

**ANNUAL REPORT**  
**September 16, 1983 – September 29, 1984**

**Contract AID/DPE-0537-C-00-1028-00**



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## I. INTRODUCTION

This report describes the accomplishments of Family Health International (FHI) under AID Contract No. DPE-0537-C-00-1028-00 for the period of 16 September 1983 through 29 September 1984.

The need for continued strong support for contraceptive development, evaluation and safety studies was demonstrated during the past year by a team of FHI researchers who estimated that deaths due to pregnancy and childbirth accounted for almost 30 percent of all deaths to women of reproductive age in Egypt and Indonesia. In Egypt, the deaths due to complications of pregnancy were 16 times more numerous than in the United States. Those at greater risk are older, high parity women who have typically advanced beyond their ideal family size. There is a continuing need for health researchers to focus on the development of more effective contraceptives, more appropriate delivery systems, more adequate surveillance programs and a wider range of acceptable, less costly methods.

Throughout the year Family Health International has pursued contraceptive development, evaluated contraceptive effectiveness and safety, and studied ways to improve the delivery of health and family planning services.

Major accomplishments of the past twelve months include:

- preliminary analysis of a landmark study of the relationship

between breast-feeding and ovulation

- implementation of a large-scale research program to evaluate the diffusion of natural family planning in a urban setting in Latin America
- publication of the first estimates of cause-specific female mortality and its relationship to contraceptive use in the developing world
- organization of Phase III trials of NORPLANT® implant system
- long-term follow-up of female sterilization and IUD use and their association with a series of rare adverse effects
- completion of studies documenting the safety of vasectomy and the health consequences of DMPA use and the initiation of more studies of the safety of other methods.

Family Health International also continued to provide specialized training to strengthen the capacity of local research programs to carry out high quality biomedical research aimed at improving the health and welfare of people in the rural area of the world's poorest countries. FHI sponsored or co-sponsored seminars, conferences and training programs to provide the latest information of contraceptive development, safety and delivery systems to providers of health care and health policymakers around the world.

This report divides the work of FHI into four areas: Clinical Trials, Contraceptive Safety, Program Evaluation and Field Development and Training. The work conducted within each area -- represented by a division at FHI - is described in the following sections.

## **II. CLINICAL TRIALS**

Major emphases in the Clinical Trials Division have been directed to the areas of systemic and vaginal methods of contraception. In addition, work has been expanded on approaches to non-surgical female sterilization, and the vast data sets in the IUD and voluntary surgical female sterilization research areas have been analyzed and evaluated for the preparation of publications. New initiatives had been planned in female sterilization.

Consultant Reports (CRs) were prepared for nearly 50 collaborators. A listing of the CRs is found in Appendix A. Status lists for ongoing studies are found in Appendix B.

A reporting on specific accomplishments of the study areas follows.

### **A. Systemic Contraception**

#### **1. Long-acting Steroids**

A major goal of FHI 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 methods show promise for meeting this goal. FHI is currently working with injectable microencapsulated steroids and implants.

**a) NET Microspheres**

Efforts to improve delivery systems for currently used steroids have led to the development of a long-acting injectable contraceptive that permits the continuous low-dose administration of the progestin, norethindrone (NET).

FHI is working with PARFR, Ortho Pharmaceutical, and Stolle R & D to obtain FDA marketing approval for a 90-day, biodegradable injectable formulation of NET microspheres. A holdup in the research has occurred, but the technology is a robust one and solutions are apparent and are being implemented.

In early 1984, PARFR and FHI initiated five of the six studies of the NET injectable planned under the Phase II protocol of the IND. Fourteen women had been admitted to the studies when one pregnancy occurred. The studies were temporarily stopped. The failure was apparently related to an inadequate rate of release of NET from the formulation. The drug has been reformulated, and preclinical and clinical Phase I studies are being conducted prior to continuing the PARFR-sponsored Phase II trials in FY'85.

FHI is supporting the work to scale-up the production of NET microcapules which will be necessary when Phase III trials are initiated.

**b) NORPLANT® Contraceptive Subdermal Implants**

A multicenter, 2000-case clinical trial of NORPLANT® subdermal implants is planned. The product has received approval for marketing in Finland where it is manufactured by Leiras Pharmaceuticals. The NORPLANT® system consists of six Silastic capsules which are designed to be implanted subdermally in the upper arm by a minor surgical procedure. The system releases levonorgestrel into the bloodstream at a rate of about 50 mcg per day during the first year and about 30 mcg/day over the next four years. Studies will be initiated in early 1985 in Bangladesh (600 cases), Nepal (400 cases), Sri Lanka (600 cases) and the Philippines (400 cases). Investigators will receive standardized training in the proper insertion and removal techniques at Raden Saleh clinic in Jakarta, Indonesia. Additional studies for 1985 are planned for Singapore and Egypt.

The objective of the studies is to evaluate efficacy and overall acceptability of the NORPLANT® system, as measured by side effects, pregnancy and continuation rates. 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 administered to all potential family planning acceptors. Also, acceptors and providers will be asked their subjective opinions about the method at a six-month follow-up visit.

All study sites have been identified and investigators have reviewed the protocol and study materials. Negotiations with local government review committees are completed and approval has been received or is expected soon in all countries with a planned FY'85 initiation date. FHI has begun consideration of appropriate systems for the post-marketing surveillance of this new modality of contraceptive.

**c) NET Biogradable Implants**

Phase II norethindrone (NET) biodegrading implant studies have been sponsored by PARFR at three centers to determine the efficacy of a continuous low-dose administration of NET via pellet implants. FHI monitored these studies and is currently conducting data analysis.

Preliminary evaluation of the data indicated that the four-pellet system is superior to the three-pellet system; no pregnancies have been reported for the four-pellet system, compared with three pregnancies for the three-pellet system. Blood level for NET are satisfactory on the duration of use and the pattern of uterine bleeding appears to be acceptable.

**d) Other Injectables**

Currently available injectable contraceptives have not been provided in any FHI sponsored program. However, data analysis for programs of injectable and oral contraceptive distribution which have been developed by other agencies is being conducted in Egypt, Guatemala,

Mexico, Sri Lanka and Thailand. These analyses are designed to determine differences in rates of continuation and reasons for termination between steroids administered by the two delivery systems and to uncover more serious side effects, if any. Admission data has been collected retrospectively from patient clinic records for acceptors of both methods prior to 1981. A single follow-up visit is being attempted to determine continuation status.

Preliminary analysis of the first 1000 admissions shows a two-year cumulative life table rate of 64.4 for injectable users and 69.9 for oral contraceptive users. About 60% of the women have been followed up. Discontinuation for menstrual problems was greater for injectable users, 6.5, than for oral contraceptive users, 4.2. These results may change as more women are followed up.

### **Future Plans**

Other countries that will be explored as possible study sites for NORPLANT® subdermal implants include Costa Rica, Guatemala, Panama, Haiti, Argentina, Peru, Venezuela, Nigeria, Ghana, Morocco and Sudan. It is likely that at least 4-5 countries from among this list will become involved in NORPLANT® implant studies during 1986 and another 4-5 during 1987. Also, increased experience and data on the NORPLANT®-2 covered rod system is likely to lead to comparative trials of the two systems.

When Phase II PARFR-funded NET microsphere studies resume, 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 material relevant to the US FDA for marketing approval.

NET biodegradable implants may be ready for Phase III testing within the next year.

## **2. Oral Contraceptives**

FHI has continued to compare the efficacy, safety and acceptability of formulations. Special emphasis has been placed on low estrogen dose pills and their acceptability in the developing world.

### **a) Norinyl 1/35**

A multicenter clinical trial of Norinyl 1/35 designed to evaluate its acceptability in comparison with Brevicon or Lo-Ovral, two other low-dose tablets, and Norinyl 1/50, a standard-dose pill, is ongoing at a total of 15 sites. 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 vs. Brevicon trial. Brevicon users had significantly higher discontinuation rates for menstrual problems and side effects, resulting in a significantly lower 8-month continuation rate, 41.3 compared with 60.0 for Norinyl 1/35 users. Breakthrough spotting and/or bleeding was the most frequently reported menstrual problem

and headaches was the most frequently reported side effect causing pill discontinuation.

A Norinyl 1/35 vs Lo-Ovral comparison is being conducted at six centers. Norinyl 1/35 had a significantly higher 8-month termination rate for menstrual problems (Table 2). Breakthrough bleeding was the most frequently reported menstrual problem causing discontinuation. Cumulative life table continuation rates at 8 months were 77.5 for Norinyl 1/35 users and 81.7 for Lo-Ovral users.

Five centers are participating in the Norinyl 1/35 vs. 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 8 months were 84.3 for Norinyl 1/35 and 85.6 for Norinyl 1/50. Efforts are currently being made to improve follow-up rates.

) **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 currently negotiating with oral contraceptive manufacturers to obtain supplies for this study.

) **Progestogen-only Oral Contraceptives**

A comparative trial of the progestogen-only oral contraceptive, Microval, and non-hormonal methods of contraception was active in

Egypt during the last year. One study was previously terminated in Malaysia due to slow patient recruitment and poor follow-up, but two were completed in Argentina and India. The objectives of the studies were to evaluate the acceptability of a progestogen-only contraceptive among breast-feeding women, to determine differences in infant growth rates between pill acceptors and non-hormonal contraceptors, and to identify side effects associated with each method. A total of 981 women chose Microval, and 856 women chose a non-hormonal method of contraception, including those who chose no method. Table 4 lists the primary reasons for termination from the study for all patients by center and group.

The only pregnancies to occur were at the center in Argentina, where three (1.2%) and six (2.4%) pregnancies were reported in the progestogen-only and non-hormonal groups, respectively. Ten infant deaths were reported: four in Egypt and six in India. In Egypt, three of the deaths were in the progestogen-only group and one in the non-hormonal group; the life table rates were not significantly different. In India, all six deaths were in the progestogen-only group, but the rate of loss to follow-up in both groups was more than 40% by the end of the study so that a complete assessment of infant mortality in this study is not possible. Results from Argentina and Malaysia suggest no differences between the progestogen-only and non-hormonal groups with respect to growth of the infants. In Egypt, on the other hand, infants of mothers using progestogen-only OCs grew more rapidly throughout the follow-up period than infants of non-hormonal methods users. In India, infant

head circumference was significantly larger for the OC group; weight and length were generally somewhat larger, but not significantly so.

Center selection has been completed for a 4000-case, 20-center non-comparative clinical trial of the progestogen-only oral contraceptive, Ovrette, which is designed to evaluate the acceptability, safety and effectiveness of this minipill among breast-feeding women. Four sites have initiated admissions and the remaining centers are being supplied with study materials. All subjects will complete 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 Lo-ovral, (2) comparative evaluations of various low-dose oral contraceptives, and (3) an evaluation of the acceptability of switching from a standard to a low-estrogen dose pill.

