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I. INTRODUCTION

This report describes the accomplishments of Family Health International (FHI) under AID Cooperative Agreement Number DPE-0537-A-00-4047-00 for the period of 30 September 1984 through 31 March 1985.

FHI's long-term objectives are to widen the range of family planning choices available to couples and to provide objective information on their risks and benefits. Nearly all the large pharmaceutical manufacturers, previously the main source of research and development for contraception, have pulled out of this field. A heavy burden of responsibility, therefore, falls on FHI and the small group of not-for-profit institutions who continue to work in family planning, in relation to the needs of both the developed and the developing world.

In the short-term, FHI's most useful contribution in widening family planning choices is often the study and introduction of methods that are already approved for use in the USA and other countries, but have not been widely or imaginatively introduced in the Third World. One such current strategy is the study of progesterone-only oral contraceptives as a part of a specific effort to meet the contraceptive needs of lactating women.

Several methods of family planning have beneficial as well as adverse side effects. FHI is presently exploring the possible role of spermicides in preventing sexually transmitted diseases.

Even the most effective methods of family planning are useful only if they are accessible and acceptable to those in need. FHI has conducted needs assessment studies that provide information on the accessibility and acceptability of different methods. Studies of the knowledge and attitudes of providers of services have also been conducted, including those providing natural family planning (NFP) services.

The enhancement of the skills of Third World researchers continues to be an important aim of FHI. To this end, FHI provides technical assistance to local research programs, conducts workshops and training seminars.

Major initiatives of the past six months include:

- site selection, physician training and initiation of NORPLANT® implant studies in five countries
- initiation of studies on the use of quinacrine and tetracycline as a possible method of nonsurgical female sterilization under an Investigational Exemption for a New Drug (IND) from the US FDA.
- implementation of a four country study on physicians knowledge and attitudes toward NFP

- completion of a study on contraceptive steroids and the risk of reproductive cancers in Latin America

- development of a standardized curriculum for clinical trials training.

FHI's work is divided into four areas: Clinical Trials, Reproductive Epidemiology, Program Evaluation and Field Development and Training. A small effort has been launched in the area of Contraceptive Development, specifically in the field of immunocontraception. Progress reports of projects in the different research areas appear in the following sections.

II. CONTRACEPTIVE DEVELOPMENT

FHI conducts clinical trials on methods of contraception developed by PARFR (Program to Applied Research in Fertility Regulation), WHO (World Health Organization), and overseas, as well as any pioneered by commercial manufactures that may have a wide application. In order to use resources effectively, FHI must watch the development of potential new methods carefully and, whenever possible, plan ahead so as to permit the expeditious introduction of new methods into human studies.

In the current reporting period, FHI has been paying special attention to possible developments in the field of immunocontraception. A report is being prepared covering the progress of the main laboratories working in this field in America and Europe, and a one day meeting on immunocontraception will be sponsored at NIH in June 1985. The aim of these two activities is to determine what particular animal and laboratory studies need be undertaken before immunocontraceptives enter Phase I clinical trial.

III. CLINICAL TRIALS

The Division of Clinical Trials continues its emphasis in the development and evaluation of new contraceptive products and on studies of the efficacy, safety and acceptability of currently available agents, providing suggestions for their improvement. A major goal is to develop one or more effective, long-acting methods of contraception that do not require daily motivation, but are easily reversible. Long-acting steroidal injectables and implants now under development show promise for meeting this objective. Extensive research is being conducted to develop a method of nonsurgical female sterilization that can be safely offered by medical or paramedical personnel in large-scale programs; a series of sclerosing agents are being evaluated in preclinical and clinical studies. FHI also continues to expand its emphasis on the development of new vaginal contraceptives with particular attention now being focused on D-propranolol. And finally, the Division continues efforts to identify the most appropriate new technologies of female and male sterilization for the developing world.

Commensurate with the broad purpose of evaluating the acceptability of currently available products in new situations, the Clinical Trials Division is studying oral contraceptive use in various cultural settings. In addition, work is in progress both to assess new designs in IUDs and to evaluate the role of training in IUD efficacy and safety.

As all of these clinical studies are dependent upon the availability and interest of clinical scientists and physicians, the Division maintains a dynamic program for the identification and development of new investigators. As a service to its investigators, the Division wrote Consultant Reports (CRs) on completed studies. A list of these is found in Appendix A. The Study Status Lists for ongoing FHI studies are found in Appendix B.

A. Systemic Contraception

1. Long-acting Steroids

a) NET Microspheres

FHI continues to work with PARFR (Program for Applied Research in Fertility Regulation), Ortho Pharmaceutical and Stolle R&D on a 90-day injectable biodegradable formulation of microspheres that permits the continuous low dose administration of the progestin norethindrone (NET). The product has been reformulated to give a better release rate, and Phase I testing at the University of Alabama at Birmingham is scheduled to begin in May. FHI is continuing to support work to scale up the production of NET microspheres that will be necessary when Phase III trials are initiated.

b) NORPLANT® Implants

The objective of the NORPLANT® subdermal implant studies is to introduce the NORPLANT® system into countries that have no previous experience with this method 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.

In addition, an attempt will be made to identify some of the sociodemographic characteristics and culture-specific factors that may affect widespread acceptability of NORPLANT® implants, using an interview questionnaire that is administered to potential acceptors in selected centers. Acceptors and providers will be asked their subjective opinions about the method at a 6-month follow-up visit.

Five investigators from Southeast Asia have received standardized training in the proper insertion and removal techniques at Raden Saleh Clinic in Jakarta, Indonesia. An additional six physicians from that region will be trained in April-May 1985.

Clinical trials were initiated during this reporting period in Bangladesh and Nepal. Three centers in Bangladesh and two centers in Nepal will recruit 200 cases each. As of 31 March, data have been received on a total of 25 insertions.

c) NET Biodegradable Implants

The three PARFR-sponsored studies evaluating the NET biodegradable implant systems are complete. Data analysis has been performed at FHI and sent to the principal investigator to be used in a final report to the FDA. A total of 82 women entered the studies; 51 received three pellets and 31 received four pellets. Data indicated that the four-pellet system is probably superior to the three-pellet system; no pregnancies were reported for women receiving four pellets compared with two pregnancies in the first six months for women receiving three pellets. Pregnancies occurred at 137 and 138 days after insertion. Data showed acceptable menstrual bleeding patterns with fewer reports of amenorrhea in the four-pellet group.

d) Other Injectables

Evaluation of continuation rates for injectable and oral contraceptives that have been supplied by agencies other than FHI is being conducted in Egypt, Mexico, Sri Lanka and Thailand. Preliminary analysis of the first 1200 admissions shows a two-year cumulative life table continuation rate of 65.2 for injectable users and 64.9 for oral contraceptive users. About 70% of the women have been followed up. Discontinuation rates for menstrual problems was greater for injectable users, 9.1, than for oral contraceptive users, 1.1. Amenorrhea was the most frequently reported problem for injectable users.

Future Plans

When Phase II PARFR-funded NET microsphere studies resume in the Fall of 1985, FHI will continue support with study monitoring, data collection and analysis. Pending a favorable experience in Phase II trials, FHI will design and implement the Phase III clinical trials and the preparation of data and study materials relevant to the US FDA to obtain marketing approval.

Negotiations are being finalized with investigators from Haiti, Ghana and Nigeria for clinical trials of NORPLANT® subdermal implants. Training of these investigators will be conducted in Santo Domingo, Dominican Republic, in Summer 1985. Other countries that are being explored as possible study sites for 1986 include Guatemala, Panama, Peru, Venezuela and Argentina. Also, increased experience with the NORPLANT®-2 covered rod system may lead to comparative trials of the two systems. A strategy has been developed to support the widespread introduction of NORPLANT® implants into the national family planning program in Egypt. One component of this strategy is the establishment of a comprehensive patient registry that will permit both postmarketing surveillance research and cohort analysis of acceptors and non-acceptors.

2. Oral Contraceptives

FHI has continued to compare the efficacy, safety and acceptability of oral contraceptive formulations. Special emphasis has been

placed on low estrogen dose pills and their acceptability in the developing world.

a) Norinyl 1/35

Norinyl 1/35 is being evaluated in a fifteen-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. Preliminary analysis of these studies is presented in the three tables found at the end of the section.

Table 1, shows data from the four centers in the Norinyl 1/35 versus Brevicon trial. Brevicon users had significantly higher discontinuation rates for menstrual problems, side effects and other medical reasons, resulting in a significantly lower eight-month continuation rate, 41.4 compared with 55.3 for Norinyl 1/35 users. Breakthrough spotting and/or bleeding was the most frequently reported menstrual problem, and headaches were the most frequently reported side effect causing pill discontinuation.

A Norinyl 1/35 versus Lo-Ovral comparison is being conducted at six centers. Norinyl 1/35 had a significantly higher eight-month termination rate for menstrual problems (Table 2). In this study, breakthrough bleeding was the most frequently reported menstrual problem causing discontinuation. Cumulative life table continuation rates at eight months were 77.2 for Norinyl 1/35 users and 81.7 for Lo-Ovral users ($p > 0.05$).

Five centers are participating in the Norinyl 1/35 versus Norinyl 1/50 trial. There were no differences between the two pill groups with respect to event or continuation rates (Table 3). Continuation rates at eight months were 82.3 for Norinyl 1/35 and 83.9 for Norinyl 1/50.

b) Oral Contraceptives With and Without Iron

A protocol has been prepared for a double blind placebo-controlled trial to study the effects of iron supplement tablets on the reported side effects and acceptability of oral contraceptives. FHI is planning to obtain supplies for this study from Kemia Farma of Indonesia and plans study initiation in Summer 1985.

c) Progestogen-only Oral Contraceptives

A comparative trial of the progestogen-only oral contraceptive Microval and non-hormonal methods of contraception was active for follow-up in Egypt during the reporting period. Center selection has been completed for a 4000-case, 20-center noncomparative clinical trial of the progestogen-only oral contraceptive Ovrette. The trial is designed to evaluate the acceptability, safety and effectiveness of this minipill among breast-feeding women. Eighteen sites are actively recruiting acceptors and two centers being supplied with study materials are scheduled to start the study shortly. All subjects are scheduled to complete 12 months of follow-up.

In order to establish the acceptability of the progestogen-only pill in a population of breast-feeding women, an expanded strategy has been developed to distribute and evaluate Ovrette in several countries, preferably through a community-based or health post system. Studies have begun in Mali and Brazil. This expanded strategy will also provide 12 months of follow-up.

Future Plans

FHI plans to initiate three additional multicenter trials of oral contraceptives in interval women: 1) an evaluation of Triphasic formulations compared with LoFemenal 2) comparative evaluations of various low-dose oral contraceptives and 3) an evaluation of the acceptability of switching from a standard to a low-dose estrogen pill.

Published results of studies to assess the effect of oral contraceptives on milk yield during lactation have indicated inconsistent findings. FHI plans to conduct a study using a crossover design in which each woman will serve as her own control. A detailed protocol for the study is being developed and initiation is planned for late 1985.

Table 1

Cumulative Lifetable Rates for Comparative Studies
of Norinyl 1/35 versus Brevicon

	Norinyl 1/35 (N=409)	Brevicon (N=419)
Accidental pregnancy		
1 month	0.3	0.3
4 months	0.8	0.3
8 months	0.8	0.3
Menstrual problems		
1 month	2.7	3.7
4 months*	8.4	16.2
8 months**	13.6	27.1
Side effects		
1 month*	1.2	4.0
4 months**	2.1	9.5
8 months*	7.2	13.7
Other Medical Reasons		
1 month*	0.3	2.0
4 months**	3.1	3.4
8 months**	3.1	7.4
Continuation		
1 month	89.5	85.8
4 months**	71.9	61.0
8 months**	55.3	41.4
Follow-ups		
1 month	88.5	87.6
4 months	67.6	68.1
8 months	48.1	48.1

* p < 0.05

**p < 0.01

Table 2

Cumulative Lifetable Rates for Comparative Studies
of Norinyl 1/35 versus Lo-Ovral

	Norinyl 1/35 (N=625)	Lo-Ovral (N=621)
Accidental pregnancy		
1 month	0.0	0.0
4 months	0.9	0.0
8 months	0.9	0.0
Menstrual problems		
1 month	1.3	0.5
4 months	3.1	1.3
8 months*	4.7	1.3
Side effects		
1 month	0.5	0.7
4 months	2.7	1.9
8 months	3.8	3.4
Other Medical Reasons		
1 month	0.4	0.4
4 months	0.6	1.3
8 months	1.7	1.6
Continuation		
1 month	96.1	97.1
4 months	87.0	87.4
8 months	77.2	81.7
Follow-ups		
1 month	88.5	91.0
4 months	69.9	71.5
8 months	45.3	48.3

* $p < 0.05$

Table 3

Cumulative Lifestable Rates for Comparative Studies
of Norinyl 1/35 versus Norinyl 1/50

	Norinyl 1/35 (N=753)	Norinyl 1/50 (N=747)
Accidental pregnancy		
1 month	0.0	0.0
4 months	0.2	0.0
8 months	0.2	0.0
Menstrual problems		
1 month	1.1	0.7
4 months	2.6	2.9
8 months	3.8	3.7
Side effects		
1 month	0.6	1.2
4 months	2.1	2.5
8 months	2.7	3.5
Other Medical Reasons		
1 month	0.0	0.3
4 months	0.5	1.0
8 months	0.9	1.6
Continuation		
1 month	96.9	95.8
4 months	88.8	88.3
8 months	82.3	83.9
Follow-ups		
1 month	93.6	93.4
4 months	83.1	83.5
8 months	70.6	72.6

B. Vaginal Contraceptives

1. Barriers and Spermicides

In the past six months, FHI has continued to evaluate several vaginal contraceptives. The number of subjects and reasons for discontinuation are listed by method in Table 4 at the end of this section. The ongoing study in Yugoslavia has found no differences in efficacy or acceptability between Neo Sampooon tablets, containing the spermicide, menfegol, and contraceptive foam. A comparative study of Neo Sampooon and the diaphragm in Bangladesh has suggested that the burning sensation associated with the effervescent Neo Sampooon tablets is unacceptable to many women. Apparent equivalence of Emko Vaginal Tablets (EVT) and Ortho Vaginal Tablets (OVT), each containing nonoxynol-9, 100 mg, has been observed in Egypt.

Four recently initiated comparative tablet studies are now underway in two U.S. sites and two sites in Ghana. These studies compare Ortho vaginal tablets (OVT) containing nonoxynol-9 with tablets containing menfegol (Neo Sampooon repackaged). Follow-up has not progressed sufficiently at these sites to assess tablet acceptability. Recruitment of subjects at the U.S. sites continues to be difficult.

2. Propranolol

FHI recently conducted a series of in-vitro studies which confirmed that D-propranolol is a sufficiently good spermicide to warrant

further development. Although D-propranolol has about one-third the spermicidal potency of racemic DL-propranolol, it has only about one-hundredth of L-propranolol's beta-blocking potency; consequently it is expected to be more acceptable than DL-propranolol as a spermicide. Additional tests conducted by FHI showed D-propranolol penetrated cervical mucus at low molecular concentrations and subsequently prevented sperm ascent.

In a clinical study of D-propranolol conducted in London with FHI support, subjects inserted 40mg or 80mg D-propranolol tablets or 100mg nonoxynol-9 tablets vaginally prior to intercourse, and then reported within three hours for postcoital examination of cervical and vaginal mucus. Results from four of ten subjects completing the protocol to date show that the 80mg D-propranolol tablet is as effective as 100mg nonoxynol-9 in inhibiting sperm motility 100% in both vaginal and cervical mucus.

Future Plans

FHI will continue to evaluate several of the barrier and spermicidal methods investigated during the past year. The comparative trials of Neo Sampoo and foam, and OVT and EVT will be completed in 1984-1985. Comparative trials of OVT (menfegol) and OVT (nonoxynol-9) will continue in the U.S. and in Ghana.

Emphasis will be placed on the continued development of D-propranolol as a spermicide. FHI plans to conduct Focus Group research to determine women's preference for different vaginal

products such as gels, creams and tablets. Based on these results, FHI will begin work on formulation of D-propranolol as a spermicide in anticipation of clinical trials. FHI also plans to submit an IND to the FDA for clinical development of D-propranolol as a spermicide.

Table 4
**Results of Studies Active Under the Comparative Vaginal
 Vaginal Contraceptive Protocol
 October 1984 - March 1985**

Reasons for Discontinuation

Location	Method	# of Admissions	Accidental Pregnancy	Planned Pregnancy	Medical	Discomfort	Product Related	Other Personal
Yugoslavia	Neo Sampoo	116	9	3	0	21	1	13
	Foam	119	11	6	0	22	1	10
Egypt	Neo Sampoo	166	5	1	1	7	0	4
	Foam	164	6	0	1	7	0	1
Egypt	Neo Sampoo	176	4	0	3	4	4	21
	Foam	173	2	2	1	4	4	24
Bangladesh	Neo Sampoo	76	5	4	1	17	0	7
	Diaphragm	94	7	1	2	7	6	5
Minnesota	EVT-nonoxydol-9	13	1	0	0	2	1	2
	OVT-nonoxydol-9	19	2	1	0	2	0	3
Texas	EVT-nonoxydol-9	56	6	0	1	5	2	8
	OVT-nonoxydol-9	51	4	1	2	1	5	4
Egypt	EVT-nonoxydol-9	70	10	1	1	3	1	7
	OVT-nonoxydol-9	70	11	0	1	6	1	10
North Carolina	EVT-nonoxydol-9	14	2	0	0	2	1	1
	OVT-nonoxydol-9	19	2	0	0	3	1	2
Ghana	OVT-nonoxydol-9	36	0	0	0	0	0	0
	OVT-menfegol	35	0	0	0	0	0	0
Ghana	OVT-nonoxydol-9	6	0	0	0	0	0	0
	OVT-menfegol	4	0	0	0	0	0	0
Michigan	OVT-nonoxydol-9	4	0	0	0	0	0	1
	OVT-menfegol	9	1	0	0	0	0	1
Texas	OVT-nonoxydol-9	14	1	0	0	0	0	1
	OVT-menfegol	12	1	0	0	1	0	0

C. Surgical Female and Male Sterilization

1. Surgical Female Sterilization

FHI continues to evaluate various techniques of tubal occlusion. One of the larger evaluations being conducted is a comparison of the Filshie Clip and the Pomeroy method via minilaparotomy in postpartum women. Data have been received from three sites conducting this evaluation. A total of 687 procedures have been performed to date (see Table 5). Three women have been excluded from analysis because random allocation was not followed for these cases. There have been two (0.6%) technical failures with the Filshie Clip procedures and three (0.9%) in the Pomeroy group. The rates of surgical difficulties are 5.7% and 6.2% for the Filshie Clip and Pomeroy groups, respectively. Surgical injuries or complications have occurred for 6 (1.8%) Filshie Clip patients and 7 (2.0%) Pomeroy patients. Few major complications occurred during the recovery period; the rates are 0.9 % in the Filshie Clip group and 0.3% in the Pomeroy group.

