due to abnormal transport of the fertilized ovum. Numerous types of bacteria can cause salpingitis; these include *Chlamydia trachomatis*, *Neisseria gonorrhoea*, genital mycoplasmas, and aerobic and anaerobic bacteria.

To investigate the relationship between chlamydia or other bacterial infection and ectopic pregnancy, investigators in Boston will perform a hospital-based case-control study. They will establish the prevalence of: 1) active infection of the fallopian tubes among ectopic pregnancy patients compared with matched patients undergoing post-cesarean section tubal ligation; 2) active infection of the endocervix among ectopic pregnancy patients compared with matched prenatal patients; and 3) serologic evidence of active (IgM) or previous (IgG) chlamydia infection among ectopic pregnancy patients compared with matched prenatal controls. Data collection began in February 1986.

Conference on Smoking and Reproductive Health

Cigarette smoking influences several aspects of reproductive health from the well-being of the fetus to the development of reproductive cancers. An FHI-sponsored international conference on the effects of smoking on reproductive health took place in San Francisco on 15-17 October 1985. The conference summarized the effects of smoking on reproductive health, with an emphasis on new findings, to review smoking cessation efforts during pregnancy and materials, and to review public health policy. Co-sponsors included the Agency for International Development, the World Health Organization, National Institute of Child Health and Human Development, Office on Smoking and Health, Centers for Disease Control and the University of California at San Francisco. A book based on the conference has been completed and is to be published in Fall 1986.

Effect of Smoking Among Breastfeeding Women on Infant Growth

Using data from a non-randomized clinical trial of progestin-only contraception among breastfeeding women, the impact of smoking on infant growth after birth was evaluated. Despite having a mean birth weight of 242 grams less than infants of nonsmokers, infants of heavy smokers showed no catch-up growth during the first four months of unsupplemented breastfeeding. Women who smoked only during breastfeeding (not during pregnancy) had infants with comparable growth to the growth of infants of non-smokers.

The Male Influence on Spontaneous Abortion

There is increasing evidence to suggest that male exposure to hazardous substances (usually in the workplace) can impair reproduction. A study was initiated in March 1985 that uses the Finnish hospital discharge registry and census data to examine the relationship between fetal loss and exposure to certain agents with recognized reproductive toxicity. The registry permits use of a sample of 73,000 exposed and 1.5 million unexposed men and has the ability to control for maternal history and exposure to substances associated with an increase in spontaneous abortion. The sample size permits reliable detection of as little as a 3% increase or decrease in the rates of fetal loss. The cohorts have been identified and linked, and analysis will be done in Spring 1986. Preliminary computer linkage has been completed and a Finnish collaborator will visit FHI to perform the analysis in Summer 1986.

Cohort Study of Oral Contraceptive Users

During this reporting period, FHI continued to collaborate with the Contraceptive Evaluation Branch of the National Institutes of Health in organizing a large cohort study in England to investigate the influences on health of low-dose oral contraceptives and other hormonal contraception (including the newly approved DMPA). This study is patterned on the first Royal College of General Practitioner's Oral Contraceptive study--a landmark prospective study that helped to establish much of our knowledge of the health effects of the pill. The new study, also from the RCGP, will include 100,000

women of reproductive age. FHI's contribution has consisted of technical and financial assistance with the pilot study and non-recurring initial costs, including computer support. The pilot study indicates that it is feasible to follow women as they move around the country and switch doctors; inclusion of these women will reduce the high loss to follow-up of the first study. Evaluation of computer hardware and software was completed in March 1986.

Cardiovascular Disease and Oral Contraception

It is a recognized fact that myocardial infarction and stroke are associated with oral contraceptive use; since those early reports, this association has been confirmed by three major cohort studies and a large number of case-control studies. However, almost all of the research involves women taking oral contraceptives with relatively high doses of both estrogen and progestin. Today's pill formulations contain much lower doses of both hormones, and while the risk of cardiovascular disease associated with these formulations is thought to be lower, this has yet to be demonstrated. FHI is collaborating with the Department of Community Medicine and General Practice, Radcliffe Infirmary of Oxford (UK) in a case-control study of young women with fatal myocardial infarction. This study began in early 1986. Information on contraceptive history and presence of other risk factors for myocardial infarction will be collected from surviving family members and the deceased's physician.

C. Planned Projects

The Effect of Condom Use on Mild Cervical Dysplasia

Richardson and Lyon found in a non-random, uncontrolled 1981 study that condoms were an effective means of treating cervical dysplasia: 98% of women with cervical dysplasia treated only with condoms for six months showed complete regression of the disease. No other study has been done to confirm these findings. In Durango, Mexico, 200 women with mild dysplasia will be allocated to a condom or control group and observed after three months for changes in the cervical dysplasia.

Clinical Trial to Manage the Side Effects of Oral Contraceptive Use

In Zacatecas, Mexico, an investigator has had success with managing certain side effects of oral contraceptives with Vitamin B6. The primary purpose of this study is to measure the severity and rates of side effects associated with initiation of oral contraceptive use between the two study groups: women taking 150 mgs of Vitamin B6 daily and those taking a placebo. The side effects of nausea, headache and irritability may be directly or indirectly ameliorated with therapeutic doses of Vitamin B6 as used to manage similar side effects of early pregnancy. A less specific measure of the regimen's success will be a comparison of continuation rates between the two groups at three months.

Oral Contraceptives and Osteoporosis

Estrogen therapy is known to retard osteoporosis in menopausal women. Although bone loss is accelerated after menopause, loss actually begins well before. FHI is developing a study with the Department of Radiology of North Carolina Memorial Hospital to determine whether the bone mineral density of premenopausal women in their 40s who have taken oral contraceptives is greater than that of women who have never used oral contraceptives. The bone mineral density of the lumbar spine will be measured by dual photon absorptiometry; information on other risk factors for osteoporosis and contraceptive history will be collected by interview. The mean bone density of never-users of oral contraceptives will be compared with that of current and former users.

Presence of Human Papilloma Virus in Cervical Tumors

In collaboration with the Virology Division of the CDC and the Department of Pathology of the University of the West Indies (Jamaica), FHI will examine tissue from the cervical tumors of cases in our case-control study (described above). The tissue samples will be prepared at UWI, and examined for the presence of the HPV at the CDC; DNA typing will also be done at the CDC. A pathologist from UWI will assist with the work at the CDC.

Maternal Mortality

FHI is developing similar studies of maternal mortality in Haiti and in Kenya. Both will start with the obstetric ward and expand to all hospital wards and then to the community. This diverse approach should permit estimation of maternal mortality ratios and the degree of under-reporting associated with a single method approach to measurement. Both of these studies will be undertaken with Mission funds. The Haiti study will be done in collaboration with Columbia University.

Oral Contraceptives and Hepatitis B

Hepatitis B is an important public health problem in many developing countries and may contribute to the high rates of liver cancer. Since oral contraceptives are metabolized in the liver, they may have an effect on the course of liver diseases. FHI has begun to develop studies to determine the possible role of oral contraceptives in the transmission and progression of Hepatitis B. An appropriate site is being sought.

Rheumatic Heart Disease and Contraceptive Use

Since estrogens can induce coagulation changes that are particularly dangerous to women with rheumatic heart disease, a low-dose, progestin-only contraceptive would seem the best means of contraception for these women. As NORPLANT® is introduced in Egypt, a

cohort of women with RHD will be recruited to use NORPLANT®. Physiologic parameters of coagulation changes, ventricular size and valvular competence will be monitored to help anticipate the occurrence of adverse events such as embolisms and cardiac failure. An appropriate site for this study is being investigated.

V. PROGRAM EVALUATION

In order to meet the evaluation needs of health/family planning programs in developing countries, the Program Evaluation Division supports research in three areas: family planning evaluation, maternal and child health/family planning, and natural family planning/breastfeeding. Some studies focus on the acceptability, use, and client satisfaction with family planning methods in non-clinical settings, including in the general population. Other studies evaluate the performance of delivery systems and the knowledge and attitudes of providers toward the methods they deliver.

A. Family Planning Evaluation

Although many of FHI's family planning evaluation studies are tailor made and one-of-a-kind, FHI has focused on several general areas: provider knowledge and attitude surveys; adolescent fertility surveys; studies on access to sterilization; evaluation of different family planning service delivery systems; and demographic projects. Methodologies range from in-depth interviews and focus groups to hospital-based studies and household surveys.

The evaluations are intended to provide information to improve the programs. The link between service providers and clients is especially crucial. Several studies assess the family planning knowledge and attitudes of providers (such as physicians) or commercial distributors. Other studies focus on accessibility of

services, acceptability of new methods, program impact, and family planning needs, attitudes, and knowledge of special segments of the population (adolescents, males).

New initiatives include studies of acceptability of new methods, particularly NORPLANT®; studies on compliance of pill use in the general population; and studies on the quality of family planning services.

1. Provider/Client Surveys

Throughout much of the developing world, oral contraceptives are generally acquired without first making a visit to a physician. Retailers and community-based distributors play an important role in determining what clients know about this and other methods. Such information may affect how users cope with problems and ultimately affect continuation rates and user satisfaction.

Honduras: Survey of CBD Distributors

In collaboration with the Family Planning Association of Honduras (ASHONPLAFA), a survey of distributors and promoters in the Honduras community-based distribution (CBD) program was carried out. Costs of data collection were paid for by the local AID Mission. A final report has been prepared. Results show that (1) a high percentage of distributors work in areas where contraceptives are not available from other sources, especially low-cost sources; and (2) training of distributors to recognize contraindications of the pill, to advise

women with side effects, and to know the appropriate way to use family planning methods needs to be strengthened. Two papers have been prepared using these data and have been submitted to journals. One has been accepted by the PAHO Bulletin and the second is under consideration.

Nepal: Contraceptive Retail Sales Study

The Nepal Contraceptive Retail Sales (CRS) Company is a private company that began assisting governmental family planning activities in 1978 by bringing temporary family planning methods to couples through existing retail outlets (including medical shops, general shops and pan shops). The CRS program offers pills, condoms and foaming contraceptive vaginal tablets at very low cost. In 1984, the CRS company distributed almost half (47%) of all condoms distributed in Nepal, and more than one-fifth (22%) of all oral contraceptives. One of the components of the program is to assist in educating and motivating individuals to select and correctly use the appropriate CRS product for family planning.

This study surveys a sample of retailers and consumers from a large number of urban medical shops which provide standard and low-dose oral contraceptives and contraceptive foaming vaginal tablets. Since the vast majority of medical shops selling pills and contraceptive vaginal tablets are in urban areas, the study is focusing on these areas. Knowledge, attitudes, correct and incorrect usage, and problems associated with specific CRS methods sold at medical shops

are being assessed for about 400 retailers and approximately 1200 consumers of CRS products.

Pretesting was completed in January 1986, fieldwork initiated in late February 1986 and as of the end of March, interviews were completed with 761 consumers and 297 retailers.

Mexico: Promoter's Knowledge of Contraceptives

In Juarez, Mexico a survey of community-based distributors including those involved in recruiting women, men and young adults is being designed. The first phase of the study, which used focus groups with providers, is underway. Insights gained will be incorporated into the design of the questionnaire to be used in the second phase.

One of the goals of this project is to determine whether or not promoters who have a thorough knowledge of the products they distribute are more successful at recruiting and maintaining clients than other promoters. Other factors such as follow-up visits to those who do not return for contraceptives and neighborhood meetings to recruit more users, may also affect the promoters' performance. This study will provide FEMAP with predictors of distributor performance and recommendations on how to improve training programs for promoters in order to raise contraceptive prevalence and improve continuation rates.

Nigeria: Survey of Physician Attitudes and Practices Regarding
Modern Methods of Contraception

Especially in Africa, where contraceptive use is low and the medical profession is conservative or ambivalent about allowing non-physicians to provide contraception, it is important to obtain information about physician attitudes toward providing family planning. In Nigeria there is no organized family planning program, and physicians are the major providers of contraceptive services. This study, conducted by the Fertility Research Unit of the Department of Ob/Gyn, University College Hospital, Ibadan, assessed the attitudes and practices of physicians regarding modern methods of contraception.

The investigators selected a sample of cities with university teaching hospitals and within each city, chose a teaching, general and private hospital. Nurses interviewed all Ob/Gyns and house officers on staff at each of the teaching hospitals, and all resident physicians in the general and private hospitals over the period October - December 1984.

While the physicians expressed favorable attitudes towards contraception, few were using contraceptives themselves to space births, and among those using contraceptives to limit childbearing few were using permanent methods, such as tubal ligation or vasectomy.

Most of the respondents recommended contraceptives to their patients (85%), but only half provided them. Ob/Gyns and general practitioners were the most likely to provide contraceptives (92% and 82%, respectively), and other specialists and interns, least likely (32% and 38%, respectively). The main methods provided were orals, IUDs and tubal ligations.

Physicians expressed concern over population growth, but many also believed that family planning is foreign to the culture and promotes promiscuity. More than 50% disapproved of non-physicians distributing IUDs, 68% orals and 76% injectables. If contraceptive use is to increase in Nigeria, physicians need to have a more positive attitude toward family planning, to be more assertive in promoting and providing methods, and to work with nurses and paramedical staff in distributing contraceptives outside the hospital setting.

The final report has been completed and a paper entitled "Physician Attitudes: An Aid or a Barrier in the Provision of Family Planning Services in Nigeria?" was presented at the American Public Health Association meeting in November 1985. A paper has been accepted by Studies in Family Planning and will be published in July 1986.

Brazil: Family Planning Advice of Physicians

Data from a contraceptive prevalence survey conducted in the State of Sao Paulo in 1978 showed that use of vasectomy was virtually nonexistent. Since that survey was conducted, a program to provide

vasectomy services was begun by Dr. Marcos de Castro. The number of vasectomies performed increased steadily from 612 procedures performed in the period February 1981 - February 1982, to 1423 in the period March 1982 - February 1983. While the prevalence of vasectomy has undoubtedly increased in metropolitan Sao Paulo, it is still low overall. In order to realize the potential for increased vasectomies, it is important to know what role physicians play in promoting this method.

The objectives of this study were to determine under what circumstances physicians would recommend vasectomy and tubal ligation to their patients or their partner; whether the recommendation by the physician of vasectomy or tubal ligation is dependent upon the health of the partners; how age, parity, and fertility intentions of the couple affect the physician's recommendation of vasectomy; and whether these physicians would be interested in sterilization for themselves or for their spouses.

Data collection was concluded in May 1984, and a preliminary report was written. Virtually all of the urologists performed vasectomies and 75% of the Ob/Gyns performed tubal ligations. Ob/Gyns and surgeons were most likely to report that they performed both procedures. Physicians' recommendation of sterilization increased with age and parity of patient. Within age-parity groups, physicians tend to recommend the procedure they know best and rarely refer the client's partner for sterilization.

A paper based on the study findings was presented at the annual meetings of the American Public Health Association (APHA) in November 1985. A paper will be prepared and submitted for publication.

Honduras: Survey of Oral Contraceptive Purchasers

Point-of-purchase surveys can be used to evaluate the impact of new programs to provide contraception. When a new source of supplies is added, it may gain customers who switch methods or sources or may attract new users. Also such surveys provide information on what purchasers of contraceptives know about contraception.

The Social Marketing Program of the Asociacion Hondurena de Planificacion Familiar (ASHONPLAFA) is carrying out a survey of purchasers of oral contraceptives at a sample of pharmacies where Perla, the program's standard dose pill, is sold.

The purposes of the survey are: a) to determine the knowledge of OCs (including how to take the pill, expected side effects and what to do if one or more pills are skipped) among purchasers of oral contraceptives including Perla; b) to determine whether the social marketing program is attracting low and middle income women to use oral contraceptives (for example, are the characteristics of Perla buyers different from those of women buying other brands of OCs?); c) to determine previous contraceptive use of buyers and source of previous method (i.e., is the program attracting non-users, users of other methods or users of other brands of pills?); d) to determine the reasons for the visit to the retail outlet at which orals are

purchased, purchasing patterns, travelling time and method of transportation to the outlet; and, e) to determine if buyers seek information about contraception from pharmacy staff and if they consider the pharmacist an important source of information.

Data collection was extended until May 15, 1986, when preliminary results showed that about half of the purchasers were not users. This necessitated increasing the sample size and the length of time for field work. A report will be completed in the second half of 1986.

2. Accessibility, Acceptability, and Effectiveness of Selected Methods

Sterilization is one of the two most prevalent methods in most developing countries. However, even in countries in which it is a common method, there may be barriers to its use. In Africa, where the prevalence of sterilization is low, programs to provide information and counselling may be necessary for women to overcome their fears and adopt this method. Finally, information on long term satisfaction provides a good measure of project success.

Honduras: Access to Sterilization

This is a continuing study of women's interest in and barriers to sterilization in Honduras. The first phase of the study was carried out at two hospitals in Honduras in 1980-1981. Results showed that fewer than half the post-partum women who expressed a desire for

voluntary sterilization, (42% in Tegucigalpa and 21% in San Pedro Sula) actually obtained the operation at or within four months of delivery. A follow-up study included all women who had not had a tubal ligation, but who said at the time of the first study that they were still interested in being sterilized. Of these women, more women had become pregnant (more than 40%) in each group than had been able to overcome barriers to sterilization and been able to obtain the operation (33% in Tegucigalpa and 15% in San Pedro Sula). The main reasons women cited for not following through and getting sterilized were: 1) time and family problems, 2) economic reasons and 3) opposition of the husband. Over the whole study period, a far higher percentage of interested women were sterilized in Tegucigalpa (52%) than in San Pedro Sula (29%).

Since the original study was conducted, a number of factors changed that should increase the number of sterilizations in Tegucigalpa. Because little has changed in San Pedro Sula to promote sterilization, this part will be omitted from the new study. A third study conducted in the latter half of 1984 sought to determine the contribution of each of these factors in affecting the percentage of women sterilized.

All women hospitalized for delivery at the hospital Materno Infantil during a two-month period were interviewed following delivery and prior to discharge. Information on whether they were sterilized was obtained. A follow-up record was completed for all women planning to be sterilized but not sterilized at the time of hospitalization for delivery. If the woman returned to ASHONPLAFA for sterilization, this

information was noted on the form. Women who did not return to the clinic for sterilization within four months of delivery were interviewed at home to determine if they had been sterilized in the four months since delivery and if not, why.

This third study found that among women 25 or older with at least three children and who wanted no more, 9% and 17% were sterilized at vaginal delivery in 1980 and 1984 respectively. Part of this change may be attributed to increased demand among women 25-29 (who met age parity requirements in 1984 but did not do so in 1980) and partly to increased facilities available for postpartum sterilization. A paper on the initial findings was presented at the APHA meetings in November 1985. Data analysis of the second phase of the study (interval sterilizations for women not sterilized during hospitalization for delivery) is underway. Analysis will now focus on interval sterilization among women interested in, but not sterilized, postpartum.

Brazil: Access to Sterilization

In collaboration with the Pathfinder Fund, FHI developed a project in Brazil to analyze the factors that cause women, who say they are interested in tubal ligation and who make inquiries concerning the surgery, but fail to follow through and get sterilized. Over the period 1 June - 31 August 1983, all clients were interviewed concerning their interest in sterilization; women who were approved for surgery were monitored through the process of obtaining a tubal ligation for a period of three months. Follow-up interviews were

scheduled with all unsterilized but approved women at the end of the three-month period.

Of 1286 new clients, 1256 requested sterilization; of these, 925 were approved. Of approved women, 639 scheduled surgery and of these, 595 were sterilized within three months of approval. While approval is dependent mainly on demographic variables, especially age and parity, follow-through is also related to a woman's education and income. At the initial visit among women who were approved for sterilization, those who were users of less efficient methods were less likely to get sterilized than were users of efficient methods. This is because users of less efficient methods are required to switch to a more efficient method before sterilization is scheduled in order to ensure that they are not pregnant at the time of surgery.

A final report was prepared and submitted to AID. This report has been widely circulated in Brazil. A paper was submitted to Studies in Family Planning. Based on comments of reviewers, the paper is being revised. A paper was also presented at the APHA meetings in November 1985.

Nigeria: The Effect of FS Counseling on the Rate of Female Sterilization

The prevalence of female sterilization is very low in Nigeria. At the University of Benin Teaching Hospital (UBTH) in Benin City, Nigeria, many women do not get sterilized, possibly because of presumed opposition from their husbands or their own fears of

complications of the surgery. This latter fear may be the result of inadequate counseling.

The specific objectives of this study were to determine the effects of counseling on the female sterilization rate, to study the effects of socio-demographic factors on the acceptance of female sterilization, and to assess the potential impact of the increase in demand on available facilities.

The study design is a randomized trial. The sample includes all grandmultiparae (5 or more previous deliveries) attending the prenatal clinic and delivering at UBTH. The sterilization rate among grandmultiparae who are counseled is being compared with that of women who are not counseled. In January 1986, the investigator successfully completed the admission of 1,000 women into the study. Completed forms have been received at FHI from 669 of these women who have now completed the study. Follow-up of all women admitted into the study should be completed by June 1986.

Sri Lanka: Follow-up of Tubal Ligation Cases

AID has a clear policy of not paying "incentives" for any aspect of family planning. In 1980 the government of Sri Lanka, using non-AID funds, initiated a program that reimbursed all individuals sterilized in Sri Lanka for costs (lost work time, transportation, etc.) associated with the operation. The amount paid has varied since the introduction of the program as has the response of the community. This study attempts to assess the effect of government-cash payments

on the decision to accept sterilization and on long-term satisfaction with the method. It will provide information relevant to policy making in Sri Lanka and elsewhere.

The investigators selected a sample of 1350 acceptors of female sterilization from the 16,301 women served by Community Development Services (CDS) in urban, rural and estate sectors from 1980 through 1983. The samples were stratified by date corresponding to the government incentive program so that comparisons in satisfaction could be made among groups receiving different payment amounts. The questionnaire obtains information on the acceptors' socio-demographic characteristics, pregnancy and contraceptive history prior to sterilization, motivation, complications of the operation, the effect of the incentive, if any, on the decision to be sterilized, and overall satisfaction with sterilization.

Fieldwork, begun in December 1984, has been completed for all three sites. The analysis to date suggests that cash payments may have brought forward the time when a couple or individual accepted voluntary sterilization, but did not induce individuals into a decision they subsequently regretted.

A paper entitled "Incentives and Satisfaction: A Study of Female Sterilization Acceptors in Sri Lanka" was presented at the American Public Health Association meeting in November 1985. There have been delays in receiving the final 600 forms. These interviews have been completed but the CDS has not yet translated and sent them to FHI.

NORPLANT® Acceptability Surveys

NORPLANT® is a new method of contraception and creates an opportunity for studying potential interest in the population for this new method. The first studies are concerned with acceptability among clinic populations.

As part of FHI's Clinical Trials project to monitor new acceptors of NORPLANT® in several countries, the Program Evaluation Division is studying the factors that affect the acceptance of NORPLANT®. A NORPLANT® Acceptability Questionnaire that records information for all women considered to be potential acceptors of NORPLANT® was developed. Results will show reasons why women are interested or not interested in trying the method and what factors correlate with interest. The first NORPLANT® Acceptability Surveys (NAS) were initiated in Nepal and Bangladesh in February 1985. Studies began in Nigeria, Ghana and Haiti later in the year. Preliminary analysis has been completed for the Nepal and Bangladesh study sites and a report is currently under preparation. It might also be noted that questions on acceptability of NORPLANT® were also included in a rural household survey in Sri Lanka. Results will be available before the end of the fiscal year.

Haiti: Condom Acceptability Study

The condom is an important method of family planning but one sometimes ignored in family planning programs oriented towards women. However, partly because of growing concern with STDs, acceptability seems likely to increase.