The next year will also see initiatives in the following areas:

#### **Expanded progestogen-only strategy**

In an attempt 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.

#### Oral Contraceptive Compliance

How well women comply with proper oral contraceptive administration can affect the efficacy and side effects of the medication? The question may prove particularly important for the more complex triphasic pills now available in several countries. Protocols for a series of studies to explore compliance to pill taking are being developed. Initially focus groups will be used to establish a questionnaire-based method in a clinical setting. A special dispenser 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 strategy will use the tools developed in the foregoing studies to assess the effect of motivational methods on compliance. They will be used to indicate effective methods of improving compliance in oral contraceptive users. The first two approaches will be implemented in 1985 with the third strategy being implemented in 1986.

#### Progestogen-Only Pill and Milk Yield

Several studies to assess the effect of oral contraceptives on milk yield during lactation have been published, but all have design or measurement flaws. A crossover design in which each woman serves as

her own control will be utilized and milk yield will be measured over a period of 24 hours. The study will be implemented during 1985.

Table 1

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

	Norinyl 1/35 (N=308)	Brevicon (N=326)
Accidental pregnancy		
1 month	0.0	0.0
4 months	0.0	0.0
8 months	0.0	0.0
Menstrual problems		
1 month	2.0	4.6
4 months*	6.6	15.1
8 months**	12.2	25.8
Side effects		
1 month*	0.8	4.2
4 months**	2.2	10.0
8 months*	8.5	15.4
Other Medical Reasons		
1 month*	0.4	2.3
4 months**	1.7	2.9
8 months**	1.7	7.2
Continuation		
1 month	91.1	84.6
4 months	75.8	61.5
8 months	60.0	41.3
Follow-ups		
1 month	79.5	85.3
4 months	59.3	62.7
8 months	38.4	42.4

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\* 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=514)	Lo-Ovral (N=510)
<b>Accidental pregnancy</b>		
1 month	0.0	0.0
4 months	1.2	0.0
8 months	1.2	0.0
<b>Menstrual problems</b>		
1 month	1.4	0.5
4 months	3.9	1.5
8 months*	5.9	1.5
<b>Side effects</b>		
1 month	0.7	0.9
4 months	3.0	1.9
8 months	4.5	3.7
<b>Other Medical Reasons</b>		
1 month	0.5	0.2
4 months	0.8	1.9
8 months	1.8	2.3
<b>Continuation</b>		
1 month	96.0	97.2
4 months	85.6	86.3
8 months	77.5	81.7
<b>Follow-ups</b>		
1 month	81.3	86.1
4 months	55.4	60.2
8 months	42.7	47.7

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\*  $p < 0.05$

Table 3

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

	Norinyl 1/35 (N=714)	Norinyl 1/50 (N=711)
<b>Accidental pregnancy</b>		
1 month	0.0	0.0
4 months	0.0	0.0
8 months	0.0	0.0
<b>Menstrual problems</b>		
1 month	0.8	0.6
4 months	2.2	2.6
8 months	3.3	3.3
<b>Side effects</b>		
1 month	0.3	1.2
4 months	1.7	2.8
8 months	2.6	3.9
<b>Other Medical Reasons</b>		
1 month	0.0	0.3
4 months	0.4	1.1
8 months	1.0	1.9
<b>Continuation</b>		
1 month	97.6	96.0
4 months	90.3	89.2
8 months	84.3	85.6
<b>Follow-ups</b>		
1 month	90.6	90.4
4 months	76.3	77.3
8 months	53.3	55.3

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TABLE 4

Reasons for Termination from the Clinical Trials  
of Progestogen-only Oral Contraceptives  
in Lactating Women, By Study Site

Reasons for Termination	Argentina		POC (N=248)	Egypt		POC (N=244)	India		POC (N=239)	Malaysia	
	POC (N=250)	Non-Hormonal (N=251)		Non-Hormonal (N=241)	Non-hormonal (N=243)		Non-Hormonal (N=121)				
Discontinued study contraceptive	4	2	47	0	40	0	5	0			
Discontinued breast-feeding	7	24	11	0	3	0	11	1			
Pregnancy	3	6	0	0	0	0	0	0			
Infant death	0	0	3	1	6	0	0	0			
Lost-to-follow-up	133	138	49*	93*	117	187	193	118			
TOTAL	147	170	110	94	166	187	209	119			

\* As the study in Egypt is not yet complete, some of these women may not be lost-to-follow-up.

## **B. Vaginal Contraceptives**

### **1. Barriers and Spermicides**

FHI has continued to evaluate a number of vaginal contraceptives in the past year, including the sponge, diaphragm with spermicide, Neo Sampoo foaming vaginal tablets containing the spermicide, menfegol, Emko (EVT) and Ortho (OVT) vaginal tablets containing the spermicide, nonoxynol-9, Ortho vaginal tablets containing menfegol (Neo Sampoo repackaged) and spermicidal foam. Six multi-center comparative trials evaluating these methods were ongoing during 1983-1984. Nineteen studies were active during the year, 17 of these were providing follow-up data.

The table at the end of the section summarizes the results of these trials. Five studies compared the contraceptive sponge with Neo Sampoo (Study 782), two compared the sponge with the diaphragm with spermicide (Study 783), three compared Neo Sampoo with foam (Study 785), four compared Neo Sampoo with EVT (Study 786), one compared Neo Sampoo with OVT and EVT (Study 795), and four compared OVT with EVT (Study 793). The results for Studies 782, 783, 786, and 795 should be considered the final report for these trials.

In study 782 conducted in Yugoslavia, Taiwan and Bangladesh, the sponge was as effective at preventing pregnancy as Neo Sampoo tablets, but led to a greater number of discontinuations for discomfort and personal reasons and had a significantly lower continuation rate at twelve months. In the two centers conducting

Study 783 (England and Canada), the diaphragm was significantly more effective and acceptable (as measured by continuation rates) than the sponge. No significant differences in effectiveness or acceptability were observed between Neo Sampoo and foam in Study 785 (Egypt and Yugoslavia). In both Study 786 (Ghana, Egypt, Guatemala and Peru) and Study 793 (United States and Egypt), comparability of the vaginal tablets was demonstrated, although recruitment proved to be difficult in all centers except Ghana and Egypt. In a three-way comparative study (Study 795) of Neo Sampoo with OVT and EVT conducted in Ghana, personal discontinuations among EVT acceptors were higher than for the other two tablets, whereas continuation rates were highest among women who used Neo Sampoo.

## **2. Propranolol**

In vitro tests have shown propranolol, a beta-blocker frequently prescribed to treat hypertension and cardiac arrhythmia, to be a highly effective inhibitor of sperm motility. Moreover, a Chilean study has shown that when propranolol tablets are inserted into the vagina daily, except during menses, propranolol is an effective spermicidal agent.

A clinical study of DL-propranolol conducted in London with FHI support, has shown that propranolol, when taken orally, is concentrated by an unknown mechanism in cervical mucus. This raises the question whether propranolol could be given in high enough oral doses to produce a spermicidal action vaginally.

## Future Plans

FHI will continue to evaluate several of the barrier and spermicidal methods investigated in the past year. The comparative trials of Neo Sampoo and foam (Study 785) and OVT and EVT (Study 793) will be completed in 1984-1985.

In 1985, FHI will sponsor trials of various oral doses of D-propranolol. This approach is promising since D-propranolol has a potency of about one-hundredth that of racemic propranolol in its cardiovascular effects, yet is of approximately equal potency in its spermicidal actions. D-propranolol might either be used vaginally, or even orally to produce a contraceptive effect without risk of systemic effect.

After a careful review of existing data on the usefulness of propranolol as a contraceptive agent, FHI will submit an IND to the FDA for clinical development of DL-propranolol as a vaginal spermicide. Depending upon the outcome of preliminary D-propranolol studies and the availability of the product for clinical trials, an IND for this isomer will be submitted in late FY'85.

Added emphasis will be placed on a comparison of Ortho vaginal tablets with menfegol versus those with nonoxynol-9. A variety of new compounds will be screened for potential spermicidal activity. Such devices as the disposable diaphragm and the spermicidal condom will receive priority because of their potential widespread acceptance.

Little or no attention has been paid in the past to objective assessment of the use-effectiveness of the condom in preventing pregnancy. Protocols for retrospective and prospective studies of the condom have been completed and studies will be implemented during 1985.

Twelve-month Gross Cumulative Life-table Rates  
per 100 Women for FHI Comparative Female Barrier Studies

	Study 782		Study 783		Study 785		Study 786		Study 795			Study 793*	
	Sponge (N=701)	Neo Sampoon (N=666)	Sponge (N=245)	Diaphragm (N=246)	Foam (N=436)	Neo Sampoon (N=438)	Neo Sampoon (N=223)	EVT (N=229)	Neo Sampoon (N=99)	OVT (N=10)	EVT (N=100)	OVT (N=158)	EVT (N=152)
<b>Terminations</b>													
Accidental pregnancy	10.2	11.7	25.7**	9.3	7.9	7.2	14.0	12.2	9.6	11.3	12.5	16.8	15.7
Allergic reaction	0.2	0.2	1.5	0.7	0.0	0.0	0.0	2.3	0.0	1.9	1.9	1.5	1.7
Discomfort	12.8**	9.3	13.3	7.1	10.5	10.7	7.1	4.1	0.0	2.7	12.8**	7.8	10.7
Product-related	18.1**	2.7	7.5	5.3	1.6	2.8	2.1	3.0	0.0	2.9	12.3**	6.4	3.2
Other medical	1.4	3.1	5.5	2.7	0.7	1.9	1.1	1.9	4.1	1.4	1.4	0.0	0.0
Planned pregnancy	8.7**	3.9	6.0	5.7	2.3	1.0	3.3	0.0	6.7	5.4	9.0	2.3	1.0
Other personal	15.8**	8.0	26.1	27.4	13.4	4.3	8.1	7.5	22.8	36.6	34.5	13.5	14.4
Continuation	48.4**	66.6	38.4**	52.7	68.2	67.0	68.8	72.4	62.4	48.6	38.5**	59.8	60.7
Follow-up	74.1	78.0	79.0	73.4	44.2	42.0	32.0	33.2	80.3	77.8	76.7	62.2	67.6

\*Only six-month life-table rates available for this study

\*\*Significant difference between rates (p < 0.05)

## **C. Surgical Female and Male Sterilization**

### **1. Surgical Female Sterilization**

During the contract year, FHI continued to evaluate various techniques of tubal occlusion with emphasis on the safety of the surgical procedure and the security of tubal occlusion combined with minimal damage to the tube. Data have been received from three sites comparing the Filshie Clip and the Pomeroy method applied via minilaparotomy (table follows). A total of 536 procedures have been performed on postpartum women. There was one (0.4%) technical failure in the Filshie Clip group and three (1.1%) in the Pomeroy group. The rates of surgical difficulties in the Filshie Clip and Pomeroy groups were 6.4% and 8.5%, respectively. Surgical injuries or complications occurred for five (1.9%) Filshie Clip patients and seven (2.6%) Pomeroy patients. Few complications were reported from sterilization to discharge; the rates were 1.1 and 0.4 for the Filshie Clip and Pomeroy groups, respectively. Early follow-up has been completed for 211 (79.6%) women in the Filshie Clip group and 202 (74.5%) women in the Pomeroy group.