Early follow-up (< 30 days post-sterilization) is now complete for 285 (86.4%) women in the Filshie Clip group and 265 (75.9%) women in the Pomeroy group. Approximately 50.0% 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 (17.9%) Filshie Clip patients and 53 (20.0%) Pomeroy patients. These complications consisted of two readmissions to the hospital,

one in each group, and incision-related problems. The readmission in the Pomeroy group was because of profuse vaginal bleeding. One night of observation was required. The reason for the readmission in the Filshie Clip group was unspecified; treatment consisted of observation only.

During the six-month follow-up interval (1 - 8.5 months post-sterilization), four women, three in the Pomeroy group and one in the Filshie Clip group, were readmitted to the hospital. The one Filshie Clip patient was readmitted for a gall bladder operation and the three readmissions in the Pomeroy group were for menorrhagia, cervical conization and curettage. No pregnancies have occurred.

Table 5

Filshie Clip and Modified Pomeroy
Events During Surgery and at Follow-up

Event	Filshie Clip (N=332)		Modified Pomeroy (N=352)	
	No.	%	No.	%
Technical failures				
Change in approach due to adhesions	0	-	1	0.3
Two techniques used due to:				
Obesity	0	-	1	0.3
Tumors	1	0.3	0	-
Difficulty in application	1	0.3	0	-
Only one tube	0	-	1	0.3
TOTAL	2	0.6	3	0.9
Surgical difficulties				
Entering peritoneum	2	0.6	0	-
Visualizing tube	6	1.8	11	3.1
Grasping tubes	8	2.4	8	2.3
Occluding tubes	2	0.6	0	-
Uterine involution	0	-	2	0.6
Obesity	1	0.3	0	-
Mesosalpinx varicose	0	-	1	0.3
TOTAL	19	5.7	22	6.3
Surgical injuries/complications				
Tubal/mesosalpinx injury without bleeding	1	0.3	1	0.3
Tubal/mesosalpinx injury with bleeding	5	1.5	5	1.4
Soft tissue emphysema	0	-	1	0.3
Women returning for early follow-up				
	285	86.4	265	75.9
Readmission to the hospital				
	1	0.4	1	0.4
Incision complications				
Serous discharge	26	9.1	22	8.3
Inflammation	14	4.9	16	6.0
Abscess	5	1.8	5	1.9
Bleeding	1	0.4	1	0.4
Incomplete dehiscence	3	1.1	8	3.0
Other	1	0.4	0	-
Total women with 1+ complications				
	51	17.9	53	20.0

A comparative evaluation of the Filshie Clip and the Secuclip via minilaparotomy in interval women is underway at three centers in Latin America. A total of 159 procedures have been performed. There have been two (2.4%) technical failures, both in the Filshie Clip group. In each case, obesity necessitated a change in approach. Surgical difficulty rates are comparable for the two techniques at 7.1% and 9.3% for the Filshie Clip and Secuclip, respectively. Rates of surgical injuries/complications are also similar at 3.6% for the Filshie Clip group and 2.7% for the Secuclip group. Few major complications have occurred during the recovery period; 8 (9.8%) Filshie Clip patients and 6 (8.0%) Secuclip patients developed problems at that time. All of these complications were related to the surgical incision. Early follow-up has been completed for 47.6% of the women in the Filshie Clip group and 42.7% of the women in the Secuclip group. At early follow-up, complications were noted for a total of 11 (27.5%) and 9 (28.1%) women in the two groups, respectively. The majority of these complications were incision-related. No pregnancies have been reported to date. The patients will be followed-up through 12 months poststerilization.

Data have been received from one of the three centers in Latin America conducting a comparative study of the Filshie Clip and the tubal ring via Minilaparotomy in interval women. Seventy-four women have been admitted to the study. There have been no technical failures reported. Surgical difficulty rates are relatively high for both techniques; 27.6% and 28.9% for Filshie Clip and tubal

ring procedures, respectively. Most of these difficulties were caused by inadequate local anesthesia that resulted in patient movement during the procedure. General anesthesia is now being used for all procedures and the incidence of surgical difficulties has decreased. Rates of surgical injuries/complications are comparable at 13.8% and 13.3% for the respective groups; most of these were injuries to the tube or the cervix and most occurred during the initial procedures. One complication has been reported during the recovery period for a woman in the tubal ring group; none of the women in the Filshie Clip group experienced complications at that time. A total of 19 (65.5%) Filshie Clip patients and 24 (54.5%) tubal ring patients have returned for an early follow-up visit. All women will be requested to return for follow-up through 12 months poststerilization.

One comparative study of the Secuclip and the tubal ring has recently been completed in Indonesia. A total of 102 Secuclip and 98 tubal ring procedures were performed via minilaparotomy in interval women. One technical failure was reported in the tubal ring group; there were no technical failures in the Secuclip group. The only surgical difficulty occurred when grasping the tubes during a tubal ring procedure. Few surgical injuries or surgical complications were reported; the rates were 1.0% and 2.0% for women in the Secuclip and tubal ring groups, respectively. No complications occurred during the recovery period for women in either group. The follow-up rate at one month was 100.0% for each group, and the incidence of complications was low. Long-term follow-up data, through 12-months poststerilization, was available

for approximately 25.0% of the patients. Two luteal phase pregnancies were reported in the tubal ring group. No other major complications were reported during the follow-up interval.

FHI has been assessing the long-term effect of surgical female sterilization at three sites, one in Thailand and two in Bangladesh. In Thailand, 263 women have returned for a long-term follow-up visit five years poststerilization. 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 7 (2.7%) poststerilization pelvic surgeries have been reported so far. Three of these surgeries were performed on women sterilized with the Hulka Clip, including one hysterectomy, one diagnostic laparoscopy and one colpoperineorrhaphy. The remaining four surgeries were reported for women sterilized by use of electrocoagulation. These surgeries included one hysterectomy, two cases of dilatation and curettage and one unspecified procedure. Most women (99.7%) have indicated satisfaction with their decision concerning sterilization.

A total of 288 women have returned for long-term follow-up at a site in Bangladesh where a comparative study of tubal ring and modified Pomeroy occlusion was conducted from 1977-1978. Three pregnancies have been reported, two in the tubal ring group and one in the Pomeroy group, yielding respective pregnancy rates of 1.5 and 0.7 at 72 months. One abdominal/pelvic surgery of dilatation and curettage has been performed on a tubal ring patient during the follow-up

interval. The women (94.8%) have generally expressed satisfaction with the sterilization procedure.

Long-term follow-up data are also being collected at an additional site in Bangladesh where a comparative evaluation of the tubal ring and the Pomeroy method was conducted in 1978. The long-term follow-up study has just begun; twenty women have returned for a visit. No pregnancies, poststerilization surgeries or complications have been reported to date.

FHI is collaborating with PARFR to evaluate the Intratubal Device, a nylon plug inserted at the tubal ostia which may be removed to restore fecundity. Three sites are conducting this evaluation and 97 procedures have been performed. There have been two (2.1%) technical failures, one due to a vasovagal reaction and the other because of inadequate anesthesia. Insertion difficulties have been reported for 13 (13.4%) procedures, consisting primarily of difficulties visualizing the tubes. The rate of injuries/complications at insertion is 6.2%. Early follow-up is now complete for 31 (32.0%) women and few complications have been noted. Follow-up will continue for 12 months poststerilization.

Future Plans

During the remainder of the year, FHI plans to initiate several new studies. As mentioned previously, two sites will begin a comparison of the Filshie Clip and the tubal ring applied via minilaparotomy in interval women. In addition, four sites have been selected to

compare these two techniques via laparoscopy; two sites are expected to initiate the study this year. Evaluation of the Filshie system will be expanded in several ways. Comparison with the Wolf Clip, for both laparoscopic and minilaparotomy procedures, is planned and two new sites will be sought for the postpartum Filshie versus Pomeroy comparison. FHI will also collaborate with Femcare to conduct three noncomparative studies of the Filshie Clip in Canada. A pilot study of the Femtest device, for determining tubal patency, has just begun in Chile and, if initial results are encouraging, five other sites will be selected.

2. Male Sterilization

Final plans have been made for a study of percutaneous occlusion of the vas. A total of 100 men will be admitted to the study in London. The men will be sterilized either by the standard incision and diathermy method used at the clinic or by the percutaneous method, which eliminates the need for a surgical incision. It is anticipated that the study will begin in May, and follow-up will be done through 24 weeks poststerilization.

D. Nonsurgical Female Sterilization

The development of a rapid, effective and safe nonsurgical method that can be performed by paramedical personnel remains a high priority for FHI.

1. Quinacrine Hydrochloride

Long-term follow-up of women (N=500), who have been sterilized by transcervical administration of quinacrine pellets continues; 48-month follow-up is being collected from two sites in Chile.

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 is planned for initiation in Spring 1985, at the University of Texas Health Sciences Center in San Antonio. This study will include a 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 more effective than the 10-minute releasing product. Therefore, FHI will submit an amendment to the quinacrine IND to conduct a Phase I 30-day pre-hysterectomy study of this slower releasing formulation.

2. Tetracycline Hydrochloride

The Phase I study of the transcervical insertion of 100 mg of tetracycline hydrochloride pellets 24 hours before hysterectomy has been initiated at the Johns Hopkins University in Baltimore. The study will evaluate tetracycline pharmacokinetics and include

histological examinations of uterine and fallopian tube tissues. A 30-day pre hysterectomy study is also being developed.

Studies in rats continue in Scotland to determine whether the damage caused by tetracycline hydrochloride is related to its acidity (pH2) or to a specific effect on the oviductal epithelium.

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.

3. Methylcyanoacrylate (MCA)

Two-year follow-up of women who have been sterilized with MCA has been completed by FHI for studies previously funded through PARFR. FHI continues study monitoring, data collection, processing and data analysis for three PARFR-funded MCA studies evaluating a two-procedure regimen.

Future Plans

Evaluations of the safety and sclerosing effect of 100-minute releasing quinacrine pellets (250 mg) and tetracycline pellets (1000 mg) on uterine and fallopian tube tissue when administered 30 days before a scheduled hysterectomy will be initiated in the next six months.

E. Intrauterine Devices

1. IUDs With and Without Strings

FHI continues to conduct a clinical trial comparing the TCu200 IUDs with and without marker strings in order to determine the possible role of strings in the etiology of pelvic inflammatory disease (PID). Preliminary analysis of 776 women from four centers, with an overall follow-up rate of 60%, reveal no differences between the two groups with respect to 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 7.0 for the strings group and 1.7 for the without strings group ($p < 0.01$). This difference may be related to the relative ease of removing an IUD with strings compared to removing an IUD without strings.

2. 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. Continuation 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, Egypt, Yugoslavia and the Philippines are collecting three year follow-up data on women enrolled in this evaluation.

In Yugoslavia, one center has completed three year follow-up. The TCU380Ag and the Multiload Cu375 are comparable in terms of efficacy and complications and complaints. The expulsion rates, however, were 3.8 for the TCU380Ag and 10.4 for the Multiload Cu375, a difference approaching statistical significance ($p < 0.06$).

3. Wing Sound II Evaluation

Follow-up for the four studies evaluating the Wing Sound II is complete. Final data analyses are currently underway.

4. Evaluation of the TCU380A

An evaluation of the TCU380A IUD has been designed to provide data on the acceptability of the FDA-approved TCU380A by comparing it to locally used IUDs throughout the world. Investigators in Egypt, Thailand, Indonesia, Turkey and Venezuela have been recruited during the past six months. The studies in Indonesia and Thailand will be large multicenter trials. Initiation of the first studies is expected in May. Recruitment of centers in additional countries will continue.

5. Adapted T versus TCU200

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

determined by the use of the Cavimeter II, an instrument designed for this purpose.

A small pilot study will be initiated in Thailand in May 1985.

Future Plans

A trial has been designed to compare the Merchant Copper Coil, a ring-shaped copper intrauterine device to the TCu200, the standard T-shaped copper device. Plans to conduct this trial are pending an evaluation of the manufacturing facilities and quality control procedures for the Merchant Copper Coil.

The Brush Retriever, a device developed at FHI to retrieve IUD strings that have migrated into the uterus, will be evaluated in up to 25 sites around the world as soon as a suitable manufacturer of the device is identified and the devices are available.

IUDs placed in the uterus through the incision immediately following Cesarean section continues 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 being designed.

FHI's interest in conducting clinical trials of the levonorgestrel-releasing IUDs in developing countries continues. At present there is no indication, however, of when FHI's participation in this research will be feasible.

F. Investigator Network Needs

There are currently eleven on-going studies under FHI's Investigator Network Needs strategy. In keeping with the objectives of this strategy all of these studies address special research interests of the area in which they are being conducted and, with only one exception, they involve investigators who are conducting their first FHI-related clinical trial.

These clinical trials focus on a variety of contraceptive methods: there are 4 in IUDs, 3 studies in the systemic area, 3 in female sterilization and 1 in male sterilization. For ease of discussion, the progress of the individual studies will be grouped by contraceptive method area.

1. IUD Studies

The four ongoing IUD studies are in various stages of completion. Dr. Ismail El-Essaily's study of the Copper-T versus the Lippes Loop D was the first to get started in October 1983 is now coming to a close. Some difficulty has been encountered in obtaining adequate follow-up. At six months, the continuation rate for the CuT200 was 92.4 compared to 76.2 for the Lippes Loop D.

Dr. Damrong's study of the ML 250 versus Copper T in postpartum women has just passed the halfway mark in completing its scheduled 300 admissions. The results of this study will be of particular

interest to Thailand's family planning program where the ML 250 is the IUD provided through the government sponsored program.

The two most recent IUD studies initiated under the Investigator Network Needs strategy are both being conducted in Northern Nigeria. One of the investigators has been recommended by the AID Affairs Officer in Nigeria as a potential candidate for a NORPLANT® study and, thus, his IUD study should serve as a particularly important introduction to quality clinical trial research.

2. Sterilization Studies

The Brazilian 2000 case survey of laparoscopy with the tubal ring is nearing completion. To date 1,560 women have been followed up at six months or more (up to 24 months) following their surgery. Of these 19 (1.2%) have become pregnant. Forty-six (2.9%) other complications or complaints were documented, the most common of which are adnexal pain, vaginal bleeding other than menses and menstrual pattern disturbances.

In contrast to the above study designed to address the safety and efficacy of a specific procedure, the multi-center surveys of male and female sterilization in Haiti were designed to identify and provide training to new investigators.

In the male sterilization studies in Haiti, all of the men were sterilized via ligation with absorbable sutures, but the approach to the vasa varied. One hundred eighteen men underwent a single

vertical incision, while 71 men underwent a double vertical incision. There were two cord hematomas in the double incision group. No technical failures occurred in either group.

Of the 1668 cases of female sterilization from Haiti, 286 interval women and 478 postpartum women were sterilized using the Pomeroy method via minilaparotomy. A total of 589 interval women and 209 postpartum women underwent laparoscopic surgery, and had their tubes occluded with tubal rings. The remaining women were sterilized via various other approaches and techniques.

There were eight technical failures in the Pomeroy groups that caused a change in technique; these were mainly the result of surgical difficulties. There was one tubal injury in each of the Pomeroy groups. Surgical injuries in the ring group occurred for 28 women (3.5%); there were 14 cervical lacerations and 14 tubal injuries, distributed equally between the two groups. Follow-up continues for this study.

3. Systemics

Three studies on different systemic methods are ongoing and a fourth, involving locally-available progesterone-only pills in Zimbabwe, is currently under development.

Two of the currently ongoing studies are designed to evaluate the safety and acceptability of Depo-Provera. One compares two groups of women, both of whom have been using DMPA for at least a year

before study entry, but at different dosages and intervals (25mg per month versus 150mg per three months). Thus far, the data collected from 85 cases indicate that more women receiving 150mg of DMPA complain of amenorrhea (56.5%) than do women receiving 50mg DMPA (12.1%). The continuation rate, however, is higher in the 150mg group with 87.4 per 100 continuing at 12 months in this group compared to 53.0 per 100 in the group receiving 50mg monthly.

In the remaining Depo-Provera study, the Gambia Family Planning Association has completed the retrospective recording of 400 admission records, evenly divided between women who began using oral contraceptives or Depo-Provera prior to June 1981. They are now in the process of following up these 400 women and thus far too little data have been collected for meaningful analysis. However, given the positive working relationship with the GFPA on this initial project, FHI would like to conduct a comparative oral contraceptive study with them on conclusion of the first study.

A final systemic study, being conducted in Mali, compares Noriday and Lo-Femenal, two locally available oral contraceptives. This study is being conducted by the Maternal and Child Health Center associated with the Ministry of Health and, again, this was FHI's first clinical trial with this center. Once this study was underway, the center expressed interest in and was selected for an additional trial under FHI's expanded progesterone-only pill strategy.

As this summary indicates, studies under the Investigator Network Needs strategy have been conducted predominantly with investigators new to FHI and often new to clinical trial research. In many cases, these initial studies have led to further collaboration with FHI. To ensure that the studies are well-planned, all trials initiated in the past year have had the guidance of a specific protocol, generally developed in consultation with the investigator so that special interests relating to the methods selected for study were addressed. Since October 1984, site visits have been made to six of the centers involved in these ongoing studies and in the upcoming six months all but one of the remaining studies will be visited.