A Haitian study was designed to evaluate the effectiveness of a condom distribution program in the Cite Simone district of Haiti's capital and largest city, Port-au-Prince. The project is assessing reasons for use and for non-use, and obtaining information on the sources of condoms used by men residing in the study area. It will be used to design effective approaches to increase condom use among Haitian couples who are not otherwise protected against unwanted pregnancy. In addition, couples identified as condom users will be followed for a period of twelve months in an effort to assess the use effectiveness of the method.

This investigation, initiated in February 1986, is expected to continue for 24 months. Coding and data analysis will be done in Haiti, with on-site technical assistance from FHI's technical monitor.

US: Comparative Study of the Today™ Vaginal Contraceptive Sponge with Traditional Use vs. Use During the Fertile Phase

The TODAY™ sponge is a new barrier contraceptive for which FHI conducted initial clinical trials. A study involving the contraceptive sponge is being conducted through the Los Angeles Regional Family Planning Council (LARFPC), to compare the use of the contraceptive sponge at every intercourse with the use of the sponge during only the fertile phase as identified by the woman after training in the Fertility Awareness Method (FAM) of natural family planning. Prior to recruitment, the LARFPC staff developed data collection instruments, brochures, inventory logs and menstrual/coital diaries. VLI, the manufacturer of the contraceptive sponge, is providing the sponges gratis. The design called for 200 volunteers to be randomized, 100 in each study group, and are to be followed for one year.

This study has been seriously hampered by recruitment problems. An adequate number of women expressed interest in the study, but only a minority were eligible. Unexpectedly high numbers of women had just come off the pill, had abnormal pap smears or would not accept randomization into study groups. The recruitment period was extended and some women were re-contacted after the post-pill period or after their pathologic cytologies had been treated. Various avenues of the media were explored, but major networks and stations refused to air public service announcements about the study. A sample of 35 women attending the clinic at one session found 15 women had used the sponge and did not want to use it again; 10 of the women were

satisfied with oral contraceptive use; one woman was interested in learning more about the study; one woman was satisfied with the cervical cap; one woman was satisfied with the diaphragm; one woman was gay and another woman was not in need of a contraceptive method. Clinic intake workers agreed that this survey represented prevailing attitudes toward the sponge. It appears that approximately one half of prior sponge users abandon it. Of those who are pleased with the method, most purchase sponges outside of the clinic and return only for annual examinations.

Recruitment has ended and follow-up is in progress. Active recruitment yielded only a small number of cases (27 in one group, 26 in the other) compared with the original goal of 100 per group. Follow-up will end by January 1987.

3. Household Surveys (including Secondary Analysis)

Household surveys are an important source of information on contraception, breastfeeding and MCH care. They provide baseline data to show where and what type of services are needed. Multiple surveys can show the impact of programs to provide contraception, promote breastfeeding or vaccinate children. The first three projects involve or have involved both data collection and analysis. The latter three projects support secondary analysis of data.

Honduras: Maternal and Child Health and Family Planning Survey

In 1984, a survey of 5500 households was conducted in Honduras to obtain information on both maternal and child health and family planning, including use and source of family planning, use of primary care facilities, breastfeeding and child mortality and other aspects of reproductive health. The survey sought to estimate: current levels of fertility and infant mortality; sources of obstetric care; prevalence and duration of breastfeeding; incidence of diarrhea among children under 5; percentage of children who had been immunized; pregnancy intentions; ideal family size and the percentage of women who had experienced unplanned pregnancies; contraceptive use by method and by source; reasons for terminating use of family planning; incidence of reported problems among ever users of oral contraceptives and the impact of this experience on method discontinuation. The survey included a module on care provided by traditional birth attendants, information important in a country such as Honduras where more than half of all deliveries occur at home.

The main source of oral contraceptives was ASHONPLAFA; the private sector and the Ministry of Health (MOH) were the other main providers. The main provider of sterilization was also ASHONPLAFA through its programs at the MOH and private hospitals.

The percentage of all women aged 15-44 in union that were contracepting increased from 27% in 1981 to 35% in 1984 (Tegucigalpa/San Pedro Sula, 56%; other urban areas, 45%; rural areas, 24%).

Most of the increase was in female sterilization. The total fertility rate declined from 6.4 in 1981 to 5.2 in 1984. The total fertility rate is lowest in Tegucigalpa/San Pedro Sula (3.1), intermediate in other urban areas (4.6) and highest in rural areas (6.5).

A research dissemination seminar is planned for June 1986. Participating organizations include the Ministry of Health, Management Sciences for Health, CONSUPLANE, ASHONPLAFA, and FHI.

Future plans include a follow-up survey in 1987. These data will allow us to evaluate programs which provide contraception, promote breastfeeding and provide MCH services.

Mexico: Combined Reproductive Risk and Contraceptive Prevalence Survey

Funds and technical assistance have been given to the Federation of Private Family Planning Associations in Mexico (FEMAP) to design and implement a Combined Reproductive Risk and Contraceptive Prevalence Survey. The survey was conducted in selected areas of the cities of Leon and Saltillo in the summer of 1984. The data generated from this survey are being used as an evaluation tool for the FEMAP affiliates that have recently begun providing services in these two cities. The data will play a role in measuring the effects of the FEMAP CBD model and will be used to help these programs operate in a more efficient and effective fashion.

The data collection phase of this project is completed. A preliminary report shows that contraceptive use is fairly high. Contraceptive use was 59% in Saltillo and 52% in Leon.

The use of periodic abstinence was high in Leon (11%) compared to Saltillo (3%). In general, the percentage of women who were contracepting in both cities increased with age, number of living children and education. Opinions about convenience and accessibility of contraception, perceptions of methods, and reasons for discontinuing OCs will assist in program development.

Dr. Rebeca Ramos visited FHI in August 1985 and worked with staff in preparing the project report and a final report will soon be available.

Brazil: Secondary Analysis of Survey Data

This in-house project supports the analysis of data collected in several household surveys in Brazil. During this year, two papers using data from the surveys were published in scientific journals: "Sterilization in the Northeast of Brazil" (Social Science & Medicine, 1985) and "Cesarean Delivery in the Northeast Region of Brazil, 1978-80" (American Journal of Public Health, May 1985). "Side Effects and Discontinuation of the Pill in Southern Brazil" has been accepted for publication in the Journal of Biosocial Science.

Philippines: Proximate Determinants of Fertility

FHI is funding a secondary analysis of data collected in four surveys carried out during the past two decades in the Philippines. The purpose of the analysis is to study the trends in and proximate determinants of fertility. The study is being carried out by the staff of the University of the Philippines (UPPI), where the project is based, and Professor John Casterline of Brown University, an FHI consultant. It commenced in November 1985. Analysis of fertility trends and decomposition of these trends in terms of the proximate determinants (e.g., breastfeeding, marriage, contraceptive use) will be carried out in the Spring 1986.

Thailand: Secondary Analysis of CPS III Data

In Thailand, as in many other countries, supplementary feeding is introduced early in lactation, decreasing the period of postpartum amenorrhea and increasing the need for early resumption of contraception. The third Contraceptive Prevalence Survey (CPS III) collected detailed information on infant feeding practices, postpartum amenorrhea and contraceptive use in order to study the relationships among these variables. Analysis of these data is underway by Drs. Peerasit and Knodel in Thailand.

4. Surveys of Young Adults

In many places rapid urbanization has led to the breakdown of many of the traditional norms concerning sexuality and fertility and

premarital pregnancy among adolescents has become a serious national concern. These surveys are usually the first source of objective information on a group whose problems need to be recognized in the design and implementation of programs to improve reproductive health at the national level.

Nigeria: Sexual Behavior, Contraceptive Practice and Reproductive Health Survey of Young Adults

In the context of a high and increasing incidence of unwanted pregnancy among Nigerian adolescents, a survey of 1800 never-married residents of the Ibadan area of Oyo State, aged 14 to 25 years of age, was conducted by the Family Planning Unit, University College Hospital, Ibadan. The purpose of this investigation was to learn about perceptions and practices relating to reproductive health. Findings showed that a substantial proportion were sexually active, and that despite comparatively high contraceptive prevalence among such individuals, many were still engaging in regular sexual relations without contraceptive protection. Nearly half the secondary and university students and two-thirds of those not currently enrolled in school had been pregnant. Among respondents who had been pregnant, almost all reported that they had electively terminated their pregnancies. These findings, as well as a discussion of existing and needed reproductive health care services for young adults in Nigeria, are included in the study's final report, which has been distributed to health providers and policy makers in Nigeria.

A revised version of that report (Nichols et al., "Sexual Behavior, Contraceptive Practice and Reproductive Health Among Nigerian Adolescents") was published in the March/April 1986 issue of Studies in Family Planning.

Liberia: Reproductive Health Knowledge, Sexual Behavior and Contraceptive Practice Among the Young Adult Population

In response to a request from the Medical Director of the John F. Kennedy Memorial Hospital Maternity Center in Monrovia, FHI participated with the Liberian Ministry of Health and Social Welfare in the design and implementation of a community-based survey in 1985 in Liberia's capital to ascertain the reproductive health needs of its young unmarried population. The study found a substantial unmet need for reproductive health knowledge. During the period covered by this report, FHI researchers collaborated with Liberian investigators in the preparation of papers based on the study's findings, which will be submitted to suitable professional journals in the US and in West Africa, and a two-day workshop in Monrovia attended by representatives of Monrovia's medical, educational, legal and religious communities, as well as international donor agencies, was held.

Mexico: KAP Survey of Young Adults

Mexico City has one of the world's largest population concentrations and, like many exploding cities of the Third World, faces a massive problem of unintended pregnancy that challenges civil leaders as well as adolescents and their parents.

The Center for Orientation of Adolescents (CORA) in Mexico City provides a variety of services to young adults in two areas of the city. Interviews were conducted with approximately 1500 men and 1750 women from a randomly selected household sample of the areas where CORA is active. The field work was initiated in March and concluded in August 1985. Data entry and editing were coordinated in-country by the Mexican Academy for Medical Demography. Data analysis began in October 1985 at the CDC in Atlanta.

This survey is the first large effort of its kind in Latin America. It determined: a) the proportion of young adults who are sexually active and the proportion contracepting; b) the methods and source of methods being used by the sexually active; c) the regularity of use of methods; d) preferred family size and the psychosocial factors that influence sexual decision-making. The survey will be used to develop and improve information and service programs aimed at adolescent reproductive health.

Papers were presented at the American Public Health Association in November 1985, and the First International Conference on Adolescents in Oaxtepec, Mexico, in December 1985. Additional presentations will

be made at the Population Association of America (PAA) and the US-Mexico Border Health Association, both to be held in April 1986.

B. Maternal and Child Health/Family Planning

In some countries, the health benefits of family planning still need to be documented and publicized. Although maternal and infant mortality rates are high, partly due to pregnancies that occur too early, too late, or are too closely spaced, family planning programs have either to be established or to reach the more remote areas of the country. In such settings, FHI is conducting studies of pregnancy monitoring and of health consequences of illegal abortion, maternal mortality, infant and child mortality and morbidity, and unmet needs for family planning.

1. Pregnancy Monitoring Studies

Most African countries have come to realize that health-for-all cannot be achieved simply by increasing the number of hospitals and health care providers. Throughout the Sahel, poor and deteriorating economic conditions emphasize the need for comprehensive health and family planning policies. In times of economic austerity, policymakers and economic planners are looking for ways to achieve better utilization of existing resources to improve health. In most African countries, hospitalization for pregnancy-related reasons currently makes up the largest portion of care needed by and provided to women. These services also constitute a substantial proportion of

all hospital-based health care. Decreasing the risks associated with early, late, numerous or closely spaced pregnancies is a serious concern among those involved in the delivery of health care. Consequently, birth spacing as a health measure for both mothers and their infants is becoming an increasingly accepted concept in many African countries.

During the period covered by this report, data collection continued at three previously initiated projects in Senegal, Ivory Coast and Zaire, using newly developed questionnaires and other survey instruments. Site visits by FHI technical monitors were made to review project implementation, and to work with in-country collaborating investigators in planning the analysis of data collected and the reporting and dissemination of findings.

The studies are expected to be completed during FY86 and 87, with final reports prepared and disseminated to appropriate audiences at both policy making and service delivery levels, as well as to collaborating organizations and funding agencies. A regional conference has been proposed to enable investigators in these three country studies to present and compare their major findings and their implications, and to outline courses of action to improve the delivery of obstetric care services in sub-Saharan Africa.

Research findings from each of the country projects will be shared with government policy-making officials, health care providers, and international donor agencies. The broad goal of this program is to assist in the design of appropriate service delivery and training

programs to improve maternal and child health. Areas that can be addressed through study findings include better utilization of limited medical personnel, hospital facilities and traditional birth attendants (TBAs), improved prenatal screening, and better counseling and services for birth spacing.

Senegal: Obstetric Surveillance and Determinants of Mortality to Women of Reproductive Age in the Sine Saloum Region

To gain a better understanding of factors affecting maternal and child health in a largely rural region of Senegal, this project has been designed to collect and analyze information on obstetric care and the determinants of mortality to women of reproductive age in the Sine Saloum region. Approximately 8500 deliveries over a period of one year have been monitored in a representative sample of health facilities in the project area. Information is available from village level health huts, health posts, sub-regional health centers and the regional referral hospital. Data on obstetric history, prenatal care, referral status, delivery and pregnancy outcome have been recorded by health care providers trained in the collection of data.

In a second phase of the project, initiated in FY 86, all deaths occurring to women of reproductive age in the project area are being investigated by a trained interviewer to determine the cause of death. Institutional deaths will be investigated both in the health institution and at the place of residence of the deceased.

Particular attention will be given to deaths resulting from pregnancy or childbirth.

During the period covered in this report, data have been received and are presently being tabulated at FHI and at the Bureau National du Recensement in Dakar, using microcomputer facilities provided under a separate FHI grant.

The results of this study will provide policy-relevant information on the relationship of family planning services and primary health care and maternal and child care activities in the region. In addition to addressing a series of research questions about pregnancy-related care and outcomes in the Sine Saloum, this project will help to reinforce the health service statistics through the design and implementation of a uniform reporting system for obstetric care that can serve as a model for the entire country.

Ivory Coast: Pregnancy Care Surveillance in Abidjan

Ivory Coast, like its neighboring countries, has given priority to improving the health of its people, in particular that of mothers and children. However, the contributions that high fertility and inappropriate pregnancies (too early, too late, too closely spaced) make to maternal, infant and child mortality is not well understood by policymakers. Less is known about the details of pregnancy and childbearing in West Africa than in any other part of the world. Existing evidence points to high rates of neonatal and maternal morbidity and mortality. There is also anecdotal information from

Ivory Coast of a growing incidence of illegal abortion, particularly among adolescents. What proportion of scarce health resources go to treating these young women for complications, what degree poorly-performed illegal procedures contribute to pregnancy-related morbidity and mortality and how the numbers might be reduced is unknown.

This project is collecting data on a representative sample of women hospitalized for pregnancy-related care in the capital city, Abidjan, over a one-year period. Special attention is given to studying referral patterns from the eleven maternity centers of the city to the two major referral hospitals. To date, data on approximately 14,000 deliveries have been collected and computerized and preliminary data tabulations completed. A seminar at the end of the data collection and analysis period will present results to staff who participated in the study as well as policymakers to discuss priorities in improving pregnancy-related care and pregnancy outcomes. The data will serve as a basis to develop service programs addressing priority needs.

Zaire: Traditional Birth Attendants

This project involves the collection of data on women hospitalized for pregnancy-related care at the major referral hospital in Karawa over a two-year period. In addition, because most maternity care is provided in the home by TBAs, this project includes the development and implementation of a registry system, based on oral reports, to collect data on home deliveries attended by TBAs. Information from

the registry, along with concurrent information gathered on institutional deliveries at the referral hospital, will provide a more complete picture of the factors that affect maternal and perinatal mortality in Karawa, and provide information for the ongoing AID-sponsored TBA training program there. Special attention is being devoted to studying TBA referral patterns. In addition, an estimate of the rate of infant mortality is being made and causes of infant death determined for the home deliveries by following up those infants over a one-year period.

Data collection is in progress and will continue throughout the 1986 fiscal year. Follow-up data collection will continue through 1987.

2. Maternity Care Monitoring Studies

In addition to FHI's work in monitoring pregnancy outcomes in Senegal, Ivory Coast and Zaire, data collection continues in other locations. A hospital-based study in Haiti and MCM investigations in the Middle East and in other locations in sub-Saharan Africa have been completed. A number of reports and publications have been prepared using data previously collected; others are in preparation.

Haiti: Maternity Care Monitoring (MCM)

Data have been collected on deliveries during a 13-month period (November 1984-November 1985) in the Western Region, the most populous region, of Haiti. To date, information has been collected on more than 4900 deliveries. Seven maternities are involved in data

collection activities. In certain areas, data are being collected on home deliveries assisted by traditional midwives. The major goals of this project are: (1) to enable health care providers and policymakers to better identify problems and needs in maternity care and family planning service programs; and (2) to establish an efficient standardized system of data collection on obstetric care that can be used in assessing needs, evaluating programs and generating health service statistics. The project uses standard FHI data collection forms and processing systems to collect and analyze data. The study was implemented in collaboration with the Division de l'Hygiene Familiale et de la Nutrition (DHFN). Dr. Jacqueline Polynice Pierre-Louis of the DHFN is coordinating the study. Data collection is currently underway and will be completed during FY86.

Maternity Care Monitoring (MCM in-house)

The overall aim of this study area is to assist in insuring the most cost-effective use of the limited resources available to improve maternal and infant care and to document the need for improved family planning services by drawing attention to the expressed wishes of women for access to contraception. Two consultant reports were written for Maternity Record studies completed in Rwanda and Nigeria. The former is being translated into French for in-country distribution. In addition, MCM studies were completed at sites in Egypt and Sudan; data from these investigations are at different stages of analysis.

Four papers based on Maternity Record or Pregnancy Wastage Record data are in press or were published during the last six months: "Abortion Experience Among Obstetric Patients at Korle-Bu Hospital, Accra, Ghana", Journal of Biosocial Science; "Hospital Deaths in a High Risk Obstetric Population", International Journal of Obstetrics and Gynecology; "Referrals by Traditional Birth Attendants in Northeast Brazil", American Journal of Public Health; and "Methodological Issues in Collecting Data from Traditional Birth Attendants", International Journal of Obstetrics and Gynecology Special Edition. Reproductive Health in Africa: Issues and Options, the monograph based on FHI's maternity care experience in sub-Saharan Africa, is being translated into French.

Finally, partial funding was provided for the secondary analysis of information collected on 22,000 women delivering at the University Hospital in Zaria, Nigeria. Papers based on these analyses are in press.

Obstetric Care in Africa (Monograph)

Under previous Maternity Care Monitoring (MCM) subgrants, several studies have been conducted in Africa to obtain information on obstetric care and family planning. Results of these studies were used to prepare a monograph that discusses the following topics: maternal mortality, antenatal care, obstetric practice, family size, fertility intentions, breastfeeding, contraceptive use and postpartum family planning. The English version has been published and

distributed. The French version has been translated, and printing and distribution are scheduled for this year.

3. Pregnancy Wastage Studies

Deliberate termination of pregnancy in developing countries is often a direct consequence of the limited knowledge and non-availability of effective contraceptive methods among the sexually active population. In addition to posing a major health problem, the hospitalization and treatment of patients with complications resulting from illegally induced abortion consumes a substantial portion of scarce medical resources adversely affecting other branches of medicine.

FHI has provided technical and financial support to two recently completed studies of pregnancy wastage. Results will be used to impress upon health policymakers and service providers the contribution safe and effective contraceptive services can make to reducing the number of unwanted pregnancies.

Zaire: Multi-center Pregnancy Wastage

A hospital-based study of the social determinants and medical consequences of pregnancy wastage was initiated in November 1982 in ten medical centers located in three regions of this central African nation. Under the direction of the Comite National des Naissances Desirables (CNND), the study was to document the incidence and nature of complications associated with pregnancy wastage requiring

hospitalization and to estimate the level of contraceptive knowledge and use among women whose pregnancies were interrupted.

During the 18 months of data collection (November 1982 - April 1984), a total of 2465 women were admitted to the ten participating centers for treatment of medical complications following abortion. At least one-fourth of the total abortions had been illegally induced, frequently with resulting fever, infection, bleeding and lesions/lacerations requiring medical attention. Thirteen patients died as a result of these complications.

A report on the findings and implications of this study has been prepared and distributed in conjunction with the CNND and research investigators at several of the participating centers. Entitled "Determinants and Consequences of Pregnancy Wastage in Zaire: A Study of Patients Requiring Hospital Treatment in Kinshasa, Matadi and Bukavu", this report is available in both English and French. The goal is to impress upon Ministry of Health officials and private service delivery programs the critical importance of contraceptive services in reducing the incidence--and associated economic and human costs--of unsafe and illegally procured abortions throughout Zaire. This report has been translated into French and is being distributed to appropriate agencies and individuals in Zaire by the CNND.

In August 1985, a conference was held in Kinshasa at which the results of this investigation were presented and discussed. CNND staff plan to prepare pamphlets and other informational materials based on the results of this study, and to travel to CNND regional

offices to conduct small seminars emphasizing the importance of family planning as a means of avoiding unwanted pregnancies and their consequences.

Bolivia: Pregnancy Wastage

This subgrant funded a multicenter study of women hospitalized for complications associated with illegally induced and spontaneous abortions at 11 hospitals in five cities in Bolivia.

Over a 12-month period, beginning July 1983, socio-demographic, family planning and clinical information were recorded. It is estimated that at least 23% of the 4371 abortions were illegally induced. The women who deliberately terminated their pregnancies tended to be younger, nulliparous and not in union. Almost 1% of the patients died. Of the illegally induced cases, 65% were induced by Medically Trained Practitioners (mostly curetage), and 35% by non-MTPs (mostly inserting a foreign object). The higher a woman's education, the more likely she was to seek out a trained practitioner. Women whose abortions were induced by curetage were less likely to experience fever and lesions, but had longer hospital stays. Sixty percent of those women hospitalized with complications resulting from induced abortion reported they did not use a contraceptive method during the month they became pregnant and nearly half of these gave as their reason a lack of knowledge. After medical treatment, 77% planned to use contraception, the IUD being their most frequent choice. Results show the need to improve the delivery of family planning services in Bolivia.

Sr. Luis Llano Saavedra, Project Director, spent two weeks at FHI during the fall of 1984 to participate in the analysis and the writing of the report. A symposium, attended by an FHI staff member, took place in March 1986 to disseminate the findings of this study among the appropriate health and legislative officials in Bolivia.

4. Maternal Mortality Studies

The reduction of deaths associated with pregnancy and childbirth is an important goal of many public health programs, particularly in developing countries, where overall mortality is high and maternal deaths constitute as much as 20-25 percent of all deaths to women of reproductive age.

In FHI's Program Evaluation Division, studies of maternal mortality are underway in the Sine-Saloum Region of Senegal, as part of the pregnancy monitoring investigation described above, and in Egypt. In addition, FHI is supporting the secondary analysis of data collected on maternal deaths in other Senegalese studies and in The Gambia.

The overall objective of these studies is to identify the causes of reproductive age mortality as a first step in the development of health interventions to reduce the number of deaths from those causes thought to be preventable. A secondary objective is to show that, despite the attendant publicity concerning the health effects of various modern methods of child spacing, the **relative risks** of

contraception versus repeated childbearing in developing countries may show a very different picture.

Egypt: Giza Maternal Mortality Study

A recent study of reproductive age mortality in the Governorate of Menoufia in Egypt found that the maternal mortality rate for that governate was 28 times higher than the maternal mortality rate for the United States in 1981. The results of the Menoufia study have been used by President Mubarak in setting policies for health care in Egypt.

This study seeks to determine the incidence and causes of maternal deaths in the Governate of Giza, Egypt. Information is being collected on all maternal deaths occurring in the Giza, Imbaba and Osim health sectors during a twelve month period. The deaths are expected to be registered at the local health bureaus, whether or not they occurred in a hospital.