All complications reported at early follow-up were incision-related; complaints of pelvic pain were reported for one (0.5%) woman in the Filshie Clip group and three (1.5%) women in the Pomeroy group. No pregnancies have occurred to date. FHI will continue to collect follow-up data for 12 months poststerilization.

## Filshie Clip versus Modified Pomeroy

### Events During Surgery and at Early Follow-up

Events	Filshie Clip (N=265)		Modified Pomeroy (N=271)	
	No.	%	No.	%
<b>Surgical difficulties</b>				
With equipment	0	-	1	0.4
Entering peritoneum	2	0.8	0	-
Visualizing tubes	6	2.3	13	4.8
Grasping tubes	7	2.6	9	3.3
Occluding tubes	2	0.8	0	-
<b>Total</b>	<b>17</b>	<b>6.4</b>	<b>23</b>	<b>8.5</b>
<b>Surgical injuries</b>				
Tubal/mesosalpinx injury without bleeding	1	0.4	1	0.4
Tubal/mesosalpinx injury with bleeding	4	1.5	5	1.8
<b>Surgical complications</b>				
Soft tissue emphysema	0	-	1	0.4
<b>Women returning for early follow-up</b>				
	211	79.6	202	74.5
<b>Incision complication</b>				
Serous discharge	24	11.4	18	8.9
Inflammation	15	7.1	16	7.9
Abscess	5	2.4	5	2.5
Bleeding	1	0.5	1	0.5
Incomplete dehiscence	2	0.9	8	4.0
<b>Total women with light complications</b>	<b>47</b>	<b>22.3</b>	<b>48</b>	<b>23.8</b>

A comparative evaluation of the Filshie Clip and the Secuclip is underway at three centers in Latin America. A total of 115 procedures have been performed. There have been two (3.4%) technical failures, both in the Filshie Clip group. Surgical difficulty rates are comparable for the two techniques at 8.5% and 10.7% for the Filshie Clip and Secuclip, respectively. Rates of surgical injuries/complications are also similar, 3.4% for the Filshie Clip group and 3.6% for the Secuclip group. Reports of complications and complaints from the time of sterilization to discharge have been slightly, but not significantly, higher for the Filshie Clip procedure (14.0%) than for the Secuclip procedure (8.9%). Early follow-up has been completed for only eight women; the women will be followed-up through 12 months poststerilization.

Data continue to be received from one comparative study of the Secuclip and the tubal ring in Indonesia. No technical failures or surgical difficulties occurred in the 102 Secuclip procedures, and only one surgical injury (a uterine perforation) was reported for these cases. Twelve-month follow-up has been completed for approximately 22% of the women in each group. One luteal phase pregnancy has been reported in the ring group; no other major complications have been reported during the follow-up period.

FHI is assessing the long-term effect of surgical female sterilization at two sites, one in Thailand and the other in Bangladesh. In Thailand, 113 women have returned for a follow-up visit 24 months or longer poststerilization. No pregnancies have

occurred. A total of six (5.3%) poststerilization abdominal/pelvic surgeries have been reported, including two hysterectomies, one dilatation and curettage, one diagnostic laparoscopy, one colpoperineorrhaphy and one unspecified procedure. The indications for the two hysterectomies and one D & C included two cases of carcinoma in situ and one case of prolonged bleeding. The diagnostic laparoscopy was performed on a woman with severe abdominal pain, but no complications were found. Most women (98.2%) have indicated satisfaction with their decision concerning sterilization.

A total of 258 women have returned for long-term follow-up at the Bangladesh center. Two pregnancies have been reported, one occurring at 30 months poststerilization and one at 72 months poststerilization, yielding a cumulative life-table pregnancy rate of 0.9 at 72 months. There has been one (0.4%) abdominal/pelvic surgery of dilatation and curettage during this follow-up interval. The women (95.0%) have generally expressed satisfaction with the sterilization procedure.

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. The studies are being conducted at three sites, and 71 procedures have been performed to date. There have been two (2.8%) technical failures, one due to a vasovagal reaction and the other because of inadequate anesthesia. Insertion difficulties have been reported for 9 (12.7%) procedures, primarily consisting of difficulties visualizing the tubes. The rate of injuries/complica-

tions at insertion is 7.0%, including three (4.2%) patients experiencing a vasovagal reaction. No complications have been reported for the women during the time from the procedure to discharge; however, seven (10.1%) women complained of pelvic pain during this time. Early follow-up is complete for 23 (32.4%) patients. Few complications or complaints have been noted. Follow-up will continue for 12 months poststerilization.

### **Future Plans**

During the next year, FHI plans to initiate several studies. Three sites will compare the Filshie Clip to the Tubal Ring applied via minilaparotomy in interval women. Comparison of these two techniques will also be conducted at four centers applying the techniques via laparoscopy. Evaluation of the Filshie system will be expanded by comparison with the Wolf system, for both minilaparotomy and laparoscopy procedures. In addition, six studies of a new device for determining tubal patency (FEMTEST) are planned for the upcoming year. Finally, plans are being developed for the study of piroxicam (Feldene) as a single dose long-acting analgesic for poststerilization pain.

## **2. Male Sterilization**

A study of male sterilization was completed in late 1983. The study, designed as a 1000-case surveillance of vas ligation and excision, revealed no surgical injuries or difficulties and few complications or complaints at early follow-up. Long-term events,

from three to 12 months poststerilization, also support the general conclusion that vasectomy is safe and effective. A total of 701 (70.1%) men returned for long-term follow-up during the study. Only two (0.3%) complications were reported, including one case of scrotal abscess and one case of scrotal hematoma.

#### **Future Plans**

A clinical trial of the percutaneous vas occlusion techniques is planned for 1984-1985. The technique has undergone initial testing independently of FHI using microdiathermy needle which had been developed in London in collaboration with FHI. The procedure is performed under local anesthesia and eliminates the need for a surgical incision. Elimination of the surgical incision holds the promise of reducing the potentially painful and serious side effects associated with any surgical procedure; the risk of infection should be substantially diminished, especially in poor countries where it is difficult to keep the scrotum clean after operation.

#### **D. Nonsurgical Female Sterilization**

In developing countries the demand for female sterilization usually exceeds the ability of the countries to provide services; therefore, the development of a rapid, effective and safe nonsurgical method that can be performed by paramedical personnel remains a high priority. In developed countries, such as the United States, a nonsurgical method of sterilization could considerably reduce the

high cost of sterilization services, thereby making the method accessible to more women.

#### 1. Quinacrine Hydrochloride

Long-term follow-up of women (N=500), who have been sterilized by transcervical administration of quinacrine pellets continues; 36-month follow-up has been completed in one study (N=150) with a cumulative gross life-table pregnancy rate of 4.3 per 100 women. Few of the women examined at three years had problems.

A 10 case study of the absorption and elimination of quinacrine following the transcervical administration of 250 mg of quinacrine hydrochloride pellets 24 hours before hysterectomy has been completed in San Antonio under an approved Investigational Exemption for a New Drug (IND). There were no adverse effects. Blood quinacrine concentrations ranged from 0.0 to 99.1 ng/ml over the 24-hour period between insertion and hysterectomy. Quinacrine levels peaked for all women by four hours postinsertion.

A mean of 415 mcg of quinacrine was excreted in the urine over the first 24 hours; an average of 2.2 mg were excreted over the first 48 hours. Quinacrine assays were conducted in tissue specimens from the anterior, posterior, left and right tubes and the cervix. Similar concentrations were detected in all sections, ranging from 28.8 to 45.3 mcg/mg.

A second Phase I study under the IND will determine the effect of intrauterine insertion of 250 mg of quinacrine hydrochloride pellets in 10 women one month before hysterectomy. This study will include a histological evaluation of uterine and fallopian tube tissue in addition to a determination of quinacrine pharmacokinetics.

During the past year, FHI has continued to provide data analysis assistance, with non-AID funding, to Dr. J. Zipper for an evaluation of 100-minute releasing quinacrine pellets.

## **2. Tetracycline Hydrochloride**

During 1984, FHI was granted an IND to study the absorption and elimination of tetracycline following transcervical insertion of 1000mg of tetracycline hydrochloride pellets 24 hours before hysterectomy. This study will be initiated at Johns Hopkins University in November 1984. A 30-day pre-hysterectomy study is also being developed.

A study of the effect of buffered vs nonbuffered tetracycline in rats indicated that the hydrochloride salt of tetracycline was likely to be the most effective. Further studies in rats are being conducted in Scotland to determine whether the damage caused by tetracycline hydrochloride is related to its acidity (pH2) or to a specific effect on the oviducal epithelium.

### **3. Methylcyanoacrylate (MCA)**

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

#### **Future Plans**

An evaluation of the safety and effect of quinacrine and tetracycline on uterine and fallopian tube tissue when administered 30 days before a scheduled hysterectomy will be initiated in the next year.

A series of pre-hysterectomy studies are also planned to determine the influence of modifying the rate of release of quinacrine for the pellet dose form and to explore the possible effect on adjunctive therapies. A four-year follow-up of women who were sterilized by quinacrine pellets will be conducted at two sites in Chile.

### **E. Intrauterine Devices**

This past year was one of transition for IUD research at FHI. Several research strategies were completed or neared completion, and new research directions were explored. Data from the remaining active studies were processed, but the primary focus was on writing final reports, both for individual studies as well as for entire

strategies. Particular emphasis was placed on writing Consultant Reports on the Delta studies. New strategies were developed for implementation in the next year.

### Strategies Active During the Past Year

#### 1. Evaluation of the TCU 380Ag

The silver-cored copper wire of the TCU 380Ag is expected to prolong the effective life of this IUD. The effectiveness, safety and acceptability of the TCU 380Ag compared with the Multiload Cu 375 and Cu7 were evaluated in two separate multicenter clinical trials.