Two new studies were initiated under the Investigator Network Needs strategy in the past six months and two other studies are under development.

Future Plans

It is anticipated that the number of new studies will increase to approximately 16 following the recruitment of investigators attending the Asian Clinical Trials workshop.

G. Other Studies

FHI has provided ultrasound machines to four sites in Egypt. This equipment will be used for training in IUD insertion and for prenatal care. A consultant from the University of North Carolina

Medical School has provided the necessary training at the four sites.

IV. REPRODUCTIVE EPIDEMIOLOGY

Research in the Reproductive Epidemiology Division focuses on four related areas:

A. The exploration of the relationships between contraception and disease (both mortality and morbidity), including (a) the identification of special conditions that influence this association, and (b) the balance of benefits and risks of contraception;

B. The exploration of the association between contraception and cancer;

C. The relationships between contraception, sexually transmitted diseases and infertility;

D. Reproduction and health.

Almost all of the epidemiologic work evaluating specific risks and benefits of contraceptive methods has been done in the developed countries (primarily the US or UK). Although it is sometimes assumed that the findings from these studies are applicable to the developing world, this has not been demonstrated. Not only are the disease patterns different in developing countries thus changing the public health impact of certain associations, but there are important differences between women in the developed and developing countries in areas such as nutrition, propensity to cardiovascular

disease or exposure to other environmental carcinogens. Some research suggests, for example, that OCs may be less likely to increase the risk of thromboembolism in Asian than in Western populations. Almost every association found between contraception and disease in developed countries needs to be confirmed in the developing world. In addition, it is likely that there are associations between contraception and disease that can be best studied in the developing world because of different disease incidence or prevalence, contraceptive use, subject identification, treatment or other factors.

A. Exploration of Relationships Between Contraception and Disease

Epidemiologic and clinical studies have demonstrated both benefits and risks to be associated with almost every method of contraception. Hypotheses about associations continue to be generated on the basis of clinical observation, animal studies, and earlier epidemiologic studies among others. The design and implementation of studies to test these hypotheses is the prime focus of this Division, and several studies in this area are underway or in the development stage.

1. Cohort Study of Oral Contraceptive Users

During this reporting period, FHI in collaboration with NIH, has initiated investigation into the feasibility of 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 Practitioners' Oral Contraceptive study--a landmark prospective study which helped establish much of our knowledge of the health effects of OCs. The new study will probably include 100,000 women of reproductive age. FHI's contribution will consist of technical and financial assistance with the pilot study and non-recurring initial costs, including the evaluation of present computer hard- and software.

2. Morbidity Among Contraceptive Users

For the most part, studies of morbidity in contraceptive users have been limited to populations of women who are predominantly white and over the age of 25. Data from hospitalizations among 26,507 young, black women who attended the Grady Memorial Hospital Family Planning Clinic between 1968 and 1976 have been analyzed. Age-adjusted hospitalization rates (per 1000 woman years) were compared for women using oral contraceptives, IUDs and DMPA. Overall, women using OCs were hospitalized 30% less often than IUD or DMPA users who were hospitalized at about the same rate. The rate of hospitalization for circulatory disease was no higher among OC users than among users of other methods. Compared with women using IUDs, users of OCs and DMPA were less likely to be hospitalized for benign breast disease (respectively, risk ratios = 0.5 and 0.2 with 95% confidence limits 0.3, 0.7 and 0.1, 0.5) and for pelvic inflammatory disease.

Women hospitalized for carcinoma in situ of the cervix (CIS) were four times as likely to be using DMPA as either OCs or IUDs.

However, the relatively high rate of CIS hospitalizations among DMPA users is probably not associated with the contraceptive. The duration of use of DMPA was short, and many women at high risk of CIS were encouraged to use DMPA as a contraceptive. Among women who had at least three years of use of either OCs, IUDs or DMPA, the CIS-hospitalization rates for users of the three groups were 0.9, 0.8 and 0.5 per 1000 woman years respectively. In addition, women with abnormal Pap smears were referred to the family planning clinic from the Grady Tumor Clinic for the purpose of receiving DMPA to prevent pregnancy while further diagnostic work was being done. Two papers from this analysis have been submitted for publication.

3. Prevalence of Contraindications to Methods

Few developing countries have available mortality and morbidity data. But information on the prevalence of conditions which contraindicate use of specific contraceptive methods (especially OCs) is needed by public health officials making choices for country programs. In collaboration with the National Family Planning Coordinating Board of Indonesia (BKKBN), FHI is collecting 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 will supplement the RAMOS study in Indonesia (which collected data on mortality only). Data collection was completed during this reporting period; data processing and analysis will take place in Indonesia and is expected to be complete early in 1985.

4. The Perceptions of Physicians and Midwives of Risks of Oral Contraceptive Use

The purpose of this study is to determine how health professionals who provide oral contraception perceive the method, and whether they are as well-informed about the benefits as they are about the contraindications and risks associated with oral contraceptive use. Information was collected through focus group discussions. The data are being processed and analyzed in Indonesia, and a report is expected during the next six months.

5. 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. The study began in June 1984 and is being conducted in collaboration with the Johns Hopkins University.

A similar study is being conducted in Israel with children exposed to medroxyprogesterone acetate (MPA) used to treat threatened abortion. This study examines the same indices as the Thai study, but will also consider handedness, degree of aggression and several psychological factors relating to masculinity. The questionnaire

was pretested in 1984, and data collection began in February 1985. Hebrew University in Jerusalem is the collaborating institution.

6. Sterilization as a Risk Factor for Hysterectomy

Several investigators have suggested that tubal sterilization increases the risk of dysfunctional uterine bleeding and subsequent hysterectomy. During the last year, FHI began the development of two studies designed to evaluate this hypothesis. One study was initiated during the reporting period in Mexico. This study uses the case-control method to compare the prevalence of sterilization in women undergoing hysterectomies for the indications of dysmenorrhea or abnormal uterine bleeding with the prevalence among clinic-based controls and among women having hysterectomies to treat fibromas. A second study in Singapore will compare the hysterectomy rate of women undergoing tubal sterilization five years previously with that of an equal number of women undergoing minor gynecologic surgery (not related to dysfunctional bleeding) during the same time period. This study is not being developed presently for administrative reasons.

7. Special Conditions Influencing the Relationship Between Contraception and Disease

Initial evaluation of methods of contraception is usually accomplished through clinical trials that involve carefully controlled conditions. Often the physicians have been specially trained, patients are carefully selected to exclude women with all

contraindications, procedures are standardized, and complications are closely monitored. Once the contraceptive is adopted, however, less careful attention is given to each patient receiving the drug. It is also useful to evaluate the reliability and acceptability of a contraceptive method under these "real life" circumstances. Sick women need contraception as well as healthy women, and providers need to know the most appropriate method for them.

Sickle Cell Disease: Sickle cell disease is considered by many to contraindicate the use of OCs. However, beneficial effects of DMPA in women with sickle cell disease in Jamaica have been reported, and other studies suggest that progestins favorably influence the course of the disease. The small dose of estrogens in the new OCs appear not to increase the risk of clotting problems. To determine whether oral contraceptives show the same benefits as DMPA, FHI is undertaking a clinical trial in the same population as the DMPA study. An Investigational New Drug (IND) application for the use of OCs in this study was approved by the FDA during this reporting period. Patient recruitment began in March 1985 and will continue through March 1986. Patients will be followed for 18 months.

Two hundred women of reproductive age who were receiving treatment at the Sickle Cell Clinic of Korle Bu Hospital in Accra, Ghana, were asked what methods of contraception they had ever used and where they obtained those methods. In spite of the risks associated with pregnancy for women with this disease, only 25% of these women were presently using contraception. Oral contraception was the choice of most women (29%) currently using contraception, but the use of less

effective methods (54%) remained common. Although abortion is illegal in Ghana, 35% of the women who were using contraception had had an abortion. A paper describing these results was published in the January 1985 issue of the British Journal of Family Planning.

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 found in the developing world. Since oral contraceptives are metabolized in the liver, FHI has begun to develop studies to determine the possible role of oral contraceptives in the transmission and progression of the disease. An appropriate site is being sought.

Rheumatic Heart Disease and Contraceptive Use: The new OCs have lower doses of estrogen than earlier formulations, but fears of coagulation changes prevent many physicians from prescribing OCs for patients with rheumatic heart disease. A protocol to study the safety of hormonal contraceptive use among women with rheumatic heart disease has been developed and an appropriate site for this study is being investigated.

Cervical Dysplasia: Some studies have shown that oral contraceptive users have low levels of serum folate which predisposes them to dysplasia-like changes in cervical cells. A clinical trial to evaluate the effect of folate supplements on cervical dysplasia among oral contraceptive users in Mexico has been developed. Information on other risk factors for cervical dysplasia will also be collected.

Surgical Contraception by Nonphysicians

Although the safety of both male and female sterilization has been well documented, there are situations in which safety can be compromised. The provision of these services by nonphysicians would greatly increase their availability in developing countries, but concern has been expressed that the procedure would be less safe than in the hands of physicians. To determine whether trained paramedics can perform vasectomies with safety and efficacy rates comparable to those of physicians, FHI is evaluating 1500 procedures done by paramedics in a program in Indonesia. Men will be visited in their homes and asked about complications experienced with the procedure. Because of recall difficulties, minor complications may be under-reported. Data collection began in 1984 and was completed during this reporting period. Preliminary results suggest that both complication and failure rates are low.

8. The Balance of Benefits and Risks of Contraception

Whether there is a net benefit from use of one method of contraception as opposed to another or to no method depends on several factors including the user's age, the risks associated with other methods, the risks associated with pregnancy and childbirth, and the disease pattern in the area. The Division has developed a means of assessing the balance of risks and benefits in a readily understandable manner.

Reproductive Age Mortality Survey (RAMOS)

Data collection was completed for both RAMOS studies (in Menoufia, Egypt and in Bali, Indonesia) in the last contract year. One paper using data from both studies and one using data from one study have been submitted for publication. Other analyses are underway.

A reproductive mortality rate of 45.8 per 100,000 married women was found in Menoufia, and 68.2 in Bali. 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. The annual contraceptive-associated death rates were estimated at 3.9 per 100,000 contraceptive users in Menoufia, and 2.0 per 100,000 users in Bali. 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). Comparison of data from the RAMOS study in Menoufia with national data reported to WHO suggests that only about half of direct obstetric deaths are reported as due to obstetric causes.

Risks and Benefits of Oral Contraceptives

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, there is a very slight **increase** in life expectancy; for women over 30, there is a small decrease in life expectancy. Because the majority of oral contraceptive users in the United States are young women for whom benefits of oral contraceptive use outweigh risks, the overall effect is a very small increase (<1 day) in the life expectancy of American women. These differences are so small as to be of no practical significance. A paper describing this analysis has been presented at the PAA meeting and has been submitted for publication. A paper describing a similar analysis for a developing country was presented at the 1984 SAC meeting in Jakarta and analyses using data from other developing countries will be undertaken in the next fiscal year. The beneficial effect tends to be greater for women in developing countries, and the benefits remain through age 35.

B. The Exploration of the Association Between Contraception & Cancer

1. Breast and Cervical Cancer and DMPA in Costa Rica

Fear of reproductive cancer among DMPA users was the primary reason for the 1984 disapproval by the Food and Drug Administration of this drug as a contraceptive for use in the United States. Animal studies suggested that DMPA might increase the risk of breast cancer, but no human study has shown this. Similarly, animal studies have suggested a possible increase in risk for cervical

cancer, but no study in humans has been done. FHI is working to fill this gap in knowledge with a study being undertaken in collaboration with the Centers for Disease Control, the Costa Rican Demographic Association and the Social Security Administration of Costa Rica. Costa Rica has a nationwide tumor registry considered to be relatively complete. DMPA has been used as a contraceptive in Costa Rica since 1970; by 1981, 9% of women aged 15-49 (or 47,000 women) had used DMPA. Interviews have been conducted with 190 women with breast cancer and 700 women with cervical cancer (both invasive and in situ). The 872 controls were drawn at random from the nation's population.

Data collection was completed during the period, and the data are presently being edited and prepared for joint analysis by FHI and the CDC. Analysis is expected to begin in fall of 1985.

2. Cervical Cancer and Contraception in Jamaica

In spite of several case-control studies in developed countries, the relationship between cervical cancer and oral contraception is not clear. FHI has developed a case-control study of cervical cancer and contraception in Jamaica. Both OC and DMPA use will be examined. Jamaica has one of the world's highest rates of cervical cancer. More than half (55%) of women in union use contraception, and approximately 15% of women have used DMPA. Interviews will be conducted with 200 women with invasive or cervical carcinoma in situ and 400 controls.

The study will be conducted in collaboration with the Jamaica Cancer Society and has the endorsement of the Obstetrics and Gynaecology Society. The election of a new Chairman of the Board of Directors of the Cancer Society has contributed to delays in obtaining their approval, and access to the Tumor Registry is still being negotiated. As soon as approval is received, a pretest will be conducted and further refinements of the study questionnaire will be made.

3. 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. FHI has developed a case-control study using data from the CDC's Cancer and Steroid Hormones (CASH) 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. Randomly selected population controls are frequency matched to cases on several factors. Analysis will begin when data tapes are received from the CDC.

4. Prostatic Cancer and Benign Prostatic Hyperplasia

A study is being conducted in collaboration with Kaiser Permanente of California to examine the relationship between vasectomy and prostatic cancer and benign prostatic hyperplasia. 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. To date approximately 100 cases of prostatic hypertrophy and 40 cases of cancer have been identified through a computer search. Matched control subjects are now being identified as part of a retrospective cohort study. The medical records of cases and controls will be compared and incidence rates will be calculated for men with and without vasectomy. Data collection began in July 1984 and was completed in March 1985.

C. **Exploration of the Relationships Between Contraception, Sexually Transmitted Diseases (STDs) and Infertility**

Sexually transmitted diseases are probably the leading cause of infertility worldwide. FHI is launching a major cross-divisional effort to understand the relationship between contraception, STDs and infertility. Oral contraception has been shown to reduce the risk of STDs, and it has been hypothesized that use of spermicides is also protective. The association of IUDs with PID, and hence with infertility, has reduced their acceptability in some areas; modification of insertion practices may serve to reduce that tendency.

1. The Effect of Prophylactic Antibiotics on Post-IUD Insertion PID

A randomized double-blind trial has been designed 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 is being analyzed. The main study began in December 1984. By 31 March 1985, approximately 560 women will have been enrolled in the study and follow-up should be complete for 230.

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.

2. The Effect of Contraception on Sexually Transmitted Diseases

FHI has initiated a prospective study to determine the prophylactic effect of the contraceptive sponge on transmission rates of gonorrhea, chlamydia, trichomonas and monilia. During this reporting period the questionnaires were pretested and staff were trained in use of the chlamydia immunofluorescent diagnostic test.

The study was initiated in November 1984 at the Venereal Disease Division of the Ministry of Public Health of Thailand. One hundred and sixty-two (162) person-weeks of sponge use, and 134 person-weeks without sponge use have now been completed.

A cross-sectional study of the relationship between contraceptive use and the prevalence of STDs is underway at the Margaret Sanger Center, Planned Parenthood of New York City. Information has been abstracted from the medical charts of women who attended the Center's STD clinic or who sought minor gynecologic care. Preliminary analysis shows no protective effect of spermicide use. Additional analyses will be conducted through this fiscal year.

D. Reproduction and Health

Contraception is one important aspect of reproductive health, but other aspects of reproduction also attract FHI's interest.

1. The Male Influence on Spontaneous Abortion

Evidence increasingly suggests that male exposure to hazardous substances (usually in the workplace) can impair reproduction. A study was initiated in March 1985 which 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. This registry permits use of a sample of 73,000 exposed and 1,500,000 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.

A review of the epidemiologic evidence suggests that the adverse effect on reproduction of male exposure to hazardous substances may be mediated by sperm. The review has been accepted for presentation at the Third International Congress of Andrology.

2. 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. FHI will sponsor an international conference on the effects of smoking on reproductive health scheduled to take place in San Francisco on 15-17 October 1985. The purpose of the conference is to summarize the recognized effects of smoking on reproductive health, to emphasize the new findings such as the effects on fecundability or Sudden Infant Death Syndrome, to review smoking cessation efforts and materials and to review public health policy.

Cosponsors include 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.

Future Plans

The Reproductive Epidemiology Division will place a greater emphasis in the future on documenting the long-term health effects of contraceptive use, including the effect on reproductive cancers, and on the relationships between sexually transmitted diseases, contraceptive use and reproductive health. These three areas together will account for approximately 60% of effort over the next five years.

V. PROGRAM EVALUATION

The Program Evaluation Division conducts studies in the areas of natural family planning and breast-feeding as well as reproductive health.

A. Natural Family Planning

Research in Natural Family Planning (NFP) is being conducted in five areas: basic research, programmatic research, studies on NFP teaching, surveys on use effectiveness of NFP and FP methods in the general population; and research on breast-feeding as a natural method of child spacing. Considerable emphasis is also put on dissemination of findings.

1. Natural Family Planning Studies

a) Introduction and Evaluation of a Natural Family Planning Project in Lima, Peru

A total of 278 couples have been enrolled in NFP instruction through the Asociación de Trabajo Laico Familiar (ATLF) service. One hundred and seventy are in the training phase and 58% have successfully completed training and are in the follow-up phase. Fifty couples have been discontinued from the project; half did not comply with the guidelines of their chosen method or the project. There have been nine pregnancies.