The study objectives include the establishment of an effective system for locating maternal deaths, identifying maternal deaths that are currently preventable, determining the factors associated with maternal mortality and creating a profile of high-risk women. Household interviews began in August and hospital data collection began in September 1985.

Once maternal deaths are identified, trained interviewers (social workers) visit the household of the deceased and interview family

members about the circumstances surrounding the maternal death and the symptoms the deceased woman manifested prior to her death. A medical panel is assessing the specific causes of death from the family interviews. Additional information is being collected for maternal deaths occurring in hospitals and is being compared with the results of the home interviews of family members of the deceased.

During the first six months of data collection, 70 maternal deaths were identified and interviews with family members completed.

Data collection for this study will be completed in late 1986. In addition to addressing a number of important research questions on factors related to maternal mortality in Egypt, this project will also help to reinforce health service statistics through the design and implementation of a uniform reporting system for maternal deaths. Information will be used to design public health measures that will reduce the frequency of maternal deaths occurring in the home and hospital settings throughout Egypt.

Senegal: Support to ORSTOM for Secondary Analysis of Data
on Maternal Mortality

Maternal mortality in rural Senegal is thought to be nearly 70 times higher than in developed countries. Maternal death is a serious hazard for Senegalese women, who average 7.4 births over their reproductive lives.

In the whole of sub-Saharan Africa, data on maternal mortality and its determinants and implications are scarce. This three-year project is a systematic attempt to collect data on death and childbirth and to bring together a spectrum of demographic, sociological, nutritional and medical information obtained from households in a small rural area of Senegal.

The activities of the project include secondary analysis of two existing data sets: one for the Sine Saloum Region of Senegal, and the other, for women and children attending a health center.

The questionnaire was designed to study the determinants of mortality among women of reproductive age. Data collected and analyzed thus far indicates that approximately 50% of all deaths to women of reproductive age can be attributed to maternal causes. ORSTOM estimates that the maternal mortality ratio in the region was about 8.9 deaths per 1000 deliveries. Similar results have been reported in a study in nearby Gambia. These are among the highest levels of maternal mortality studied anywhere. Data collection is now complete and ORSTOM researchers are analyzing the data, and will submit a report on this work during the next reporting period.

5. Other Studies

Brazil: Parteiras in the Northeast

The great majority of the world's maternal deaths occur in developing countries and the majority of these deaths involve deliveries

attended by TBAs. The program of the Maternidade Escola Assis Chateaubriand (MEAC) directed by the late Dr. Galba Araujo has been unusually innovative and effective in training and supervising TBAs to ensure safe deliveries.

In an earlier project, information was obtained on deliveries by traditional birth attendants (parteiras) at four obstetric units in the rural and semi-urban areas surrounding Fortaleza in the Northeast of Brazil. These data showed that TBAs at these obstetric units referred all but a very few of the high risk cases. Recently, TBAs have been trained to work in more remote rural areas. In these more sparsely populated areas, obstetric units of 5-7 beds are not feasible, and the program has emphasized setting up one-room units attached to the homes of TBAs and to training TBAs who will continue to attend deliveries at the homes of patients.

While the best of the trained TBAs working in the larger obstetric units have been shown to do a good job in making appropriate referrals, no information has been available for the TBA who continues to do home deliveries or who manages a one-bed unit. This study fills this gap by obtaining information on the referral and deliveries of all TBAs working in a rural area of the State of Ceara.

A second purpose of this study is to obtain information concerning infant mortality and causes of death. Because of the low prevalence of breastfeeding in the Northeast of Brazil, it is expected that the incidence of diarrheal diseases will be high and that diarrheal

diseases will account for a significant proportion of infant mortality.

Data collection was initiated 1 May 1984 and for one year, questionnaires on home and hospital deliveries were completed for all residents for the county of Trairi. The county has a population of about 35,000, and during the one year period, 1823 births were reported. There are approximately 80 TBAs who work in the area, and 66% of the deliveries occurred at home. Referrals by TBAs are being linked to hospital deliveries. More than 95% of deliveries have at least one follow-up form.

Follow-ups are being conducted at six weeks, six months, one year and 18 months to determine the infant and mother's survival status, feeding practices and contraceptive use. When a child dies, a physician interviews the mother to determine the cause of death, treatment and future pregnancy intentions. By the end of December 1985, records of 101 infant deaths had been collected. Half of those infant deaths appear to be linked to diarrhea and dehydration.

The training and use of TBAs in conjunction with a highly medically oriented system of maternity care and the review of causes of infant deaths is an innovative accomplishment that will attract study and attention as an example for other parts of the world.

Egypt: Extent and Attitudes Toward Female Circumcision

Recent studies of female circumcision have shown a high prevalence of this practice, especially among less educated women. In attempting to assess the magnitude of the problem and attitudes toward the practice, a study of various populations has been undertaken.

Women coming to Ain Shams University Hospital, Cairo, for delivery have been interviewed regarding pregnancy and labor complications and attitudes toward female circumcision. A clinical questionnaire assesses the medical complications for each of these women.

Approximately 910 of the expected 1000 patient/clinical questionnaires have been received at FHI and have been coded and entered into the computer system. The attitudes of 500 young women age 14 to 27 were also surveyed. Data analysis has shown that circumcision is practiced by the large majority of women in the study population, and that--despite the associated complications with pregnancy and childbirth--it appears to be firmly rooted as a cultural practice.

Thailand: Follow-up of Infants in Sukhothai Province

By providing information on the rate of infant and early child mortality and the factors associated with survival, this study will provide the Ministry of Public Health with information useful for designing programs to reduce mortality and promote contraception.

Data on all infants included in a study of obstetric deliveries in Sukhothai Province, in north central Thailand, are being collected at 1, 3, 6, 9, 12 and 18 months after delivery. An infant monitoring form, completed by a Village Health Volunteer (VHV), provides information on pregnancy and contraceptive status of the mother, infant and child mortality, and infant feeding and weight if the child is alive. If the child has died, an Auxiliary Nurse Midwife (ANM) from a health center interviews the mother concerning symptoms the infant experienced, medical help received, medication used, infant feeding patterns and immunizations. Funding covers the design of data collection instruments, the collection of data, analysis, preparation of report and papers, and dissemination of information.

Data collection, begun in April 1985, is almost complete. The first phase of data analysis is planned for the summer of 1986. This phase will provide information on stillbirths and neonatal deaths.

Future Plans: Family Planning Evaluation and Maternal & Child Health/Family Planning

The time ahead will be a period of reordering the goals of the Program Evaluation Department's work in reproductive health. Both governmental support for and individual interest in family planning has been increasing in many African countries, so that there is less need to undertake studies designed to sensitize policymakers to the need to introduce contraception. On the other hand, as active family planning programs become established, there arise new needs for the evaluation of their activities in order to make them as acceptable

and effective as possible within the limited resources available. Below are listed several new areas the Program Evaluation Division will be pursuing in the coming months.

1. Pill Compliance

Methods currently in use, such as oral contraceptives (OCs), sometimes have disappointingly low use-effectiveness, possibly because providers give little or no instruction to acceptors. Studies of user compliance, provider knowledge and client-provider interaction will yield practical information on how use-effectiveness can be increased.

There are almost no data on the compliance patterns among women who accept the pill inside or outside a clinic setting. In many countries poor compliance may be an important contributing factor to high discontinuation rates. One possible explanation is that women may not be taking pills correctly and -- as a result -- may be experiencing unacceptable side effects. A 1985 study by Seaton in Bangladesh found very high rates of non-compliance among OC acceptors in the Matlab district. FHI is seeking sites to replicate and extend this study. FHI is testing a simple device to record OC use and is increasing the scope of previous studies by looking at reasons for and implications of non-compliance. Possible locations are Colombia, Thailand and Senegal and studies will have four components: focus groups to examine the general knowledge and perceptions of users and discontinuers about OC use; interviews with acceptors to ascertain their perceptions about the method and their pill-taking behavior;

interviews with providers to determine their knowledge of OCs and strategies to increase method acceptability and compliance; and if possible, objective recording of use.

2. Provider Studies

Other studies of client-provider interaction are planned. In Juarez, Mexico, a survey of community-based distributors and a sample of their customers will be conducted. The objective will be to determine whether promoters who have a thorough knowledge of the products they distribute are more successful at recruiting and maintaining clients than other, untrained, distributors. The impact of other factors, such as follow-up visits to those who do not return for contraceptives or neighborhood meetings to recruit new acceptors, will also be assessed. Information collected in this study will provide program managers with predictors of distributor performance and recommendations on how to improve promoter training programs in order to increase contraceptive acceptance and continuation rates.

3. Acceptability

The future of new methods, such as NORPLANT[®], partly depends on how sensitively they are introduced and on the receptivity of the population. Motivation of clients to continue use despite non-serious but unanticipated side effects is an important issue, as are factors relating to the long term satisfaction of users. Studies are currently being developed to determine how best to introduce new methods in diverse settings.

4. Attitudes of Males

Men are often closely involved in childbearing decisions, although comparatively few studies have focused on their contraceptive attitudes and behavior. FHI's current Condom Acceptability Study in Haiti was designed to explore how to make family planning available and acceptable to urban men. In Nigeria, an investigation into the contraceptive knowledge, attitudes and practices of males is planned as service delivery programs are being initiated. Studies have found that in certain states of Nigeria more men than women are using a modern method. Information to be collected will be used to make recommendations for a rational and effective program of voluntary fertility control through the inclusion of counseling, education and contraceptive services for men as well as women.

5. Young Adults

FHI is presently developing two studies to examine reproductive health issues of young adults in developing countries. Both are in sub-Saharan Africa and make use of data collection instruments designed for and used in recently completed investigations described above.

Surveys will be conducted in Harare, Zimbabwe and in urban areas of The Gambia. Although Zimbabwe probably has the highest rate of contraceptive use in sub-Saharan Africa, many women have a first pregnancy before age 18. No data are available for the Gambia on

adolescent pregnancy, but we suspect Gambia is similar to neighboring countries. In order to improve policy making and, where appropriate, programs that provide information on reproduction and contraceptive services, more information is needed on the current level of knowledge concerning reproduction, the percentage who are sexually active, the knowledge, attitudes and practices toward contraception, and aspirations concerning marriage, family and careers.

6. Other Studies

Finally, FHI is developing three projects in Kenya, several of which were proposed at a Workshop on Research Methods in Epidemiology, held in Mombassa in August 1985. They include: (1) Oral Contraceptive Compliance, (2) Complications of Female Sterilization, and (3) Health Workers' Attitudes Toward and Provision of Family Planning. AID Mission funding is currently being sought to support some of these project activities in Kenya.

C. Natural Family Planning/Breastfeeding

FHI initiated studies in natural family planning with the creation of an NFP research unit in 1983. The NFP Advisory Committee played an important role in assessing needs and setting research priorities. To forge a better integration of NFP with FHI's research activities on other methods of family planning, an NFP/BF unit was established in 1985 as one of three units in the newly-created Program Evaluation Department. By 1985 the FHI NFP/Breastfeeding program had become the largest single element of its kind in the AID portfolio.

In 1986 FHI has continued to support basic research, programmatic research, and surveys on the use-effectiveness of natural family planning methods in the general population. These studies create awareness about the function, acceptability and potential impact of NFP programs. Considerable emphasis is also put on the dissemination of findings.

Future work in NFP/Breastfeeding is being coordinated with the AID funded NFP project at Georgetown University, Washington, DC. FHI's work in NFP/BF is guided by the conviction that no single method of family planning is socially, culturally or psychologically acceptable to all couples wanting to control their fertility. No method of family planning is "perfect". Therefore, a cafeteria approach to family planning, in which NFP is one of the methods available, is necessary to provide choices for couples making decisions concerning fertility control. FHI encourages family planning agencies and organizations to incorporate NFP in their standard program. At the

same time, FHI believes that those practicing NFP have the right to information or referral to other methods of family planning. FHI believes that NFP should be promoted on its own merit rather than emphasizing the disadvantages of other methods of family planning. FHI has been working closely with programs offering NFP only as well as multi-method programs.

FHI has long recognized the importance of breastfeeding as a natural method of child spacing. In many developing countries, breastfeeding prevents more pregnancies than all other forms of contraception combined. This is in addition to the nutritional and protective health benefits breastfeeding provides for infants. There is, however, growing evidence of declining duration of breastfeeding among particular groups of women in developing countries. Some countries may have to increase contraceptive use dramatically just to hold fertility level, if breastfeeding continues to decline. Our work is directed toward measuring the child spacing effects of breastfeeding as well as studying ways to enhance this effect.

1. Natural Family Planning Studies

Peru: Introduction and Evaluation of an NFP Project in Lima

This project is designed to provide answers on how much effort, in human and financial resources, is required to set up an NFP service program in a developing country and how many people, at what cost, will use such a service and with what effectiveness.

A total of 278 couples were enrolled in NFP instruction through the Asociacion de Trabajo Laico Familiar (ATLF) by the end of the recruitment phase. A total of 4,979 people attended information meetings about the NFP service during the recruitment period. These meetings typically included about 15-20 couples each. The enrollment period is now finished, as well as the instruction period, and all couples are either in active follow-up, have completed a 12 cycle follow-up, or have discontinued. At last report, 36% of the enrolled couples had discontinued, the majority during the early part of the training period.

Several important findings have emerged; the following six factors were positively associated with the likelihood of remaining in the program:

- . age of the woman
- . length of marriage
- . number of living children
- . age of youngest child
- . amount of participation of male partner in learning and using the method
- . the woman (or couple) was recruited as part of a group (e.g., woman's club) rather than as an individual

The educational level of the couples in the study was concentrated at the primary school and secondary school years of completion. But those who completed only primary school had a greater likelihood of staying in the NFP program than those who completed both primary and

secondary school. The median income of those who are currently in the program was slightly greater than those who discontinued.

Follow-up will be completed in late 1986.

Sri Lanka: Family Planning Surveys

In several countries, the untutored use of the "rhythm" method and "traditional" methods of family planning is widespread. Between 1976 and 1981, the proportion of contraceptive users using these "non-program" methods increased from approximately 15% to more than 25% in Sri Lanka. This increase has generated a high degree of curiosity among family planning program managers and policymakers in Sri Lanka. In order to determine whether these practices have a demographic impact, and whether they suggest a latent demand for NFP services, FHI is currently supporting two family planning survey projects in Sri Lanka.

The first project, with the Department of Census and Statistics, involves following up a national sample (both urban and rural) from the 1982 Contraceptive Prevalence Survey. The basic purpose is to investigate the reasons for the increase in the use of "non-program" methods. The first part of the project, which involved in-depth interviews to identify local and folk expressions used to refer to "non-program" methods of family planning, is completed. The findings of the first phase were utilized to develop the survey questionnaire.

Survey fieldwork began in early March 1985 and was completed in May 1985. More than 2,300 women of reproductive age and 580 of their husbands were interviewed. The data are being analyzed. The final report will include eight chapters covering such topics as knowledge and misconceptions about modern and traditional family planning methods, contraceptive use, switching and discontinuation, and husband and wife communication and decision-making in family planning matters. A seminar to highlight the findings of the study will be held in May 1986.

The Family Planning Association of Sri Lanka has undertaken the Rural Family Planning Survey project, which measures the use-effectiveness of various family planning methods, including traditional and natural methods. A newly developed methodology uses retrospective data (up to three years preceding the survey date) to estimate use-effectiveness of each family planning method (individual as well as combined methods). Data collection instruments have been prepared based on the information obtained from focus groups. A training workshop for interviewers and supervisors was held in 1985 during which the questionnaire was pretested. The fieldwork for the project will be completed in April 1986. Approximately 3,500 rural women will be interviewed. Community level data are also being collected.

Bangladesh: Caritas Service Statistics Project

FHI supported a project to analyze service statistics of the CARITAS (a voluntary Catholic social service organization) NFP program in Bangladesh. Since 1976, CARITAS has provided training to, and

collected data from, 2,453 eligible women in 13 districts of the country. The NFP program has 29 centers including one in Dhaka. FHI provided support to a local research agency, the B-SMERT Corporation, to process the service statistics and assist CARITAS to improve the service statistics system. The final report of the project has been submitted to FHI. Results are scheduled to be presented at the IFFLP Meeting in Ottawa in June 1986.

Egypt: Evaluation of an NFP Program

A small retrospective study was undertaken in Egypt to examine the characteristics of those who entered a Billings program to determine which couples completed the six month training period and used the method successfully and which couples did not. In this project, procedures were developed for locating and interviewing people trained in the past to determine the feasibility of research in continuation and effectiveness rates. A description of couples already trained was compiled and stratified according to the couple's family planning intentions and the incidence of pregnancy. The final report of this project will be available within the next few months.

India: Evaluation of NFP in a Tribal Population and Technical Assistance CREST

In the course of preparing a report, Natural Family Planning in India: An Overview, Dr. Mary Thormann was informed that 8,000 Lombardis, a tribal population, had been instructed in NFP and that

accurate records had been maintained. Since tribal populations in India usually have low levels of formal education and little exposure to development, they are an interesting test case of whether such couples can successfully learn to use NFP methods. A subsequent site visit revealed that although 9,500 couples had apparently been instructed in NFP in the Vijayawada Dioceses of Andhra Pradesh, only 420 of those were Lombardis. Complete records had not been maintained and no follow-up information was available. Copies of records for 400 NFP acceptors were made. Of these, only three were identified as Lombardis. At this point, the project ended due to opposition by the President of the Natural Family Planning Association of India.

FHI also supported Dr. Mary Thormann as a consultant to CREST to help revise and update the book, The Natural Family Planning Teacher. The new version was published by the Asian Trading Corporation in the Fall 1985.

Canada: Study of the Relationship of Cervical Characteristics to Mucus and Temperature Symptoms among Experienced NFP Users

With FHI support, SERENA Canada has conducted a secondary analysis of NFP charts of women experienced in cervical self-examination. The analysis addresses the temporal relationship between the cervical changes found by self-examination and the vulvar mucus and waking temperature signs at the end of the cycle's fertile phase. The findings demonstrate that cervical changes are good indicators of the

actions of estrogen and progesterone since they correspond well with the peak mucus symptom and temperature shift. Fairly large intra-woman variations were observed which may be the effect of a learning curve. Comparisons between women above and below 40 years suggest that the cervical signs are not impaired with age. The final report is available and publication is planned.

US: Analysis of Baseline and Follow-up Data from NFP Programs in Five Countries

The purpose of this study is twofold: 1) to analyze baseline socio-demographic data on natural family planning acceptors in five countries and 2) to assess continuation and use-effectiveness among these acceptors. Analysis of these data will provide a better understanding of the associations between socio-demographic variables and NFP use and continuation, and will allow international comparison of five programs (in the US, Kenya, India, Korea and Bangladesh). Data on approximately 200 consecutive NFP acceptors in Billings Ovulation method programs in each of these countries are being analyzed by Dr. Miriam Labbok of the Department of Population Dynamics, the Johns Hopkins University. Dr. Hanna Klaus initiated the study and data collection while the Johns Hopkins University is responsible for data analysis and write up.

US: Secondary Analysis of Chilean Data on NFP and Breastfeeding

Dr. Alfredo Perez has gathered data on more than 400 breastfeeding women in Santiago, Chile who practiced the Billings Method. These

data are being analyzed by Dr. Miriam Labbok at Johns Hopkins University. She is exploring the associations of signs and symptoms of NFP with infant feeding behaviors. This analysis should help refine the role of NFP symptoms in lactating women and their value in predicting the return of fertility. Information on the efficacy of the Billings Method in this special population will also be obtained. Publications of the results should be of interest to the NFP community, lactating women and family planning professionals.

NFP Research Methodology Workshop

As recommended by the NFP Advisory Committee, FHI is sponsoring an NFP Research Methods Workshop as part of the 4th World Congress of the International Federation for Family Life Promotion (IFFLP) in Ottawa, Canada, 23 June - 3 July 1986. The objective of the workshop will be to create a pool of NFP program managers who are capable of identifying potential NFP research areas in their respective countries and are able to work with funding and technical assistance agencies in designing and carrying out NFP research projects. The workshop will be sponsored jointly by FHI, IFFLP, WHO and the Johns Hopkins University.

US: Development of NFP Evaluation Forms

With the Johns Hopkins University and IFFLP, FHI is developing simplified forms and manuals to evaluate pre-existing as well as new NFP programs. The form to be used for the evaluation of a pre-existing program includes teaching, use-effectiveness and

discontinuation items. This instrument will permit the efficient evaluation of retrospective data.

A second set of forms is being developed for new NFP programs. This set includes four instruments, one each to measure acceptability, teaching, use-effectiveness and discontinuation. These forms are designed for prospective data collection.

The forms will be reviewed at the Ottawa NFP Research Workshop. Following the workshop, the participants will be asked to pretest the forms in their respective countries and the results will be used to finalize the forms. FHI plans eventually to develop a micro-computer package to process the forms and produce a set of standard tables.

UK: Physicians' KAP Study Regarding NFP in Selected Developing Countries

Since NFP receives uneven acceptance around the world and because physicians are often the leaders of social acceptance of family planning methods, FHI supported a study which explored the knowledge, attitudes and behavioral intentions of physicians toward NFP programs. This KAP study was implemented by the Institute for Population Studies at the University of Exeter, UK in Mauritius, Peru, the Philippines and Sri Lanka.

In-country principal investigators (PIs) initially conducted pilot interviews, or focus groups, with small numbers of providers. Then they attended a meeting at Exeter with Institute staff and designed a

cross-cultural KAP questionnaire based on those interviews. Quota samples of 100 suitable respondents were selected within each country and interviews were conducted by the PIs. They prepared summary reports of the results and reconvened to refine their country's reports. At this second meeting, they prepared a cross-cultural report and finalized a model questionnaire that can serve as a tool for subsequent researchers in other countries.

The findings suggest that the amount of NFP knowledge a physician has and the physician's overall attitude toward a particular method (i.e., whether a method is good, useful or scientifically sound) can predict a physician's willingness to provide services, seek information, and in essence, encourage his/her patients to use (or not use) a method. Knowledge and the religiosity of the physician were particularly important in the Philippines. Several publications are in preparation, and the findings of the study will be presented at the IFFLP World Congress in June 1986.

NFP Review Paper

At the request of the Demographic Data for Development (DDD) Project of Westinghouse Health Systems, FHI prepared a monograph entitled Periodic Abstinence in Developing Countries: Update and Options. The paper contains new information on prevalence levels of periodic abstinence methods, use-effectiveness and psychosocial issues. A final section describes program and policy considerations for family planning policymakers and program managers in developing countries. A description of selected countries where periodic abstinence is

popular is appended. The monograph will be published as an Occasional Paper of the DDD Project of Westinghouse in mid-1986. It has been widely reviewed and should make a major contribution to information dissemination about periodic abstinence. We hope to have copies available at the IFFLP meeting in Ottawa in June 1986.

2. Breastfeeding Studies

Family Planning programs have given insufficient attention to breastfeeding which is a major means of birth spacing in many developing countries. It is both a natural method of birth spacing and highly significant to the welfare of the infant. FHI's research addresses the birth spacing effect of breastfeeding and how it can be maximized.

Multi-center Longitudinal Study of Breastfeeding and Return to Fertility in Selected Developing Countries

This study follows a small group of breastfeeding women from delivery through ovulation and compares them to non-breastfeeding controls to determine the effect of breastfeeding patterns on the timing of ovulation. The aim is to provide guidelines that individual women can follow to determine when to initiate another family planning method.

Centers in four countries are involved in this study. Pramongkutklao Hospital in Bangkok, Thailand and the Instituto de Investigacion Cientifica in Durango, Mexico have completed the study, and several

findings appear below. Data from the Assiut University Hospital have been collected and are being queried at this time. Data collection is in progress at the National Research Institute for Fertility Control in Karachi, Pakistan. The data from Mexico and Thailand have clearly documented the contraceptive effects of breastfeeding, and in particular the effect of breastfeeding frequency. The frequency of breastfeeding per day, night and 24 hours was similar in both sets of women during the week of the first ovulation (i.e. a mean of nine breastfeeding episodes per 24 hours with a range of 0-15 episodes). This similarity of breastfeeding frequency occurred despite the great difference in median duration until first ovulation, at five months in Mexico and nine months in Thailand.