A final report on these two trials was presented at the 1984 PARFR Workshop, "Intrauterine Contraception: Advance and Future Propects". In the TCU 380Ag and Multiload Cu 375 trial, the IUDs showed similar, low event rates. Pregnancy rates were less than 1.0, and continuation rates were approximately 90 percent at one year post-insertion. In the TCU 380Ag versus Cu7 trial, both IUDs also showed similar event rates. Higher expulsion rates in this trial contributed to overall continuation rates of about 80% at one year postinsertion. The risk of subsequent hospitalization or pelvic infection was low in both trials. There was one uterine perforation related to sounding in the Multiload Cu 375 comparative trial. There were two cervical perforations; both occurred in the TCU 380Ag and Cu7 trial, one with each device. Side effects leading to IUD removal were few; one year bleeding and pain removal rates

and removal rates for other medical reasons were each less than 5.0 per 100 women.

In the comparative trial of the TCU 380Ag and the Multiload Cu 375, significantly more women wearing the TCU 380Ag reported inter-menstrual pelvic pain, but this was in the group under 30 years of age and did not lead to increased removals for pain. Other menstrual-related problems were reported with similar frequency for each of the two IUDs.

Two and three year follow-up data continue to be collected at two sites. The site comparing the TCU 380Ag with the Cu7 still shows comparable event rates for both devices. At the second site three year follow-up data has been gathered from women enrolled in a study to compare the TCU 380Ag and the Multiload Cu 375. With a follow-up rate of 70% at 36 months, the difference in the three year expulsion rates of the TCU 380Ag (3.8) and the Multiload Cu 375 (10.4) approaches statistical significant ( $p < 0.06$ ).

## **2. Postpartum IUD Insertion**

Previous research by FHI demonstrating the safety of postpartum IUDs is contributing to a renaissance in the use of this option. In Mexico in 1984, partly building on FHI supported research, more than 80,000 devices were inserted postpartum. FHI research has shown that the training of the person inserting the device is the most important factor affecting expulsion rates. The intrauterine placement of the Delta T and the TCU 220 has been compared at one

site by echosonography over a 3-month interval following postpartum insertion. Delta T and TCu 220 IUDs were each randomly assigned to fifty women and inserted within 10 minutes of placental expulsion. Echosonograms were taken at one hour, 24 hours, one month and three months postinsertion to determine placement of the IUD within the uterus at each of these times. Three month expulsion rates were 14.3 for the Delta T group and 10.0 for the TCu 200 ( $p > 0.10$ ). Analysis of the echosonography data is planned for early 1985.

### **3. TCu 200 With and Without Strings**

Pelvic inflammatory disease (PID) is a serious complication that is associated with IUD use. To examine the possible role of the IUD marker strings in the etiology of PID, FHI is conducting a comparative trial of the TCu 200 with and without strings. Preliminary analysis of 723 women from four centers with an overall follow-up rate of about 56% (two centers have completed the study and two are continuing to collect data) reveals no difference in reports of infection or inflammation.

One center that has completed the study had a significantly higher removal rate for bleeding/pain in the "with" strings group than in the without strings group ( $p \leq 0.05$ ), although there were no differences between the groups in the numbers of women who reported bleeding or pain complaints at follow-up. At this center this difference may be related to the relative ease of removing the IUD with strings compared to the stringless IUD. The difference in removal rates is not currently present at any other center.

#### **4. Wing Sound II**

A uterine sounding instrument, the Wing Sound II, is being evaluated in a four-center PARFR-sponsored trial. FHI has been responsible for data analysis. A total of 1059 women have been enrolled in this study and follow-up is now complete at three centers with completion expected at the fourth by January 1985.

A preliminary report on these studies was presented at the 1984 PARFR Workshop, "Intrauterine Contraception: Advances and Future Prospects". To date, the low incidence of termination events has precluded a determination of any relationship between uterine size and termination events. Data from 551 sounding procedures did demonstrate however, a low incidence of technical difficulties (1%), complications (such as bleeding) which did not require treatment (1%), and severe pain (1%).

#### **Future Studies**

Training and surveillance of postpartum IUD insertion will continue at selected sites. FHI will continue to collect long-term follow-up data on studies evaluating the TCU 380Ag. Where feasible, other centers that took part in the original trial may also be recruited to continue collecting long-term follow-up data.

Three new strategies approved by AID will be initiated in the coming year. The first is a programmatic study to evaluate the TCU 380A in

several countries around the world. The TCU 380A will be compared with locally used devices to determine acceptability in different geographic locations. The 380A differs from the TCU 380Ag in that the copper wire does not have a silver core and thus the effective life span may be shorter than that of the TCU 380Ag.

The second strategy is the comparison of the TCU 200 with an experimental IUD, the Merchant Copper Coil (MCC). This IUD, developed by Dr. Rohinee Merchant of Bombay, India, is circular in shape with a break in the circle to increase its flexibility. Copper wire is wound around the IUD, exposing a total surface area of 251 mm<sup>2</sup>. It is expected that the copper will increase the effectiveness of this ring IUD relative to other earlier devices. The inventor expects that the circular shape will enhance effectiveness because a larger area of uterine mucosa will be exposed to the copper than is usually exposed with a Copper T.

Dr. Karl Kurz has developed a technique of trimming the horizontal arms of the TCU 200 based on the assumption that the width of the fundus of many women is too small to accommodate the standard TCU 200. 'Dimensional incompatibility' may be a primary reason for expulsions, complications such as perforation and infection, and side effects such as bleeding and pain. A pilot study will be initiated in the next year. If results from the initial study are promising, a larger trial will be planned which will include enough women to answer the question of whether the adapted T performs better than the standard T in terms of expulsion and termination rates and reported side effects.

In addition to these three approved strategies, plans are being made to evaluate a brush IUD retriever developed at FHI. Evaluation during the coming year will focus on its use in retrieving IUDs with missing strings. Investigators who are interested will be sent several retrievers and will be asked to complete a short evaluation form with each use. This evaluation will begin soon after an adequate supply has been manufactured (late 1984).

#### **F. Investigator Network Needs**

FHI's Investigator Network Needs strategy was approved by AID in November 1982. It is an important component of the clinical trial program in that it provides the flexibility necessary to conduct small scale studies in diverse geographic areas and for investigators with different research needs and skills. Studies funded under this strategy are designed to meet one or more of the following objectives: 1) provide baseline data on services offered; 2) introduce proven technology that may be new to the particular geographic area of the study; 3) involve influential leaders in a country's family planning efforts; 4) meet the needs of individual investigators involved in research projects of special interest and importance to their communities and; 5) identify and provide training to new investigators interested in conducting quality clinical trial research on new contraceptive technologies.

There are nine on-going studies being conducted under this strategy. A complete study status listing is included in (Appendix B). All

three IUD studies are being conducted with investigators new to FHI and their initial study management indicates that they may prove valuable additions to FHI's collaborative network.

Three sterilization studies having varied objectives are ongoing. The 2000 case survey of laparoscopy (tubal ring) is being conducted with Dr. Helio Aquinaga to demonstrate the long-term safety and efficacy of sterilization in Brazil where it remains a controversial procedure. In the group of 1,545 women who have thus far been followed up at six months or more (up to 24 months) following their laparoscopy, 16 (1%) have become pregnant. Thirty-seven other complications or complaints were documented, seven related to menstrual pattern disturbances, one salpingectomy, and 11 complaints of adnexoral pain. During 1985, all two-year follow-ups will be completed and final analysis will begin.

In contrast to the Brazilian study, multi-center surveys of male and female sterilization in Haiti were designed to gather baseline data on these procedures and to identify and provide training to new investigators. One of the investigators has proven to be outstanding and will be encouraged to continue as an active collaborator in FHI's clinical trial network.

Three studies focus on systemic methods of contraception. Noriday and Lo-Femenal, two locally available oral contraceptives, are being studied in Mali. Patient enrollment has begun. Two other trials have been designed to evaluate different aspects of 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 too little data have been received to indicate major differences in either the acceptability or number and type of side effects. However, based upon the research experience already obtained during this study, the investigator in Brazil has been assigned by ABEPF to become one of the five investigators in a progestogen-only pill study to be initiated in December 1984. The Gambia Family Planning Association is also gaining research experience in the retrospective study of 400 women who used Depo-Provera at three rural clinics in comparison to those who used oral contraceptives.

As this summary illustrates, most of the investigators conducting studies under the investigator network needs strategy are new to FHI. In the past year, therefore, special attention has centered on ensuring that all newly developed studies have very specific, well-designed protocols and that the investigators are given adequate instruction both prior to and during initiation of the research project. In the year ahead attention will be focused on providing adequate monitoring and assistance to ongoing studies. Up to ten additional new studies will be initiated in 1985 as potential investigators or special research needs are identified.

### **III. CONTRACEPTIVE SAFETY**

The Contraceptive Safety Division has developed nine new projects within the last contract year. Studies are planned on the protective effect of contraceptives on sexually transmitted diseases and female sterilization as a risk factor for hysterectomy. Additionally, planned projects include clinical trials of prophylactic long-acting antibiotic use to prevent post-IUD insertion infection and folate supplementation to prevent the progress of cervical dysplasia in women taking oral contraceptives. FHI also worked at such topics as occupational influences on reproduction, smoking and reproductive health and the male influence in spontaneous abortion. Studies initiated in earlier reporting periods are presently in different stages of completion.

#### **A. Reproductive Cancers**

##### **Breast and Cervical Cancer and Depo Provera in Costa Rica**

Lack of adequate epidemiological data on reproductive cancers among Depo-Provera users was a primary reason for the rejection of this drug as a contraceptive agent for use in the USA by an expert committee that reported to the FDA in October 1984. FHI is working to correct this omission and also provide insights that may be useful in evaluating other long-acting steriods. A study is 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. Depo Provera 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 Depo Provera. This study will examine approximately 250 cases of breast cancer 250 cases of invasive cervical cancer and 600 cases of cervical carcinoma in situ. The 600 controls are drawn at random from the nation's population.

Pretesting and questionnaire revision took place in June and July, interviewers were trained in August and data collection began in September 1984. Data collection will be completed by December 1984.

#### **Cervical Cancer and Depo Provera in Jamaica**

Jamaica has one of the world's highest rates of cervical cancer. Prevalence of contraception is high, and approximately 15% of women have used Depo Provera. Interviews will be conducted with 200 women with invasive or cervical carcinoma in situ and 400 controls.

The protocol is in final form, the questionnaire has been reviewed and preliminary pretesting has been done. A study manager has been hired and interviewers have been selected but not yet trained.

The question of confidentiality is still under discussion with the Tumor Registry, the Obstetric and Gynaecological Society and the Board of Directors of the Jamaica Cancer Society. As soon as these questions have been resolved, the training of interviewers will begin (probably in collaboration with the CDC), and the pretest will take place.