Among those couples in the follow-up phase, 29 are currently practicing the sympto-thermal method and 21 the mucus method. It took the average couple 4.7 cycles to complete training. Follow-up will continue until well into the next year.

b) Indonesia: Breastfeeding and the Modern Health Sector

The purpose of this project is to collect information to assist hospital administrators and perinatal care providers (that is, obstetricians, pediatricians, nutritionists, nurse-midwives and nurses) to establish a "rooming-in" system throughout all the hospitals in Indonesia. The project identifies the nature and extent of needs, problems and obstacles in program development for rooming-in. The specific objectives are: (1) to assess (a) the attitudes towards breastfeeding and rooming-in among the perinatal

care providers, and (b) their knowledge regarding infant health and contraceptive effects of breastfeeding; (2) to determine attitudes toward and knowledge about rooming-in among key hospital administrators; (3) to investigate the current hospital policies and practices regarding rooming-in and infant feeding, and; (4) to examine attitudes toward breastfeeding among mothers who enter hospitals for delivery. The data collection phase has just been completed. Three papers based on the results of the study will be presented at the Conference of Hospital Administrators to be held 8-15 May 1985 in Jakarta. The Principal Investigator will also present the findings at the Congress of OB/GYN for Asia and the Pacific to be held in September 1985.

c) Physician's KAP Study Regarding Family Planning, NFP and Breast-feeding in Selected Developing Countries

This study is being implemented by the Institute of Population Studies at the University of Exeter, U.K. Its purpose is to study the knowledge, attitudes and practices (KASP) of actual and potential family planning providers, especially physicians, regarding family planning, with a special focus on NFP, fertility awareness and breastfeeding. In each of four selected developing countries, a Principal Investigator (PI) has been recruited and has conducted loosely structured pilot interviews or focus groups with small numbers of providers. In addition, the PI attended a meeting at Exeter with Institute staff and other PIs in order to design a cross-cultural KAP questionnaire based on those interviews. Quota samples of 100 suitable respondents were selected within each

country and interviews are now in progress. The local investigator will prepare summary reports of the results and reconvene in Exeter to refine the country report, prepare a cross-cultural report and to develop and finalize a model questionnaire that can serve as a tool for subsequent researchers in other countries.

d) Mexico NFP Site Visit

In September 1984, FHI sent an evaluation team to visit the WOOMB (World Organization Ovulation Method-Billings) NFP program in Mexico. The team spent several weeks visiting the central office and a number of regional offices. A report and recommendations was prepared and is under revision. Although the NFP centers visited varied in teaching approach and record keeping practice, the team concluded that there were enough interested and capable NFP centers to conduct a study of acceptability and use effectiveness of NFP with the WOOMB program. The team was impressed that many of the user couples they talked with felt that NFP had improved the quality of their married lives. It remains to be seen whether a use effectiveness/acceptability study can be worked out that will be acceptable to all parties, including the two governments involved.

e) Sri Lanka Family Planning Surveys

Two family planning survey projects are currently underway in Sri Lanka. One is being undertaken by the Department of Census and Statistics, and the other by the Family Planning Association of Sri Lanka (FPA/SL). Both projects focus on understanding the apparent

sudden increase in the use of traditional and modern natural family planning methods. 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 and interest among the family planning program managers and policymakers in Sri Lanka.

The project with the Department of Census and Statistics is following up a national sample from the 1982 Contraceptive Prevalence Survey, which includes both urban and rural populations. 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 conducting in-depth interviews to identify local/folk expressions used to refer to "non-program" methods of family planning, has been completed and a report is available. The findings of the first phase were utilized to develop a survey questionnaire. The survey will cover approximately 2,800 women of reproductive age and 500 of their husbands. Survey fieldwork began in early March 1985 and is expected to be completed in early May 1985.

The main purpose of the survey project being conducted by the FPA/SL is to determine use-effectiveness of various family planning methods, including traditional and natural methods. A methodology developed by Dr. John Laing of the Population Council is being applied. This 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). Unlike the project with the Census and Statistics Department, this survey focuses on FPA's rural villages. The first phase of the project, which involved conducting "focus group" sessions, has been completed. Based on the information obtained from focus groups, a questionnaire has been drafted. The questionnaire is being translated into Singhalese. The pretest is planned for June and the actual fieldwork is planned to be undertaken in July-August 1985.

f) Nepal: Technical Assistance

A site visit was made to Nepal to discuss with the Swiss Association for Technical Assistance (SATA) the possibility of undertaking a joint operations research project in natural family planning in Nepal.

Dr. Peter Schubarth, Head of the Health Sector of SATA operates a multi-method family planning program in which all modern methods of contraceptive services, as well as natural family planning services are provided, including the Dorairaj Modified Mucus Method in which the duration of abstinence is considerably shorter than the Billings Method. As of December 1984, the Program had recruited approximately 700 ever-user couples of the Dorairaj Method, with 60% continuation rate after 12 months. Since Dr. Schubarth plans to return to Switzerland and will be replaced, FHI is waiting to see whether his replacement will continue the NFP program. If so, work towards developing an ovulation project may continue.

g) Bangladesh: Caritas Project

Caritas, a voluntary Catholic social service organization, began a natural family planning project in 1976 in Bangladesh. Since then, it has provided NFP training to and collected data from 2,453 eligible women in 13 districts of the country. The NFP project has 29 centers including one in Dhaka. The Caritas NFP Project requested Family Health International to provide assistance in data processing and improving their service statistics system. FHI requested a local organization, the B-SMERT Corporation, to do the work under the guidance of Dr. Ghyasuddin Ahmed.

During the period of this report, the project was initiated and a preliminary report prepared. The final report is currently being written. The project is expected to be completed by August 1985.

h) Expert Meeting on Ovarian Hormone Determination

A meeting of international experts in the area of ovarian hormone determination was held in the Research Triangle Park area on 13-15 December 1984. Twenty-five researchers from Australia, Europe, Canada and the United States attended. The main purposes of the meeting were: (1) to review the state of the art of various methodologies of determining ovarian hormone levels and/or predicting ovulation; (2) to recommend future research directions for selected methodologies, and; (3) to recommend an appropriate methodology for a field study of NFP among breastfeeding women.

A future research directions questionnaire containing 10 suggested research areas in basic research and 10 research ideas in applied research was circulated to all the participants after the meeting. The 20 research ideas were ranked and are being presented to the NFP Advisory Committee 2nd Annual Meeting for discussion of future directions in NFP research activities.

A summary of the meeting was prepared by Dr. Kenneth Campbell. This summary will be published in "Research Frontiers in Fertility Regulation". Currently, FHI staff are negotiating with several major international medical publications for the publication of the entire seven papers and discussions of the meeting.

i) India: NFP evaluation of Tribal Population

A project to provide information regarding NFP promotion among the tribals, primarily the Lambardies in Vijayawada, Andhra Pradesh, India is being carried out by an in-country consultant. The project examines the history of NFP instruction, description of population served and methodology employed. Demographic data, current use, and continuance and prevalence rates are being obtained from a sample of charts available.

A second project in India is being carried out by the Consultant. This project is an evaluation of the CREST (Center for Research Education Services and Training for Family Life Promotion) program and to assist the CREST Director with plans for expansion of CREST activities.

j) NFP Review Occasional Paper

At the request of the Demographic Data for Development Project of Westinghouse Health Systems, FHI is preparing a paper entitled "Periodic Abstinence in Developing Countries: Update and Policy Options." The paper highlights definitional issues and contains new information on prevalence levels of periodic abstinence methods, use-effectiveness and psychosocial issues. A description of specific countries where periodic abstinence is popular is included. There is also a section that describes policy options for family planning policymakers in developing countries.

The monograph will be published as Occasional Paper of the DDD Project of Westinghouse in mid-1985.

k) Comparative Study of the Today Vaginal Contraceptive Sponge With Traditional Use vs. Use During the Fertile Phase

This study is being conducted through the Los Angeles Regional Family Planning Council (LARFPC). Its purpose is 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. Recruitment of subjects began in September 1984. Prior to recruitment, the LARFPC staff developed data collection instruments, brochures, inventory logs and menstrual/coital diaries. Three of LARFPC's FAM instructors were selected to serve as

instructors for the study, presentation of material and the use of forms. Study supplies were ordered, received and placed at the clinic site in time for recruitment. VLI, the manufacturer of the contraceptive sponge, is providing free sponges. Two hundred volunteers will be randomized, 100 in to each study group. Study participants will be followed up to a year.

Recruitment into the study has been slow although the anticipated numbers of potential subjects have expressed interest in the study. Unexpectedly high numbers of women were not randomized into the study because they were in the post-pill period, had abnormal pap smears or did not want to be randomized. Some of these women will be recontacted at a later date when they are no longer in the post-pill period or after their pathologic cytologies have been treated. Consequently the original recruitment period may be extended.

1) Effectiveness of NFP in Urban Egypt - Phase I

This project was undertaken at Ain Shams University in Cairo. The purposes of the study were (1) to discover the most appropriate local language for referring to periodic abstinence methods, (2) to collect information on research conducted in Egypt or neighboring Arabic countries on periodic abstinence, (3) to ascertain the degrees of interest among hospital clients in learning and using a modern NFP method, and (4) to provide NFP counseling to a small number of women in order to develop easy-to-use teaching and record-keeping materials.

Regarding the first goal, through loosely structured interviews, physicians and social workers ascertained that the term "safe period", which is a direct translation from the Arabic, is the expression most easily understood. "Sexual abstinence", "periodic abstinence" and "rhythm" are not familiar terms, nor is the term "cervical mucus" known or its relationship to family planning. Regarding the second goal, the available local literature, including three large bibliographies in both English and Arabic published by the Egyptian Board of Family Planning produced no reference to periodic abstinence. Computer searches by FHI also produced very little regarding NFP in Egypt.

Regarding the third goal, the project staff developed a questionnaire and used the tool to interview 500 OB/GYN and pediatrics out-patients. These interviews indicated sufficient local interest in NFP. Two thirds of the women interviewed were illiterate; 91% were housewives and three quarters had experience using other contraceptives such as pills and IUDs. Nineteen percent had heard of the safe period method and 77 % of these women were literate.

Seventeen definitions of the safe period were offered by the 500 women. Two thirds thought that their husbands would reject the method due to the abstinence requirement, and 28% expressed a willingness to learn the method.

Sixteen women were taught the mucus method and half were continuing its use at 6 months. The local investigator concluded that the

method was a good one for carefully selected women, i.e., regularly cycling, literate women with infrequent intercourse.

A second phase of the project is now being negotiated. This is one of the few studies of the acceptability of NFP methods among a Muslim population.

2. Breastfeeding Studies

a) Seminar on Breastfeeding in Manila, Philippines

As part of FHI's effort to give greater prominence to the role of breastfeeding in family planning and to help disseminate research findings for policy development, an international seminar on breastfeeding was sponsored in August 1983, in Manila. There were about a dozen participants from outside the Philippines and several others from the Philippines. Participants included researchers, policymakers, health administrators and news media. In order to disseminate the contents of the conference to a wider audience, FHI has edited and processed the papers of the conference for publication in a Special Supplement of the Journal of Biosocial Science. The submitted manuscripts include a paper on FHI's five-country study on hospital practices regarding breastfeeding. Within the Philippines, a whole issue of Population Forum was published on breastfeeding in September 1984, summarizing key papers from the Manila Conference. The special issue of the Journal of Biosocial Science is scheduled for publication in May 1985.

b) Longitudinal Study of Breastfeeding and Return to Fertility

This study is being conducted in four countries. The purpose is to follow a small group of breastfeeding women from delivery through ovulation and compare them to non-breastfeeding controls regarding the time when ovulation returns, and to determine the effect of breastfeeding patterns on the timing of ovulation.

1. Pramongkutklao Hospital, Bangkok, Thailand

In the Thai study, the last breastfeeding subjects completed their participation in the study in September 1984. The local investigator, Dr. Boonsri Chuntrasri, was named FHI's first Sharon Camp Fellow and came to FHI in October 1984. She is carrying out the in-depth analysis of the Thai data during this time. The first of three papers about the Thai data will be submitted for publication this summer.

2. Assiut University Hospital - Assiut, Egypt

Follow-up and laboratory determinations will be completed in April 1985. This center had been besieged by laboratory equipment problems that kept hormone analysis behind schedule. Data analysis will begin in May 1985.

3. Instituto de Investigacion Cientifica - Durango, Mexico

This center is conducting a second phase with only breastfeeding subjects who are recording the precise duration and time of day of feedings, in addition to the frequency and type of feeding. Follow-up is expected to continue throughout the coming year.

4. National Research Institute for Fertility Control -
Karachi, Pakistan

This is the fourth and final setting for the multi-center breastfeeding study. Contract negotiations, staff training (in Bangkok, Thailand) and the placement of all study commodities in the field has been completed. The study is scheduled to begin in 1985.

Future Plans

Momentum is being built up in developing NFP/BF projects. The NFP Advisory Committee has also made a number of suggestions about research leads.

Planned NFP projects include: several programmatic use effectiveness studies in Kenya; a follow-up of Ovulation Method (OM) users in Egypt; a comparison of NFP and FDP acceptors in a multi-method program in the Philippines; a comparison of the effectiveness of assistance to test new meters and home kits which measure

estrogen and progesterone; a use effectiveness survey in Bangladesh which focuses of the "safe period"; a comparison of calendar rhythm and a modern NFP method in Egypt; and an evaluation of the Tamil Nadu NFP project, should the study receive Government of India approval. FHI would also like to support a project on teacher qualifications in NFP.

In the area of breast-feeding as a natural method, four studies are under development: one in a rural (and later, an urban) setting in the Philippines in which one group of newly delivered women will be given simple guidelines on breast-feeding while the control group receiving the guidelines resumes menses later; a multi-center study on defining the NFP symptoms which can be used by breast-feeding women; a study of child spacing practices in Niger among nomads; and a secondary analysis of data on breast-feeding women in an NFP program in Chile.

B. Reproductive Health

Most of the projects in reproductive health are either evaluations of family planning programs or health research which examines the connections between maternal and child health and family planning. The research approaches range from hospital-based maternity studies to provider surveys and household-based surveys. In the health area, the goal has been to increase the representativeness of births studied and to increase the follow-up period.

a) 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 has been increasing 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 probably very low and substantially lower than tubal ligation. In order to realize the potential for the spread of vasectomy, it is important to know what role physicians play in promoting this method.

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

Data collection was concluded in May 1984, and the preliminary report is being written. It was found that 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 who performed tubal ligations were the most likely to recommend tubals. The same was true of physicians performing and recommending vasectomy.

Recommendation of sterilization was also associated with health conditions (for any health condition) physicians were more likely to recommend vasectomy if they did vasectomies and tubal ligation than if they did female sterilizations. Generally, female sterilization was more often recommended if the woman experienced problems, and vasectomy if the man experienced problems. Interestingly, a high percentage of physicians, including those who performed tubal ligations but not vasectomy, would recommend vasectomy in cases in which the wife had problems. Moreover, vasectomy was more often recommended for couples in which the woman had health problems than was tubal ligation recommended for couples in which the man had health problems. Overall results show a high readiness among physicians to promote vasectomy.

b) Mexico: KAP Survey of Young Adults

The Center of Orientation of Adolescents (CORA) in Mexico City provides a variety of services to young adults in two subregions of the city. In order to develop and improve their health-related

programs further, a survey was planned to collect information from 15-24 year olds on their knowledge, attitudes and practices relating to reproductive health.

Interviews are being conducted with approximately 1000 men and 1000 women from a randomly selected household sample of the two subregions where CORA is active. The fieldwork was initiated in mid-March and will be concluded by the end of April. Data entry and editing are being coordinated in-country by the Mexican Academy of Medical Demography.

This survey is the first large effort to study knowledge, attitudes and practices as they relate to reproductive health among young adults in Latin America. Specific objectives of the survey include determining a) the proportion of young adults who are sexually active, and, of these, the proportion contracepting; b) which methods and sources are being used by the sexually active; c) the regularity of use of methods; d) preferred family size and the psychosocial factors that influence decision-making as it relates to sexual behavior. Long-range objectives include providing data for policy makers at a national level for Mexico as well as other Latin American countries.

c) Honduras: Technical Assistance to ASHONPLAFA

The Social Marketing Program of the Asociación Hondureña de Planificación Familiar (ASHONPLAFA) will carry 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 a pill(s) is 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 (Perla), i.e., 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; 3) to determine if buyers seek information about contraception from pharmacy staff and if they consider the pharmacist an important source of information.

A pretest for the questionnaire is scheduled for June and interviews will be conducted over a four-month period, beginning in July.

d) Africa: Secondary Analysis of African Survey Data

In recent years, FHI has undertaken several activities to assess the practice of and demand for contraceptive services in a number of West African countries. A 1981 study in Lagos, Nigeria, examined the use of and attitudes toward modern and traditional childspacing

practices among reproductive age women in a rapidly urbanizing society. The following year, in collaboration with the Pathfinder Fund, FHI provided support to University College Hospital in Ibadan, Nigeria, to conduct a survey on the sexual, contraceptive and reproductive behavior of adolescents. In 1983, a study was undertaken in Dakar, Senegal, among clients at the three family planning clinics then providing services; the objective was to understand the factors associated with contraceptive acceptability and use among those few couples in the region seeking to limit or space their pregnancies.

Following the submission of project reports on the above activities, FHI has continued with more in-depth analysis from these and similar survey data. During the period covered by this report, technical papers from the Ibadan and Dakar studies have been prepared, translated when appropriate for in-country review, and submitted to appropriate journals for publication. In addition, assistance in data analysis has been provided to a field investigator in Ile-Ife, Nigeria, seeking to identify subgroups of the local population in greatest need of family planning to be offered in a newly designed service delivery program whose goal is to reduce the incidence of pregnancy wastage and its associated social and economic costs.

e) Mexico: Combined Reproductive Risk and Contraceptive
Prevalence Survey

This project provides funds to the Federation of Private Family Planning Associations in Mexico (FEMAP) to design and implement a Combined Reproductive Risk and Contraceptive Prevalence Survey that was conducted in selected areas of the cities of Leon and Saltillo. The data generated from these surveys will be used as an evaluation tool for the FEMAP affiliates that have recently begun providing services in these two cities. It is expected that the data from these surveys will ultimately 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 now completed. A preliminary report shows that contraceptive use is high in the two cities surveyed. In Saltillo, 59% of the women surveyed were contracepting and 52% in Leon.