Similarly, small proportions of women in both settings ovulated prior to all three of these events: the initiation of supplementation, vaginal bleeding or menses, and the three month birthday of the child. Some of the early ovulations observed probably had defective luteal phases, and so the risk of conception before any of these three events is very low. Among the controls, under comparable conditions, 40-50% were ovulatory.

A series of reports and publications from this study are being prepared.

Philippines: Effect of an Education Program on Breastfeeding Practices and Duration of Postpartum Amenorrhea in a Rural Area

FHI is supporting a prospective study with Silliman University in Dumaguete, Philippines, in which pregnant women are being taught techniques and principles for maximizing the nutritional and contraceptive benefits of breastfeeding. A control group of mothers not exposed to such teaching is also being monitored. The duration of postpartum amenorrhea and patterns of infant feeding will be compared between the group receiving the educational program and the control group. During this reporting period, the education program was designed, data collection instruments were pre-tested, staff were trained, and pregnant women were recruited. The study team has developed and tested educational modules on breastfeeding practices that may enhance the postponement of a menses such as breastfeeding on demand, breastfeeding at night, etc. They have printed attractive posters and other materials. Monthly follow-up data are being collected at this time. All study subjects have been recruited (135 in all) and are being followed up until they have two menses.

Indonesia: Breastfeeding and the Modern Health Sector

The purpose of this project was to collect information to assist hospital administrators and perinatal care providers (i.e., obstetricians, pediatricians, nutritionists, nurse-midwives and nurses) to establish a "rooming-in" system throughout all hospitals in Indonesia. The project identified the nature and extent of needs, problems and obstacles related to implementing a new policy for

rooming-in. The specific objectives were: to assess the attitudes about breastfeeding and rooming-in and knowledge about the infant health and contraceptive effects of breastfeeding, of perinatal care providers, hospital administrators and mothers who enter hospitals for delivery; and to investigate the current hospital policies and practices regarding rooming-in and infant feeding.

Three papers based on the results of the study were presented at the Conference of Hospital Administrators held 8-15 May 1985 in Jakarta and were well received. A set of resolutions, based on the survey findings, were passed at that conference and were recommended to the Department of Health for implementation.

Based on the needs, as assessed by this survey, the AID Mission in Jakarta has expressed interest in supporting the development of a training program for the management of breastfeeding and rooming-in in Indonesian hospitals. Study findings were also presented at the Congress of OB/GYN for Asia and the Pacific held in September in Colombo, Sri Lanka and at the World Congress of OB/GYN in Berlin, 15-21 September 1985.

The final report of the project is being prepared and in order to disseminate the results to an international audience, two papers will be forwarded for publication.

US: Breastfeeding Trends in Developing Countries

Despite the widespread impression that breastfeeding is plummeting throughout the developing world, there is remarkably little research on breastfeeding trends. FHI is supporting a project, being carried out at Brown University, to analyze breastfeeding trends over the last decade in selected developing countries.

A set of sixteen developing countries has been identified in which at least two nationally representative surveys in the last decade gathered comparable information on breastfeeding and other aspects of reproductive behavior. These surveys cover a diverse set of nations in three continents. In each case, the first of the pair of surveys is part of the World Fertility Survey and the second is a Contraceptive Prevalence Survey. Comparable data from the two time points can be used to establish the feeding patterns in effect in each country at those times. This analysis will look at trends for each of the countries considered as well as for subgroups (urban/rural, educated/illiterate, etc.). Due to budgetary constraints, the present project is for analysis of data for only a few of the countries identified (Dominican Republic, Sri Lanka, Jamaica, Haiti and possibly Kenya).

Multi-Center: Study of NFP Used by Breastfeeding Women in Selected Countries

FHI has initiated the first setting of a multi-center study of NFP use among breastfeeding women with SERENA, CANADA. During the

reporting period, Drs. Suzanne Parenteau-Carreau, Anna Flynn and Barbara Gross, the Principal Investigators, met at FHI to finalize the protocol and obtain consensus on the operational definitions to be utilized during data collection and analysis.

Breastfeeding mothers who are experienced NFP users will record their mucus symptoms, basal body temperature, cervical position (in some cases), and infant feeding information on a daily basis. Daily urine samples and serial ultrasonography (in some cases) will reveal the time of onset of ovarian follicular activity and first postpartum ovulation. The data analysis will be oriented toward finding the simplest NFP rules to predict the onset of fertility in the breastfeeding women, and to determine the role of breastfeeding in the occurrence of the NFP symptoms. We plan to initiate the other two sites by mid 1986. Discussions are underway with Georgetown University for them to be involved in this study.

Future Plans: Natural Family Planning

NFP Advisory Committee:

The NFP/BF Advisory Committee will meet for the third time 21-22 April 1986. Special attention will be given to completed and ongoing breastfeeding research and on reviewing a strategy for future research in breastfeeding as a child spacing method.

Kenya: Evaluation of Two NFP Programs and Technical Assistance

Preparations for two NFP studies in Kenya were made during the reporting period. The first project in Nyeri/Othaya District will: (1) investigate the similarities and differences of long- and short-term users of the Ovulation Method, (2) assess the efficacy of methods practiced among long-term users and, (3) examine economic, demographic and socio-psychological motivational factors associated with low and high degrees of efficacy of NFP methods practiced in Kenya.

The second project will be carried out in Meru Province, a district with a population of nearly one million. NFP was introduced and has been actively pursued under the auspices of the Diocese of Meru. Kenya Catholic Services (KCS) has prepared a list of 1000 couples who have been trained in NFP (mostly OM), 450 of whom are believed to be continuing users. The project will involve a baseline survey and follow-up of continuing users to determine the efficacy of the method practiced.

FHI continues to provide technical assistance for the Pathfinder Fund supported NFP project in Kenya. The project introduces NFP educational services at the Kenyatta National Hospital and seven Maternity hospitals. This project is to be undertaken in collaboration with the Kenya Medical Research Institute in Nairobi. It is the first time NFP services are offered as part of family

planning service delivery in Kenyan Government hospitals. The project will train selected nurses in these national hospitals in NFP teaching methods.

Mexico: NFP Use Effectiveness Study

An NFP service program, CEIPLAN, based in Mexico would like to conduct an evaluation of use effectiveness, continuation and client satisfaction with NFP. An extensive site visit was conducted in the Fall of 1984 to determine the need and feasibility of such a study. A summary of the final report of the site visit is now available for distribution. The study design is being finalized, based on discussions among FHI consultant Dr. Harrison McKay, several government officials and the Executive Director of CEIPLAN. Assuming AID/Mexico approval and agreement on the design and budget, the study could start by the Summer of 1986.

Indonesia: Multi-center Trial of Three NFP Approaches

A proposal for a prospective multi-center trial of three NFP methods in Indonesia was prepared at a working meeting held in Jakarta in 1985. The main objectives of this project are to implement a scientifically valid study aimed at evaluating the teaching, learning and use-effectiveness of three NFP approaches: 1) the Ovulation (Billings) Method, 2) the modified mucus method and 3) a mix of the two methods. Plans are to conduct the project in five locations in Indonesia where there are on-going NFP programs. The implementing

agency will be PERDHAKI (Voluntary Health Services Association of Indonesia). The study is scheduled to start in mid-1986.

Philippines: Effectiveness of NFP in a Multi-Method Setting

The Family Planning Organization of the Philippines now provides, through its affiliate network, a variety of family planning methods for spacing and limiting family size. It has included calendar rhythm but not modern NFP methods. The organization would like to upgrade its NFP services and then compare use effectiveness, continuation, client satisfaction, and cost effectiveness of five "temporary" methods: NFP (probably the Ovulation Method), pills, injections, spermicides and condoms. Five affiliates will enroll the first 40 acceptors of each of these five temporary methods. Clients will be followed up for one year. The current plan is for Georgetown University to fund the first part of the project, upgrading NFP services, with FHI to support the evaluation phase. Realistically, FHI's part will not start until FY87.

Sri Lanka: Trends and Determinants of Changes in Use of Natural and Traditional Methods

The purpose of this project is to investigate the factors behind the rise in traditional contraceptive use, using three data sets: the 1975 World Fertility Survey, the World Bank-supported national survey of 1979, and the 1982 Contraceptive Prevalence Survey. The hypothesis considered most plausible and the one to be tested in this

analysis is that compositional differences between the three survey samples, in particular with respect to duration of marriage, account for a major part of the upward trend in traditional method use. Since age at marriage has also increased significantly in Sri Lanka, it is likely that the recently married cohorts are also older hence less interested in permanent (or highly effective) methods until they achieve their ideal family size.

The steps for testing this explanation will involve: a) examining trends in and shifts between modern and natural contraceptive use during 1975 to 1982; b) standardizing the prevalence levels by duration of marriage to control for compositional differences among childbearing women sampled in the surveys; and, c) conducting a decompositional analysis of the natural method prevalence level at both aggregate and individual levels.

The project will be carried out at the Carolina Population Center in collaboration with the Sri Lanka Department of Census and Statistics starting in June 1986 and will be completed in this fiscal year.

Australia: Development of Home Assay Kits for NFP Users

FHI plans to provide core support to Professor James Brown at the University of Melbourne for the purpose of replicating and field testing enzyme immunoassay home test kits for predicting and detecting ovulation. The kit is intended to be used by women whose mucus patterns are difficult to interpret (e.g., breastfeeding and pre-menopausal women) and by teachers while they are instructing new

clients. The kits may improve a couple's confidence while learning and using NFP, as well as improve the effectiveness of NFP. This work is also being supported by the Ovulation Method Research Center.

Future Plans: Breastfeeding

Effect of an Education Program on Breastfeeding Practices and Duration of Postpartum Amenorrhea

A rural breastfeeding study is underway in the Philippines that is evaluating the impact of an educational program promoting frequent breastfeeding on the postpartum amenorrheic period. We hope to replicate this study in other areas: an urban area of the Philippines, in Egypt or in Honduras. We are currently seeking local funding for in-country field costs in several sites.

US: Determinants of Breastfeeding in the Philippines

A secondary analysis of three national fertility surveys in the Philippines (1973, 1978, and 1983) is planned at the University of North Carolina. The purpose is to identify the social and economic factors associated with different breastfeeding patterns over time. It is important to identify groups where changes in breastfeeding are occurring in order to plan appropriate intervention programs.

Breastfeeding as a Child Spacing Method: A Pamphlet for Program Managers and Physicians

Many family planning managers and physicians are skeptical that breastfeeding makes a major contribution to child spacing for the individual woman. This pamphlet would review research findings on the effectiveness of breastfeeding, compared with other methods used in the postpartum period. It will review research that has attempted to predict returning fertility and will suggest guidelines that breastfeeding women can use to decide when they should stop relying on breastfeeding as a child spacing method. This project may be done with other organizations (tentatively, the WHO and Georgetown University).

VI. FIELD DEVELOPMENT AND TRAINING

The Field Development and Training Division (FDT) has as its primary objectives the development of institutional research capabilities and skilled investigators in priority countries through training and institutional development programs; the transfer of contraceptive technology to LDC programs; and the dissemination of research findings and information through publications, workshops, seminars and support for collaborating investigators to attend international conferences. In addition to providing funding and staff support for these activities, FDT plays a major role in providing field support to the other research divisions, including the identification and development of projects and coordination of the field approval process through local governments and AID Missions, study monitoring as needed, and coordination of international travel.

Activities during this reporting period are separated into the following areas: institutional development - support to family health research centers (FHRCs); training; transfer of contraceptive technology; and information dissemination.

A. Institutional Development - Support to Family Health Research Centers (FHRCs)

1. Maturing FHRCs - The majority of FDT funding goes to support six FHRC's established, for the most part, in mid to late 1970s. These programs vary in focus, structure and level of development depending

on the context in which they operate, but share the common goal of providing a national research resource for family planning policymakers and providers in their countries. The six well established FHRC's are located in Thailand, Indonesia, Bangladesh, Sri Lanka, Egypt and Sudan. Activities funded during this reporting period are described below for each FHRC, as are activities planned for the next six months.

Thailand Fertility Research Association (TFRA)

The TFRA was established with FHI assistance in 1979 to serve as a national center for research in support of the National Family Planning Program (NFPP). The TFRA is a private, non-profit organization that operates within the administrative structure of the Ministry of Public Health (MOPH) in Bangkok, and therefore enjoys a close two-way relationship with the NFPP. As such, it is uniquely situated to enlist and coordinate capable researchers from both the private and public sectors--including centers serving small towns and rural populations. The TFRA's network consists of physician researchers from each of the country's medical schools and from numerous MOPH hospitals and MCH centers all over Thailand. The TFRA's close association with the MOPH also assures that research findings will reach relevant policymakers.

Successive FHI subgrants since 1980 have provided financial and technical support aimed at developing the TFRA's skills and resources, meeting core administrative costs, and funding specific research studies. The MOPH has also provided significant core

support, in the form of office space, transportation and personnel, and, since October 1983, it has also assumed the direct study costs for the Sukhotai Province MCM program, formerly supported by FHI. In addition, the TFRA is now conducting two clinical trials with funding from private pharmaceutical companies and has initiated three major studies under separate contracts with FHI. Final approval is expected soon for a study with funding from AID (bilateral funds).

The TFRA has made good progress in developing its data processing and analysis skills. A new TI-352 microcomputer was installed in October 1984, and training provided in its use. The TFRA's model TI-1 was transferred to a collaborating center at Khon Kaen. In May 1984, the TFRA's research analyst, Ms. Pattaka Piyapinyo, visited FHI for six weeks of training in microcomputer use and data analysis.

Ms. Pattaka has written consultant reports on several completed TFRA studies and is monitoring current studies. Plans are now being finalized to provide similar training at FHI to the TFRA's data collection coordinator, Ms. Mukda Takudtong, in June 1986.

During this reporting period, the TFRA completed the following studies:

- Study of microdose OCs: Microlut vs Exluton
- Long term follow-up study of IUD acceptors

Work continued on the following studies:

- Comparative study of mini IUDs: Minigravigard vs Nova T vs ML Short

- Comparative interval female sterilization study:
Filshie clip vs tubal ring via laparoscopy
- IUD perforation study (in analysis stage)

Just initiated, in March 1986:

- Comparative interval female sterilization study:
Filshie clip vs modified Pomeroy technique via
minilaparotomy

In addition to the preceding studies, the TFRA is currently conducting several studies under separate contracts with FHI and other funding sources.

These studies include:

- Infant health follow-up in Sukhotai (FHI)
- Postpartum sterilization by nurses (FHI)
- Progestogen-only pills for lactating women (FHI)
- Perception of pill safety survey (FHI)
- Follow-up study of Uttradit IUD campaign (AID)
- Eugynon vs Microgynon 30 (Schering)
- Ovral vs Marvelon (Organon)
- MCM research in Sukhotai (Ministry of Health)

Core support contributes to the TFRA's ability to carry out effectively both subagreement and other contract studies. As FHI's core support is gradually phased out, the TFRA will seek additional core support from the Thai Ministry of Public Health and indirect cost reimbursement as part of their grants and contracts from all sources. A visit to Thailand in March 1986 by FHI's financial

management consultants (from Deloitte, Haskins & Sells International, (DH&S)) provided an in-depth assessment of the TFRA's current systems and needs for future assistance in this area.

Indonesia Fertility Research Coordinating Board (BKS PENFIN)

Since January 1979, FHI has provided financial and technical assistance to the BKS PENFIN, a private, non-profit fertility research organization located in Bandung, Indonesia, and composed of 14 (originally 12) member centers that are Government University teaching hospital departments of Ob/Gyn. The BKS PENFIN was established to serve the research needs of the Indonesian national family planning program. With FHI assistance, the BKS PENFIN has conducted a wide range of contraceptive clinical trials, maternity care studies and other reproductive health research. It has conducted numerous training activities and conferences to upgrade the clinical research skills of Indonesian physicians while disseminating widely the results of the BKS PENFIN studies.

As both the capacity of the BKS PENFIN centers to do clinical research and the capacity of the Secretariat at Bandung to coordinate such research (including data processing, analysis and computer skills) have increased, so too has the BKS PENFIN's ability to attract research work from various sources. The BKS PENFIN uses its own Texas Instruments TI-352 microcomputer (provided by FHI in 1984) and has access to a mainframe computer in Bandung. A TI-1 microcomputer (provided in 1982) has been transferred to BKS PENFIN's center in Yogyakarta. In fact, since October 1982, FHI subgrants to

the BKS PENFIN have no longer included direct support for specific studies. Rather, their recent subgrants have provided institutional development assistance and core support to help the BKS PENFIN carry out the varied research program that it has developed in cooperation with several other funding sources, including the Indonesian Government, international agencies, private pharmaceutical companies and, more recently, FHI's Clinical Trials Division.

During the past year, highest priority has been given to completion of the large BKKBN Biomedical Research Program, involving comparative IUD and oral contraceptive studies. The IUD study was completed on schedule, and a preliminary report has been made to the BKKBN. Opportunities exist for useful secondary analysis of this data set, with FHI assistance. The oral contraceptive study had to be extended due to slow recruitment, but the data collection phase has now been completed. Data processing and analysis have also been delayed due to technical difficulties. Training provided to the BKS PENFIN's new Senior Program Officer, Dr. Soeprapti Thaib, during her visit to FHI October-November 1985, included assistance in processing and analyzing their large OC data sets. Final reports have recently been completed by BKS PENFIN and submitted to BKKBN.

Another top priority over the past year has been to plan and initiate a gradual transition from FHI grant support to contract funding. Future levels of core support provided by FHI will decline, but FHI will seek to contract with BKS PENFIN to conduct both FHI strategy studies and Indonesian programmatic research proposed by the BKS PENFIN with the endorsement of the BKKBN. Reduction in core support,

beginning in FY86, will have to be made up through reduced general administration costs and indirect cost recovery through implementation of an overhead system. A major objective in the coming year involving FHI assistance will be to implement the planning and financial management systems necessary to make this transition. A visit to BKS PENFIN by DH&S consultants in March 1986 provided an opportunity for an in-depth assessment of the financial systems and needs.

Already, several FHI contract studies have been planned for FY86-87, including a 3000 case evaluation of the TCU380, a 300 case study of the Filshie Clip vs Tubal Ring (via laparoscopy), and a study of oral contraceptives with and without iron supplements. The TCU380 and Filshie Clip studies were initiated in FY86. Planning and training for the OC with iron study have also been completed, with initiation of data collection scheduled to begin soon. Other studies, funded by non-FHI sources, are also continuing, and new ones are planned. BKS PENFIN is trying to maintain a diversified program of research (including both contraceptive and reproductive health components), with a correspondingly diversified range of funding sources. BKS PENFIN will make its data processing facilities available, on a cost reimbursement basis, to another non-government organization, PERDHAKI, that is conducting an FHI study of three NFP approaches.

Training plans for this year in cooperation with FHI include workshops on clinical trials research methods and data analysis. Opportunities to collaborate on multicenter epidemiological research, which would include a training component, are being explored.

Family Planning Association of Sri Lanka (FPA/SL)

The Family Planning Association of Sri Lanka (FPA/SL) is a non-governmental organization providing family planning clinical services, motivation of potential acceptors and contraceptive products to the country. After nearly ten years of clinical trials collaboration with FHI, a Family Health Research Center was established within the Research and Evaluation wing of the FPA/SL in late 1983. The current subagreement marks the third year of funding for this project.

During this period, activity has focused on four areas: clinical trials research, network development, research training and report writing. While subcontract clinical trials of NORPLANT® involving 475 women (including 75 cases under a research contract with Leiras Pharmaceuticals) are on-going at the FPA's two clinical sites in Colombo and Kandy, two new subcontract studies were undertaken: a 300-case comparative study of the oral contraceptives Triquilar and Lo-Femenal, and a 300-case comparative study of the IUDs TCU380A and Multiload Cu250. The latter study is being undertaken by an FPA staff physician who received training at FHI's Research Methods Workshop in Singapore in July 1985.

A second physician who attended that workshop is the FPA's first collaborating investigator. This physician, who works at the Faculty of Medicine in Galle, has also initiated a study of the IUDs TCU380A and the Multiload Cu250, under the supervision of the FPA. Staff at

the Galle center were trained in data collection methods by FPA staff.

A research methods workshop, based on the materials used at the Singapore workshop is also being planned for May 1986. In addition to FHI personnel, the workshop will be led by FPA staff and other Sri Lankan physicians who were trained last summer in Singapore.

Responses to the workshop advertisement have numbered over 100 physicians from a broad range of organizational affiliations, and are far in excess of the anticipated interest.

Reports published recently include "Knowledge and Attitudes about Reproductive Health among Youth in Sri Lanka," and "Considerations in Improving Follow-Up in Clinical Trials", both of which were written by Dr. Sriani Basnayake, Medical Director of the FPA/SL. FHI staff also assisted Dr. Basnayake in the analysis of clinic records and editing of her paper, "Depo-Provera Use in Sri Lanka: Acceptor Characteristics, Continuation and Side-Effects".

Studies underway with subagreement funding include "Attitudes Toward Vasectomy" (report being written), "Follow-up of Female Sterilization Acceptors" (enrollment complete; follow-up in progress), and "Infertility Study" (data collection complete; data analysis underway). A study to look at the variables influencing acceptance of vasectomy will be initiated before the end of the fiscal year.

Other studies conducted under contract to FHI include a survey of oral contraceptive pill safety (completed in February) and a large

Rural Family Planning Survey (on-going). The latter will provide extremely useful information relating to acceptability, satisfaction, and reasons for continuation and discontinuation of family planning methods.

The FPA/SL's TI-352 microcomputer has been continuously used almost since the day it was installed in July 1984. With a computer programmer trained at FHI and two data processors, the FPA/SL has attained a high level of proficiency, and uses the computer for various management purposes as well as research. The FPA/SL is exploring purchase of an IBM PC-AT to supplement and handle spill-over from the TI-352.

The FPA/SL devoted considerable energy this winter to development of a five-year plan which provides a framework for management, research, and funding. The plan reflects the slow decline of FHI core funding and its replacement with funds from other sources. The plan has been submitted to the Ministry of Plan Implementation and AID/Colombo for their approval of the intended directions of the organization.

Bangladesh Fertility Research Programme (BFRP)

The Bangladesh Fertility Research Programme (BFRP) has probably the most extensive network of centers and clinical investigators of any of the Family Health Research Centers. It has historically been the primary coordinating body for clinical trials research in the country and is viewed by the Ministry of Health and Population Control as the

gateway for introduction of new contraceptive methods into the country.

The BFRP was established in 1976 as a quasi-governmental research organization funded by the International Fertility Research Programme (IFRP). It operates under the guidance of an Executive Council chaired by the Secretary of the Ministry of Health and Population Control. The BFRP coordinates a network of 35 participating hospitals, clinics, researchers and has a core administrative staff responsible for planning, implementing, and monitoring research.

During this six month period, studies were underway at twelve different centers. Subcontract studies included three 200-case introductory NORPLANT® trials, and a non-comparative subcontract study of the progestogen-only pill, Exluton. A comparative study of Triquilar and Marvelon was also initiated. Subagreement studies included a double-blind, three-way comparative study of three oral contraceptives; two comparative studies of oral contraceptives supplemented with vitamins; a comparative IUD study of TCu380A vs ML 375; two comparative IUD studies of the Cu200 with vitamin supplements; and a long-term follow-up of female sterilization.