### **Anovulation and Risk of Breast Cancer**

Several investigators have examined 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 for breast cancer. FHI has developed a case control study using data from the Cancer and Steroid Hormones (CASH) study to examine the association between breast cancer and MOCs. The almost 5000 cases of breast cancer in the CASH data will allow 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 as soon as data tapes are received at FHI.

### **Folate Supplementation and Cervical Dysplasia**

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

## **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. Animal studies have suggested that vasectomy may increase the risk of malignancy, but some researchers have suggested that vasectomy may provide a protective effect against prostatic cancer. In this study, 250 cases of prostatic disease will be identified through a computer search, and their medical records will be compared with those of up to four controls for each case. Data collection began in July 1984 and will be completed during the coming year.

### **B. Other Long Term Effects of Contraception**

#### **Contraceptive Use at Grady Hospital**

Analysis was completed during the contract year of the patterns of contraceptive choice among a cohort of 36,298 black women who attended the Grady Memorial Hospital Family Planning Clinic sometime between 1967 and 1976. Oral contraceptives were the most popular choice, but were inversely related to the age of the contraceptive. IUDs were the second most popular choice, but their use dropped sharply between 1967 and 1976. Depo Provera was the third most commonly selected method, and its popularity increased with time. By 1974, women over 35 years old were as likely to choose Depo Provera as oral contraceptives or IUDs. The demand for sterilization increased throughout the study period especially among

women 30 years old or more. Barrier methods were used primarily as temporary or transition methods.

Analysis is continuing on the hospitalization experiences of the black family planning clients. Women using Depo Provera or a barrier method were more likely than oral contraceptive or IUD users to be hospitalized. However, Depo Provera and barrier users were generally less healthy than oral contraceptive or IUD users when they entered the family planning program. To adjust for the different health states, analysis will be restricted to women who were not hospitalized in the year before admission to the family planning clinic. Hospitalization rates will be calculated for women using each method of contraception.

#### **Health Survey of Depo Provera Users**

This project evaluated the health of both current and former users of Depo Provera in Indonesia. Endometrial biopsies were taken from a subsample and evaluated for endometrial cancer. Data collection was completed on this project before the present reporting period, but analysis has continued through the period. A paper prepared during this fiscal year will be presented at the annual meeting of the Society for the Advancement of Contraception in November 1984.

#### **Effects of in utero Depo Provera Exposure**

Two studies are being conducted. In Thailand, approximately 1200 children who were exposed to Depo Provera while still in utero,

either because of contraceptive failure or because of unnoticed pregnancy at the time of the injection. These children will be 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 will be conducted in Israel with children exposed to medroxyprogesterone acetate used to treat threatened abortion. Approval from AID is pending.

#### **Return to Fertility of IUD Users**

Using a special type of multivariate regression (Cox proportional hazards model), this study evaluates the influences of length of IUD use and type of IUD on the time to conception following IUD removal for a planned pregnancy. 540 women from Ljubljana, Yugoslavia entered the study during the period 1964 to 1972, and follow-up records were available through 1980. Background variables such as parity, age at removal, duration of marriage and previous history of pelvic inflammatory disease (PID) were controlled.

This analysis found age at IUD removal and previous history of PID to be significantly associated with time to conception. No evidence was found to indicate that type of IUD or duration of IUD use had any effect on the time required to conceive once the IUD was removed.

### **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 test this hypothesis. One 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 gynecological surgery (not related to dysfunctional bleeding) during the same time period. This study is presently on hold for administrative reasons. A second study is being developed in Mexico which will use the case control method to compare the prevalence of sterilization in women undergoing hysterectomies with the prevalence among hospital-based controls.

### **Vasectomy by Paramedical Workers**

A large hospital-based vasectomy program in Indonesia has no resources for following up patients who often come long distances for the service. Because the procedure is done by paramedical workers, it is of interest to determine whether the complication and failure rates are at acceptable levels. In this study, 1500 men having had vasectomies through the program will be visited in their homes and asked about complications experienced with the procedure. Because of recall difficulties, minor complications may be underreported. Data collection began during this reporting period and will be completed during 1984.

### **C. Contraception for Women with Chronic Diseases**

#### **KAP Study of Women with Sickle Cell Disease**

Two hundred women of reproductive age who were receiving treatment from 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 29% of women currently using contraception, but 34% were using methods with low effectiveness; another 20% were using methods of only moderate effectiveness. Although abortion is illegal in Ghana, 35% of the women who were using contraception had had an abortion. The British Journal of Family Planning has accepted a paper describing these results.

#### **Clinical Trial of Oral Contraceptives in Women with Sickle Cell Disease**

Because of the reported beneficial effects of Depo Provera in women with sickle cell disease in Jamaica, FHI will undertake a clinical trial in the same population to determine whether oral contraceptives show the same benefits. The questionnaire and protocol are in final form. An Investigational New Drug (IND) application is awaiting approval by the FDA. The study will begin once the investigator receives the drugs and placebos.

## **Oral Contraceptives and Hepatitis B**

Hepatitis B is an important public health problem in many developing countries and may contribute to elevated rates of liver cancer. 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. Sites in Taiwan and Hong Kong are under consideration.

### **D. Contraception and Sexually Transmitted Diseases**

#### **The Effect of Spermicides on Sexually Transmitted Diseases (STDs)**

FHI has developed a prospective study to determine the prophylactic effect of the Today® contraceptive sponge against STDs. This study will be initiated in November 1984 in Bangkok, Thailand. One objective of the study is to determine the use-effectiveness of the spermicide-impregnated (nonoxynol-9) contraceptive sponges in preventing chlamydia and gonorrhea infection. Another objective is to determine factors (such as douching) that are related to the use-effectiveness of the spermicide in preventing vaginal and cervical infections. Two groups of women will be followed: users of spermicide-impregnated contraceptive sponges and women who will not receive sponges but are using more effective contraceptive methods (oral contraceptives, IUDs, injectables and female sterilization). Use-effectiveness for each woman will be determined by the time from entering the study until infection with chlamydia or gonorrhea occurs. The number of sexual contacts, history of previous

infections, age, reproductive history, compliance with contraceptive use, douching and other personal hygiene habits are to be evaluated as potential risk factors related to use-effectiveness.

### **The Effect of Contraceptive Use on Sexually Transmitted Diseases**

A record review study of the relationship between contraceptive use and STDs was initiated during the past fiscal year. The study measures the prevalence of various gynecologic conditions among women attending the Margaret Sanger Center, Planned Parenthood, New York City, in 1983 and 1984. Information from the charts of women who sought minor gynecologic care or who were treated in the STD Clinic is abstracted. Available data include diagnosis, contraceptive use prior to the visit, age, marital status, parity and STD history. Prevalence rates will be established for users of oral contraceptives, barrier methods, and IUDs, as well as for noncontraceptors.

### **The Effect of Prophylactic Antibiotics on Post-IUD Insertion PID**

A randomized double-blind clinical trial has been designed to study the role of prophylactic antibiotics, given at IUD insertion, in preventing pelvic inflammatory disease (PID). This trial is the first of its kind and is scheduled to begin in early November 1984.

Twelve hundred women will be screened for gonorrhea and chlamydia before IUD insertion. They will then be given a single dose of doxycycline or placebo and the IUD inserted. The women will be

followed for one month to determine whether there is a significantly lower rate of PID among women given the antibiotic than among those given the placebo. If the gonorrhea or chlamydia cultures were positive, the woman will be treated at her follow-up visit.

Information on gonorrhea and chlamydia infection at the time of IUD insertions can be used to study how these conditions affect the risk of post-IUD insertion PID.

#### **E. Risks and Benefits of Contraception**

##### **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, and analysis is underway. One paper has been completed using data from both studies and has been submitted for publication. Several other papers will be written during the next fiscal year. Data from the Indonesian study were presented at a one-day seminar in Jakarta, and data from the Egyptian study will be similarly presented in Cairo in February 1985.

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).

### **Risks and Benefits: Oral Contraceptives**

A great deal of information is now available from many sources in immediate and long-term benefits and risks of oral contraceptive use. FHI has been working to display various aspects of this vast accumulation of data in a simple, 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. A paper describing this analysis has been submitted to a journal. Analyses using data from developing countries will be undertaken in the next fiscal year.

### **Hospital Discharge Survey**

Because few developing countries have mortality and morbidity data, FHI is collecting information on hospital discharge diagnoses for women of reproductive age. The study is being conducted in all teaching hospitals in Java, Indonesia. 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 began during the summer of 1984; data processing and analysis will take place in Indonesia and is expected to be complete by the end of 1984.

### **The Attitudes of Physicians and Midwives to Oral Contraceptive Use**

The purpose of this study is to determine whether health professionals who provide oral contraception are as well informed about the benefits as they are about the contraindications and risks associated with oral contraceptive use. This information will be collected through focus group discussions. The data will be processed and analyzed in Indonesia and a report is expected during the next fiscal year.

## **. Reproductive Health**

### **The Male Influence on Spontaneous Abortion**

Choices in fertility regulation include the ability to produce healthy children when desired as well as to delay or avoid

childbearing. Evidence increasingly suggests that male exposure to hazardous substances (usually in the workplace) can impair reproduction. This project will use the Finnish hospital discharge registry and census data from Finland 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 with the ability to control for maternal exposure. The sample size will permit reliable detection of as little as a 3% increase or decrease in the rates of fetal loss.

#### **Smoking and Reproductive Health**

FHI has begun to explore the possibility of cosponsoring a conference on the effects of smoking on reproductive health. Although further development of this project will take place during the next report year, the conference itself will probably take place during fiscal year 1986.

#### **Occupational Influences on Reproduction**

This project examines occupational influences on reproduction and builds on work completed during the last fiscal year to complete a literature review of occupational hazards to reproduction.

#### **IV. PROGRAM EVALUATION**

Recently the Natural Family Planning and Reproductive Health Divisions merged in order to strengthen the resources available to both programs and to avoid duplication. Since the programs were administered separately during the contract year, their projects and future plans will be presented here separately.

##### **A. Natural Family Planning**

During this year, FHI's program of research in natural family planning expanded considerably. Research priorities were established and interested programs and researchers located. By the end of the funding year, nine projects had been completed, 17 were ongoing and 11 were under development. The first meeting of the NFP Advisory Committee was held in March, 1984.

##### **1. Natural Family Planning Studies**

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

This project is being conducted through the Asociacion de Trabajo Laico Familiar (ATLF) in Lima. Its purpose is to study the process of implementing an effective Natural Family Planning (NFP) program in a developing country. During the first half of the contract year, the ATLF staff experimented with various programmatic alternatives, especially the number of couple training sessions that

would be used, the precise curriculum for each class, the levels of supervision that would be required and the assignment of administrative responsibilities for the project. Although these programmatic characteristics will be open to refinement throughout the project, several policies have proved very successful. For example, ATLF's recruitment strategy involving the use of schools and businesses in the target district of Surquillo had led to the enrollment of 73 couples by the end of the fiscal year. The policy of waiting until the first day of the menstrual cycle (menses) before formally enrolling a couple kept 52 couples waiting to enroll and prevented 10 women, who were already pregnant, from enrolling.