The method mix varied among the two cities; women surveyed in Saltillo were more likely to report using sterilization (26%) and other modern methods of contraceptives (IUD, 16%, oral 9%) than women in Leon (sterilization 10%, IUD 14% and orals 8%). The use of rhythm 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.

f) Honduras: ASHONPLAFA Data Analysis

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 in which 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.

g) Thailand: Infant Mortality and Breast-feeding

The objectives of this study are to (1) determine in greater detail than has hitherto been done the prevailing infant feeding practices of mothers and some of the reasons underlying them and (2) to assess the extent of any relationship between infant feeding practices and infant mortality.

Data were obtained from a household survey conducted in the Northeast of Thailand. (Survey costs not covered by FHI).

Unfortunately, the number of deaths is lower than expected, and few deaths occur after weaning (the region where the study was conducted has the longest period of breast-feeding in Thailand). Also, most women supplement and do so early, and there are few cases of full-

breast-feeding. Because of these problems, the project will put greater stress on analysing data on feeding practices. Analysis of infant mortality/breast-feeding data will be useful mostly in showing possibilities of working with such data. The questionnaire would probably be more useful in an area with higher mortality and lower duration of breast-feeding.

h) Honduras: Access to Sterilization

This is a continuing study of the 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 low percentages of women interested in getting a tubal ligation, (42% in Tegucigalpa and 21% in San Pedro Sula) were actually sterilized before discharge from hospital for obstetric delivery 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, 33% in Tegucigalpa and 15% in San Pedro Sula had been sterilized in the period since the first study was conducted. Higher percentages had experienced a pregnancy, more than 40% in each group. 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 was sterilized in Tegucigalpa (52%) than in San Pedro Sula (29%).

Since the original study was conducted, a number of factors have changed which should increase the number of sterilizations in Tegucigalpa. A third study seeks to determine the contribution of each of these factors in affecting the percentage of women sterilized. Because little has changed in San Pedro Sula to promote sterilization, this study focuses on tubal ligation in Tegucigalpa only.

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 a 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 were sterilized in the four months since delivery and if not, why not. Data collection was completed in January 1985 and analysis is underway.

i) US: India Birth Spacing

Child mortality, morbidity, nutrition, growth and development are influenced by maternal fertility as well as by numerous social, environmental and biological factors. The specific aim of this study is to examine the influence of birth spacing on child growth.

It is hypothesized that short prior and/or subsequent intervals will be associated with growth impairment of the index child. Should this secondary analysis of data support the hypothesis, there are obvious implications for promoting the acceptance of family planning programs as a means of improving maternal and child health.

As part of the Johns Hopkins University Narangwal study in rural Punjab, India between 1968 and 1973, weight and height measurements were taken prospectively to age 36 months on children born in the study villages. Maternal pregnancy histories were retrospective to the study date and thereafter. Pregnancy histories include information on parity, birth interval lengths, maternal age and contraceptive use, and prior child loss. Information on social factors such as caste, family wealth, income, and literacy and education of father and mother is also available. The Department of International Health has used some of these data in an examination of spacing effects on child survival. However, the effects of spacing on child growth have never been examined.

Secondary data analysis will require examination of Narangwal growth curves and their comparison to NCHS and Harvard standards, determination of distribution of births by interval length, interval length by maternal age, mean height and weight for age of child by prior and subsequent interval length, regression of growth on interval length. Potential effect modifiers such as maternal age, parity, child loss and socioeconomic status will be controlled for and truncation biases will be adjusted for by use of life table procedures. Merging of the pregnancy history tape and the

anthropometric survey tape has linked 2625 children for whom there is the relevant information on dependent and independent variables. Analysis is underway.

j) Brazil: Technical Assistance to CPAIMC

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, to fail to follow through and get sterilized. Over the period 1 June to 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. It has been widely circulated in Brazil. A paper is in preparation.

k) Honduras: Follow-up Depo-Provera Users

The Family Planning Association of Honduras (ASHONPLAFA) began providing Depo-Provera in 1967. Following the decision in the United States not to approve Depo-Provera, ASHONPLAFA suspended use of the drug in 1978. During this eleven year period, 3604 women received Depo-Provera from the ASHONPLAFA program. Twelve percent of all ASHONPLAFA clients were using Depo-Provera when it was suspended from the program.

The purpose of this study was to determine what decisions Depo-Provera users made concerning contraceptive use after ASHONPLAFA stopped providing it. What percentage of women purchased Depo-Provera at a pharmacy? Of those who were interested in continuing to use Depo-Provera, what percentage did not do so because they did not know where to obtain it or because it was too expensive? What other methods of contraception, if any, did these women select? What are their opinions about Depo-Provera, and would they like to receive it again from ASHONPLAFA?

The study population included all women who received an injection of Depo-Provera from ASHONPLAFA within six months of the suspension of Depo-Provera. Of the 539 women eligible for the study, 311 were interviewed; the remaining women had moved or could not be located.

Although 85% of the women interviewed said they would have continued using Depo-Provera had the program not ended, only 15% did continue. Locating a source was a major barrier to the continued use of Depo-Provera, only a small percentage of women knew where to buy it. For those who did buy Depo-Provera from the pharmacy, one of the main reasons given for termination of use was the high cost. Even among women who switched to orals after the Depo-Provera program ended, few bought them at the pharmacy. Most women returned to ASHONPLAFA or to an ASHONPLAFA-sponsored program for contraception.

Depo-Provera was regarded as a highly desirable method. Among women still at risk of pregnancy--fecund, sexually active, non-sterilized women--about three in four said they would like to receive Depo-Provera from ASHONPLAFA.

1) Honduras: Maternal and Child Health and Family Planning Survey

A survey 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, breast-feeding and child mortality. It also includes a reproductive health component. The sample included 5500 households.

Specifically, the survey sought to estimate: current levels of fertility and infant mortality; sources of obstetric care; the prevalence and duration of breast-feeding; the incidence of diarrhea among young children; the percentage of young children who had been immunized; pregnancy intentions; ideal family size and the

percentage of women who had experienced unplanned pregnancies; the percentage of women who were contracepting by method and by source; reasons for terminating use of family planning; the percentage of women who had never used contraceptives; the unmet need for contraception; and finally, the incidence of reported problems among ever users of oral contraceptives and the impact of this experience on method discontinuation.

Data collection was completed in December 1984. Coding of the data will be completed in March and editing in April. Analysis will be conducted April/May and a final report will be available in August 1985. Preliminary tabulations (using data from a household sheet processed on a microcomputer in Honduras) show that the percentage of women aged 15-44 in union that were contracepting is 35% (Tegucigalpa 56%), other urban areas (45%), rural areas (24%). The percentage contracepting increased from 27% in 1981 to 35% in 1984. Most of the increase was in female sterilization. A report will be available in April based on results from the summary sheet.

m) Matamoros Secondary Analysis

Four reports utilizing data from the Reproductive Risk Factors Survey in Matamoros are in preparation. A general summary of results of that study will be presented at the APHA meetings in November 1985.

n) 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 in Benin City, Nigeria, many women do not get sterilized because of presumed opposition from their husbands or their own fears of complications of the surgery. This later fear may be the result of inadequate counseling.

The specific objectives of this study are to determine the effects of counseling on the female sterilization rate, to study the effects of sociodemographic 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 attending the prenatal clinic and delivering at UBTH. The sterilization rate among grandmultiparae who are counseled will be compared to that of women who are not counseled. Since September 1984, the investigator has admitted 300 women into the study. Twenty of these women have now completed the study; they have completed the admission form, received the counseling (if applicable), delivered their babies and completed the six-week postpartum follow-up form. Eleven women have been sterilized, seven from the counseled group and four from the control group.

Women will continue to be admitted into the study through August 1985 and will continue to be followed up through December 1985.

o) Sri Lanka: Follow-up of Tubal Ligation Cases

Because female sterilization is such an important method of family planning in Sri Lanka, and because of the permanent nature of the method, this study seeks to determine long-term satisfaction with contraceptive sterilization and to investigate the various factors that determine and/or relate to satisfaction. The study is collecting data on acceptors of sterilization to determine overall satisfaction with the methods and the effect of the government's incentive program on motivation and long-term satisfaction. In 1980 the Government of Sri Lanka initiated an incentive program that paid cash incentives to all individuals sterilized in Sri Lanka. The amount paid as an incentive has varied since the introduction of the program.

The investigators selected a sample of 1350 acceptors of female sterilization from the 16,301 women served by Community Development Services (CDS) from 1980 through 1983. FHI selected 450 from the Colombo clinic, 300 from estate hospitals and 600 from a rural district hospital. The samples were stratified by date corresponding to the government incentive program so that comparisons in satisfaction can be made among groups receiving different incentive amounts. The questionnaire obtains information on the acceptors' sociodemographic 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.

The interviewers began the field work in November 1984 and have contacted 150 women from the Colombo sample. They will complete the Colombo and estate samples by May 1985 and the district sample by August 1985. The final report will be completed in October 1985.

An abstract entitled "Incentives and Satisfaction: A Study of Female Sterilization Acceptors in Sri Lanka" has been submitted to the American Public Health Association for presentation at the 113th Annual meeting in November 1985.

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

Contraceptive use in Nigeria is low with no organized Family Planning program, physicians are the major providers of contraceptive services. This study, being conducted by the Fertility Research Unit of the Department of Ob/Gyn, University College Hospital, Ibadan, assesses 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, selected a teaching, general and private hospital. Plans were made to interview all Ob/Gyns and house officers on staff at each hospital using a questionnaire developed to obtain information on the physicians'

attitudes toward specific methods of family planning in general, and on their attitudes toward specific methods of family planning (with emphasis on male and female sterilization). Information was also collected on the proportion of physicians who actually provide family planning services, and the barriers preventing them from providing these services.

Since July 1984, the interviewers have contacted 730 physicians and have completed interviews with 672. Those physicians who did not complete the interview, refused, were on leave, or were no longer on staff at the hospital. The data collection will be completed by May 1985 and the final report by August 1985.

An abstract entitled "Physician Attitudes: An Aid or a Barrier in the Provision of Family Planning Services in Nigeria" has been submitted to the American Public Health Association for presentation at the 113th Annual meeting in November 1985.

q) Oral Contraceptive Compliance

How well women comply with proper oral contraceptive administration can affect the efficacy and side effects of the product. The question may prove particularly important for the more complex triphasic pills now available in several countries. The study will be conducted in three phases. In Phase I, focus groups will be used to establish a questionnaire-based method in a clinical setting. In addition, a special dispenser designed to measure compliance objectively will be included to validate the questionnaire. The

second phase of studies will use the same questionnaire and take place in the same geographical area, but will measure compliance in a nonclinical setting, such as a community-based distribution system. The third phase will use the tools developed in the previous two phases to assess the effect of motivational methods on compliance. These results will then be used to indicate effective methods of improving compliance in oral contraceptive users.

Plans are underway to develop a protocol that addresses the first phase of studies. A prototype of the pill dispenser has been designed and is being tested for refinement. Studies included under Phase I will be implemented in late 1985 or early 1986.

Future Plans

Anticipated research which evaluates family planning programs includes: a pharmacist-consumer survey in Nepal which focuses on a contraceptive retail sales program; an evaluation of factors affecting the productivity of three types of community-based family planning distributors in Juarez, Mexico with a focus on providers' knowledge of family planning; a study of the acceptability and use effectiveness of condoms in Haiti; a survey on the use effectiveness of traditional methods (as well as modern methods) in Southern Thailand; an experiment to see whether counseling services affect contraceptive use in Zimbabwe; adolescent surveys in Brazil and Mexico (noting that the later does not refer to the previously proposed NFP physician attitude study for Mexico); studies on pill taking patterns of women in the general population, with an emphasis

on compliance to the recommended regimen--possible to be done in Morocco and/or Nepal; and studies on delivery of family planning services in Colombia and Kenya.

Anticipated health related studies include "second generation" maternity care monitoring studies in the Camerouns, Niger, and Zimbabwe. "Second generation" studies refer to studies that attempt to obtain and follow up representative samples of births, rather than those occurring only in hospitals.

VI. FIELD DEVELOPMENT AND TRAINING

The Field Development and Training Division (FDT) serves a key role in identifying research needs of programs in developing countries, assuring that projects are carried out with the highest degree of confidence and quality, and maximizing the usefulness of research findings to strengthen programs that serve reproductive health needs. The goals of FDT are:

- 1) to help develop research skills of individuals and institutions that make up FHI's international collaborative network; and
- 2) to share the findings of FHI supported studies and other relevant research with health care providers, policymakers, and the general public.

During the reporting period, FDT activities under the Cooperative Agreement were in four major areas:

- A. Training in Research Methods
- B. Institutional Development
- C. Transfer of Contraceptive Technology
- D. Information Dissemination.

A. Training in Research Methods

For a second year, FHI is providing technical assistance for the development of an epidemiologic training program to be implemented by the Instituto de Investigacion Cientifico of the Universidad Juarez, Durango, Mexico. Under a five-year grant from the UNFPA, the Instituto is training and funding investigators to conduct epidemiologic studies in the area of reproductive health, with emphasis on benefits and risks. A three week workshop in August 1984 trained ten Mexican physicians. Eight projects were designed during the project and three of the studies are in progress with funding from other sources. A second workshop is set for November 1985. FHI is continuing to develop and improve the training materials. Assistance to the Instituto will continue throughout the life of their project in the implementation, evaluation, and improvement of the training and research activities.

As reported in the last Annual Report, Dr. Boonsri Chuntrasri, from Bangkok, Thailand was selected as FHI's first Sharon Camp Fellow.

Dr. Boonsri arrived in October 1984, and is expected to be in residence at FHI through April 1985, completing the analysis of data from a study on the relationship between breast-feeding and return to fertility. This study was supported by FHI. The Fellowship Program provides support for senior researchers to spend 6 to 12 months at FHI working on projects of their choice. Fellows are selected competitively from proposals and supporting documentation they submit to indicate their research capability and the relevance of their research topics to family health.

Letters and other publicity materials have been sent to centers and key contacts around the world to solicit applications for the 1985-86 Fellowship Program. Invitations for full proposals will be sent to the top finalists by 30 April, and final selection of one or two fellows will be made by 30 July.

Providing training in clinical trials research methods not only contributes to the transfer of skills and technology by FHI to other countries; it also provides a good mechanism of identifying, training, and initiating collaboration with new members of FHI's international investigator network. Responding to a growing number of requests from several countries, FHI has undertaken, in this fiscal year, a major project to develop a standardized clinical trials research methods training curriculum for use in workshops on this subject. A complete training package, with self-instructional training modules, lecture and lab materials, and associated teaching aids, are being produced by an in-house FHI team. The services of an outside instructional technologist are also being utilized.

A first workshop using the new standardized training curriculum, will be held in Singapore, 22-27 July. Planning is underway for this training activity. Approximately 12 participants are being sought from Nepal, Sri Lanka, Malaysia, and the Philippines. The workshop will be conducted and coordinated in close cooperation with the National University of Singapore, Department of Ob/Gyn, which will provide both logistical and training support. To be considered, applicants must be interested and able to actually conduct clinical trials at their home center in collaboration with FHI.

B. Institutional Development

The Field Development and Training Division provides broad support to several developing country institutions to build local research organizations capable of responding to country needs for reproductive health research. The major support for this institutional development program is being provided under AID Grant pha/G-1198. Additional support for specific activities is provided under the Cooperative Agreement.

Providing local research institutions with data processing and analysis capability is a vital part of FDT's institutional development program. During the past six months, support under the Cooperative Agreement for this activity was focused on three areas:

1. New Microcomputer Installations
2. Software Development
3. In-house Microcomputer Related Training

1. New Microcomputer Installations

With major funding under the Grant, new microcomputer installations were made in: Durango, Mexico; Cairo, Egypt; Bandung, Indonesia; Bangkok, Thailand; and Dakar, Senegal. Testing of hardware before field placement is funded under the Cooperative Agreement, as is all software development.

The installation in Durango, Mexico, was made at the Instituto de Investigacion Cientifica del Universidad Juarez, Estado de Durango, in October 1984. The system installed there was a Texas Instruments Business System 351 with 256 K 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. The Instituto is currently using the machine for scientific investigation in such areas as statistical analysis of the comparison of the menstrual cycles of women using various types of contraceptives and the effects of four different low dose oral contraceptives.

The installation in Cairo, Egypt, was made at the Egyptian Fertility Care Association (EFCS) in November 1984. The system installed there was a Texas Instruments Business System 352 with 256 K bytes of main memory, two workstations, one printer and mass storage devices consisting of one 1.2 megabyte floppy disk and one 17 megabyte Winchester disk. The EFCS is using the microcomputer for data entry and statistical analysis of Maternity Care Monitoring data using software developed at FHI specifically for the EFCS version of the MCM

form. Data from a recently initiated IUD study are now being processed as well.

The installation in Bandung, Indonesia, was made at the BKS-PENFIN, in October 1984. The system installed in Bandung was a completely redundant Texas Instruments Business System 352 with 512 K bytes of main memory, four workstations, two printers and mass storage devices consisting of two 1.2 megabyte floppy disks and two 17 megabyte Winchester disks. The redundancy of the system makes it highly unlikely that the system will ever experience down time as each component of the system is duplicated on-site. The Texas Instruments Model 1 Microcomputer that was used previously at BKS-PENFIN headquarters is scheduled to be transferred to one of the other centers in Indonesia at a future date. BKS-BENFIN has completed an extremely large multicenter IUD study using the TI and FHI-provided software for data entry and analysis. The study itself consisted of some 5,000 cases and 65 centers and subcenters, making it one of the largest in the world to date.

The installation in Bangkok, Thailand, was made at the Thailand Fertility Research Association (TFRA), in October 1984. The system installed at the TFRA was a Texas Instruments Business System 352 with 256 K bytes of main memory, two workstations, one printer and mass storage devices consisting of one 1.2 megabyte floppy disk and one 17 megabyte Winchester disk. The BS 352 replaces a TI Model 1 which has been transferred from TFRA headquarters to a collaborating center. The TFRA is currently using the microcomputer for capture and statistical analysis of data on Female Sterilization, Maternity Care

Monitoring and IUD studies using the standard software packages developed at FHI.