After nearly 8 months without a full-time director, the new appointee, Dr. Halida Akhter, joined the organization in February 1986. After attending the FHRC Directors Conference in Chiang Mai, Dr. Akhter returned to Bangladesh and immersed herself in orientation and planning activities. In the midst of a round of introductory meetings with government and international agency officials and study

investigators, Dr. Akhter developed a comprehensive workplan for fiscal year 1986. Plans were made for FHI technical assistance in research methodology including a refresher course for BFRP staff and for a research methods workshop to be held for clinical trials investigators in the Fall. Discussions also began for expansion of the NORPLANT® clinical trials studies and a re-designed study of female sterilizations with and without antibiotics. Dr. Akhter is exploring donor funding for expanded NORPLANT® trials and a maternal mortality study.

By June 1986 the BFRP will publish a brochure describing its goals and the activities it is both currently undertaking and plans to carry out during FY'86. A newsletter summarizing research findings and exploring topical research issues on family planning will be released at the same time.

BFRP plans to establish data processing capability, with the installation of a TI-351 microcomputer and the training of BFRP staff in its use. The microcomputer, which should reach Dhaka in June 1986, will open many new opportunities for the organization for processing its own data and contracting to process data generated elsewhere. In-house data analysis will become possible for the first time, rather than having to send all data to FHI for processing. With these changes, BFRP looks forward to a dynamic and progressive year.

Egyptian Fertility Care Society (EFCS)

The Egyptian Fertility Care Society (EFCS) is a voluntary organization affiliated with the Egyptian Medical Association. Founded in 1974 with a membership of over 260 medical specialists, EFCS nationally works closely with the Egyptian Ministry of Health (MOH), the National Population Council (NPC), the Egyptian Society of Ob/Gyn and the Egyptian Family Planning Association. Internationally, EFCS has maintained working relationships with FHI, the WHO, PIACT, AVS, JHPIEGO, AID and others. The EFCS has been recognized by officials of the National Population Council as the research wing of the Egyptian National Population Program.

FHI began support for the EFCS in October 1980. The purpose of this support is to develop an independent research institution through training and research assistance. The current subagreement concentrates on clinical trials, information dissemination, individual training and workshops. All projects are designed to: expand knowledge of the safe, effective and acceptable usage of family planning methods; increase the knowledge and skills of the EFCS staff; and expand the research capabilities of EFCS through motivation and training of a large network of medical collaborators.

In order to expand EFCS's data processing and analysis skills FHI donated a Texas Instruments microcomputer in August 1984. FHI under this agreement also provided required follow-up and training.

During 1984 and 1985, EFCS conducted the following activities:

Institutional Development

- EFCS moved to larger, more adequate office space.
- Program Officer and two Scanner Operators were hired.
- Two Clinical Trials Workshops were held.
- EFCS staff received training on the use of the microcomputer.
- The Data Collection Coordinator received two weeks training on data analysis at FHI.

Research Activities

- A comparative study of the TCU 200 vs ML 250 vs Lippes Loop C was conducted at three centers.
- A maternity care monitoring study was initiated at three centers.

Over the same period EFCS assisted in the following projects under separate agreement:

- Coordination of a comparative study TCU380A vs TCU200 at four centers (ongoing).
- Conducted a NORPLANT® coordinating meeting (April 1984).
- Conducted a Breastfeeding Workshop (August 1984).
- Published a Physicians/Pharmacist Bulletin. (Finalized December 1985).

Under the new subagreement the following activities are planned:

- Continuation and expansion of the MCM study initiated under SIN 1259
- Continuation of the ongoing 3-way IUD study
- Initiation of a comparative three-way oral contraceptive study (Triovular® vs. Ovral® vs. Nordette®) - (January 1986)
- Two clinical research skills workshops will be held (19 July 1986).
- The publication of the "Fertility Care Bulletin" will continue.
- There will be EFCS investigator meetings in June 1986, 1987 and a MCM meeting in November 1986.
- The Data Analyst will receive further training at FHI in June 1986.
- Follow up training for the Texas Instruments microcomputer will take place in August 1986.

In addition to the above listed studies, core support received will indirectly support the following studies:

- A study on the perceptions of oral contraceptive pill safety
- Completion of an injectable contraceptive study funded by the WHO

With FHI support the EFCS has been able to grow as a research institute of national prominence. EFCS is entering a new era in which independence will be sought through improved financial management skills and the diversification of funding sources. A

draft five-year plan has been submitted to FHI for review on an initial phase of the process. The current two-year agreement became effective as of 1 January 1986.

Sudan Fertility Control Association (SFCA)

The SFCA has received assistance from FHI beginning in 1979. Since that time this FHRC has established itself as a national organization for research in family planning and maternal and child health. Membership of the SFCA has grown to more than one hundred, mostly obstetrician-gynecologists and physicians interested in family planning. Plans are being initiated to expand SFCA activities into areas outside of Khartoum. The SFCA places major emphasis on the development of its clinical trials capability in order to determine safe, effective and acceptable methods of family planning for the Sudan. To achieve geographic and organizational expansion the SFCA emphasizes training, workshops and projects that will expose members to new learning experiences in regional research projects.

FHI subgrants have provided financial and technical support aimed at developing the SFCA's skills and resources, meeting core administrative costs and funding specific research studies. SFCA has also received financial support from AID/Khartoum and AVS. AID is supporting a Model Family Planning Clinic that is utilized by the SFCA as a research center.

To expand their data processing and analysis skills the SFCA will receive from AID an IBM PC-AT computer this year. AID will also

provide software for research and management capabilities. FHI will, in turn, train SFCA staff to use the computer.

During 1984 and 1985 the following activities were conducted:

- A knowledge, attitudes and practices (KAP) survey concerning family planning among manufacturing workers. (Study completed, report published, Arabic translation in print).
- A survey on the trends of breastfeeding among Sudanese women. (Data collection completed, analysis underway).
- A survey of the knowledge and attitudes of family planning among nonphysician family planning workers. (Data collection completed, report published, Arabic translation in print).
- A survey on male attitudes toward family planning.
- A clinical study of female circumcision was conducted at Soba Hospital. (Data collection completed, analysis underway).
- A KAP survey was conducted in the area surrounding the Model Family Planning Clinic. A workshop was conducted (August 1985), with FHI instructors, on research methodology in Khartoum, Sudan.
- Three workshops were conducted to train SFCA staff on interviewing skills.

In addition to the above listed studies, core support received has indirectly supported the following studies:

- A progesterone-only pill study (ongoing)
- A maternity care monitoring study in Port Sudan Hospital (first phase of data collection completed)
- A vasectomy information project.

Under the new subagreement the following activities are planned:

- A multicenter study of oral contraceptives in Sudan
- A vanguard acceptors study of family planning in Eastern Sudan
- An evaluation of a training program for a group of senior midwives
- A focus group study on knowledge, attitudes and practices of modern traditional and natural methods of family planning in Sudan
- An evaluation of the impacts of health education on infant/maternal health and the acceptance of family planning
- A study investigating the causes of infertility at Soba Hospital, Khartoum
- Two workshops to be held in Eastern Sudan on research methods and clinical trials

The current two-year agreement became effective on 1 March 1986 and will extend until 29 February 1988.

FHRC Directors Conference

From 2-7 March 1986, the Second Family Health Research Centers Directors Conference was held in Chiang Mai, Thailand. The theme of the conference was long term planning, and focused on developing skills to enable FHRCs to plan for institutional and research strategy development including options for obtaining funding from multiple sources as FHI implements its plan to reduce core funding. The meeting also provided an opportunity for a review of progress on a number of issues introduced at the first FHRC conference in September 1984. A two day scientific session provided each FHRC an opportunity to present and discuss research implemented through its program. The conference was hosted by the Thailand Fertility Research Association (TFRA) and was attended by 13 leaders (three from TFRA, two from the other FHRCs- in most cases the chief policy person and the chief program manager) of the FHRCs in Bangladesh, Egypt, Indonesia, Sri Lanka, Sudan and Thailand.

FHI Attendees included the Director of FHI's Field Development and Training Division (which coordinates FHRC activities), the three FDT program coordinators for the FHRCs, the FDT coordinator for African programs, and the Director of FHI's Clinical Trials Division. In addition, two consultants from the accounting firm of Deloitte, Haskins & Sells International attended to provide special financial management input.

The first half of the week was devoted to discussions of planning and management issues, and the second half concentrated on scientific

issues. Session topics in the latter included NORPLANT® Studies, Social Determinants of Contraceptive Use, Voluntary Sterilization, Pregnancy Outcomes and Postpartum Contraception, Systemics, and Intrauterine Devices. Speakers were asked to focus on the "process" (conceptualization, methodology, policy implications, and information dissemination) rather than "results" of their research which made the presentations a good learning forum for replicating the successes and avoiding the failures of other centers.

The conference received very positive comments by participants in the post-conference evaluation.

2. Newer FHRCs - As resources permit and as interest and absorptive capacities allow, FDT has begun some new institutional development programs in new areas -- Mali, Niger and Brazil. At present these research funding and technical assistance programs are small, but thriving. Progress in each of these programs is described as follows:

Brazil: ABEPF

Financial and technical support are being provided to the Brazilian Association of Family Planning Entities (ABEPF) of Rio de Janeiro, Brazil. The project seeks to strengthen ABEPF's clinical research capabilities by funding a full time data collection/research coordinator (DCRC). The DCRC is currently coordinating a 1200 case FHI-funded progestogen-only pill clinical trial. Nearly 75% of the admissions have been completed. Patient follow-up is currently

ongoing with data being shipped to FHI on a regular basis for analysis. With FHI technical support, the DCRC has developed systems which permit an effective evaluation of data quality. Also, the DCRC has traveled to each of the six participating centers to monitor data quality and to respond to data queries in a timely manner. In addition, during this reporting period the DCRC has concentrated on identifying other international organizations with an interest in supporting research. Efforts have been made to develop research strategies that address the organization's priorities.

Technical Assistance to the CNSF/Niger

The Centre National de Sante Familiale (CNSF) was established in November 1985 by the Ministry of Health with the goal of coordinating family planning activities in Niger. The Ministry of Health requested FHI to provide technical assistance to the CNSF to strengthen and increase its capacity to conduct research activities in reproductive health. A series of research activities were proposed following the National Seminar on Family Health and Development in January 1985. The technical assistance focuses on three areas: (1) biomedical research, (2) training and (3) institutional development.

The first activity was the Vanguard Family Planning Acceptor Study for which data collection was completed in October 1985. Study questions focused on the socio-demographic characteristics of acceptors, their obstetric history, their reasons for desiring to contracept and how they learned of the Center. The data were

analyzed locally and the final report will be completed in April. Study results will help to determine target groups as well as the orientation of information, education and communication activities. A follow-up study has been proposed for 1987 to evaluate the changing profile of clientele coming to the center.

Twenty-two physicians participated in the National Seminar on Contraceptive Technology which took place 24 February-1 March 1986 in Niamey at the CNSF. The goal of the seminar was to present the different contraceptive methods, their advantages, disadvantages and contraindications. Also, the seminar introduced the notion of relative risk comparing contraception and pregnancy and the role of family planning in improved maternal and child health.

An ongoing activity is the oral contraceptive surveillance study that was initiated in March 1986 at the CNSF. This study will follow 200 pill acceptors for a one year period to determine rates, side effects, effectiveness, and discontinuation. The two most commonly prescribed oral contraceptives will be studied. In order to strengthen research expertise, data processing and analysis will be done locally.

Technical Assistance to AMPPF/Mali

FHI has provided technical assistance to the Association Malienne pour la Protection et la Promotion de la Famille (AMPPF) since 1981. The goal of this technical assistance has been to reinforce the AMPPF's research infrastructure to conduct and coordinate family

planning research activities in Mali. Activities up until this present subagreement have included an analysis of clinic records (1972-80), evaluation of the AMPPF's activities, development of a new clinic record and monthly reporting system (which is used nationally), and an IUD surveillance study.

The present support builds on previous activities and emphasizes the AMPPF's role as coordinating body for family planning in Mali. Current activities include an oral contraceptive surveillance study of 200 women to determine side effects, continuation rates and reason for discontinuation over one year. Recruitment is finished and the study is now in the follow-up period.

There is also an ongoing evaluation of clinic records. The clinic records from 1981-84 have been coded and are being entered on the microcomputers at the Sahel Institute. Analysis will be done in-country in collaboration with a Malian demographer. Comparison of the results of the first analysis (clinic records 1972-80) and the present analysis (clinic records 1981-84) will show the changing profile of clientele, preferred methods and continuation rates.

In preparation for a training program planned for Summer 1986 a survey is being conducted by the AMPPF in collaboration with the Division de Sante Familiale to determine the type and extent of training each midwife has already received and its perceived weaknesses. With this information, better decisions can be made to maximize the impact of training.

The research assistant at the AMPPF, M. Hamidou Toure, has taken on more responsibilities in supervising ongoing surveillance studies in the Maternal and Child Health centers. He will receive additional training at a summer course in the US and spend a week at FHI afterwards for specific training in FHI procedures.

In the particular case of the AMPPF, FHI has been requested by AID/REDSO to provide more generalized technical assistance and support beyond the strictly research focus. A number of activities in the current subagreement will strengthen the service capacity of the AMPPF in addition to building research skills. FHI will further develop its general support to the AMPPF in its full range of activities, including services, logistics systems, management and management information systems, as well as research.

In order to enlarge its funding base, the AMPPF is planning to submit proposals to a variety of organizations involved in family planning activities. FHI will provide technical assistance to the AMPPF during the spring and summer to develop these project proposals.

Senegal FHRC

A trip scheduled during the fall of 1985 to explore the potential for an FHRC in Senegal was postponed due to the loss of personnel in the FHI office coordinating the Africa/Near East region which necessitated a reordering of priorities. Development of this activity will depend on availability of funds.

3. Technical Assistance and Support for FHRCs - In addition to the funding for core support and programmatic research provided through subagreements with the FHRCs, projects are also funded to enhance the management capabilities and data processing and analysis skills of the FHRCs.

Microcomputer Training and Development

Microcomputer training and development consists of four basic areas:

a. New Microcomputer Installations

A new microcomputer installation is currently being planned for the Bangladesh Fertility Research Programme (BFRP). This installation has been planned for some time, but was delayed pending the appointment of a new Executive Director of the BFRP. The BFRP microcomputer will be a Texas Instruments Business System 351 with 256K bytes of main memory, two workstations, one printer, and mass storage devices consisting of one 1.2 megabyte floppy disk and two 5 megabyte Winchester disks. As some time has elapsed since the installation was originally planned, the various components have been tested and certain ones sent to TI for servicing, to assure that all parts are in working order upon arrival in Bangladesh. An export license for the TI BS351 was applied for in January 1986 and received in-house at FHI 12 March 1986. The new director of the BFRP, Dr. Halida Akhter, visited FHI 17 February 1986. A meeting was held, during which the environmental requirements for the designated computer room were reviewed, including electrical current, proper

grounding, air conditioning and flooring. Customs clearance was also discussed, and Dr. Akhter agreed to facilitate clearance of the microcomputer into Bangladesh. An installation trip by FHI staff is planned for June 1986.

b. Follow-up Visits to Existing Microcomputer Sites

Follow-up visits were made to Colombo, Sri Lanka; Bangkok, Thailand; and Dakar, Senegal.

A follow-up visit was made by FHI staff to the Family Planning Association of Sri Lanka in December 1985. The primary purpose of this trip was to assess the progress of the FPA since the installation of a TI Business System 352 in July 1984 and to determine future needs in the areas of training, software and additional hardware. The FPA may be acquiring additional hardware, with support from INTRAH (Chapel Hill, NC) and a portion of the trip was spent gathering information on what hardware compatible with the FPA's needs, could be obtained and serviced in Sri Lanka. In addition, the trip included a review of the current usage of the computer, along with suggestions and recommendations on how to use it more effectively and efficiently. FHI staff installed and provided training in the use of the Oral Contraceptive Patient Summary (OCPS) software package and a data entry program designed for use with extremely large data collection instruments. Time was also spent reviewing the FPA's current surveys and making recommendations on how best to use the computer for related data entry and analysis.

A follow-up visit was also made to the Thailand Fertility Research Association in December 1985. The primary purpose of this trip was the installation and training in the use of the OCPS software package and to review the progress and use of the TI BS 352 by the TFRA staff. Time was also spent going over systems operation and the importance of data management on the machine.

A follow-up visit was made to the Bureau National du Recensement in Dakar, Senegal, in March 1985. The primary purpose of this trip was an assessment of training absorption, utilization of both hardware and software and additional training in systems operations and management. The OCPS software package was installed, and BNR staff trained in its use. The BNR is also interested in the acquisition of additional hardware, and the possibilities of expansion of the current system as well as communication with IBM hardware were explored.

C. Software Refinement

Modifications to software during the reporting period consist of the following:

1. New system software for the Oral Contraceptive Patient Summary (OCPS) questionnaire was completed. It is a complete package and includes data entry, invalid code and range checks, consistency checks and standard tables.

2. Modifications were made to all of the other FHI Clinical Trials packages to incorporate the new OCPS system and to facilitate user interaction.
 3. Modifications were made to the FS and IUD Clinical Trials programs to allow tables to be run prior to completion of data entry of all acceptors in the study.
 4. A new data entry program was written to allow for extremely large data collection instruments to be entered onto the TI Business System computers for data analysis. This program was developed specifically for the Family Planning Association of Sri Lanka.
 5. The table specifications for the Maternity Care Monitoring system are currently being reviewed by the research staff at FHI. Any modifications the researchers agree should be made will be incorporated into the existing software.
- d. In-house Microcomputer Related Training and Documentation.

In-house training was provided for Dr. Soeprapti Thaib, the Senior Program Officer of the BKS PENFIN in Bandung, Indonesia during her

visit to FHI in October 1985. Dr. Soeprapti received an overall orientation to microcomputers and their potential use in research and administrative applications. She was also given an introduction to the TI BS352 and each of the software packages currently available on it.

A new Users Guide for all FHI-developed software currently available on the TI Business Systems computers was produced. This manual includes documentation for the Clinical Trials Package, the Data Analysis Package, Lifetable Analysis, Data Entry, Random Allocation, Sample Size Determination and the Select program.

Based on the follow-up visits to the various microcomputer sites, two in-house workshops to be held at FHI for advanced users are being considered:

1. Advanced system concepts, to include more in depth data management techniques and system generation.
2. FORTRAN-78 on the TI Business System to include working with core limitations and the use of overlays.

Also, based on the follow-up visits, the interest of some sites in hardware expansion and in the interests of increased IBM compatibility, a communications package which would enable the TI BS to be linked to IBM PCs and compatibles was purchased. Extensive

testing is planned in-house prior to being installed on any of the systems in the field.

Management Assistance to FHRCs

One of the major objectives of the FHI Family Health Research Center (FHRC) program is to assist in the development of institutions capable of functioning as self-reliant research centers. This involves the design of appropriate research focused on the needs of the FHRC's country family planning programs and the ability to plan and implement the research with sound management of scarce resources.

The institutional development process involves a period of transition. During this period, strengthening of financial management capabilities is seen as preparing the FHRC for financial independence. FHRCs must develop the ability to plan for future needs, obtain financial support to carry out their program, have a workable system to recover core costs from research contracts, and be able to demonstrate fiscal accountability to prospective donors.

FHI has contracted with the accounting firm of Deloitte, Haskins & Sells International (DH&S) to provide technical assistance to the FHRCs to strengthen their financial management capabilities and their overall ability to manage multiple sources of funding to implement their programs.

Two DH&S staff members attended the FHRC Directors Conference in Chiang Mai, Thailand. During this trip they also conducted extensive

discussions with the TFRA and later traveled to Indonesia to review in detail the financial management assistance needs at the BKS PENFIN. During the next six months DH&S will finalize its assistance plan for AID approval and begin implementation of the program, with priority given to Indonesia and Thailand. An initial needs assessment visit to Bangladesh is planned in conjunction with the technical assistance visits to the other Asian centers.

Mexico: Development of Computerized Service Statistics System.

During this reporting period, FHI provided funds to the Mexican Federation of Private Family Planning Association (FEMAP) to improve their institutional capability to utilize service statistics in evaluation of research activities. Funds provided through this project will enable FEMAP to develop the capacity to monitor and evaluate ongoing family planning program activities, permitting a more systematic evaluation of the program. When this project is completed FEMAP will have a computerized system of service statistics in the Juarez program.

The computerization of FEMAP's service is the key to the successful implementation of a planned project within the Juarez CBD program to determine what factors affect "promoter" productivity. This project will relate the "promoter's" background characteristics, knowledge of contraceptives, and community activities with client recruitment and continuation rates.

B. Training

1. **Research Methods Training Workshops** - To enhance the research skills and capabilities of collaborating investigators and to develop and expand the number of highly skilled researchers in FHI's international network, support is provided for research training workshops. During this funding period, the following research training activities were implemented:

CT Training Curriculum Development

FHI's new Clinical Trials Research Methods curriculum was successfully implemented for the first time in a one-week workshop last July, in Singapore. That workshop was aimed at training and working with 12 new Asian investigators from Sri Lanka, Nepal, Malaysia and the Philippines. Almost all of these 12 participants have subsequently initiated FHI supported clinical trials. Some are also involved in similar training of other potential investigators in their own country. Following the Singapore workshop, minor modifications were made to the curriculum and an outside professional review was carried out under contract with consultants in Mexico, who are also translating the finalized materials into Spanish.

A second workshop utilizing the new curriculum was conducted by FHI in Egypt in December 1985. A third workshop (utilizing the finalized curriculum, in Spanish) is planned in Panama next July. The FHI curriculum has also been shared with the WHO for possible use in

developing a course on management of clinical research in Indonesia, tentatively scheduled for late 1986.

Panama: Clinical Trials Research Course

Regional and national workshops are an ideal way to meet clinical trials training needs in the developing world. A workshop on Clinical Trials Methods for Contraceptive Research will be held in conjunction with the School of Medicine, Department of Obstetrics and Gynecology of the Universidad de Panama on 21 - 26 July 1986.

Fifteen trainees will be selected from Mexico, Peru, Brazil, Colombia, Ecuador, Venezuela and Panama. The training will use the standardized curriculum developed for the Singapore workshop. The trainers will be two FHI staff members, both involved in the development of the curriculum materials. In addition, two consultants, one from Mexico who has participated as a trainer in the course on research methods for reproductive epidemiology in Durango, and an FHI investigator with ample experience in FHI's clinical trials research program, have been contacted to serve as trainers.

The training will be product oriented with as many participants as possible returning to their countries with an FHI-supported clinical trials study in hand.

Mexico: Epidemiologic Training

For a third year FHI provided technical assistance to an epidemiologic training program implemented by the Instituto de

Investigacion Cientifica of the Universidad Juarez, Durango, Mexico. Under a five-year grant from the UNFPA, the Instituto trains investigators to conduct epidemiologic studies in the area of reproductive health, with emphasis on benefits and risks. A three-week workshop in November 1985 trained ten physicians from Mexico, and one each from Panama and Guatemala. PAHO supported the training of the Central American participants. Twelve projects were designed during the workshop, and four of the studies are in the final stages of approval for funding from various sources. A collaborative research group called the "Mexican Interuniversity Group for Epidemiologic Research in Reproductive Health" has been spawned by the experience of the project. It is based in Durango, and the members are some of the alumni of the first two workshops. As a collaborative group they intend to undertake investigations that could not be carried out by an individual center. The next training workshop, set for November 1986, will focus on strengthening the Mexican Interuniversity Group.

Development of an Analysis Curriculum for Clinical Trials

In support of its international network of investigators, FHI is preparing standardized training materials for the analysis of data from clinical trials of contraceptive methods. The materials will be designed for use in a course of four to five days, intended mainly for current or potential researchers and/or their research assistants, who are interested in doing their own analyses. Investigators who desire a more complete understanding of the analysis process will also be appropriate students. The format of

the training materials will be a set of essentially self-instructional modules designed to present step-by-step instructions for analysis of data from contraceptive clinical trials. FHI specialists in biostatistics and clinical trials will develop the content. The materials will be completed by the summer of 1986. A primary target for use of these training modules will be the core staff and investigators who make up the Family Health Research Centers.