During the past year, the senior NFP instructor attended an intensive NFP training course in the United States and consultants from the Fundacion Carvajal in Cali, Colombia, as well as Dr. Arlene McKay, FHI Consultant, provided technical assistance to the teachers and Project Director. Recruitment will continue until early 1985 and follow up until early 1986.

#### **Kenya: Needs Assessment**

At the request of AID/Kenya Mission through AID/Washington, FHI undertook an assignment with three main objectives: (1) to assess the current status of NFP in Kenya; (2) to assess the potential for training, research and expansion of NFP services; and (3) to submit recommendations concerning the above, with a view to assisting the USAID Mission to Kenya to establish priorities in the area of NFP, especially for bilateral assistance.

A report, based on the site visit, was submitted to the AID Mission/Kenya and is available upon request.

#### **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. The final report and recommendations will be available in early November 1984. If appropriate, a program evaluation follow-up study; possibly in use effectiveness, will be designed.

#### **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 will follow up a sample from a national level 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 are being utilized to develop a survey questionnaire. The survey will cover approximately 1,300 women of reproductive age and 340 of their husbands.

The main purpose of the survey project being conducted by FPA/SL is to determine use-effectiveness of various family planning methods, including traditional and natural methods. For this purpose, 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. Information obtained from the focus group will be utilized to develop the questionnaire on use-effectiveness.

### **Bangladesh: Safe-Period Study**

The main purpose of the project is to explore the extent to which traditional family planning methods can be effectively used by those Bangladeshis who prefer to use them. The project will be implemented in two rural areas within access to Dhaka. It will be done through the Bangladesh Fertility Research Programme. Field work will likely start in 1985.

### **Support of Participants to Hong Kong NFP Meeting and NFP Monograph**

FHI provided partial support for a dozen participants at the Third International Congress and the International Federation for Family Life Promotion (IFFLP) in Hong Kong, November 1983. Out of the special sessions on NFP program development, training and evaluation came the monograph Natural Family Planning: Development of National Programs. This book has been distributed widely by AID, IFFLP, and FHI and will serve as a useful reference book on major NFP programs around the world.

### **NFP Review Occasional Paper**

At the request of the Demographic Data for Development project of Westinghouse Health Systems, FHI is preparing a paper entitled "NFP as a Method of Birth Spacing in Limitation in Developing Countries". The paper will contain new information on NFP prevalence levels, use-effectiveness, cost-effectiveness, and descriptions of specific countries where NFP is popular. There is also a section that

describes NFP policy options for family planning policymakers in developing countries.

The monograph will be published as Occasional Paper of the DDP Project of Westinghouse in early 1985.

**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 and received training on their responsibilities 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 into each study group. The recruitment period is scheduled to end in 1985. Study participants will be followed up to a year.

## **Effectiveness of NFP in Urban Egypt - Phase I**

This project is being undertaken at Ain Shams University in Cairo. The purposes of the study are (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 degree 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 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 short questionnaire and used the tool to screen 500 OB/GYN and pediatrics clinic patients. These data are currently being analyzed to

determine local interest in NFP. Should significant interest be expressed, a second phase of the project will be proposed in which instruction in a modern NFP method is made available to clients of Ain Shams University Hospital and evaluated. This would be one of the few studies of the acceptability of NFP methods among a Muslim population. Work toward the fourth goal is in progress.

### **Volumetric Vaginal Fluid Pipette**

In this basic research project of Dr. Gebhard Schumacher of the University of Chicago, on the volumetric vaginal fluid pipette is used to collect the vaginal/cervical fluid. The volume of fluid is recorded on a daily basis. Most of the one dozen volunteers who used the device were able to observe a clear mid-cycle increase in volume. Although a wide variation in baseline fluid volume was observed across women, within subjects, a three to 30-fold rise in fluid volume was perceptible.

A final report is forthcoming and will contain an analysis of the daily hormone profiles vis-a-vis the fluid volume data to determine the extent to which fluid volume is a predictor of ovulation. The vaginal pipette will be produced commercially.

### **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, UK. Its purpose is to study

the knowledge, attitudes and practices (KAP) of actual and potential family planning providers, especially physicians, regarding family planning, with a special focus on NFP, fertility awareness and breast-feeding. In each of five selected developing countries, a principal investigator (PI) is being recruited to perform the following tasks: (1) conduct loosely structured pilot interviews or focus groups with a small number of providers, (2) attend a meeting at Exeter with Institute staff and other PIs in order to design a cross-cultural KAP questionnaire based on those interviews, (3) select a quota sample of 100 suitable respondents within their country and interview them, (4) prepare a summary report of the results, and (5) reconvene in Exeter to refine the country report and 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.

A social psychologist from the University of Florida with special expertise in KAP surveys and family planning research, Dr. Lawrence Severy, is serving as a consultant to the project. Dr. Severy's role is to ensure the appropriateness of the PIs regarding their background and experience and ability to implement the study both administratively and technically, to brief the PIs before the first Exeter meeting, and to work with the Institute staff as liaison and instructor to the PIs throughout the project.

During the year, contacts were made with prospective PIs and the structure of the pilot interviews was determined. The working

meetings at Exeter are scheduled for February 1985 and July 1985, with data collection occurring between those dates.

#### **Expert Meeting on Ovarian Hormone Determination**

A meeting of international experts in the area of ovarian hormone determination will be held in the Triangle area on December 13-15, 1984. The three main purposes of the meeting are: (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 breast-feeding women. Assays and other techniques for determining hormone levels in serum, urine, saliva and breast milk will be critiqued regarding their validity, reliability, invasiveness, acceptability, practicality, logistics and cost. The planning for this meeting took place during the period covered by this report.

#### **Support to other NFP Projects**

During the contract year, FHI provided a grant to an Argentinian physician to study at the NFP Research and Training Center of the University of Chile, Santiago. Dr. Sylvia Rinaudo completed a two-month fellowship at the Hospital Clinico J. J. Aguirre, in which she taught and followed up NFP clients with atypical fertility conditions (e.g. breast-feeding, premenopausal) and participated in ongoing research projects, among other activities. Upon completion of her fellowship, Dr. Rinaudo was described as capable of

organizing and administering an NFP service at her hospital in Rosario, a role that she undertook upon her return to Argentina.

Also during the reporting period, FHI shared the support of a local NFP instructor's course with the Family Planning Division of the North Carolina Department of Public Health. Three FHI staff persons attended the course, which was taught by Mrs. Mary Conroy, RN, instructor-trainer of New England Natural Family Planning--a renowned instructor trainer with over twenty years' experience in the field. This training was essential for the health professionals present who were to become NFP teachers, and the course proved very useful to the FHI staff who will apply their knowledge of the subtleties of chart interpretation and distinctions between various NFP methods in the design and evaluation of future NFP research projects.

## **2. Breast-feeding Studies**

### **Seminar on Breast-Feeding in Manila, Philippines**

As part of FHI's effort to give greater prominence to the role of breast-feeding in family planning and to help disseminate research findings for policy development, an international seminar on breast-feeding 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 for the conference to a wider audience,

plans are now under way to publish selected papers in a special supplement of the Journal of Biosocial Science, to be published in 1985. The revised manuscripts have been submitted to the journal. They include a paper on FHI's five-country study on hospital practices regarding breast-feeding. Within the Philippines, a whole issue of Population Forum was published on breast-feeding in September 1984, summarizing key papers from the Manila Conference.

### **Breast-Feeding Workshop**

A two-day workshop was held in Ismailia, Egypt on May 24-25, 1984. Its objectives were to share and document currently available information on the health, economic, religious, and family planning aspects of breast-feeding and to spread that information to the people in Egypt. Toward this end, renowned physicians, researchers and university professors presented papers on the current status of breast-feeding in the country, underscoring the need for active breast-feeding promotion. Distinguished reporters from newspapers, television and radio composed the audience. Questions from this important audience guided the animated discussions, and many interviews were held between media personalities and the health professionals throughout the workshop.

The workshop proved highly successful in sensitizing key media persons to the health and family planning hazards associated with artificial feeding and gave them evidence from current Egyptian research to support this position.

The workshop was implemented by the Egyptian Fertility Care Society which has since turned its attention to following up these media contracts to keep breast-feeding promotion in the news.

### **Infant Feeding Practices in the Philippines**

During the fiscal year, FHI provided support to an ongoing research project in San Pablo City, Laguna, the Philippines, entitled, "A Longitudinal Study of the Relationship between Infant Feeding Practices and Child Health." In this study mothers were interviewed at the time of the birth (plus or minus two days), and then at one month intervals for six months. The sample was composed of 90 women from a variety of social strata. Descriptive anthropologic models of their infant feeding practices were constructed. At the outset of the study, a six month follow-up period was thought to be sufficient to examine factors that affect infant feeding. The richness of the data collected in the first six months, however, suggested that extending follow-up until the children were one year of age would be highly desirable. FHI supported the second six months of follow-up and anticipates a report at the completion of the project. The study is being implemented by Robert Lipton, a visiting Research Associate at the University of the Philippines Population Institute.

### **Longitudinal Study of Breast-Feeding and Return to Fertility**

This study is being conducted in four countries. The purpose is to follow a small group of breast-feeding women from delivery through

ovulation and compare them to non-breast-feeding controls regarding when ovulation returns, and to determine the effect of the breast-feeding patterns on the timing of ovulation.

**Pramongkutkiao Hospital, Bangkok, Thailand**

In the Thai study, the last breast-feeding subjects completed their participation in the study in September 1984. The local investigator, Dr. Boonsri Chuntrasri, has been named FHI's first Sharon Camp Fellow and will be in residence at FHI from October 1984 through April 1985. She will carry out the in-depth analysis of the Thai data during this time.

**b. Assiut University Hospital - Assiut, Egypt**

Follow-up continues at this center and laboratory determinations should be completed by April 1985. This center was besieged by laboratory equipment problems that have now been rectified.

**c. Instituto de Investigacion Cientifica - Durango, Mexico**

This center is conducting a second phase with only breast-feeding 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.

**d. National Research Institute for Fertility Control - Karachi,  
Pakistan**

This is the fourth and final setting for the multi-center breast-feeding study. Contract negotiation, staff training (in Bangkok, Thailand), and the placement of all study commodities in the field occurred by the end of this year. Recruitment is scheduled for the start of 1985.

**Future Plans**

Future plans include the following: preparation of protocols for two multi-center studies, one on the effectiveness of NFP methods for breast-feeding women and the other, an experiment to see if the post-partum amenorrheic period can be extended by giving breast-feeding women simple guidelines on breast-feeding patterns.