The installation in Dakar, Senegal, was made at the Bureau National du Recensement (BNR), the National Census Bureau, in January and February 1985. The system installed at the BNR was the same as that installed in Bandung, Indonesia, and consisted of a completely redundant Texas Instruments Business System 352 with 512 K bytes of main memory, four workstations, two printers, two 1.2 megabyte floppy disks and two 17 megabyte Winchester disks. The primary use of the system so far has been in collection and analysis of Maternity Monitoring (Surveillance Obstetricale). The software being used for this consists of a generalized data entry system and SPSS programs developed specifically for the BNR in-house at FHI.

2. Software Development

Software developments to date consist of the following:

- 1) Major enhancements to the generalized data entry system (DESY) to include file updating and sorting capabilities.
- 2) Conversion of the standard Maternity Care Monitoring software to accommodate the data collection instruments specific to the Egyptian Fertility Care Society in Cairo.
- 3) Maternity Monitoring programs in SPSS for reject, valid code and contingency checks tailored for the needs of the BNR in Senegal.
- 4) A generalized SELECT program for all those sites possessing FHI supplied TI microcomputers to enable the selection of records based on specific criteria for more detailed analysis of sub-sets of larger files.

3. In-house Microcomputer Related Training

Training on the microcomputer here at FHI has consisted of both training of in-house staff and staff of collaborating institutions. A programmer from CPAIMC in Rio de Janeiro, Brazil, Carlos Augusto Ribeiro, spent one week at FHI (25 February - 1 March 1985) learning and working with the version of SPSS for the microcomputer. Training of in-house staff has consisted of individual instruction in use of the BS 352 for staff members directly concerned with the FHRCs that currently have these machines and, additionally, in-house training in the use of the TI Personal Computers for all those interested.

In addition to providing major institutional support, the FDT Division also provides technical assistance to selected program on a more limited basis to upgrade research capabilities. During this reporting period, FHI has provided consultant services by Dr. Rowland V. Rider, Professor Emeritus at Johns Hopkins University, to the Family Health Bureau of the Sri Lanka Ministry of Health. The objectives of this technical assistance were:

a) to review the family planning service statistics system of the FHB,

b) to advise the FHB regarding data collection, data processing, and report generation of family planning service statistics,

c) to assist FHI in developing a framework for long-range planning and target setting,

d) to advise on incorporating the foregoing within an integrated management information system.

Dr. Ryder's consultancy took place in March 1985.

C. Transfer of Contraceptive Technology

During this funding period, financial and technical support was continued to the Brazilian Association of Family Planning Entities, ABEPF and Rio de Janeiro, Brazil. This provides for training and core support for the implementation and management of a multicentered clinical trial of progestogen-only pills among lactating women. The project funds two separate but interrelated components, a full time data collection/research coordinator, and a pre-study initiation workshop. Both of these components enhance the research capabilities of ABEPF and constitute a strategy to facilitate this organization's efforts to implement and coordinate country appropriate research strategies on a national level. To date the prestudy initiation workshop has been completed and the 1,000 case clinical trial is ongoing. The Data Collection Coordinator is managing all aspects of the project.

The Philippine Commission on Population (POPCOM) and the Philippine OB/GYN Society (POGS) identified a need to update OB/GYNs in contraceptive technology and family planning practices. In November 1984, FHI funded and provided speakers for a Contraceptive Technology Workshop in Manila to address this need as well as to provide a forum for discussion among service providers and clinical researchers. The objectives of the workshop were:

1) to update OB/GYNs (both urban and rural) in recent developments in contraceptive technology and selected issues in reproductive health;

2) to discuss the current Philippines population program and identify mechanisms by which individual physicians can contribute to it more effectively;

3) to further develop an FHI strategy for contraceptive biomedical research as it relates to the Philippine situation;

4) to help identify future directions and needs that the Philippine population program should address;

5) to identify and clarify the role of the OB/GYN in providing fertility management services.

The workshop was attended by more than sixty Philippine physicians (primarily OB/GYNs) and was held in conjunction with the annual meeting of the Philippine OB/GYN Society, 8-10 November 1984.

FHI sponsored three international speakers: Dr. Henry Burger of Melbourne Australia; Dr. Allen Rosenfield of Columbia University; and Dr. Andrew Kaunitz of the CDC in Atlanta.

D. Information Dissemination

FHI continues to support 500 subscriptions to the International Journal of Gynecology and Obstetrics, for developing world researchers whose interests parallel those of FHI. FHI also continues to provide editorial assistance on manuscripts submitted from developing

countries. A new contract for these activities began 1 January 1985. IJGO continues to improve in size, quality, and financial profitability since originally being taken over by FHI (IFRP) in 1976. The publisher has announced its intention to increase the size of the Journal by 50 percent beginning in 1986. FHI is considering ways to increase the Journal's coverage on issues of particular relevance to developing world physicians.

Issues number 1 and 2 of Volume 6 of Network, FHI's quarterly newsletter, were published during this reporting period, in accordance with FHI's publication schedule. Distribution remains at about 2,300. Responsibility for determining content for each issue passed during the reporting period from a special committee to the more general Information Management Committee. As a result of a recent review, FHI expects to revise the printing format to improve the graphic layout, although no major changes in content are planned. FHI continues to recognize a need for Network to be available to speakers of Spanish and French.

During the reporting period, a strategy was drafted and presented to the Scientific Committee for the development and dissemination of interpretive materials based on FHI's research. The strategy calls for identification of a small number of major themes, each to be articulated in a number of ways for dissemination to informed lay audiences both in the U.S. and in developing countries. Its implementation will require some improvement in FHI's access to important scientific and lay media, and to scientific writing talent. Partly in relation to this, FHI appointed an Information Management

Committee, with representation from each of FHI's research departments, to coordinate the various components of our information dissemination system.

A number of articles based on FHI data were accepted for publication in various journals. A list of these papers is found in Appendix C.

In addition to its regular publications, FHI provides for distribution of other relevant research findings published in journals and as monographs. Currently, two projects of this type are being carried out.

Work is proceeding on the translation into Spanish, printing and distribution of a series of five articles published by the CDC 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 Risk of Ovarian Cancer;" "Oral Contraceptive Use and the Risk of Endometrial Cancer;" and "The Noncontraceptive Health Benefits from Oral Contraceptive Use." The first four articles were published in Family Planning Perspectives and the fifth one in the Journal of the American Medical Association.

Translations for this project have been completed. The articles are now being typeset and it is expected that the printing and mailing will be completed by the end of May.

These papers will be distributed throughout Latin American centers, schools of medicine, clinics, etc. During the last reporting period, these same articles were translated into French and distributed to FHI investigators in francophone countries.

The printing and distribution of a female sterilization manual Tubal Occlusion via Minilaparotomy, published in Mexico in 1979 by Dr. Mario Domenzain and the Institution de Nutrition, is underway.

The FS manual has been submitted for bids. Printing should be completed by late May and mailing by early June. This manual will be distributed to Latin American Centers, family planning associations, free-standing clinics and selected schools of medicine where FHI knows, through its investigators, that minilaparotomy is a preferred method of tubal occlusion.

FHI believes that international meetings 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 four international conferences. The meetings were attended by the following individuals.

1) XI Latin American Congress of Obstetrics and Gynecology, Caracas, Venezuela, October 21-26, 1984.

- Dr. Luis Kushner, La Paz, Bolivia

- Dr. John Nagahata, Lima, Peru

- Dr. Felipe Romero, Lima Peru
- Dr. Eduardo Israel, Valdivia, Chile
- Dr. Gustavo Argueta Rivas, San Salvador, El Salvador

2) World Federation Sub-Saharan Conference "Reproductive Health Management in Sub-Saharan Africa," Freetown, Sierra Leone, November 5-9, 1984.

- Dr. Samba Duale, Karawa, Zaire
- Prof. Alabi O. Ladipo, Ibadan, Nigeria
- Dr. Alex Omu, Benin, Nigeria
- Dr. Cecil Klufio, Accra, Ghana
- Dr. Joseph Lauroy, Dakar, Senegal
- Dr. Nlandu Mangani, Kinshasa, Zaire

3) Second International Conference on Maternal and Neonatal Health (IAMANEH), Monastir, Tunisia, November 22-26, 1984.

- Dr. Saneya Saleh, Cairo, Egypt
- Dr. Fe del Mundo, Quezon City, Philippines
- Dr. S. Firoza Begum, Dhaka, Bangladesh
- Dr. Silvia Bomfim Hypr-lite, Fortaleza, Brazil

4) Annual Meeting of the Society for the Advancement of Contraception, (SAC), Jakarta, Indonesia, November 26-30, 1984.

- Dr. Ruben Apelo, Manila, Philippines
- Dr. Rohinee Merchant, Bombay, India

- Dr. Charles Ng, Singapore
- Dr. Erlinda Germar, Manila, Philippines
- Mr. Ephraim Despabiladeras, Manila, Philippines

FHI will continue to sponsor individual investigators to specific conferences. Planned activities for the remainder of FY '85 are:

- 1) Tenth Asian and Oceanic Congress of Obstetrics and Gynecology, Colombo, Sri Lanka, September 5-10, 1985.
- 2) Society for the Advancement of Contraception Annual Meeting, Bordeaux, France, September 9-13, 1985.
- 3) XI World Congress of Gynecology and Obstetrics (FIGO), West Berlin, Germany, September 15-20, 1985.

Future Plans

The major areas of activities planned for the next six months and sponsored under the FDT division have been discussed in the preceding sections. In addition, planning for a major new area of focus is underway. During the coming years, FDT plans to hold annual meetings of Regional Task Forces to enhance the development of FHI research strategies in response to regional needs, and to facilitate the communication of research needs and findings among senior policymakers in the regions. The first such meeting is now under development. Funds will be provided for the formation of a Research Advisory Committee for Latin America (RACLA). It is anticipated that the

Committee will serve as a mechanism to provide FHI with expert counsel in its effort to formulate country specific and regional strategies that more closely match the health policy and programmatic needs of the region. Selection criteria for membership will include priority countries for population activities, research experience, service delivery and population policy expertise. The committee will provide FHI with a more effective means of meeting the mutual needs and interests of FHI and Latin America during the coming decade.

VII. MANAGEMENT

Protection of Human Subjects Committee (PHSC)

Two meetings of the Protection of Human Subjects Committee (PHSC) were held at FHI on 9 November 1984 and 7 March 1985 to review 34 research proposals, inclusive of amendments and those for expedited review.

Three new members were appointed for three-year terms:

Mrs. Thelma M. Battle, Assistant Principal, Hillside High School, Durham, NC. She is certified by the State of North Carolina in Administration, Counseling, School of Social Work, Social Studies and French. Mrs. Battle taught the third and fourth grades for three years in Lagos, Nigeria.

Dr. Dennis M. Campbell, Dean of the Divinity School and Professor of Theology at Duke University, Durham, NC. He is a United Methodist

minister who has served as a local church pastor, college chaplain, professor, and college and university administrator. A noted lecturer, seminar leader and author, Dr. Campbell is the author of two books: Authority and Renewal of American Theology and Doctors, Lawyers, Ministers: Christian Ethics in Professional Practice.

(Dr. Campbell replaces Rev. Timothy Kimrey who rotated off the committee as of 31 December 1984.)

Dr. Josefina C. Tiryakian, Research Scholar, Department of History at Duke University, Durham, NC and a part-time Assistant Professor at North Carolina State University, Raleigh, NC. A native of Puerto Rico, Dr. Tiryakian has conducted research projects (including family planning) in the US, Spain, France, Puerto Rico, Peru and Mexico.

Technical Advisory Committee (TAC)

The next meeting of TAC has been scheduled for 27 June 1985.

Expenditures

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

Expenditures

1 October 1984 - 31 March 1985

Salaries & Fringe Benefits	\$ 762,839
Service Centers	256,108
Consultants & Professional Fees	62,703
Contracted Labor	14,617
Travel - domestic	30,747
Travel - foreign	175,648
Supplies - office	6,417
Supplies - medical	32,906
Printing & Reprints	10,053
Equipment Rental	679
Equipment Maintenance & Repair	273
Medical Equipment	3,928
Freight	2,475
Dues & Registration Fees	2,669
IJGO Subscriptions	22,500
Other Purchased Services	30,704
Other expenses	(534)
Bank Service Charges	535
Data Purchases	48,416
Subagreements	421,753
General and Administrative Costs	545,685
	<hr/>
Total	\$ 2,431,121

VII. FUTURE PLANS

During the second half of the year, FHI will continue implementing projects already developed and develop additional ones for initiation in the coming year. In Clinical Trials, more studies that are part of the NORPLANT® strategy will be initiated. Training for and initiation of the comparative studies of the Filshie vs Wolf clip has been scheduled. Initiatives in the development of vaginal contraceptives and implementation of barrier contraceptives studies will continue.

Reproductive Epidemiology will continue to develop various studies and further analyze data collected from previous studies. The conference on Smoking and Reproductive Health will also demand staff attention.

Program Evaluation will continue to analyze data both from studies of NFP and breast-feeding as well as those in the area of reproductive health. A number of new initiatives are planned for the second part of this year and the next year.

Field Development and Training will fund a research methodology/clinical trials workshop for investigators in Asia, continue planning for the Research Advisory Committee for Latin America (RACLA) and work on further developing the information dissemination plan for FHI.

FHI is also devoting time and funds to initiatives in the Contraceptive Development area. Contraceptive Development will become a more prominent area in the work of FHI during the coming months as initiatives in this area are better developed.

.SEMIAN

APPENDIX A
CONSULTANT REPORTS

Completed Consultant Reports (CRs)

October 1, 1984 - March 31, 1985

Title	Prepared for	Center #	Study #
Evaluation of Trasyolol-Medicated Lippes Loop on Menstrual Blood Loss in Santiago, Chile	X. Tacla	086	562
Male Sterilization by Excision and Ligation at the Health Unit, Dhaka, Bangladesh	S. Ahmed	723	730
A Comparison of the Copper T 200 vs. Multiload Cu 250 in Interval and Postabortion Women in Bangladesh	S.M. Aslam	163	6902
Results of Trials of the Collatex Sponge and Neo Sampooon Vaginal Tablets in Rangpur, Bangladesh	A.B. Bhuiyan	786	782
Female Sterilization via Mini-laparotomy in Dhaka, Bangladesh	A. Rahman	723	670
Surveillance of Female Sterilization in Dhaka, Bangladesh	S.F. Begum	727	6902
The Copper T 200 vs. Progestasert (3 yr.) using Hand and Inserter Techniques in Manila, Philippines	R. Apelo	600	584
Evaluation of the Wing Sound II	R. Guzman-Serani	850	594
A Comparative Study of the Copper T 200 with and without Strings in Santiago, Chile	X. Tacla	086	530
A Crossover Study from Standard Dose to Low-Dose Oral Contraceptives in Bandung, Indonesia	T. Agoestina	739	835
A Three-Year Analysis of a Comparative Study of the Copper T 200 and the Progestasert Hand vs. Inserter in Santiago, Chile	P. Lavin	852	584

<u>Title</u>	<u>Prepared for</u>	<u>Center #</u>	<u>Study #</u>
Long-term Follow-up of Female Sterilization in Kalelati Tangail, Bangladesh	R. Khan	730	630
Clinical Evaluation of the Non-spermicide Fit-Free Diaphragm in London, England	K. Lavelly	295	796

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APPENDIX B
STUDY STATUS LISTS

VAGINAL CONTRACEPTIVE STUDY STATUS LIST

DESCRIPTION OF STUDY - NON-COMPARATIVE OVT (100 MG NONOXYNOI-9) STUDY # 780

TOTAL NUMBER OF CASES - 250

I CTR	I INVESTIGATOR	I COUNTRY	I INDEX	I DATE	I SGN	I CASE	I ADM	I 1MO	I 3MO	I 6MO	I 12MO	I 1ST SHIP	I LST SHIP	I STATUS
I 0359	I EL. MACHOUB	I EGYPT	I FB 83/007	I 06/06/83	I 200	I 60	I 17	I 3	I	I	I	I 10/03/83	I 10/13/83	I CLOSED
I 8002	I COFAC	I MEXICO	I FB 83/010	I 06/10/83	I 50	I 10	I 9	I	I	I	I	I 12/07/83	I 10/10/84	I CLOSED

DESCRIPTION OF STUDY - SPONGE VS. NEO-SAMPOON (60 MG MENFEGOL) STUDY # 782

TOTAL NUMBER OF CASES - 1700

I CTR	I INVESTIGATOR	I COUNTRY	I INDEX	I DATE	I SGN	I CASE	I ADM	I 1MO	I 3MO	I 6MO	I 12MO	I 1ST SHIP	I LST SHIP	I STATUS
I 0023	I BORKO	I YUGOSLAVIA	I FB 79/008	I 10/03/79	I 450	I 450	I 561	I 319	I 424	I 350	I	I 12/02/80	I 11/82	I CR 386
I 0024	I BEHLILOVIC	I YUGOSLAVIA	I FB 79/002	I 06/19/80	I 350	I 351	I 378	I 212	I 335	I 342	I	I 11/29/79	I 01/20/82	I CR 454
I 0699	I SUN	I TAIWAN	I FB 79/009	I 03/06/80	I 350	I 153	I 160	I 79	I 89	I 54	I	I 07/24/80	I 04/19/83	I CR 484
I 0704	I BEGUM	I BANGLADESH	I FB 79/004	I 01/17/80	I 350	I 348	I 320	I 142	I 187	I 168	I	I 06/04/80	I 04/19/80	I CR 483
I 0786	I BHUIYAN	I BANGLADESH	I FB 82/005	I FCO 1203	I 100	I 102	I 101	I 61	I 55	I	I	I 06/10/82	I 08/30/83	I CR 520

DESCRIPTION OF STUDY - SPONGE VS. DIAPHRAGM STUDY # 783

TOTAL NUMBER OF CASES - 550

I CTR	I INVESTIGATOR	I COUNTRY	I INDEX	I DATE	I SGN	I CASE	I ADM	I 1MO	I 3MO	I 6MO	I 12MO	I 1ST SHIP	I LST SHIP	I STATUS
I 0272	I LEFEBVRE	I CANADA	I FB 81/006	I 06/01/82	I 300	I 240	I 300	I 159	I 153	I 77	I	I 11/17/81	I 01/05/84	I CR 502
I 0298	I GUILLEBAUD	I ENGLAND	I FB 79/006	I 06/04/81	I 250	I 291	I 253	I 177	I 199	I 164	I	I 07/25/80	I 01/09/84	I CR 485