2. Contraceptive Technology Workshops - Physicians and other health providers are not only a key resource for carrying out biomedical research activities; they influence the provision and acceptance of family planning services in a number of ways. In countries where contraceptive service and research are in the early stages of development, they are an important target audience for training in contraceptive technology. Three contraceptive technology workshops, one held in the current reporting period and the other two planned for the next reporting period, are described below.

Niger: Applied Research Methods Workshop

The Centre National de Sante Familiale plans to expand its service program to maternal and child centers in Niamey during 1986 and to other regions of Niger in 1987. This expansion necessitates training of not just service delivery personnel, but also administrators and policymakers. The National Seminar on Contraceptive Technology was proposed as a training activity to bring physicians up to date on

current contraceptive technology to foster favorable attitudes towards the family planning program and its expansion.

The National Seminar on Contraceptive Technology was held 24 February - 1 March 1986 in Niamey at the Centre National de Sante Familiale. Coordinated by the CNSF and FHI, twenty-two Nigerian physicians participated in the workshop: 9 from the interior of the country and 13 from Niamey, including two representatives from the MOH. Local as well as international experts in family planning made presentations and facilitated the seminar. Besides birth spacing, the seminar reviewed the different methods of contraception, and their advantages, disadvantages and contraindications. Emphasis was given to the notion of relative risk of contraception vs pregnancy. Recommendations emanating from the seminar stressed the need to legalize the delivery of family planning services; the creation of a national committee for family health; and increased efforts to inform and educate the population on family planning. Evaluation of the seminar by the participants was very positive, with all participants stating that they acquired new knowledge which they could use in the delivery of family planning counseling and services, as well as in the training of their staff.

Pakistan: Reproductive Health and Contraceptive Technology

The three-day workshop will take place in Lahore, Pakistan, from 28-30 April 1986. FHI support includes sponsorship of the international speakers/resource persons, consultant honoraria and all educational materials to be utilized in the workshop. The Pathfinder Fund (Boston) will cover all in-country costs.

The Government of Pakistan's Population Welfare Division has identified a need to update physicians and family planning service providers in contraceptive technology and family planning practices. The workshop will address this need as well as provide a forum for discussion among service providers, policymakers, and clinical researchers.

The objectives of the workshop are:

1. To provide an update for physicians and family planning providers (both urban and rural) in recent developments in contraceptive technology, contraceptive distribution and selected issues in reproductive health;
2. To respond to an identified need and priority of the Population Welfare Division of the Government of Pakistan with the hope and intent to build upon this cooperative relationship in terms of future FHI collaborative research in Pakistan;

3. To discuss the current Pakistan population program and identify mechanisms by which service providers can contribute to it more effectively;
4. To help identify future directions and needs that the Pakistan population program should address;
5. To develop an FHI strategy for contraceptive biomedical research (particularly in the area of introduction of contraceptives new to Pakistan, eg., NORPLANT® subdermal implants and copper IUDs, including the TCu 380A IUD).

Mexico: 2nd International Course on Family Planning, Population and Maternal Child Care

Financial support is being provided to the Academia Mexicana de Investigacion en Demografia Medica (AMIDEM) for a two week course on family planning program administration, medical demography, contraceptive methods and maternal/child health. The participants will develop skills to create family planning programs, and to interpret demographic changes, vital statistics and the demographic and social impact of family planning programs. They will receive information about institutional and community resources, integration of family planning services within community and institutional health services, orientation of new acceptors to make informed choices of the most appropriate contraceptive, and evaluation of family planning programs at all three levels of medical triage in both the urban and rural setting. The course was originally scheduled to take place

from 21 October to 1 November 1985; however, because of the earthquake in September, the AMIDEM requested an extension of the project until May 1986.

Participants will include 15 physicians from the Mexican Social Security Family Planning System, and 10 physicians from other private and public sector Mexican family planning programs in Latin America. The content of the two week course will include 75 hours of theory and 45 hours of field visits and observation of surgical procedures including IUD insertions. All participants will be evaluated through two written examinations at the beginning and at the end of the seminar. The implementation of this project is seen as an opportunity to aid in the development of AMIDEM as a Mexican training center.

3. Other Training Activities

Sharon Camp Fellowship

The Sharon Camp Fellowship Program was established at FHI in 1984, to enable 1-2 collaborating researchers each year to spend approximately six months in residence at FHI working, with the benefit of FHI facilities and collegial support, on a project of mutual relevance and interest.

The first Fellow, Dr. Boonsri Israngkura, from Thailand, was selected from among several applicants in 1984. A similar process of competitive applications was attempted in 1985; but unfortunately

none of the 30 applications received was judged satisfactory.

Subsequent contacts and correspondence with Dr. Nabil Younis, of Al Ahzar University, Cairo, led to his solicited application, which was reviewed at FHI and approved by AID as the nominee for the second Sharon Camp Fellowship. Dr. Younis proposes to accomplish two major tasks while at FHI: 1) write a family planning program manager's manual and 2) analyze data from clinical trials he has conducted in Egypt. Dr. Younis plans to be at FHI from June through November 1986.

C. Transfer of Contraceptive Technology

While all FDT activities (institutional development, training and information dissemination) enhance the transfer of contraceptive technology to programs in LDCs, two major efforts are underway to introduce specific methods through research and to put in place the mechanisms to increase the contraceptive choices available to families in the developing world.

Egypt-NORPLANT® Support (Long-Acting Contraceptive Steroids)

This three year research program is being conducted in Egypt by medical institutions and physicians under the direction of the Program Implementation Bureau of the National Population Council (NPC) and Family Health International (FHI). The project has several components: a large scale program of training and introduction designed to assess the performance of NORPLANT® implants across a broad spectrum of providers; a detailed program of clinical research

aimed at providing guidance to physicians and regulatory agencies regarding appropriate clinical management; a large-scale prospective cohort study to evaluate the relationship between NORPLANT® implants and potential sources of morbidity and mortality; a program of small acceptability studies designed to indicate patterns of acceptability in various sectors; and a post-marketing surveillance scheme to monitor rare adverse events.

Mr. Peter Miller, FHI's Program Director, arrived in Cairo, Egypt in late January and set up an office at the NPC building. Mr. Miller will coordinate and facilitate activities of the involved agencies and organizations in support of this project.

Training and Evaluation of Voluntary Surgical Contraceptive Techniques Among Private Physicians

This project provides financial support for the development and implementation of courses on voluntary surgical contraceptive procedures and techniques of tubal occlusion for private physicians in three centers in Mexico. Fifty-four physicians have been trained in minilaparotomy and are currently providing services to women in Oaxaca, Veracruz and Tijuana. Each of the participants has received a minilaparotomy kit donated by AVS. Each procedure performed during the first year after the training is being evaluated as part of a research and evaluation project. Data on each procedure performed by the trainees are being collected and analyzed by FHI. The evaluation is currently ongoing with the data collection period lasting until

October 1986. Over 600 cases have been admitted with analysis and follow-up ongoing.

Latin America Advisory Committee

The Latin America Advisory Committee (LAAC) is a new initiative designed to help FHI develop strategies to accelerate the introduction of new contraceptive technologies in the region. The Committee consists of nine senior level family planning experts and research scientists from Mexico, Brazil and Colombia. The first LAAC meeting is scheduled for 19-20 May 1986.

During this reporting period, the materials and workplan for the meeting were finalized. The committee members were contacted and all have accepted FHI's invitation to participate in LAAC. Planning and preparations for the meeting will continue so as to maximize the potential impact of the committee in FHI's efforts to bring new and improved contraceptives to family planning programs in the Latin America Region.

D. Information Dissemination

Research is useful only to the extent that its results are shared with the individuals and programs who provide family planning services, make program and policy decisions and further define the needs for research. A number of FDT activities support dissemination of FHI research findings to appropriate audiences around the world. This program of information dissemination includes specific

publications such as FHI's newsletter, network; support for journal subscriptions for LDC investigators and programs; for attendance at conferences and seminars; and through a new effort to make scientific literature on contraceptive research more useful and accessible to non-scientists who nevertheless are instrumental in the provision of family planning services.

1. Publications

Network Newsletter in English

An ongoing effort to improve the impact, readability and content of FHI's newsletter, network, led to the Information Management Committee's decision last fall to approve in advance a roster of themes that would become the focus of network issues for the coming year. The Fall 1985 issue on breastfeeding and Winter 1985 issue on vaginal contraceptives were the first examples of this effort to allow more advance planning for more cohesive publications. A Spring 1986 issue on African pregnancy surveillance studies is near completion.

The Graphics and Publications Units made a number of improvements in the design of the newsletter to make it more readable by "middle level" health care providers in developing countries. Research findings are now placed in more of a context to make them less specific and technical in their appeal. Important issues in family planning are now reviewed by using examples of research or programs in which FHI has participated. Readers in developing countries are

becoming more "visible" in the pages of network, and guest authors from developing countries are now a regular feature of the newsletter.

Plans for the newsletter include improving the quality and depth of the writing, the possible future expansion of one or two issues a year to twelve pages, and more consistent coverage of all regional areas (Asia, Africa, Latin America).

Network in Spanish

Many of the individuals and programs in FHI's network are in non-English speaking areas of the world. To strengthen information dissemination to these colleagues, the first edition of network en espanol went into press in January. The articles published in this twelve page annual issue are a selection of regionally relevant articles published in the last five issues of network in English.

Distribution to over 1300 Latin American investigators, health and family planning organizations was completed in early February. So far, responses to a survey questionnaire mailed separately have been extremely favorable. Plans for the next issue are underway. It is expected that articles published in the second issue will be written especially for the Spanish version of network and we are exploring the possibility of having a Latin American scientist as a guest author.

An annual edition of network en francaise is planned for the future as funding availability permits.

Spanish Translations

During this last reporting period, work was completed to translate, print and distribute two additional publications in Spanish. The first was a series of five articles published by the Centers for Disease Control on the risks and benefits associated with hormonal contraception: "The Food & Drug Administration and Medroxyprogesterone Acetate"; "Long Term Oral Contraceptive Use and the Risk of Breast Cancer"; "Oral Contraceptive Use and the Risk of Ovarian Cancer"; "Oral Contraceptive Use and Risk of Endometrial Cancer"; and "The Noncontraceptive Health Benefits from Oral Contraceptive Use". The first four articles were published in the Journal of the American Medical Association and the fifth one originally in English in Family Planning Perspectives. Our colleagues in Latin America have responded enthusiastically to this publication, and have expressed their praise for the timely publication of information which sheds light on a very controversial issue in countries around the world. The second publication is a manual of Tubal Occlusion via Minilaparotomy, published in Mexico in 1979 by Dr. Mario Domenzain and the Instituto de Nutricion. Distribution of both publications throughout Latin American centers, schools of medicine and clinics continued during this reporting period. So far, more than 2,000 copies have been distributed; requests for additional copies are received daily.

International Journal of Gynaecology & Obstetrics

As part of its information dissemination strategy, FHI purchases annually about 500 subscriptions to the International Journal of Gynaecology & Obstetrics that are distributed to research collaborators in an effort to provide technical literature to a wide range of researchers. The support for the Journal also involves a close collaboration with the editorial process. FHI provides editing services for up to 20 articles annually, submitted for publication from developing countries. In return, FHI shares in the annual profits of the Journal.

During this reporting period, FHI purchased a total of 522 subscriptions. A new contract agreement covering the 1986 calendar year was entered into between FHI and Elsevier Scientific Publishers Ltd., publishers of the Journal. FHI staff also met with the new editor-in-chief and the managing editor to gain a better working knowledge of the tasks involved in the production of the Journal. In recent months, editing services have been provided for four articles.

Information Dissemination - General

Some initial, practical steps have been taken toward a system for bringing FHI's research findings and a knowledge of the family planning issues to a much larger audience. Work has proceeded on ways to reach the lay public, policymakers and health care providers in certain developing countries and in the United States.

A science writer/editor with primary responsibility for writing interpretive materials and developing an information dissemination system was hired in October. The Publications staff developed a list of potential publications and media contacts in the US and countries where FHI works, and has also fully computerized the US component of this initial list.

In December, informational materials were sent to more than 100 US media outlets. Three interpretive articles were written. The first, on cigarette smoking and reproductive health, was picked up by the Associated Press, two major international magazines, numerous local/city newspapers, and a syndicated wire service used by 13 major newspapers, including the Los Angeles Times, the Washington Post and the International Herald Tribune. This initial mailing generated requests for other articles and more information about FHI research.

Two other thematic pieces were presented to FHRC directors during their conference in March. Reaction to the pieces, on "maternal mortality", "how contraceptives save lives", and "NORPLANT® implants", will help determine the shape of future interpretive pieces.

With working relationships now established with the US media and selected international media, FHI will continue working on a strategy to disseminate research findings and information on contraceptive technologies and reproductive health in countries where FHI works.

2. Conferences, Seminars, Meetings

FHI believes that international meetings, conferences and seminars are another useful way to share research findings. FDT provides support for many of our international colleagues to attend and participate in such meetings. During this reporting period FHI sponsored key investigators and colleagues to five international conferences. The meetings were attended by the following individuals:

1. American Public Health Association, Washington, D.C.,
17-21 November 1985

- Dr. Serge Armand, Director, Division of Family Hygiene & Nutrition, Port-au-Prince, Haiti

- Dr. Jacqueline Polynice Pierre-Louis, Director, MCH, DHFN, Port-au-Prince, Haiti

2. Third International Seminar on Microcomputer Applications in Health Services, Perugia, Italy, 5-15 November 1985

- Karen Johnson Lassner, CPAIMC, Rio de Janiero, Brazil

3. American Fertility Society, Chicago, Illinois, 30 September-4 October 1985

- Dr. Ricardo Rueda, Jr., Bogota, Columbia

4. American Association of Gynecologic Laparoscopists Annual Meeting, Anaheim, California, 19-23 November 1985

- Dr. Jose Moreno Arosemeno, Panama City, Panama

5. Interregional Meeting on Prevention of Maternal Mortality, Geneva, Switzerland, 11-15 November 1985

- Dr. Nanta Oaunkul, TFRA, Bangkok, Thailand

Mexico: Adolescent Reproductive Health Conference (CORA)

The recognition of adolescents and youth as an integral part of social and health programs is an increasing trend in Latin American health care circles. The numerical and proportional growth of this age group and their reproductive behavior has led to increasing concern about family planning programs to serve them. Complications of pregnancy are among the five leading causes of death for female adolescents in all subregions of Latin America and the Caribbean.

During this reporting period, FHI funded "An International Conference on Reproductive Health Among Young Adults". The conference permitted

an exchange of programmatic information, research priorities and political strategies among health professionals working with adolescents in the Latin America Region. The Conference program was divided between the topics of research, services, and educational materials. A compendium of presentations will be published that will provide government and health planners with information on adolescent reproductive health and programs in a variety of Latin American settings.

The conference has generated some concrete research ideas for development of high priority studies in the area of reproductive health for young adults.

Mexico: AIBIR Conference

Support is being provided to the Mexican Academy of Research in Reproductive Biology (AIBIR) for their Eleventh Annual meeting 3-5 April 1986. The annual symposium will include sessions on "Advances in Contraceptive Technology", "NORPLANT®", "Development and Outcome". FHI, along with other international health research organizations, will be represented at the meeting. Dr. Albert J. Siemens, Director of Clinical Trials, will deliver a paper entitled "Advances in Contraceptive Technology". The meeting provides an opportunity for FHI to discuss the new research directions in reproductive health and contraceptive technology with our Mexican colleagues.

STD Expert Meeting

FHI is sponsoring an Expert Meeting on "Sexually Transmitted Diseases in Africa" in Banjul, The Gambia, 28-30 April 1986. This meeting will be attended by recognized experts from the US, Europe and Africa to review STD research conducted in Africa and to define FHI's options for pursuing such work. Limited research studies of STDs have been undertaken in several African countries, however, not enough has been done to determine prevalence, risk factors, treatment and follow-up of these diseases, as well as study the relationship between contraceptive choice and STDs.

VII. MANAGEMENT

Protection of Human Subjects Committee (PHSC)

Two meetings of the Protection of Human Subjects Committee (PHSC) were held at FHI on 15 November 1985 and 21 March 1986 to review 33 research proposals, inclusive of amendments and those for expedited review.

Two committee members rotated off as of 31 December 1985: Drs. Mary Jane Gray and Kay Omran (OB/GYN).

Robert R. Price, Esq. (legal representative) was reappointed for a second 3-year term on 1 January 1986.

Two new members were appointed for three year terms:

Dr. Elizabeth S. Mann, Associate Professor, Department of anesthesiology, School of Medicine, University of North Carolina, North Carolina Memorial Hospital, Chapel Hill, North Carolina.

Dr. David A. Savitz, Assistant Professor, Department of Epidemiology, School of Public Health, University of North Carolina at Chapel Hill, North Carolina.

The main administrative structure of the organization has been maintained with 117 employees as of 31 March 1986.

The following table lists expenditures for the period covered by this report.

Expenditures

1 October 1985 - 31 March 1986

Salaries & Fringe Benefits	\$ 993,794
Service Centers	224,306
Consultant & Professional Fees	79,738
Contracted labor	1,843
Travel - domestic	40,594
Travel - foreign	231,278
Supplies - office	8,954
Supplies - medical	35,993
Printing & Reprints	28,177
Medical Equipment	4,694
Freight	4,663
Dues & Registration Fees	1,837
IJGO Subscriptions	24,012
Other Purchased Services	28,658
Keypunching	19,519
Other Expenses & Bank Service Charges	9,763
Data Purchases	135,071
Subcontracts	727,097
General and Administrative Costs	<u>838,420</u>
TOTAL	\$3,438,411

VIII. FUTURE PLANS

FHI's opportunity for contributing to the development of new FDA approved contraceptives, increasing the understanding and use of currently available methods and for enhancing the performance of national and non-governmental family planning programs overseas has collided with stable, or possibly even declining, budgets. Hard choices have to be made.

The allotment of funds to different divisions of FHI will continue to change. The first priority will remain with Clinical Trials and with the effective management and implementation of current work, most especially that related to the FDA approval for new methods. FHI has the largest body of skilled staff and experience of any AID cooperating agency to apply to the management of contraceptive research relevant to FDA approval. FHI will continue to make these skills available to AID and to encourage the good management of the early stages of contraceptive research both within and outside FHI. The most important areas of research will continue to be work on three month injectable, subdermal implants, NORPLANT®, non-surgical sterilization and spermicides.

FHI sees its program of work as an essential element in the overall activities of AID. As a result of AID's decision to contract with Georgetown University to conduct natural family planning, FHI's activities in this area will be reduced. At the same time, in order to assist Georgetown in getting its new program moving as rapidly as possible, FHI has agreed to implementing a subcontract from

Georgetown University to complete work on the prediction of the return of ovulation in breastfeeding women. FHI looks forward to establishing a close and business-like relationship with whatever institution is awarded AID's new CONRAD cooperative agreement. FHI will make every effort to continue to meet the various family planning research needs of AID Missions around the world.

APPENDIX A

PUBLICATIONS LIST

FAMILY HEALTH INTERNATIONAL

Semi-annual Publications List
October 1, 1985 - March 31, 1986

Published

LP Cole, DM Potts, C Aranda, B Behlilovic, E-S Etman, J Moreno, L Randic, R Apelo and M Thomas. Comparative Copper IUD Trials. In: Intrauterine Contraception: Advances and Future Prospects. GI Zatuchni, A Goldsmith and JJ Sciarra, eds. (Philadelphia: Harper & Row 1985), pp. 95-100. (85-29)

RG Wheeler, LP Cole and R. Santiso. IUDs With or Without Strings. In: Intrauterine Contraception: Advances and Future Prospects. GI Zatuchni, A Goldsmith and JJ Sciarra, eds. (Philadelphia: Harper & Row, 1985), pp. 420-426. (85-30)

LP Cole and A Goldsmith. Contraceptive Services for the Postpartum and Postabortion Woman. In: Gynecology and Obstetrics, JJ Sciarra, ed. (Philadelphia: Harper & Row), 1985, Vol. 6, Chapter 15, pp. 1-10. (85-31)

RN Shain and M Potts. Need for and Acceptability of Long-acting Steroidal Contraception. In: Long-acting Contraceptive Delivery Systems. GI Zatuchni, JS Shelton, A Goldsmith and JJ Sciarra, eds. (Philadelphia: Harper & Row), 1985, pp. 1-19. (85-32)

JH Lewis, B Janowitz and M Potts. Methodological Issues in Collecting Data from Traditional Birth Attendants. Int J Gynaecol Obstet 23(4):291, 1985. (85-33)

S Beltran and C Waszak. Estudio comparativo de dos dispositivos intra-uterinos, la espiral delta y la espiral de Lippes D colocados a pacientes postparto. Rev Colombiana Obstet Ginecol 26(1):43, 1985. (85-34)

JE Higgins, LR Wilkens, I Chi and RA Hatcher. Hospitalizations Among Black Women Using Contraceptives. Am J Obstet Gynecol 153(3):280, 1985. (85-35)

D Nichols, S Ndiaye, N Burton, B Janowitz, L Gueye and M Gueye. Vanguard Family Planning Acceptors in Senegal. Stud Fam Plann 16(5):271, 1985. (85-36)

R Bhatt and CS Waszak. Four-Year Follow-Up of Insertion of Quinacrine Hydrochloride Pellets as a Means of Nonsurgical Female Sterilization. Fertil Steril 44(3):303, 1985. (85-37)

I Chi. IUD Use in Diabetic or Lactating Women or Women After Cesarean Delivery - An Epidemiologic Perspective. Adv Contracept Deliv Syst, Monograph II, p. 287, 1985. (85-38)

I Chi, LR Wilkens and CS Waszak. Difficulty in Removal--A Neglected IUD-related Rare Event. Adv Contracept Deliv Syst, Monograph II, p. 265, 1985. (85-39)

- R Guzman-Serani, M Potts and RG Wheeler. Non-Surgical Tubal Occlusion. *Adv Contracept Deliv Syst, Monograph I*, p. 146, 1985. (85-40)
- L Randic, S Vlastic, I Matrljan and CS Waszak. Return to Fertility After IUD Removal for Planned Pregnancy. *Contraception* 32(3):253, 1985. (85-41)
- I Chi, L Wilkens and S Rogers. Expulsions in Immediate Postpartum Insertions of Lippes Loop D and Copper T IUDs and Their Counterpart Delta Devices--An Epidemiological Analysis. *Contraception* 32(2):119, 1985. (85-42)
- M Potts, I Chi and J Lippes. Comments on Sterilization Methods in China. *Am J Pub Health, letter*, 75(12):1451, 1985. (85-43)
- I Chi, SE Reid, RA Teeter, SM Rogers and LR Wilkens. IUD-Associated Hospitalization After Postpartum Insertions in Less-Developed Countries: A Study of the Host Risk Factors. *Korean J of Epidemiology* 7(1):143, 1985. (85-44)
- SM Louis and RM Pearson. A Comparison of the Effects of Nonoxynol-9 and Chlorhexidine on Sperm Motility. *Contraception* 32(2):199, 1985. (85-45)
- GS Grubb and HB Peterson. Luteal Phase Pregnancy and Tubal Sterilization. *Obstet Gynecol* 66:784, 1985. (85-46)
- DL Covington, DS Gates, B Janowitz, R Israel and N Williamson. The Hospital Environment and Infant Feeding: Results from a Five Country Study. In: *Breast-feeding and Fertility*. M Potts, S Thapa and MA Herbertson, eds. *J Biosoc Sci Suppl* 9, p. 83, 1985. (85-47)
- C Guzman, A Martinez, M Gutierrez and KS Hilton. Un estudio comparativo entre los dispositivos T 200 DE DOBRE Y ASA DE LIPPES en mujeres en periodo de intervalo. *Revista Colombiana de Obstetrica y Ginecologia* Vol. XXXVI, No. 3, p. 156, 1985. (85-48)
- R Rivera, E Ortiz, M Barrera, K Kennedy and P Ehiwandiwala. Preliminary Observations on the Return of Ovarian Function Among Breast-feeding and Post-partum Non-Breast-feeding Women in a Rural Area of Mexico. In: *Breast-feeding and Fertility*. M Potts, S Thapa and MA Herbertson, eds. *J Biosoc Sci Suppl* 9, p. 127, 1985. (85-49)
- C Aranda, D de Badia, M Mahran and PJ Feldblum. A Comparative Clinical Trial of the Tubal Ring Versus the Rocket Clip for Female Sterilization. *Am J Obstet Gynecol* 153(7):755, 1985. (85-50)
- RA Teeter. The Application of Linear Piecewise Regression to Basal Body Temperature Data. *Biom J* 27(7):759, 1985. (85-51)
- M Potts. The Pill 30 Years On: A New Perspective. *Comm Med* 7:241, 1985. (85-52)
- RA Apelo and CS Waszak. Postpartum IUD Insertions in Manila, Philippines. *Adv Contracept* 1(4):319, 1985. (85-53)
- P Lamptey, C Klufio, SC Smith and PJ Feldblum. A Comparative Study of Neo Sampoo, Ortho Vaginal Tablets and Enko Vaginal Tablets in Accra, Ghana. *Contraception* 32(5):445, 1985. (85-54)
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S Onay-Basaran, JL Olsen and RG Wheeler. Dissolution Profiles of Long-acting Quinacrine Hydrochloride Pellets II. Drug Dev Ind Pharm 11(12):2155, 1985. (85-55)