Examples of four such guidelines are: (1) breast-feed on demand and maintain night feeds, (2) wait until six months to initiate supplements, (3) after supplements are initiated, during a feeding episode, breastfeed the child first and then feed semi-solids with a spoon, and (4) do not use bottles or pacifiers.

Another breast-feeding study will take place in Indonesia. A study of hospital practices related to the promotion of breast-feeding and rooming-in will be launched in Indonesia in late 1984 or early 1985. A more anthropological spacing practices among a nomadic tribe will be carried out in Niger.

Technical assistance will continue to be provided to NFP programs in several countries including Kenya, Mexico, India, Bangladesh and Egypt. An example of such assistance is to take place in India. During an AID/New Delhi-supported consultancy to evaluate NFP activities in India, Dr. Mary Thormann became aware of a tribal population in Andhan Pradesh, where there were approximately 10,000 NFP acceptors. With the assistance of FHI, Dr. Thormann will do a site visit of this population and an evaluation of how acceptable NFP has been. She will also provide technical assistance to the CREST NFP program in Bangalore.

#### **B. Reproductive Health**

During the fiscal year, reproductive health research was concentrated in three main areas: (1) the evaluation of family planning programs; (2) the evaluation of health programs with emphasis on programs providing pregnancy-related care; and (3) studies of the obstacles to the adoption and effective use of contraceptive methods. Projects are judged on scientific merit, the potential for affecting health and family planning programs and on the availability of technical and administrative resources for carrying out the projects.

## **1. Providers of Family Planning**

### **Honduras: ASHONPLAFA Data Analysis (In-House)**

In collaboration with the Family Planning Association of Honduras, a survey of distributors and promoters in the Honduran 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. "Knowledge and Practice of CBD Distributors in Honduras" was presented at the Annual Conference of the National Council for International Health in June, 1984 and will be submitted to Studies in Family Planning for publication.

"Determinants of Community-Based Distributor Performance in Honduras" has been accepted for presentation at the annual meeting of the American Public Health Association and will be submitted to International Family Planning Perspectives.

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

Contraceptive use in Africa remains low. 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. A sample of university teaching hospital cities was selected, and within each city, a teaching, general and private hospital were selected. All OB/GYNs and house officers on staff at each hospital are being interviewed. It is estimated that about 600 physicians will be interviewed in the study. A questionnaire was developed to obtain information on the physicians' attitudes toward family planning in general, and on their attitudes toward specific methods of family planning (with emphasis on male and female sterilization). Information is also being collected on the proportion of physicians who actually provide family planning services; the proportion who would like to provide family planning services; and the barriers preventing them from providing these services. Data collection began in July, 1984, and should be completed by October, 1984. Data analysis will begin as soon as the forms are received at FHI and a final report should be available by June 1985.

**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 621 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 are to determine under what circumstances 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 analysis has just begun. Preliminary tables will be available by December 1984. The results are likely to provide insights relevant to more Latin American countries.

## **2. Acceptability/Barriers to Particular Methods**

### **Honduras: Access to Sterilization**

This is a continuing study of the interest in and barriers to sterilization in Honduras. A paper published in Studies in Family Planning, "Sterilization in Honduras: Assessing the Unmet Demand," reports on the first phase of the study 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 paper on a follow-up study conducted over the period September - December 1982 has been submitted to Studies in Family Planning. 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 were included in the second study. 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 are being interviewed following delivery

and prior to discharge. Information on whether they are sterilized is being obtained.

A follow-up record will be completed for all women planning to be sterilized but not sterilized at the time of hospitalization for delivery. If the woman returns to ASHONPALFA for a sterilization, this information will be noted on the form. Women who have not returned to the clinic for sterilization within four months of delivery will be interviewed at home to determine if they were sterilized in the four months since delivery and if not, why not. Data collection began in August, 1984.

**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 socio-demographic factors on the acceptance of female sterilization and to assess the potential impact of the increase in demand on available facilities.

The study design is a randomized trial. The sample includes all grand-multiparae 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. Data collection began in September, 1984 and will continue for one year.

#### **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, there is a need to determine long-term satisfaction with contraceptive sterilization and to study the various factors that determine and/or relate to satisfaction. This study will collect data on acceptors of sterilization to determine overall satisfaction with the method and the effect of the government's incentive program\* on motivation and long-term satisfaction.

A sample of 1350 acceptors of female sterilization will be drawn from the 16,301 women served by Community Development Services (CDS) from 1980 through 1983, 450 from the Colombo clinic, 300 from estate

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\* 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.

hospitals and 600 from a rural district hospital. The samples will be stratified by date corresponding to the government incentive program so that comparisons in satisfaction can be made between groups receiving different incentive amounts. Information will be obtained 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.

Field work will begin in November 1984, and will take three to four months to complete. Data analysis is expected to begin in March 1985.

**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 June 1 to August 31, 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.

**Honduras: Follow-up of Depo-Provera Users**

Depo-Provera was provided as a contraceptive method by the private Honduran Family Planning Association (ASHONPLAFA) from 1967 to 1978. In 1978, ASHONPLAFA stopped offering the drug because of its controversial status. However, the new Minister of Health is considering lifting the ban on Depo-Provera, which would allow ASHONPLAFA to provide this method again. A follow-up survey of the women, who were active users of Depo-Provera at the time ASHONPLAFA discontinued offering it, was carried out in 1984. Of the 311 women interviewed, 257 or 83% of the women said that they would have gotten their next injection if the program had not been discontinued. Of these 257 women only 19% actually obtained Depo through other sources. Of the remaining 209 women, 89% said that they did not know of another source of Depo-Provera.

A final report will be completed by November 1984.

**Ghana: Analysis of Male Attitudes Survey**

The purpose of this study was to determine the attitudes and knowledge of rural Ghanaian males toward both male and female sterilization. The study also includes information on knowledge and use of other forms of contraception, desired family size and source of family planning services. A random sample of rural Ghanaian male adults in 165 households selected from a population of 16,000 people (residing in 60 villages) was interviewed. The data are currently being analyzed at FHI.

**3. Analysis of Household Survey Data**

**Mexico: Analysis of a CBD Program in Matamoros**

The purpose of this project is to complete the analysis of data from the Reproductive Risk Factors Survey in Matamoros, Mexico. A report on that study was submitted to USAID during the past year. Four topics for journal articles have been identified, and work on these articles should be completed during the coming year.

**Brazil: Data Analysis and Paper Preparation**

Several papers have been or are being prepared using data from the Northeast or Southern Maternal and Child Health/Family Planning

surveys. The paper, "Sterilization in the Northeast of Brazil," has been accepted for publication by Social Science and Medicine.

"Cesarean Section in the Northeast of Brazil" has been submitted to the American Journal of Public Health. A revision was submitted in October, 1984. "Side Effects and Discontinuation of Oral Contraceptive Use in Southern Brazil" will be presented at the APHA meetings in November 1984.

### **Nigeria: Secondary Analysis of Survey Data**

FHI has undertaken several activities to examine in detail many of the factors associated with the acceptability and effective use of modern family planning in this high fertility country. Previous FHI-supported field investigations have studied the use of and attitudes toward modern and traditional childspacing practices among married women of reproductive age (Lagos, 1980-81), and the sexual, contraceptive and reproductive behavior of adolescents (Ibadan, 1982). Subsequent analyses have focused on factors relating to differential access to family planning services among various subgroups of the population, and policy aspects related to the wider availability of contraceptives among the school age population.

In addition, technical assistance to the Faculty of Health Sciences at the University of Ife has resulted in the further analysis of data collected in a recent study designed to test method acceptability and increase the level of contraceptive protection among women residing in Oyo State. The purpose of this study was to collect population-based information for use in the design of

service delivery programs to make alternatives to abortion more acceptable and available to women seeking to avoid or space pregnancies. An FHI report describes particular subgroups of the surveyed population in greatest need of effective family planning services, which are to be provided through a service delivery program to be designed and operated by the Faculty of Health Sciences.

#### **4. Surveys to Evaluate Programs**

##### **Honduras: Maternal and Child Health and Family Planning Services**

A survey is being conducted in Honduras to obtain information on both maternal and child health and family planning, including use and source of family planning, use of primary care facilities, breastfeeding and child mortality. It also includes a reproductive health component. The sample includes 5500 households.

Specifically, the survey seeks 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 have been immunized; pregnancy intentions; ideal family size and the percentage of women who have experienced unplanned pregnancies; the percentage of women who are contracepting by method and by source; reasons for terminating use of family planning; the percentage of women who have 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 began in September, 1984. Preliminary tables from Tegucigalpa, the capital city, will be available in October 1984.

**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, implement and analyze data to be collected through household surveys conducted in selected areas of the cities of Leon and Saltillo. The data generated by the surveys will be the basis for refining the family planning services provided in those two cities by the FEMAP affiliates as well as other FEMAP programs throughout the Republic. The data 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 using summary data for the city of Leon has been completed. Individual questionnaires are begin keypunched and analysis will begin shortly. A final report is expected by February of 1985.

## **Future Plans**

Future projects include the following:

1. Studies of retailers/distributors and consumers in social marketing and community-based distribution projects with emphasis on the health aspects of contraceptives, possible sites include Nepal, Honduras and Mexico.
2. A study of reproductive knowledge, sexual activity and contraceptive use of young adults in Mexico City.
3. Studies of acceptability of vasectomy and tubal ligation and new methods such as NORPLANT®.

## **V. FIELD DEVELOPMENT AND TRAINING**

As of 15 June 1984, the Training and Technology Transfer Division was merged with the Field Support Division to form a new Field Development and Training Division that, as its predecessor, supports the general program of FHI research. The goals of FDT contract activities are: 1) to help develop local skills to expand and improve the international network of investigators and institutions who collaborate with FHI on contract research; and 2) to share findings of FHI-supported studies, as well as important findings from other research organizations, with a wide audience including health care providers, policymakers and the general public.

FDT activities funded in contract year 1984 are divided into four major areas:

- 1) Training in research methods;
- 2) Transfer of contraceptive technology;
- 3) Institutional development; and
- 4) Information dissemination.

## **1. Training in Research Methods**

As reported in the last annual report, FHI conducted a two-week workshop on contraceptive technology and clinical research skills at FHI headquarters, September 26 - October 7, 1983. While the planning preparations and many expenditures for this workshop took place during the last annual report period, its actual implementation took place during the period covered by this report. A grant from the Noyes foundation funded the airfare and per diem costs of the participants. Other costs (staff time, supplies, etc.) were charged to the AID contract 1028. This was the second of two similar workshops held at FHI (the first took place in 1982) with partial funding by the Noyes Foundation. No further funding by Noyes for additional workshops of this type is considered likely.