DESCRIPTION OF STUDY - SPONGE VS. FOAM STUDY # 784

TOTAL NUMBER OF CASES - 700

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE	SGM	CASE	ADM	1MO	3MO	6MO	12MO	1ST SHIP	LST SHIP	STATUS
0332	GOLDMAN	ISRAEL	FR 81/015	06/22/81		350	350	515	193	334	161	01/20/82	08/29/84	CR LIST
0698	APICHART	THAILAND	FR 81/001	08/07/81		350	17	6				04/22/82	04/22/82	CLOSED

DESCRIPTION OF STUDY - NEO SAMPOON (60 MG MENFEGOL) VS. FOAM STUDY # 785

TOTAL NUMBER OF CASES - 1050

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE	SGM	CASE	ADM	1MO	3MO	6MO	12MO	1ST SHIP	LST SHIP	STATUS
0020	ANDOLSEK/KOZUHI	YUGOSLAVIA	FR 81/014	06/22/81		350	224	168	160	114	76	04/02/82	02/25/85	ACTIVE
0360	MAHRAN	EGYPT	FR 80/012	12/06/79		350	330	79	27	19	15	01/05/81	09/19/83	CR 531
0368	YOUSSEF	EGYPT	FR 80/013	04/16/80		350	349	360	195	308	248	02/18/81	02/02/83	CR 468

DESCRIPTION OF STUDY - NEO SAMPOON (60 MG MENFEGOL) VS. EVT (100 MG NONOXYNOL-9) STUDY # 786

TOTAL NUMBER OF CASES - 900

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE	SGM	CASE	ADM	1MO	3MO	6MO	12MO	1ST SHIP	LST SHIP	STATUS
0043	GYAMFI	GHANA	FR 81/013	06/23/81		200	146	132	69	59	42	11/11/81	03/14/84	CR 467
0365	ABDELSALAAM	EGYPT	FR 81/021	09/21/81		200	200	256	64	185	83	05/10/82	05/25/83	CR 489
0841	APROFAM	GUATEMALA	FR 81/023	11/12/81		200	67	37	10	14		06/10/82	03/21/83	CLOSED
8022	LARRANAGA	PERU	FR 81/016	07/30/81		300	39	14	8	6	6	03/11/82	07/14/83	CLOSED

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DESCRIPTION OF STUDY - NEO SAMPOON (60 MG MENFEGOL) VS. OVT (100 MG MONOXYNOL-9) STUDY # 786

TOTAL NUMBER OF CASES - 340

I CTR	I INVESTIGATOR	I COUNTRY	I INDEX	I DATE	SGN	I CASE	I ADM	I 1MO	I 3MO	I 6MO	I 12MO	I 1ST SHIP	I LST SHIP	I STATUS
I 0890	I ASHONPLAFA	I HONDURAS	I FB 82/007	I 03/21/82	I	I 200	I 25	I 14	I 4	I 3	I	I 06/23/82	I 05/17/83	I CLOSED

DESCRIPTION OF STUDY - NEO SAMPOON (60 MG MENFEGOL) VS. DIAPHRAGM STUDY # 787

TOTAL NUMBER OF CASES - 200

I CTR	I INVESTIGATOR	I COUNTRY	I INDEX	I DATE	SGN	I CASE	I ADM	I 1MO	I 3MO	I 6MO	I 12MO	I 1ST SHIP	I LST SHIP	I STATUS
I 0721	I RAHMAN	I BANGLADESH	I FB 81/002	I 02/03/81	I	I 200	I 170	I 123	I 54	I 59	I 56	I 12/07/82	I 02/18/85	I ACTIVE

DESCRIPTION OF STUDY - EVT VS. OVT (BOTH 100 MG MONOXYNOL-9) STUDY # 793

TOTAL NUMBER OF CASES - 620

I CTR	I INVESTIGATOR	I COUNTRY	I INDEX	I DATE	SGN	I CASE	I ADM	I 1MO	I 3MO	I 6MO	I 12MO	I 1ST SHIP	I LST SHIP	I STATUS
I 0222	I FOREMAN	I MINN. USA	I FB 82/002	I ??/??/??	I	I 160	I 32	I 3	I 9	I 10	I 8	I 07/08/82	I 08/20/84	I CLOSED
I 0225	I POINDEXER	I TEXAS USA	I FR 82/004	I 02/16/82	I	I 160	I 107	I 18	I 34	I 35	I 15	I 06/21/82	I 04/11/84	I CR 5.9
I 0314	I YOUNIS	I EGYPT	I FB 83/003	I 01/11/83	I	I 140	I 140	I 95	I 88	I 120	I 101	I 04/12/83	I 10/25/84	I ACTIVE
I 0907	I BERGER	I N.C. USA	I FR 82/003	I 12/??/81	I	I 160	I 33	I 10	I 9	I 9	I 3	I 03/11/82	I 02/17/83	I CLOSED

DESCRIPTION OF STUDY - NEO SAMPOON (60 MG MENFEGOL) VS. OVT VS. EVT (BOTH 100 MG MONOXYNOL-9) STUDY # 795

TOTAL NUMBER OF CASES - 300

I CTR	I INVESTIGATOR	I COUNTRY	I INDEX	I DATE	SGN	I CASE	I ADM	I 1MO	I 3MO	I 6MO	I 12MO	I 1ST SHIP	I LST SHIP	I STATUS
I 0044	I KLUFTO	I GHANA	I FR 81/020	I 09/03/81	I	I 300	I 300	I 183	I 89	I 229	I 153	I 02/25/82	I 11/02/83	I CR 519

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DESCRIPTION OF STUDY - NON-SPERMICIDE FIT FREE DIAPHRAGM STUDY # 796

TOTAL NUMBER OF CASES - 450

I CTR	I INVESTIGATOR	I COUNTRY	I INDEX	I DATE	SGN	I CASE	I ADM	I 1MO	I 3MO	I 6MO	I 12MO	I 1ST SHIP	I LST SHIP	I STATUS
I 0295	I LAVELY	I ENGLAND	I FB 82/001	I 11/03/81	I	I 450	I 109	I 8	I 3	I 75	I 65	I 03/24/82	I 11/01/83	I CR 525

DESCRIPTION OF STUDY - 100 MG PROPRANOLOL TABLET STUDY # 7790 (FCO 0674)

TOTAL NUMBER OF CASES - 200

I CTR	I INVESTIGATOR	I COUNTRY	I INDEX	I DATE	SGN	I CASE	I ADM	I 1MO	I 3MO	I 6MO	I 12MO	I 1ST SHIP	I LST SHIP	I STATUS
I 0088	I ZIPPER	I CHILE	I FB 84/002	I 12/16/83	I	I 200	I 42	I 56	I 45	I 17	I	I 02/08/84	I 01/21/85	I ACTIVE

DESCRIPTION OF STUDY - 100 MG PROPRANOLOL OVULE STUDY # 7791 (FCO 0674)

TOTAL NUMBER OF CASES - 200

I CTR	I INVESTIGATOR	I COUNTRY	I INDEX	I DATE	SGN	I CASE	I ADM	I 1MO	I 3MO	I 6MO	I 12MO	I 1ST SHIP	I LST SHIP	I STATUS
I 0088	I ZIPPER	I CHILE	I FB 85/001	I 12/16/83	I	I 200	I 19	I 4	I	I	I	I 10/24/84	I 01/21/85	I ACTIVE

DESCRIPTION OF STUDY - OVT (60 MG BENFEGOL) VS. OVT (100 MG NONOXYNOL-9) STUDY # 7798

TOTAL NUMBER OF CASES - 600

I CTR	I INVESTIGATOR	I COUNTRY	I INDEX	I DATE	SGN	I CASE	I ADM	I 1MO	I 3MO	I 6MO	I 12MO	I 1ST SHIP	I LST SHIP	I STATUS
I 0365	I ANDELSALAAM	I EGYPT	I FB 83/005	I 08/10/83	I	I 200	I	I	I	I	I	I	I	I PLANNED
I 0044	I KLUFIO	I GHANA	I FB 84/008	I 01/14/85	I	I 150	I 20	I	I	I	I	I 01/25/85	I	I ACTIVE
I 0045	I GHUNNEY	I GHANA	I FB 84/007	I 01/14/85	I	I 150	I 10	I	I	I	I	I 02/18/85	I	I ACTIVE
I	I POSSIBLE OPEN	I	I	I	I	I 100	I	I	I	I	I	I	I	I PLANNED

DESCRIPTION OF STUDY - OVT (60 MG MENFEGOL) VS. OVT (100 MG MONOXYNOL-9) STUDY # 7799

TOTAL NUMBER OF CASES - 300

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE	SGN	CASE	ADM	1MO	3MO	6MO	12MO	1ST SHIP	LST SHIP	STAT'S
0220	RUDOF	MICHIGAN USA	FR 84/003	04/11/84	I	50	12	9	5	I	I	08/20/84	02/18/85	ACTIVE
0930	PHARMACO D.	TEXAS USA	FB 84/006	06/13/84	I	50	26	21	3	I	I	10/02/84	02/11/85	ACTIVE
0957	BERNSTEIN	CALIF USA	FR 85/003		I	50				I	I			PLANNED
	HALKI	OHIO USA	FR 85/002		I	50				I	I			PLANNED
	POSSIBLE OPEN				I	100				I	I			PLANNED

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STUDY STATUS LIST FOR PROGESTOGEN-ONLY PILLS IN LACTATING WOMEN

DATE: MARCH 1985

DESCRIPTION OF STUDY - PROGESTOGEN-ONLY OC (OVRETTE) IN LACTATING WOMEN STUDY # 8875- FCO 3108-

TOTAL NUMBER OF CASES - 4000

TOTAL NUMBER OF STUDIES - 20

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE ACT	EXP			FST				LST SHIP	LST SITE	STATUS
					DATE	CASE	ADM	2MO	6MO	12MO	SHIP			
084	DELGADO	MEXICO	SYS 84/034	11/14/84	12/86	200	35	21			11/84	02/18/85	01/85 MW	ACTIVE
102	GUZMAN	PERU	SYS 84/018	07/23/84	9/86	200	63	48			7/84	12/27/84	07/84 EW	ACTIVE
110	INACAHATA/ROMERO	PERU	SYS 84/014		6/86	200							08/84 EW	ACTIVE
400	GERAIS	SUDAN	POC 85/002	02/19/85	2/87	200	116	9			2/85	02/19/85	02/85 LK	ACTIVE
422	BROQUET	RWANDA	POC 84/004		3/87	200								PLANNED
452	DOH	CAMEROON	SYS 84/030	12/4/84	6/86	200	62				12/84	12/04/84		ACTIVE
453	WRIGHT	NIGERIA	SYS 84/035		1/87	200							09/84 SM	PLANNED
483	NDIAYE	SENEGAL	SYS 84/004	11/27/84	3/86	200	12	6			11/84	02/05/85	11/84 DN	ACTIVE
831	ARANDA	COSTA RICA	SYS 84/019	09/13/84	9/85	200	200	52			9/84	01/22/85	11/84 CC	ACTIVE
840	SERRATOS	MEXICO	SYS 84/029	10/15/84	9/86	200	152	47	50		10/84	02/25/85	01/85 MW	ACTIVE
841	SANTISO	GUATEMALA	SYS 84/031	12/27/84	10/86	200	27	12			12/84	02/27/85	11/84 CC	ACTIVE
843	ARAUJO	BRAZIL	SYS 84/036	12/27/84	4/87	200	129	28			12/84	02/07/85	11/84 PB	ACTIVE
865	CHAGAS	BRAZIL	SYS 84/038	02/14/85	4/87	200	10				2/85	02/14/85	11/84 PB	ACTIVE
869	CETINA	MEXICO	SYS 84/015	07/24/84	6/86	200	88	99			7/84	02/12/85	01/85 MW	ACTIVE
871	MOGGIA	ARGENTINA	SYS 84/020	08/08/84	9/86	200	167	121			8/84	02/18/85	10/84 MW	ACTIVE
893	CZERESNIA	BRAZIL	SYS 84/037	02/27/85	4/87	200	12	1			2/85	02/27/85	11/84 PB	ACTIVE
8014	LECOIN	HAITI	SYS 84/016	08/14/84	6/86	200	200	130	61	34	6/84	02/25/85	03/85 KJ	ACTIVE
8056	OLIVERA C	BRAZIL	SYS 84/039	02/19/85	4/87	200	2				2/85	02/18/85	11/84 PB	ACTIVE
8058	ANDRADE	BRAZIL	SYS 84/041		4/87	200							11/84 PB	PLANNED
8059	NUNES	BRAZIL	SYS 84/040	02/14/85	4/87	200	23				2/85	02/14/85	11/84 PB	ACTIVE

STUDY STATUS LIST FOR EXPANDED PROGESTOGEN-ONLY STRATEGY

DATE: MARCH 1985

DESCRIPTION OF STUDY: EXPANDED STRATEGY FOR PROGESTOGEN-ONLY PILLS (EITHER SEVERAL CENTERS PER COUNTRY OR THROUGH CBD PROGRAMS)

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE ACT	EXP			FST				LST SHIP	LST SITE	STATUS
					DATE	CASE	ADM.	2MO	6MO	12MO	SHIP			
IMULTI	RUSSOWSKY	BRAZIL	POC 84/001		112/86	500							11/84 PB	PLANNED
043	CARDINER	GHANA	POC 85/001		111/86	200								PLANNED
044	KLUFIO	GHANA	POC 84/003		111/86	200							09/84 SM	PLANNED
440	BARRY/TRAORE	MALI	SYS R3/031	1/3/85	3/86	200	12	4			1/85	1/3/85	12/84 KJ	ACTIVE
457	TOURE	MALI	POC 84/002		2/87	200							12/84 KJ	PLANNED
462	ITOURE/HAMDALLAYI	MALI	POC 85/003		4/87	200							12/84 KJ	PLANNED

FAMILY HEALTH INTERNATIONAL
STUDY STATUS LIST

ORAL CONTRACEPTIVES

ACTIVE COMPARATIVE STUDIES

MARCH 1985

Study No.	Center No.	Index No.	Investigator Name and Address	Description of Study	Patient Category INT PA PP	Date SA Signed	Date Active	Date Last Shipment	No. Cases Approved	Forms Processed				
										ADM	ML	1 mo FU	4 mo FU	8 mo FU
8850	0024	83/004	Dr. Branko Behrlilovic Dom Zdravlja Belgrade, Yugoslavia	Norinyl 1/35 vs Norinyl 1/50	x	11/82	4/83	11/12/84	300	299	278	282	273	250
8850	0358	83/002	Dr. Mamlouh Shaaban Mabarrah Hospital Assuit, Egypt	Norinyl 1/35 vs Norinyl 1/50	x	12/82	7/83	1/14/85	300	300	193	138	89	69
8850	0440	83/032	Dr. Caossou Traore Ministry of Health Bamako, Mali	Noriday vs Norminest	x	7/84	9/84	1/03/85	100	52	26	9		
8850	0703	83/014	Dr. Sriani Rasnayake FPA of Sri Lanka Colombo, Sri Lanka	Norinyl 1/35 vs Norinyl 1/50 vs Norinyl 1/50+FE	x	4/83	7/83	1/28/85	500	500	454	440	291	135
8850	0821	83/013	Dr. Argueta ADS San Salvador, El Salvador	Norinyl 1/35 vs Lo-Ovral vs Norinyl 1/50+FE	x	3/83	6/83	2/25/85	450	320	300	247	170	107
8850	0831	82/009 R-1	Dr. Cecilio Aranda Caja Costarricense Del Seguro Social San Jose, Costa Rica	Norinyl 1/35 vs Norinyl 1/50	x	8/82 10/84	11/82	2/22/85	300	299	297	296	291	232
8850	0869	82/012 R-1	Dra. Thelma Cetina Centro de Investigaciones Hideyo Noguchi Merida, Yucatan, Mexico	Norinyl 1/35 vs Norinyl 1/50	x	7/82 10/84	11/82	1/22/85	300	272	231	174	131	97
807	075	76/351 R-8	Dr. Suporn Koetsawang Siriraj Hospital Bangkok, Thailand	Norinyl 1/50 vs Brevicon x vs Loestrin	x	8/83	6/83	1/21/85	300	314		242	199	

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FAMILY HEALTH INTERNATIONAL,
STUDY STATUS LIST

DEPO PROVERA

ACTIVE COMPARATIVE STUDIES

MARCH 1985

Study No.	Center No.	Index No.	Investigator Name and Address	Description of Study	Patient Category	Date SA Signed	Date Active	Date Last Shipment	No. Cases Approved	Forms Processed					>24 mo FU
										ADM	ML	1 mo FU	3 mo FU	6 mo FU	
8880	0340	83/025	Dr. Sayed Elman MISR Spinning & Weaving Hosp Mahalla El Kubra, Egypt	Retrospective Depo Provera vs Combined OCs	x	7/83	6/84	2/05/85	300	178					175
						FCO 3107									
8880	0703	83/025	Dr. Sriani Basnayake FPA of Sri Lanka Colombo, Sri Lanka	Retrospective Depo Provera vs Combined OCs	x	7/83	9/83	11/19/84	600	600					463
						FCO 3107									
8880	0869	83/023	Dra. Thelma Cetina Centro de Investigaciones Hideyo Noguchi Merida, Yucatan, Mexico	Retrospective Depo Provera vs Combined OCs	x	6/83	1/84	1/14/85	300	118					75
						FCO 3107									
8819	0893	83/001 R-1	Dr. Carlos Czeresnia Hospital Das Clinicas Sao Paulo, Brazil	Depo Surveillance Monthly vs 3-Month injections	x	3/83	4/84	2/11/85	100	84	55	32	22	10	
						FCO 3114									
8880	4010	84/017	Ms. Adama Dabo Gambia FPA Kanifing, Banjul, Gambia	Retrospective Depo Provera vs Combined OCs	x	3/84	7/84	1/31/85	400	397					51
						FCO 3114									