I Chi, M Potts and L Wilkens. Rare Events Associated with Tubal Sterilizations: An International Experience. Obstet Gynecol Surv 41(1):7, 1986. (86-01)

JA Fortney, I Susanti, S Gadalla, S Saleh, SM Rogers and M Potts. Reproductive Mortality in Two Developing Countries. Am J Pub Health 76(2):134, 1986. (86-02)

APPENDIX B

CONSULTANT REPORTS

COMPLETED CONSULTANT REPORTS

1 October 1985 - 31 March 1986

Study Number	Title	Investigator	Country/Center number
594	Evaluation of the Wing Sound	Zighelboim	Venezuela/100
787	Results of a Trial of Neo Sampooon Vaginal Tablets and the Diaphragm in Dhaka, Bangladesh	Rahman	Bangladesh/721
793	A Comparative Clinical Trial of Emko and Ortho Vaginal Tablets in Cairo, Egypt	Younis	Egypt/314
835	A Crossover Study from Standard-Dose to Low-Dose Oral Contraceptives	Agoestina	Indonesia/739
6900	Surveillance of Female Sterilization in Cayes, Haiti	Louissaint	Haiti/8009
6900	Surveillance of Female Sterilization in Petit Coave, Haiti	Lolagne	Haiti/8011
6900	Surveillance of Female Sterilization in St. Marc, Haiti	Vincent	Haiti/8013
6900	Surveillance of Female Sterilization at Six Centers in Haiti	Multiple	Haiti/Multiple
6960	Minilaparotomy With vs Without Antibiotics in Rangpur, Bangladesh	Ismail Hug	Bangladesh/786
6960	Minilaparotomy With vs Without Antibiotics in Comilla, Bangladesh	Ahmed	Bangladesh/7019
6960	Minilaparotomy With vs Without Antibiotics in Dhaka, Bangladesh	Begum	Bangladesh/704

COMPLETED CONSULTANT REPORTS (cont'd)

Study Number	Title	Investigator	Country/Center number
6960	Minilaparotomy With vs Without Antibiotics in Dhaka, Bangladesh	Khatun	Bangladesh/705
7030	Vasectomy With vs Without Antibiotics	Bhuiyan	Bangladesh/720
8825	Norinyl 1/35 vs Lo-Ovral	Moggia	Argentina/871
8850	Norinyl 1/35 vs Norinyl 1/50	Behlilovic	Yugoslavia/24
8880	Retrospective Study of Depo Provera and Oral Contraceptives Users	Mongkol	Thailand/709

APPENDIX C

STUDY STATUS LISTS

STUDY STATUS LIST
NORPLANT® Implant Studies

DATE: APRIL 1986

Description of Study: NORPLANT® IMPLANTS - FOO 3132

Study Number: 866

Total Number of Cases: 2500

Total Number of Studies: 20

Center Number	Investigator/ Country	Index Number	Date Initiated	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status
						ADM	FU Slot 1	FU Slot 3	FU Slot 6			
040	O. LADIPO NIGERIA	NOR 85/014	10/11/85	8/87	70	55	44	2		2/17/86	1/06/86	ACTIVE
041	A. COLLISON GHANA	NOR 85/012	10/16/85	8/87	100						1/17/86	PLANNED
042	C. EEMENPU NIGERIA	NOR 85/013	10/10/85	8/87	50	28	17	5		3/27/86	1/10/86	ACTIVE
100	I. ZICHELBOIM VENEZUELA	NOR 86/006		12/87	100							PLANNED
435	O. FAKEYE NIGERIA	NOR 86/004	1/13/86	12/87	50	31	6			3/14/86	1/13/86	ACTIVE
437	M. DIEJOMAGH NIGERIA	NOR 85/015	10/09/85	8/87	50	38	25	1		1/31/86	1/07/86	ACTIVE
453	J. OTUBU NIGERIA	NOR 86/005	11/08/85	8/87	50							PLANNED
600	R. APELO PHILIPPINES	NOR 85/005	2/07/85	10/87	100	21	11	6	2	2/17/86	10/16/85	ACTIVE
602	M. PUERTOLLANO PHILIPPINES	NOR 85/006	2/07/85	1/87	100						10/21/85	PLANNED
703	S. BASNAYAKE SRI LANKA	NOR 85/010	5/14/85	4/87	275	275	292	284	191	2/11/86	1/15/86	ACTIVE
704	S. BEGUM BANGLADESH	NOR 85/001	2/17/85	2/87	200	177	136	95	37	3/24/86	3/18/86	ACTIVE
718	T. CHOWDHURY BANGLADESH	NOR 85/002	2/20/85	2/87	200	188	151	125		3/24/86	3/16/86	ACTIVE

Center Number	Investigator/ Country	Index Number	Date Initiated	Expiration Date	Proposed No. of Cases	Forms Processed					Date Last Shipment	Date Last Site Visit	Status
						AIM	FU Slot 1	FU Slot 3	FU Slot 6	FU Slot 12			
721	S. RAHMAN BANGLADESH	NOR 85/003	2/19/85	2/87	200	147	106	54	19		3/24/86	3/15/86	ACTIVE
729	H. CHHETRI NEPAL	NOR 85/004	2/14/85	3/87	300	304	297	210	229	10	3/10/86	1/05/86	ACTIVE
731	S. RAJBHANDARI NEPAL	NOR 85/008	5/09/85	4/87	100	47	15	6	2		2/06/86	1/09/86	ACTIVE
749	S. CHINDATAMBY SRI LANKA	NOR 85/009	5/16/85	4/87	200	122	93	55	36		3/14/86	3/19/86	ACTIVE
758	I. VIMITHARATNE SRI LANKA	NOR 85/011	5/17/85	4/87	200	200	198	195	49		3/24/86	3/20/86	ACTIVE
8017	S. BOULOS HAITI	NOR 86/001	11/11/85	10/87	100	51	41	10			3/06/86	11/11/85	ACTIVE
8331	G. THEODORE HAITI	NOR 86/003	11/14/85	10/87	100	61	34	1			3/04/86	11/14/85	ACTIVE
8332	P. LOLAGNE HAITI	NOR 86/002	11/16/85	10/87	50	50	23				3/06/86	11/16/85	ACTIVE

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STUDY STATUS LIST
SYSTEMICS

April 1986

Description of Study: Depo Provera vs Oral Contraceptives (Retrospective)

Study Number: 8880

Total Number of Cases: 1500

Total Number of Studies: 5

Center	Investigator/ Country	Index Number	Date Init	Date Actv	Expiration Date	Proposed No. of Cases	Forms Processed		Date Last Shipment	Date Last Site Visit	Status/ Comments
							ADM	> 24 mo FU			
340	Etman/Egypt	83/025		6/84	12/85	300	294	290	1/86	2/86	Closed
703	Basnayake/Sri Lanka	83/021		9/83	7/85	600	600	473	3/85	5/85	CR in progress
709	Mongkol/Thailand	84/003		2/84	1/85	300	299	291	7/84	10/84	CR 525
869	Cetina/Mexico	83/024		1/84	12/85	300	300	236	12/85	6/85	Closed

Totals reflect number of forms loaded.

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STUDY STATUS LIST
SYSTEMICS

April 1986

Description of Study: Norinyl 1/35 vs Brevicon

Study Number: 8825

Total Number of Cases: 1500

Total Number of Studies: 5

Center	Investigator/ Country	Index Number	Date Init	Date Actv	Expiration Date	Proposed No. of Cases	Forms Processed					Date Last Shipment	Date Last Site Visit	Status/ Comments
							ADM	1 mo FU	4 mo FU	8 mo FU	12 mo FU			
81	Moreno/Panama	82/013		2/83	6/86	300	300	268	247	221	196	3/86	1/86	Active
356	Kahman/Egypt	83/015		8/83	12/85	300	215	213	191	127	66	12/85	2/86	Active
890	Nunez/Honduras	82/010		11/82	6/86	300	174	120	75	45	42	1/86	9/85	Active (Admissions closed)
8003	Albuquerque/Brazil	82/014		10/82	6/86	300	301	284	245	155	79	1/86	5/85	Active

Totals reflect number of forms loaded.

225

STUDY STATUS LIST
SYSTEMICS

April 1986

Description of Study: Norinyl 1/35 vs Lo-Ovral

Study Number: 8825, 8850

Total Number of Cases: 1500

Total Number of Studies: 5

Center	Investigator/ Country	Index Number	Date Init	Date Actv	Expiration Date	Proposed No. of Cases	Forms Processed					Date Last Shipment	Date Last Site Visit	Status/ Comments
							ADM	1 mo FU	4 mo FU	8 mo FU	12 mo FU			
40	Orolorin/Nigeria	83/027		7/84	3/86	100	95	78	74	54	28	3/86	6/85	Will close once status confirmed
370	Nada/Egypt	83/016		6/84	10/85	300	298	296	291	292	285	1/86	2/86	Will close 4/86
436	Ayangade/Nigeria	83/028		8/84	3/86	100	96	80	72	70	33	3/86	6/85	Active
821	Argueta/El Salvador	83/013		6/83	12/85	300	215	202	161	118	95	7/85	6/85	CR in progress
841	Santiso/Guatemala	82/011		11/82	12/85	300	300	116	151	121	156	12/84	6/85	CR in progress
871	Moggia/Argentina	82/015		10/82	8/84	300	300	284	239	199	161	8/84	10/84	CR 534
919	Stumpf/USA	83/022		7/83	3/85	300	292	268	264	292	83	12/84	9/84	*

Totals reflect number of forms loaded.

* Data not to be analyzed.

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STUDY STATUS LIST
SYSTEMICS

April 1986

Description of Study: Norinyl 1/35 vs Norinyl 1/50

Study Number: 8850

Total Number of Cases: 1500

Total Number of Studies: 5

Center	Investigator/ Country	Index Number	Date Init	Date Actv	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status/ Comments	
							ADM	1 mo FU	4 mo FU	8 mo FU				12 mo FU
24	Behlilovic/Yugoslavia	83/004		4/83	3/85	300	299	278	282	273	252	11/84	10/83	CR in progress
358	Shabaan/Egypt	83/002		7/83	12/85	300	300	194	139	91	96	4/85	2/86	CR in progress
703	Basnayake/Sri Lanka	83/014		9/84	10/85	500	500	454	450	380	316	10/85	5/85	Closed
831	Aranda/Costa Rica	82/009		11/82	3/85	300	299	297	296	291	290	4/85	9/85	CR 534 in progress
869	Cetina/Mexico	82/012		11/82	12/85	300	300	262	245	202	164	2/86	12/85	CR in progress

Totals reflect number of forms loaded.

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STUDY STATUS LIST
PROGESTOGEN-ONLY ORAL CONTRACEPTIVES

APRIL 1986

Description of Study: Progestogen-only Oral Contraceptives in Lactating Women

Study Number: 8875

Total Number of Cases: 4000

Total Number of Studies: 20

Center	Investigator/ Country	Index Number	Date Init./	Date Active	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status/ Comments
							ADM	2 mo FU	6 mo FU	12 mo FU			
084	Delgado/Mexico	84/034		11/84	12/86	200	110	95	65	31	3/17/86	12/85 CC	Active
102	Guzman/Peru	84/018		7/84	9/86	200	138	93	55	17	2/27/86	12/85 EM	Active
110	Nagahata/Peru	84/014		3/84	6/86	200	192	186	115	15	11/1/85 queried	12/85 EM	Active
400	Gerais/Sudan	85/002		2/85	2/87	200	200	199	181	68	3/20/86	2/86 PG	Active
422*	Broquet/Rwanda	84/004		6/85	3/87	200	14	10			6/10/85 queried		Active
452	Doh/Cameroon	84/030		12/84	6/86	200	227	128	74	22	2/17/86	3/85 NB	Active
453	Wright/Nigeria	84/035		3/86	1/87	100					3/20/86	5/85 SM	Active
483	Ndiaye/Senegal	84/004		11/84	3/86	200	62	46	23	5	1/3/86 queried	10/85 DN	Active
831	Aranda/Costa Rica	84/019		9/84	9/86	200	169	115	71	53	2/19/86	1/86 CC	Active
840	FEMAP/Mexico	84/029		10/84	9/86	200	200	164	134	39	2/27/86	12/85 CC	Active
841	Santiso/Guatemala	84/031		12/84	10/86	200	199	186	138	20	2/21/86	1/86 CC	Active
843	Araujo/Brazil	84/036		12/84	4/87	200	194	155	96	3	3/13/86	4/86 DB	Active

Center	Investigator/ Country	Index Number	Date Init./	Date Active	Expiration Date	Proposed N ^o of Cases	Forms Processed			Date Last Shipment	Date Last Site Visit	Status/ Comments	
							ADM	2 mo FU	6 mo FU				12 mo FU
865	Chagas/Brazil	84/038		2/85	4/87	200	81	49	19	1/23/86 queried	4/86 DB	Active	
869	Cetina/Mexico	84/015		7/84	6/86	200	200	184	111	38	12/26/85 (mailed 2/21/86)	12/85 CC	Active
871	Moggia/Argentina	84/020		8/84	9/86	200	200	162	1	100	3/10/86	4/86 CC	Active
893	Czeresnia/Brazil	84/037		2/85	4/87	200	94	68	83		1/23/86 queried	4/86 DB	Active
8014	Lecoin/Haiti (closed)	84/016		8/84	6/86	200	199	170	109	79	2/28/86	9/85 KJ	Active
8056	Oliveira/Brazil	84/039		2/85	4/87	200	143	99	25	1	2/4/86	4/86 DB	Active
8058	Andrade/Brazil	84/041		5/85	4/87	200	187	127	55		2/4/86	4/86 DB	Active
8059	Nunes/Brazil	84/040		2/85	4/87	200	200	167	136	1	1/23/86	4/86 DB	Active

The totals on this list represent the total number of forms loaded to date.

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STUDY STATUS LIST
EXPANDED PROGESTOGEN-ONLY OC

APRIL 1986

Description of Study: Expanded Strategy for Progestogen-only pills (either several centers per country or through CBD programs)

Study Number: 8876

Total Number of Cases: 10,000

Total Number of Studies:

Center	Investigator/ Country	Index Number	Date Init./Active	Date Expiration Date	Proposed No. of Cases	Forms Processed			Date Last Shipment	Date Last Site Visit	Status/ Comments	
						ADM	2 mo FU	6 mo FU				12 mo FU
043	Gardiner/Ghana	85/001	10/85	11/86	200	158	78		1	2/24/86	9/85 JB	Active
044	Klufio/Ghana	84/003	10/85	11/86	200	85	32			3/5/86	9/85 JB	Active
440	Traore/Mali	83/031	1/85	3/86	100	99	74	32	8	3/27/86	2/86 KJ	Active
457	Toure/Mali Traore	84/002	9/85	4/87	200	30				3/27/86	2/86 KJ	Active
460	Samake/Mali Traore	85/003	9/85	4/87	200	25	9	1		3/27/86	2/86 KJ	Active
8060	Russowsky/Brazil	84/001	3/85	12/86	300	149	91	32		2/17/86	5/85 MW	Active

The totals on this list represent the total number of forms loaded to date.

2/1/86

STUDY STATUS LIST
 PROGESTOGEN-ONLY OC VERSUS NON-HORMONAL METHODS

April 1986

Description of Study: Progestogen-only Oral Contraceptive versus Non-Hormonal Methods in Lactating Women (Repeated Studies)

Study Number: 877

Total Number of Cases: 600

Total Number of Studies: 2

Center	Investigator/ Country	Index Number	Date Init./Active	Date Active	Expiration Date	Proposed No. of Cases	Forms Processed						Date Last Shipment	Date Last Site Visit	Status/ Comments
							ADM	1mo FU	2mo FU	3 mo FU	4 mo FU	5 mo FU			
340	Etman/Egypt	85/005			4/87	300								11/85 NB	Supplies sent EDI: 4/86
871	Moggia/Argentina	85/004	10/85		4/87	300	117	65	53	46	21	6	3/11/86	4/86 CC	Active

The totals on this list represent the total number of forms loaded to date.

STUDY STATUS LIST
SYSTEMICS

April 1986

Description of Study: UC's With vs Without Iron

Study Number: 8856

Total Number of Cases: 1280

Total Number of Studies: 4

Center	Investigator/ Country	Index Number	Date Init	Date Actv	Expiration Date	Proposed No. of Cases	Forms Processed			Date Last Shipment	Date Last Site Visit	Status/ Comments
							ADM	6 wks FU	14 wks FU			
85	Bassol/Mexico	86/007			11/87	320						Will supply 4/86 EDI 4/86
621	BKS PENFIN/ Soeprati/Indonesia	86/008			11/87	320						Supplied 3/86
	Marangoni/Ecuador					320						Budget negotiations
709	Mongkol/Thailand					320						SA to AID and Investigator

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STUDY STATUS LIST
SYSTEMICS

April 1986

Description of Study: Triquilar vs Lo-Femenal

Study Number: 8840

Total Number of Cases: 1500

Total Number of Studies: 5

Center	Investigator/ Country	Index Number	Date Init	Date Actv	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status/ Comments
							1 mo ADM	4 mo FU	8 mo FU	12 mo FU			
400	Gerais/Sudan	86/002	2/86		3/88	300					2/86PG	Supplied EDI 2/86	
703	Basnayake/Sri Lanka	86/004	2/86		3/88	300						Supplied EDI 3/86	
850	Guzman-Serani/Chile	86/005	3/86		3/88	300	35				3/86CC	Forms en route	
8057	Calventi/ Dominican Republic	86/003			3/88	300						Will supply 4/86	
8058	Andrade/Brazil											Letter 1/86	

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STUDY STATUS LIST
SYSTEMICS

April 1986

Description of Study: Loestrin vs Lo-Femenal

Study Number: 8820

Total Number of Cases: 1500

Total Number of Studies: 5

Center	Investigator/ Country	Index Number	Date Init	Date Actv	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status/ Comments
							AID	1 mo FU	4 mo FU	8 mo FU			
8594	Perez Palacios/ Mexico	86/011			5/88	300							Will supply 4/86
314	Younais/Egypt	86/014			6/88	300					2/86PG		SA to AID and Investigator
8590	Rudea/Colombia					300							SA to AID and Investigator
	Lubis/Indonesia					300							

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STUDY STATUS LIST
SYSTEMICS

April 1986

Description of Study: Crossover - Noriday 1/50 to Lo-Femenal; Lo-Femenal to Noriday 1/50

Study Number: 8845

Total Number of Cases: 1200

Total Number of Studies: 4

Center	Investigator/ Country	Index Number	Date Init	Date Actv	Expiration Date	Proposed No. of Cases	Forms Processed					Date Last Shipment	Date Last Site Visit	Status/ Comments
							ADM	1 mo FU	3 mo FU	4 mo FU	6 mo FU			
23	Bresnik/Yugoslavia	85/008	6/85	11/85	12/86	300	118	54	1			3/20/86	4/86JB	Active
602	Puertollano/ Philippines	85/009	9/85		2/87	300	54	63				3/11/86	5/85SK	Active
840	Ramos/Mexico	85/010	10/85		5/87	300	5	6				3/11/86	12/85CC	Active
843	Bomfim/Brazil	86/006	2/86		10/87	300							4/86DB	Supplied 3/86 EDI 4/86

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STUDY STATUS LIST
 VAGINAL CONTRACEPTION
 3171

APRIL 1986

Description of Study: NEO SAMPOON (10 MG. NENFEGOL) VS. FOAM

Study Number: 785

Total Number of Cases: 1050

Total Number of Studies: 3

Center	Investigator/ Country	Index Number	Date Initiated/ Date Active	Expiration Date	Proposed No. of Cases	Forms Processed					Date Last Shipment	Date Last Site Visit	Status/ Comments	
						ADM	1 mo FU	3 mo FU	6 mo FU	12+ mo FU				
20	Andolsek/Yugoslavia	81/014	6/81 /	4/82	12/85	350	267	203	215	164	115	02/12/86	4/86	Active
360	Mahran/Egypt	80/012	12/79 /	1/81	12/83	350	330	61	39	15	11	09/19/83	Closed	CR 531
368	Youssef/Egypt	80/013	4/80 /	2/81	10/82	350	349	280	258	273	247	02/02/83	Closed	CR 468

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STUDY STATUS LIST
 VAGINAL CONTRACEPTION
 3171

APRIL 1986

Description of Study: OVT (60 MG. NENFEGOL) VS. OVT (100 MG. NONOXYNOL-9)

Study Number: 7798

Total Number of Cases: 600

Total Number of Studies: 4

Center	Investigator/ Country	Index Number	Date Initiated/ Date Active	Expiration Date	Proposed No. of Cases	Forms Processed					Date Last Shipment	Date Last Site Visit	Status/ Comments
						ADMI	1 mo FU	3 mo FU	6 mo FU	12+ mo FU			
44	Klufio/Ghana	84/008	9/84 / 12/84	12/86	150	140	111	96	84	17	03/05/86	1/86	Active
4500	Ghunney/Ghana	84/007	9/84 / 1/85	2/87	150	26	26	26	23	0	01/03/86	1/86	Active
773	Sumana/Thailand	85/005	9/85 /	3/87	100							3/86	Planned
	Possible Open												Planned

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STUDY STATUS LIST
VAGINAL CONTRACEPTION
3171

APRIL 1986

Description of Study: OVT (60 MG. NENFEGOL) VS. OVT (100 MG. NOROXYNOL-9)

Study Number: 7799

Total Number of Cases: 300

Total Number of Studies: 5

Center	Investigator/ Country	Index Number	Date Initiated/ Date Active	Expiration Date	Proposed No. of Cases	Forms Processed					Date Last Shipment	Date Last Site Visit	Status/ Comments
						ADM	1 mo FU	3 mo FU	6 mo FU	12+ mo FU			
220	Ruoff/Michigan USA	84/003	7/84 / 8/84	5/86	50	16	16	10	7	4	02/20/86	2/85	Active
930	Pharmaco D./Texas	84/006	8/84 / 10/84	6/86	50	31	18	16	11	2	11/25/85	9/85	Active
957	Bernstein/Calif.	85/003	7/85 /	11/86	50							2/86	Planned
909	Halki/Ohio	85/002	7/85 / 1/86	11/86	50	8	3	0	0	0	03/06/86	2/86	Active
211	Stewart/Calif.	86/002			50							11/85	Planned
014	Sakakini/Texas	86/003			50							11/85	Planned

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STUDY STATUS LIST
 VAGINAL CONTRACEPTION
 3172

APRIL 1986

Description of Study: DIAPHRAGM WITH SPERMICIDE VS. DIAPHRAGM WITHOUT SPERMICIDE VS. SPERMICIDE ONLY(DELFEN FOAM)

Study Number: 7788

Total Number of Cases: 432

Total Number of Studies: 1

Center	Investigator/ Country	Index Number	Date Initiated/ Date Active	Expiration Date	Proposed No. of Cases	Forms Processed					Date Last Shipment	Date Last Site Visit	Status/ Comments
						ADM	1 mo FU	3 mo FU	6 mo FU	12+ mo FU			
298	Guillebaud/England	85/004	9/84 / 9/85	7/88	432	13	4	1	0	0	02/01/86	4/86	Active

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STUDY STATUS LIST
FEMALE STERILIZATION

APRIL 1986

Description of Study: MiniLaparotomy - Filshie Clip vs. Wolf Clip

Study Number: 6266

Total Number of Cases: 1200

Total Number of Studies: 4

Center	Investigator/ Country	Index Number	Date Initiated	Date Active	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status/ Comments	
							AIM	1mo FU	6mo FU	12mo FU				24mo FU
0832	Lasso de la Vega/ Panama	85/013	8/85	9/85	4/87	300	205	180	1		X	03/24/86	1/86	Active
8044	Cordero/Dominican Republic	85/014	8/85	10/85	5/87	300	66	36	1		X	02/11/86	12/85	Active
0747	Arshat/Malaysia	85/024											2/86	Under Develop.

156

STUDY STATUS LIST
FEMALE STERILIZATION

APRIL 1986

Description of Study: Laparoscopy - Filshie Clip vs. Wolf Clip

Study Number: 6267

Total Number of Cases: 1200

Total Number of Studies: 4

Center	Investigator/ Country	Index Number	Date Initiated	Date Active	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status/ Comments	
							ADM	1mo FU	6mo FU	12mo FU				24mo FU
0841	Santiso/Guatemala	85/01	2/86	2/86	3/87	300	59				X	02/21/86	1/86	Active
8009	Louissaint/Haiti	85/016	8/85	9/85	5/87	300	123	82	2		X	01/23/86	9/85	Active
0864	Uribe/Mexico	85/022	11/85	1/86	9/87	300					X	01/06/86		Active
0100	Zigheboia/ Venezuela	86/001	12/85	1/86	12/88	300	10	3				03/10/86	10/85	Active

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STUDY STATUS LIST
FEMALE STERILIZATION

APRIL 1986

Description of Study: Laparoscopy - Filshie Clip vs. Tubal Ring

Study Number: 6265

Total Number of Cases: 1800

Total Number of Studies: 7

Center	Investigator/ Country	Index Number	Date Initiated	Date Active	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status/ Comments
							ADH	1mo FU	6mo FU	12mo FU			
0081	Moreno/Panama	85/002	2/85	3/85	10/86	300	300	223	235		03/11/86	1/86	FU Only
0739	Thouw/Indonesia	85/018	11/85	4/86	9/87	150				X		2/86	Pretests received.
0759	Moeloek/ Indonesia	85/019	11/85	4/86	9/87	150				X		2/86	Pretests received.
0892	Ortiz-Mariscal/ Mexico	85/012	7/85	4/86	3/87	300							Awaiting 1st forms.
8044	Cordero/ Dominican Republic	85/011	8/85	-	4/87	300				X		12/85	On hold.

2/11

STUDY STATUS LIST
FEMALE STERILIZATION

APRIL 1986

Description of Study: Minilaparotomy - Filshie Clip vs. Tubal Ring

Study Number: 6264

Total Number of Cases: 1200

Total Number of Studies: 4

Center	Investigator/ Country	Index Number	Date Initiated	Date Active	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status/ Comments	
							ADM	1mo FU	6mo FU	12mo FU				24mo FU
0083	Contreras/Panama	84/019	7/84	10/84	7/87	300	297	283	196	71	1	03/11/86	1/86	Active
0451	Githiar1/Kenya	86/004				400							2/86	EDI 5/86
0836	Nagahata/Peru	84/011	12/84	3/85	9/87	200	47	46	47			01/08/86	12/85	Active
0865	Bossemeyer/ Brazil	84/022	9/85	11/85	9/87	300	32	17				03/19/86	4/86	Active

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STUDY STATUS LIST
FEMALE STERILIZATION

APRIL 1986

Description of Study: Minilaparotomy - Filshie Clip vs Pomeroy

Study Number: 6260

Total Number of Cases: 1400

Total Number of Studies: 5

Center	Investigator/ Country	Index Number	Date Initiated	Date Active	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status/ Comments	
							ADM	1mo FU	6mo FU	12mo FU				24mo FU
0075	Suporn/Thailand	85/017	9/85	12/85	9/87	300	100	100			X	03/19/86	2/86	Active
0600	Apelo/ Philippines	83/009	4/84	4/84	7/86	300	300	214	140	147	32	02/27/86	3/86	FU only
0781	Yan/ Taiwan	84/003	4/84	4/84	2/87	200	166	131	109	70		03/10/86	1/86	Active
0832	Lasso de la Vega/ Panama	84/007	2/84	2/84	2/87	300	300	297	291	290	1	03/25/86	1/86	FU only

2/86

STUDY STATUS LIST
FEMALE STERILIZATION

APRIL 1986

Description of Study: Minilaparotomy - Filshie Clip vs. Secuclip (Admissions closed)

Study Number: 6258

Total Number of Cases: 475

Total Number of Studies: 3

Center	Investigator/ Country	Index Number	Date Initiated	Date Active	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status/ Comments
							ADM	1mo FU	6mo FU	12mo FU			
0836	Nagahata/Peru	84/005	2/84	7/84	2/87	75	75	75	72	1	01/08/86	12/85	FU only
0865	Bossemeyer/ Brazil	84/004	8/84	8/84	2/87	100	83	69	77	45	03/19/86	4/86	FU only

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**STUDY STATUS LIST
FEMALE STERILIZATION STUDY**

APRIL 1986

Description of Study: Minilaparotomy and Laparoscopy - Filshie Clip

Study Number: 6700

Total Number of Cases: 200

Total Number of Studies: 1

Center	Investigator/ Country	Index Number	Date Initiated	Date Active	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status/ Comments
							1no AMI	6no FU	12no FU	12no FU			
8063	Abdala/Brazil	85/015	6/85	7/85	3/87	200	198	196	197	02/13/86	4/86	FU Only	

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STUDY STATUS LIST
FEMALE STERILIZATION

APRIL 1986

Description of Study: Laparoscopy - Filshie Clip

Study Number: 6249

Total Number of Cases: 1900

Total Number of Studies: 9

Center	Investigator/ Country	Index Number	Date Initiated	Date Active	Expiration Date	Proposed No. of Cases	Forms Processed					Date Last Shipment	Date Last Site Visit	Status/ Comments
							ADM	1mo FU	6mo FU	12mo FU	24mo FU			
0284	Yuzpe/Canada	85/007	6/85	7/85	4/87	200	54	42			X	02/12/86	12/85	Active
0285	O'Brien/England	85/020	10/85	1/86	11/87	100	7	6			X	01/31/86	1/86	Active
0224	Condie/England	85/021	10/85		11/87	200					X		1/86	Awaiting 1st forms.
0286	Newton/England	85/021	10/85		11/87	300					X		1/86	Awaiting 1st forms.
0293	Pogmore/England	85/021	10/85		11/87	200					X		1/86	Awaiting 1st forms.
0201	Campbell/England	86/006				300					X		1/86	EDI 5/86
0200	Baird/Scotland	86/007				200								EDI 5/86
0283	Comel/Canada	85/009	2/86			200					X		2/86	Awaiting 1st forms.
0274	Ni Inc./Canada	86/005				200					X			EDI 5/86

**STUDY STATUS LIST
FEMALE STERILIZATION STUDY**

APRIL 1986

Description of Study: Longterm Follow-up of Female Sterilization

Study Number: Multi

Total Number of Cases: 700

Total Number of Studies: 2

Center	Investigator/ Country	Index Number	Date Initiated	Date Active	Expiration Date	Proposed No. of Cases	Forms Processed					Date Last Shipment	Date Last Site Visit	Status/ Comments
							ADH	1mo FU	6mo FU	12mo FU	24mo FU			
0075	Suporn/Thailand	81/014	8/81	12/83	12/86	500					453	03/20/86	2/86	Active
0723	Ahmed/ Bangladesh	84/002	8/84	11/84	12/85	200					60	7/18/85	3/86	Active

2/2/86

STUDY STATUS LIST
FEMALE STERILIZATION

APRIL 1986

Description of Study: Evaluation of Femtest - Pre and Post Sterilization

Study Number: 6102

Total Number of Cases: 210

Total Number of Studies: 3

Center	Investigator/ Country	Index Number	Date Initiated	Date Active	Expiration Date	Proposed No. of Cases	Forms Processed		Date Last Shipment	Date Last Site Visit	Status/ Comments
							ADM	FOLLOW-UP			
850	Guzman-Serani/ Chile	85/003	5/85	7/85	2/87	110	80	42	03/21/86	3/86	Active pilot study
739	Thouw/Indonesia					50					Pending results or pilot study
759	Moeloek/Indonesia					50					Pending results of pilot study

210

STUDY STATUS LIST
FEMALE STERILIZATION STUDY

APRIL 1986

Description of Study: Electrocautery vs. Filshie Clip

Study Number: 6209

Total Number of Cases: 1200

Total Number of Studies: 4

Center	Investigator/ Country	Index Number	Date Initiated	Date Active	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status/ Comments
							1mo ADM	3mo FU	12mo FU	24mo FU			
	Kubli/W. Germany					300							Under Development

2/11

STUDY STATUS LIST
MALE STERILIZATION

APRIL 1986

Description of Study: Percutaneous Occlusion of the Vas
Vs. Standard Incision and Diathermy

Study Number: 7120

Total Number of Cases: 100

Total Number of Studies: 1

Center	Investigator/ Country	Index Number	Date Initiated	Date Active	Expiration Date	Proposed No. of Cases	Forms Processed			Date Last Shipment	Date Last Site Visit	Status/ Comments
							ADH	1 mo FU	Longterm FU*			
0295	Black/England	85/001	2/85	5/85	7/86	100	101	97	271	03/04/86	1/86	FU Only

250

**STUDY STATUS LIST
IUD5**

APRIL 1986

Description of Study: Long Term Follow Up of TCu 380 AC vs Multiload CU 7

Study Number: 544, 521

Total Number of Cases: 1100

Total Number of Studies: 4

FCO: 3150

CENTER NUMBER	INVESTIGATOR/ COUNTRY	INDEX NUMBER	DATE INITIATED	EXPIRATION DATE	PROPOSED NO. OF CASES	FORMS PROCESSED					DATE LAST SHIPMENT	DATE LAST SITE VISIT	STATUS/ COMMENTS
						ADM	3MO FU	6MO FU	12MO FU	36MO+ FU			
024	BEHLILOVIC/YUGOSLAVIA	85/004	3/85	12/85	300	300	190	239	216	186	12/16/85	4/86 JB	CLOSED
081	MORENO/PANAMA	85/003	7/85	12/85	300	300	232	213	212	190	3/11/86	10/82	ACTIVE
022	RANDIC/YUGOSLAVIA	80/007	12/80	12/85	300	300	193	203	171	182	7/23/84	4/86 JB	CLOSED
600	APELO/PHILIPPINES	80/014	5/81	12/85	200	200	165	167	146	104	1/31/86	11/84	ACTIVE

25/

STUDY STATUS LIST
IUD5

APRIL 1986

Description of Study: TCu 200 Strings vs No Strings

Study Number: 530

Total Number of Cases: 1300

Total Number of Studies: 5

FCO: 3152

CENTER NUMBER	INVESTIGATOR/ COUNTRY	INDEX NUMBER	DATE INITIATED	EXPIRATION DATE	PROPOSED NO. OF CASES	FORMS PROCESSED					DATE LAST SHIPMENT	DATE LAST SITE VISIT	STATUS/ COMMENTS
						ADM	1MO FU	3MO FU	6MO FU	12MO+ FU			
841	GALICH/GUATEMALA	80/009	9/80	1/82	300	299	163	113	149	243	5/21/84	10/82 MW	CLOSED
020	ANDOLSEK/YUGOSLAVIA	80/002	3/83	12/83	500	474	409	379	366	312	3/17/86	10/83 SB	ACTIVE
086	TACLA/CHILE	81/013	8/81	8/81	100	68	66	60	63	55	2/22/85	3/83 MW	CLOSED
299	COHEN/FRANCE	81/003	7/81	6/85	100	100	90	84	81	77	11/22/85	5/84 CW	CLOSED
853	ALVAREZ/DOMINICAN REP	85/010	12/85	8/87	300	68	18				3/27/86	4/86 JB	ACTIVE

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STUDY STATUS LIST
IUD5

APRIL 1986

Description of Study: Evaluation of TCU 380

Study Numbers: 532, 536, 550, 552, 553

Total Number of Cases: 10,400

Total Number of Studies: 22

FCO: 3151

CENTER NUMBER	INVESTIGATOR/COUNTRY	INDEX NUMBER	DATE INITIATED	EXPIRATION DATE	PROPOSED NO. OF CASES	FORMS PROCESSED					DATE LAST SHIPMENT	DATE LAST SITE VISIT	STATUS/COMMENTS
						ADM	FU 1MO	FU 3MO	FU 6MO	FU 12MO+			
304	KISNISCITURKEY	85/002	6/85	6/87	300								ACTIVE
363	TOPPOZADA/EGYPT	85/005	6/85	6/87	200	50					12/16/85	11/85 NB	ACTIVE
100	ZIGHELBOIH/VENEZUELA	85/006	6/85	1/87	300	225	82	73	38		3/10/86	9/85CEC	ACTIVE
084	DELGADO/MEXICO	85/008	7/85	6/87	300	132	105	50			3/17/86	12/85CEC	ACTIVE
741	DAHURUNG/THAILAND	85/009 SUB 3101-1	5/85	5/87	1400	1206	934	473	66		3/24/86	5/85 CSW	ACTIVE
8020	AQUINAGA/BRAZIL	85/011	10/85	1/87	300	91					3/20/86		ACTIVE
825	RIVERA/MEXICO	85/12	8/85	9/87	300	200	144	56			3/14/86	12/85 CEC	ACTIVE

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STUDY STATUS LIST
IUD5

APRIL 1986

CENTER NUMBER	INVESTIGATOR/COUNTRY	INDEX NUMBER	DATE INITIATED	EXPIRATION DATE	PROPOSED NO. OF CASES	FORMS PROCESSED				DATE LAST SHIPMENT	DATE LAST VISIT	STATUS/ COMMENTS
						1MO ADH	3MO FU	6MO FU	12MO FU			
680	AFROZE/PAKISTAN	85/15			300						3/86 SK	PLANNED
401	MUHKAR/SUDAN	85/14	10/85		300	12	6			3/27/86	11/85PC	ACTIVE
BKS PENFIN	INDONESIA	85/18 SUB 3101-3			3000	NO IN-HOUSE DATA					5/86 CW	PLANNED
EFCS	EGYPT	86/008 SUB 3101-4		2/87	1000	NO IN-HOUSE DATA					11/85NB	PLANNED
101	ACOSTA/PERU	85/16	12/85		300	4				2/17/86	12/85EC	ACTIVE
821	HENRIQUE EL SALVADOR	85/17	1/86		300	11	1			3/20/86	NONE PLANNED	ACTIVE
780	CHOONG MALAYSIA	86/001	1/86		300						1/86 SK	PLANNED
	BANDARAGODA SRI LANKA	86/002	2/86	1/88	300						1/86 JM	PLANNED
779	GUNASEKERA SRI LANKA	86/003	2/86	1/88	300						1/86 JM	PLANNED

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STUDY STATUS LIST
IUD5

APRIL 1986

CENTER NUMBER	INVESTIGATOR/ COUNTRY	INDEX NUMBER	DATE INITIATED	EXPIRATION DATE	PROPOSED NO. OF CASES	FORMS PROCESSED					DATE LAST SHIPMENT	DATE LAST VISIT	STATUS/ COMMENTS
						ADM	1MO FU	3MO FU	6MO FU	12MO FU			
060	DAVID/PHILIPPINES	86/004		1/88	200								PLANNED
061	ALFONSO/PHILIPPINES	86/006		5/88	200								PLANNED
066	DACALOS/PHILIPPINES	86/007		5/88	200								PLANNED
854	BELTRAN/CHILE	86/009		1/88	300								PLANNED
8052	IISS/HONDURAS	86/010		6/88	300								PLANNED
8065	FERNANDEZ/ COSTA RICA	86/011		6/88	200								PLANNED
452	DOH/IVORY COAST	86/012		6/88	300								PLANNED
042	EKWEMPU/NIGERIA	86/013			300								PLANNED

15/

STUDY STATUS LIST
IUDS

APRIL 1986

Description of study: TCU200 vs Adapted T

Study Number: 534

Total Number of Cases: 200

Total Number of Studies: 1

FCO: 3153

CENTER NUMBER	INVESTIGATOR/COUNTRY	INDEX NUMBER	DATE INITIATED	EXPIRATION DATE	PROPOSED NO. OF CASES	FORMS PROCESSED					DATE LAST SHIPMENT	DATE LAST SITE VISIT	STATUS/COMMENTS
						ADM	FU 1MO	FU 3MO	FU 6MO	FU 12MO+			
698	APICHART/THAILAND	85/007	5/85	7/87	200	93	51	20	1	3/27/86	5/85 CSU	ACTIVE	

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STUDY STATUS LIST
 INVESTIGATOR NETWORK NEEDS
 3114

APRIL 1986

Description of Study: COPPER T 200 VS. LIPPES LOOP D

Study Number: 5536

Total Number of Cases: 450

Total Number of Studies: 2

Center	Investigator/ Country	Index Number	Date Initiated/ Date Active	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status/ Comments	
						1 mo AICI FU	3 mo FU	6 mo FU	12 mo FU				
33	El-Essaily/Egypt	IUD 83/006	10/83 / 10/83	5/85	300	300	211	210	192	158	5/85	2/85	Active
4000	Akuse/Nigeria	IUD 83/013	9/84 / 9/84	8/85	150	148	129	110	53	31	11/85	10/85	Active

25/1

STUDY STATUS LIST
INVESTIGATOR NETWORK NEEDS
3114

APRIL 1986

Description of Study: STRAIGHT STUDY OF LIPPES LOGP

Study Number: 5507

Total Number of Cases: 150

Total Number of Studies:

Center	Investigator/ Country	Index Number	Date Initiated/ Date Active	Expiration Date	Proposed No. of Cases	Forms Processed					Date Last Shipment	Date Last Site Visit	Status/ Comments
						1 mo AXI	3 mo FU	6 mo FU	12 mo FU				
42	Ekwenpu/Nigeria	IUD 85/001	3/85 / 3/85	4/86	150	150	139	113	89		1/86	10/85	Active

Description of Study: ML 250 VS. COPPER T 200B

Study Number: 5544

Total Number of Cases: 300

Total Number of Studies: 1

Center	Investigator/ Country	Index Number	Date Initiated/ Date Active	Expiration Date	Proposed No. of Cases	Forms Processed					Date Last Shipment	Date Last Site Visit	Status/ Comments
						1 mo AXI	3 mo FU	6 mo FU	12 mo FU				
741	Darong/Thailand	IUD 83/001	3/84 / 3/84	3/86	300	300	260	183	143	1	3/86	6/85	Active

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STUDY STATUS LIST
 INVESTIGATOR NETWORK NEEDS
 3114

APRIL 1986

Description of Study: FS SURVEILLANCE

Study Number: 6900

Total Number of Cases: 1700

Total Number of Studies: 2

Center	Investigator/ Country	Index Number	Date Initiated/ Date Active	Expiration Date	Proposed No. of Cases	Forms Processed					Date Last Shipment	Date Last Site Visit	Status/ Comments
						AIM	1 mo FU	3 mo FU	6 mo FU	12 mo FU			
451	Githiari/Kenya	FS 84/020	3/84 / 3/85	11/85	300	495	493	469			3/86	3/86	Closed
150	Sangaret/Ivory Coast	FS 86/002			300								Under Development
040	Otolorin/Nigeria	FS 86/003			300								EDI 6/86

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STUDY STATUS LIST
 INVESTIGATOR NETWORK NEEDS
 3114

APRIL 1986

Copy

Description of Study: DIPA (25 MG. PER MONTH) VS. DIPA (150 MG. PER THREE MONTHS)

Study Number: 8819

Total Number of Cases: 100

Total Number of Studies: 1

Center	Investigator/ Country	Index Number	Date Initiated/ Date Active	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status/ Comments	
						1 mo FU	3 mo FU	6 mo FU	12 mo FU				
893	Czeresnia/Brazil	SYS 83/001	4/84 / 4/84	7/86	100	93	72	46	38	33	2/86	5/85	Active

Description of Study: DEPO VS PILL

Study Number: 8880

Total Number of Cases: 400

Total Number of Studies: 1

Center	Investigator/ Country	Index Number	Date Initiated/ Date Active	Expiration Date	Proposed No. of Cases	Forms Processed		Date Last Shipment	Date Last Site Visit	Status/ Comments
						> 24 FU	ADMI			
010	Adama Dabo/Gambia	SYS 84/017	7/84 / 7/84	2/86	400	399	164	3/86	9/85	Active

STUDY STATUS LIST
 INVESTIGATOR NETWORK NEEDS
 3114

APRIL 1986

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Description of Study: NORIDAY VS. LO-FEMENAL

Study Number: 8850

Total Number of Cases: 200

Total Number of Studies: 1

Center	Investigator/ Country	Index Number	Date Initiated/ Date Active	Expiration Date	Proposed No. of Cases	Forms Processed					Date Last Shipment	Date Last Site Visit	Status/ Comments
						1 mo AIXI	4 mo FU	8 mo FU	12 mo FU	12 mo FU			
440	Traore/Mali	SYS 83/032	9/84 / 9/84	6/86	200	148	104	66	38	17	2/86	10/85	Active

Description of Study: OVRETTE VS. MICKRONOVUM

Study Number: 8677

Total Number of Cases: 1400

Total Number of Studies: 2

Center	Investigator/ Country	Index Number	Date Initiated/ Date Active	Expiration Date	Proposed No. of Cases	Forms Processed					Date Last Shipment	Date Last Site Visit	Status/ Comments
						1 mo AIXI	3 mo FU	6 mo FU	12 mo FU	12 mo FU			
Multi	Boohene/Zimbabwe	POC 85/006	10/85/10/85	4/87	1400	49	19	9			3/86	6/85	Active

STUDY STATUS LIST
 INVESTIGATOR NETWORK NEEDS
 3114

APRIL 1986

1292

Description of Study: STANDARD DOSE VS TRIPHASIC

Study Number: 8830

Total Number of Cases: 600

Total Number of Studies: 3

Center	Investigator/ Country	Index Number	Date Initiated/ Date Active	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status/ Comments
						ADH	1 mo FU	3 mo FU	6 mo FU			
615	Cruz/Philippines	SYS 86/										Waiting for PopCom approval.
020	Ismail/Malaysia	SYS 86/001	1/86							1/86		Awaiting forms.
	Vilamar/Philippines	SYS 86/009										Waiting for PopCom approval.

Description of Study: LOW DOSE VS STANDARD DOSE

Study Number: 8890

Total Number of Cases: 200

Total Number of Studies: 1

Center	Investigator/ Country	Index Number	Date Initiated/ Date Active	Expiration Date	Proposed No. of Cases	Forms Processed				Date Last Shipment	Date Last Site Visit	Status/ Comments
						ADH	1 mo FU	3 mo FU	6 mo FU			
679	Chrestha/ Nepal	SYS 86/013			200						1/86	LDL 3/86