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STATUS LIST FOR IUD5 STUDIES- PLANNED/ACTIVE

DESCRIPTION OF STUDY: TCu 200 STRINGS VS NO STRINGS- STUDY # 530

DATE: 1 FEBRUARY 1985

TOTAL CASES: 1100

FCO: 3101

EXP

CTR	INVESTIGATOR	COUNTRY	INDEX	FST SHP	DATE	CASE	ADM	1MO	3MO	6MO	12MO+	1ST SHIP	1ST SITE	STATUS
184	GALICH	GUATEMALA	IUD 80/009	9/80	1/82	300	299	163	113	149	243	5/21/84	10/82	MW CLOSED
020	ANDOLSEF	YUGOSLAVIA	IUD 80/002	7/83	12/83	500	287	244	228	216	105	12/31/84	10/83	SPI ACTIVE
086	TACLA	CHILE	IUD 81/013	8/81	1/83	100	68	66	60	63	56	1/12/84	3/83	MW CLOSED
299	COHEN	FRANCE	IUD 81/003	7/81	6/85	100	96	85	75	67	50	1/17/85	5/84	OW ACTIVE

DESCRIPTION OF STUDY: TCu 380 AC VS MULTILOAD CU 375 OR CU 7-STUDY # 544,521

TOTAL OF STUDIES: 7

FCO: 3101

EXP

CTR	INVESTIGATOR	COUNTRY	INDEX	FST SHP	DATE	CASE	ADM	1MO	3MO	6MO	12MO+	1ST SHIP	1ST SITE	STATUS
024	REHLILOVIC	YUGOSLAVIA	IUD 80/008	10/80	5/82	300	300	244	190	239	220	6/1/82	5/82	SM CLOSED
081	MORENO	PANAMA	IUD 80/048	5/81	1/83	300	300	270	232	213	226	2/11/83	10/82	CLOSED
340	ETMAN	EGYPT	IUD 81/025	7/81	4/83	300	299	299	293	293	239	7/29/83	5/83	CLOSED
831	ARANDA	COSTA RICA	IUD 80/047	8/81	5/83	300	300	288	288	285	276	8/30/83	6/83	CLOSED
022	PAUDIC	YUGOSLAVIA	IUD 80/007	12/80	11/84	300	300	219	193	203	582	7/23/84	10/83	ACTIVE
018	THOMAS	ENGLAND	IUD 80/020	1/81	9/83	300	166	143	94	107	109	5/11/83	5/82	CLOSED
600	APELO	PHILIPPINES	IUD 80/014	5/81	1/84	200	200	182	165	167	350	1/16/85	-	ACTIVE

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DESCRIPTION OF STUDY: WING SOUND-STUDY # 594

TOTAL NUMBER OF STUDIES: 4

DATE: 1 FEBRUARY 85

FCO: 3101

CTR	INVESTIGATOR	COUNTRY	INDEX	EXP				LST SHIP	LST SITE	STATUS				
				FST SHP	DATE	CASE	ADM				1MO	3MO	6MO	12MO+
100	ZIEGELBOHN	VENEZUELA	IUD 82/011	9/82	3/84	100	100	78	65	72	111	112/10/84	-	ACTIVE
218	SNOWDEN	ENGLAND	IUD 82/008	1/82	3/84	600	509	42	79	78	317	1/ 9/85	-	ACTIVE
363	TOPPOZADA	EGYPT	IUD 82/009	10/82	8/83	150	150	117	103	81	162	8/7/84	-	ACTIVE
850	GUEZMAN-SERANI	CHILE	IUD 82/007	1/82	2/84	300	301	227	29	159	177	4/9/84	-	CLOSED

DESCRIPTION OF STUDY: TCU 200 USED WITH IRON VS CALCIUM VS PLACEBO SUPPLEMENTS- STUDY # 535

TOTAL NUMBER OF STUDIES: 2

FCO: 1203

CTR	INVESTIGATOR	COUNTRY	INDEX	EXP				LST SHIP	LST SITE	STATUS				
				FST SHP	DATE	CASE	ADM				1MO	3MO	6MO	12MO
716	SAIDA	BANGLADESH	IUD 84/003	9/84	12/85	150	47	6	3			1/14/85	4/84	CSWI ACTIVE
721	SABERA RAHMAN	BANGLADESH	IUD 84/002	9/84	12/85	150	86	31				1/14/85	4/84	CSWI ACTIVE

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DATE: 1 FEBRUARY 1985

DESCRIPTION OF STUDY: DELTA T VS TCU 220 WITH ECHOSONOGRAPHY- STUDY # 5562

FCO: 3102

CTR	INVESTIGATOR	COUNTRY	INDEX	EXP											
				FST SHP	DATE	CASE	ADM	1MO	3MO	6MO	12MO	LST SHIP	LST SITE	STATUS	
892	JERTIZ MARISCALI	MEXICO	IUD 83/007	10/83	12/84	100	103	96	81				11/16/84		CLOSED

DESCRIPTION OF STUDY: IUDPS STUDIES UNDER THE INN NETWORK- STUDY # 5538, 5544, 5507

TOTAL NUMBER OF STUDIES: 4

FCO: 3114

CTR	INVESTIGATOR	COUNTRY	INDEX	EXP											
				FST SHP	DATE	CASE	ADM	1MO	3MO	6MO	12MO	LST SHIP	LST SITE	STATUS	
033	EL-ESSATLY	EGYPT	IUD 83/006	10/83	5/85	300	300	204	193	154	18	11/12/84	2/84	SB	ACTIVE
741	DAMRONG	THAILAND	IUD 83/001	3/84	5/85	300	160	127	77	41		11/29/84	3/84	MR	ACTIVE
4000	AKUSE	NIGERIA	IUD 83/013	9/84	5/85	150	74	46	3			112/19/84	9/84	SM	ACTIVE
042	FRWENPU	NIGERIA				150							9/84	SM	PLANNED

DESCRIPTION OF STUDY: TCU 380A VS ML 375 AT BFRP CENTERS- STUDY #5548

TOTAL NUMBER OF STUDIES: 4

DATE: 1 FEBRUARY 1985 FCO: 1203

CTR	INVESTIGATOR	COUNTRY	INDEX	EXP											
				FST SHP	DATE	CASE	ADM	1MO	3MO	6MO	12MO	LST SHIP	LST SITE	STATUS	
721	SARFRA RAHMAN	BANGLADESH	IUD 83/003	9/83	5/84	200	199	131	72	83	58	12/14/84	4/84	CSW	ACTIVE
725	CHOWDHURY	BANGLADESH	IUD 83/005	11/83	5/84	200	56	48	37	12		4/30/84	4/84	CSW	ACTIVE
707	ANABINDA	BANGLADESH	IUD 84/004	9/84	6/85	200	127	48				1/14/85	4/84	CSW	ACTIVE
165	SHAMSUDDIN	BANGLADESH	IUD 83/004		5/85	200							4/84	CSW	PLANNED
715	BIHIYAM	BANGLADESH	IUD 83/007	10/84	6/85	200	28	20				1/14/85			ACTIVE

DESCRIPTION OF STUDY: SURVEILLANCE IN MALI- STUDY # 5538

FCO: 1166

CTR	INVESTIGATOR	COUNTRY	INDEX	EXP											
				FST SHP	DATE	CASE	ADM	1MO	3MO	6MO	12MO	LST SHIP	LST SITE	STATUS	
441	TOUNKAPA	MALI	IUD 84/001	10/83	8/85	150	280	315	122	64	37	1/22/85	12/84	NR	ACTIVE

FAMILY HEALTH INTERNATIONAL
STUDY STATUS LIST

ACTIVE NONCOMPARATIVE STUDIES

MARCH 1, 1985

MALE STERILIZATION

Study Center No.	Index No.	No.	ECN	Investigator Name and Address	Description of Study	Date SA Signed	Date Pnc Active	Date Last Shipment	No. Cases Approved	ADM	Forms Processed				
											1 mo FU	3 mo FU	6 mo FU	12 mo FU	24 mo FU
7001	Multi	MS84/002	3114	Div. d'Hygiene Familiale Dept. de Sante Publique Port-au-Prince, Haiti	Vasectomy Surveillance	NA	09/06/84	11/26/84	500	120					

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FAMILY HEALTH INTERNATIONAL
STUDY STATUS LIST

MALE STERILIZATION

ACTIVE COMPARATIVE STUDIES

MARCH 1, 1985

Study No.	Center No.	Index No.	PCN	Investigator Name and Address	Description of Study	Date SA Signed	Date Active	Date Last Shipment	No. Cases Approved	ADM	Forms Processed					
											1 mo FI	3 mo FU	6 mo FI	12 mo FI	24 mo FU	
7030	0720	MS84/004	1203	Dr. S. H. Nuiyan Chittagong, Bangladesh	Excision & ligation; w/ vs w/o Antibiotics	NA		08/20/84	01/14/85	200	100	90				
7030	7016	MS84/003	1203	Dr. Lutfullah Thakurgaon, Bangladesh	Excision & ligation; w/ vs w/o Antibiotics	NA		10/11/84	02/19/85	200	100	100				

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FAMILY HEALTH INTERNATIONAL
STUDY STATUS LIST

MARCH 1, 1985

FEMALE STERILIZATION

ACTIVE NONCOMPARATIVE STUDIES

Study No.	Center No.	Index No.	Investigator Name and Address	Description of Study	Patient Category			Date SA Signed	Date Active	Date Last Shipment	No. Cases Approved	Forms Processed					
					INT	PA	PP					1 mo FU	3 mo FU	6 mo FU	12 mo FU	24 mo FU	
Multi	0075	81/014	Dr. Suporn Koetsawang Siriraj Hosp. Bangkok, Thailand	Long-term FU of tubal ring and cautery, straight and comp. studies	x	x	x	10/18/82 FCO 3103	12/83	10/31/84	500						297
6101	0255	84/017	Prof. Franco Gaspari Florence Univ. Hosp. Florence, Italy	Intra-tubal device	x			In-house FCO 3103	05/84	09/18/84	25	26	4			20	
6101	0258	84/018	Prof. Ettore Cittadini Clinica Ob/Ginec Palermo, Italy	Intra-tubal device	x			In-house FCO 3103	05/84	02/26/85	25	10			8		
6101	0279	84/016	Dr. Jacques Hamon Tenon Hospital Paris, France	Intra-tubal device	x			In-house FCO 3103	02/84	02/19/85	50	52	25		33	3	
6900	Multi	84/008	Div. d'Hygiene Familiale Dept. de Sante Pub. Port-au-Prince, Haiti	Surveillance: all approaches, all techniques	x		x	FCO 3114	03/05/84	01/23/85	1500	1068	464	327			
6900	8020	81/007	Dr. H. Aguinaga CPATMC Rio de Janeiro, Brazil	Laparoscopy: Tubal Ring	x			FCO 3114	02/11/82	12/28/84	2000	2048	1927	1491			1562

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FAMILY HEALTH INTERNATIONAL
STUDY STATUS LIST

ACTIVE COMPARATIVE STUDIES

MARCH 1, 1985

FEMALE STERILIZATION

Study No.	Center No.	Index No.	Investigator Name and Address	Description of Study	Patient Category INT PA PP	Date SA Signed	Date Active	Date Last Shipment	No. Cases Approved	Forms Processed					
										ATM	ML	1 mo FU	6 mo FU	12 mo FU	24 mo FU
0670	0723	84/002	Dr. Salahuddin Almosi DAVS Clinic Dhaka, Bangladesh	Long-term FU: Minilap: x Ring vs Pomeroy		10/19/84 FCO 3103	11/16/84	01/14/85	200	200					10
6258	0836	84/005	Dr. John Magahata Hosp San Juan de Dios Lima, Peru	Minilap: Filshie Clip x vs SecuClip		01/12/84 FCO 3103	07/05/84	07/05/84	200	75	75				
6258	0865	84/004	Dr. Ronald Rosemeyer Inst of Reprod Health Santa Maria, Brazil	Minilap: Filshie Clip x vs SecuClip		12/29/83 FCO 3103	08/20/84	02/14/85	100	40	40	25			
6260	0600	83/009	Dr. Ruben Apelo Jose Fabella Mem Hosp Manila, Philippines	Minilap: Filshie Clip vs Pomeroy	x	12/07/83 FCO 3103	04/24/84	02/19/85	300	296	293	136	11		
6260	0781	84/003	Dr. Jaw-shong Yan Tri Service Gen Hosp Taipei, Taiwan	Minilap: Filshie Clip vs Pomeroy	x	12/21/83 FCO 3103	04/13/84	01/22/85	200	75	75	41			
6260	0832	84/007	Dr. J. Lasso de la Vega Complejo Hosp Metrop. Panama City, Panama	Minilap: Filshie Clip vs Pomeroy	x	01/17/84 FCO 3103	02/26/84	01/22/85	300	300	298	297	151		
6264	0083	84/019	Dr. Contreras Hosp. Jose de Obaldia David, Panama	Minilap: Ring vs Filshie Clip FCO 3103	x	06/84	10/10/84	02/10/85	300	51	51	41	1		

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FAMILY HEALTH INTERNATIONAL
STUDY STATUS LIST

FEMALE STERILIZATION

ACTIVE COMPARATIVE STUDIES

MARCH 1, 1985

Study No.	Center No.	Index No.	Investigator Name and Address	Description of Study	Patient Category			Date SA Signed	Date Active	Date Last Shipment	No. Cases Approved	Forms Processed					
					INT	PA	PP					ADM	MI	1 mo FU	6 mo FU	12 mo FU	24 mo FU
6265	0075	84/015	Sr. Suporn Kentsawang TFRA Bangkok, Thailand	Laparoscopy: Ring vs Filshie Clip	x			Sub 1275	10/29/84	01/22/85	300	79	79	79			
6960	0704	83/004	Dr. S.F. Begum Dhaka Medical College Dhaka, Bangladesh	Minilap: w/ vs w/o antibiotics	x			FCO 1203	09/83	02/18/85	200	193	190	3			
6960	0705	84/012	Dr. S. Jabeen Sir Salimullah Medical College & Hospital Dhaka, Bangladesh	Minilap: w/ vs w/o antibiotics	x	x	x	FCO 1203	08/20/84	02/19/85	200	125	125				
6960	786	84/014	Prof. Talukoler Rangpur Med. Coll. Hospital Rangpur, Bangladesh	Minilap: w/ vs w/o antibiotics	x	x	x	FCO 1203	10/11/84	12/20/84	200	84	84				
6960	7019	84/013	Dr. Syed Ahmed Comilla RAHS Clinic Comilla, Bangladesh	Minilap: w/ vs w/o antibiotics	x	x	x	FCO 1203	09/18/84	02/19/85	200	187	187				

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APPENDIX C
PUBLICATIONS LIST

Family Health International

SEMI-ANNUAL PUBLICATIONS LIST
October 1, 1984 - March 31, 1985

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- LP Cole, JA Fortney and KI Kennedy. Menstrual Patterns after Female Sterilization: Variables Predicting Change. *Stud Fam Plann* 15(5):242, 1984. (84-26)
- SD Mumford. Vasectomy and Vasectomy Counseling. In: *Men's Reproductive Health*. Janice M. Swanson and Katherine A. Forrest, eds. (New York: Springer Publishing Company, 1984), pp. 260-276. (84-27)
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- M Potts. After the Froth has Settled. *People* 11(4):24, 1984. (84-29)
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- LP Cole, DA Edelman, DM Potts, RG Wheeler and LE Laufe. Postpartum Insertion of Modified Intrauterine Devices. *J Reprod Med* 29(9):677, 1984. (84-32)
- B Janowitz, S Wallace, G Araujo and L Araujo. Method of Payment and the Cesarean Birth Rate in a Hospital in Northeast Brazil. *J Health Politics, Policy and Law* 9(3):515, 1984. (84-33)
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- S Basnayake, JE Higgins, PC Miller, SM Rogers and SE Kelly. Early Symptoms and Discontinuation Among Users of Oral Contraceptives in Sri Lanka. *Stud Fam Plann* 15(6):285, 1984. (84-38)
- J Lauroy, L Barry, JH Lewis and NN Burton. Allaitement, contraception et espacement des naissances au Mali et au Senegal. *Perspectives Internationales de Planning Familial*. Special edition, p. 21, 1984. (84-39)

- RM Pearson, EJ Ridgway, A Johnston and J Vadukul. Concentration of D-Propranolol in Cervicovaginal Mucus. (Letter to the Editor) Lancet 2:1480, 1984. (84-40)
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- DA Edelman, SL McIntyre and J Harper. A Comparative Trial of the Today Contraceptive Sponge and Diaphragm. Am J Obstet Gynecol 150(7):869, 1984. (84-42)
- M Potts. Population Growth and Politics. Brit Med J 289:641, 1984. (84-43)
- S Koetsawang, S Srisupandit, SJ Apimas and CB Champion. A Comparative Study of Topical Anesthesia for Laparoscopic Sterilization with the Use of the Tubal Ring. Am J Obstet Gynecol 150(8):931, 1984 (84-44)
- CA Klufio, SE Reid, AA Bruce-Tagoe, MJ Rosenberg, PR Lamptey and JA Fortney. Contraceptive Use Among Women with Sickle Cell Diseases, Accra, Ghana. Brit J Fam Plann 10:113, 1985. (85-01)
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- Apelo and C Waszak. Postpartum IUD Insertions in the Philippines. PUB-067
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- L Galich, L Cole and C Waszak. A Comparative Study of the TCU 200B with and Without Strings. IUD-110
- P Miller, P Donaldson, S Basnayake and SV de Silva. The Effect of Oral Contraceptive Formulation and Field-workers: A Cautionary Tale. SYS-35
- PK Makinwa-Adebusoye, DJ Nichols and SE Kelly. Breast-feeding, Postpartum Abstinence and Contraception in Lagos, Nigeria. EVAL-86
- I Chi, M Potts and L Wilkens. Rare Events Associated with Tubal Sterilizations: An International Experience. FS-186

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