A similar workshop emphasizing basic clinical research methodologies for the development and management of clinical trials was held in Ismailia, Egypt, in July, 1984. The workshop was coordinated by the Egyptian Fertility Care Society (EFCS), with technical assistance and funding provided by FHI. Fifteen Egyptian investigators received training that will enhance their ability to collaborate directly with FHI as well as with the EFCS programmatic research network.

Training in Epidemiologic Research was a new focus for FDT this year. Mexico provided a site for the development of this area of training. Health, social, and demographic conditions in Mexico are typical of a developing country: a young population, high fertility and high maternal and child mortality. Epidemiologic studies of the population are limited, especially in the field of human reproduction, because of the shortage of trained researchers in Mexico. A joint project of Family Health International, The Instituto de Investigacion Cientifica of the Universidad Juarez, Durango, Mexico, and the United Nations Fund for Population Activities (UNFPA) seeks to fill this vacuum and ultimately to provide information vital to Mexico's national health program.

In January, 1984, the Instituto with Dr. Roberto Rivera, Director, as Principal Investigator, was awarded a five-year UNFPA grant to train and fund investigators to do epidemiologic studies in the area of reproductive health. These studies will complement clinical trials of the effectiveness and safety of contraceptive methods. In each of the first three years of the grant a three-week training course in epidemiologic research methods with emphasis on reproductive health studies will be conducted at the Instituto. As part of their training, participants will develop protocols for research projects that can be accomplished within two years. The UNFPA will be a primary funding source for the projects. Ten Mexican physicians participated in the first course July 16 to August 3. By the third year of the project, invitations to attend the training course will be extended to Caribbean and Central American health professionals.

FHI is providing technical assistance to this project through designing and executing the training course, reviewing project proposals and providing consultation in the implementation phases of funded research projects. In addition, FHI has funded the development of course materials in a self-instructional format that may be used both for the Durango program and for future training activities in support of FHI research.

Of the eight projects proposed by the participants of the first workshop the Contraceptive Safety Division is interested in supporting:

1. Risk factors for hysterectomy among young women, and
2. Folate as a risk factor for cervical cancer

The project will make a major contribution to the training of epidemiologic researchers in reproductive health in Mexico; the goal is to equip a sufficient number of individuals with the skills and latest methodology for undertaking the research needed in their country.

During the past year, FHI initiated a new fellowship training program. Named for past Chairperson, the Sharon Camp Fellowship will bring to FHI one or two investigators each year, for periods of up to 12 months, to develop their research skills by working with FHI counterparts on a major research project of their choice. Applications for the first Sharon Camp Fellowship were solicited and

the applicants' research proposals were reviewed during the past year. With concurrence of our AID monitor, the first fellowship was awarded to Dr. Boonsri Chuntrasri, of Promongkutklao Army Hospital, Bangkok, Thailand. Dr. Boonsri has been working on an FHI-funded study of Breast-feeding and Return to Fertility. She proposed to work on the analysis of data at FHI in her fellowship application. Data collection for this study was completed in September 1984, and Dr. Boonsri is expected to commence her fellowship in October. Recruitment of a 1985 Sharon Camp Fellow is planned to begin soon.

In reviewing the purpose, design, and accomplishments of past research training activities and formulating plans for future work in this area, the following observations are offered:

- 1) As a matter of general policy and principle, FHI should strive to conduct at least one major workshop per year. Although FHI is not primarily a training organization, it has an obligation to utilize its considerable staff expertise and research experience to contribute to the transfer of contraceptive and reproductive health research technology in developing countries. Moreover, such training can and should be used by FHI to further develop and expand its own international network of collaborating investigators.
- 2) The two FHI-Noyes workshops had been generally successful in subjective terms -- notably participant satisfaction -- and in meeting stated objectives regarding format and content to be presented. Also, progress had been made during the second

workshop in tying theory to practical application (and FHI network needs). The 1983 workshop was culminated, for most the participants, by the development of an FHI-funded study to carry out upon their return home.

- 3) Despite the generally positive feelings about the value of the workshops completed, more attention must be given in future workshops to defining learning objectives with measurable indicators.
- 4) Future workshops need not -- perhaps should not -- be conducted at FHI headquarters. There are obvious advantages (access to more FHI staff, departments and facilities) and disadvantages (serious disruption to other FHI activities).
- 5) Regardless of the venue of future workshops, a more cohesive, standardized and tested clinical trials method training curriculum must first be developed as an alternative to the essentially eclectic approach used in the two previous workshops.
- 6) Ultimately, FHI should develop curricula and training materials for conducting workshops in clinical trials research methods, epidemiologic research methods, program evaluation research and management of research.

Considerable work and excellent results have already been achieved in developing combined lecture/self-instructional modules for epidemiologic training in the Durango, Mexico project. Using this

as a model, FHI has begun planning for development of clinical trials modules which could be utilized in a major workshop within the next year. Work is also in the early stages for developing a research management course and program evaluation research course.

## **2. Transfer of Contraceptive Technology**

A project to develop training and education materials in support of a nationwide postpartum IUD project implemented by the Ministry of Health and Social Welfare of Turkey was completed during this contract. The project followed an earlier FHI-supported multicenter clinical trial of postpartum IUDs in Turkey. Materials such as brochures describing the postpartum IUDs were developed for hospital personnel.

A more detailed "Postpartum IUD Guide" was also developed as a basis for training physicians, nurses and midwives. Special training courses of six weeks' duration taught nine nurses, midwives and nurse midwives to do both interval and postpartum IUD insertions.

A week-long seminar on voluntary surgical contraception was conducted by Haiti's Division of Family Hygiene (DFH) with assistance from FHI. FHI provided consultant speakers and reference materials to reinforce Haiti's expanding female sterilization program and to introduce vasectomy to the family planning provider community. More than 35 physicians attended the seminar held in Port-au-Prince from November 28 to December 2, 1983. An outgrowth of the seminar was an agreement between the DHF and FHI to monitor

sterilizations in six major centers through FHI's Investigator Network Needs Strategy.

In 1981, the government of Senegal began a program to develop birth spacing services. A bilateral agreement with USAID provided the basis to develop family planning activities integrated with the maternal and child health program. The project is called "Family Health Project in Senegal" (FHP). A key element in improving the availability of family planning services, is better informed service providers. In Francophone West Africa, few physicians have received training in contraceptive technology or in gynecology. All physicians in this region have difficulties in keeping up to date with recent developments in the field of contraception, because they have limited access to reading materials and new research results. The FHP project director requested funding from FHI to conduct a continuing education workshop in response to this need.

The purpose of the workshop was to provide an update on contraceptive technology to enable participants to assist their patients in choosing appropriate contraceptive methods. Discussions centered on risks and benefits of various methods, as well as specific prescribing information. The workshop also provided an opportunity to discuss future research needs in the Senegalese environment. A Biomedical Research Unit for the Family Health Project was established in a resolution drafted by the participants at the conclusion of the workshop. The workshop was conducted on May 23 to 25, 1984 in Dakar, Senegal.

Work has begun on the development of a similar workshop to be implemented in Manila, Philippines in November, 1984. The focus will be the setting of contraceptive research priorities for the Philippine family planning program.

A subcontract with the Brazilian Association of Family Planning Entities (ABEPF) is providing financial and technical support to the Brazilian Association of Family Planning Entities, ABEPF of Rio de Janeiro, Brazil for training and core support for the implementation of a multicentered clinical trial. The research strategy to be implemented in this clinical trial is FHI's progestogen-only pill among lactating women.

The subcontract funds two separate but interrelated components, a full time data collection/research coordinator, and a pre-study workshop. The 1000 case progestogen-only clinical trial is funded under a separate project and will be administered as such.

The purpose of the project is to provide support to ABEPF as a developing national research center in Brazil. As a truly representative national level organization, ABEPF has the institutional connections and a corresponding high level of prestige in order to design, implement and disseminate the findings of country specific research projects in the field of family planning. Financial and technical assistance to ABEPF will facilitate the development of the national research coordinating capabilities and will ultimately enhance the quantity and quality of country-specific information available for Brazilian policymakers. Project planning

was carried out in FY'84. The project should be initiated by December 1984.

### **3. Institutional Development**

As part of our institutional development program, FHI has provided Texas Instruments microcomputers to a number of developing country institutions to upgrade capabilities in data processing and analysis. During FY-84, work continued under the contract to develop and refine programmer and user software tools, to test hardware before field placement, and to provide training and training-related materials to facilitate field use of the microcomputer.

Now that methods are in place for streamlining the distribution of additional systems and the development of new programs, the time demands of the project can be greatly reduced. Overhead activities involved with a new installation will always exist, but can now be kept to a minimum. The implementation of new study area applications will no longer require a large design effort; the design and controlling structures for such exist now in a general context, free of specific configuration requirements and limitations.

Priorities for the coming year include an extensive evaluation of the FHI microcomputer projects. A field evaluation is planned both to assess the applications of this technology in FHI-supported

programs and to determine the nature and extent of further work in this area.

A greater emphasis will be placed in the coming year to assure that FHI staff who work closely with the recipient institutions are prepared for field situations when visiting sites where microcomputers have been placed. Such training for FHI staff can also provide useful feedback for development of more effective training materials.

Finally, programming for additional study areas will continue. The Oral Contraceptive Patient Summary System is scheduled for programming for the microcomputer system during FY-85.

#### **4. Information Dissemination**

During the year FHI publishes many research papers in professional journals. Appendix C lists the publications for this contract year. FHI staff also attend international and national meetings where they present research findings from studies conducted by FHI.

FDT has two basic approaches to information dissemination, with a third under development. FHI 1) sponsors two regular publications activities, the International Journal of Gynaecology & Obstetrics, and a quarterly newsletter, Network; 2) supports ad hoc mailings, publications and information sharing meetings; and 3) is developing a major new strategy for disseminating critical research findings to health providers and the media in developing countries.

The International Journal of Gynaecology & Obstetrics, published by FHI from 1976 to 1981, continues to flourish under Elsevier Scientific Publishers, reporting a modest profit for the third consecutive year. FHI co-sponsors the Journal, along with the International Federation of Gynaecology and Obstetrics; provides editorial support for submissions from less developed countries; and provides subscription support for 500 subscribers, the list having been carefully edited in FY 1983. IJGO has a new Associate Editor, Professor Walter Kuhn; on his initial tour to LDC's, on behalf of the Journal, he reported that IJGO was widely available and widely read, and was the only OB/GYN Journal for which that could be said. Elsevier has announced an expansion in the size of the Journal by 250 papers for 1986, to accommodate an increasing volume of high-quality submissions. FHI intends to continue its role in making the Journal relevant to and available in developing countries.

Network: FHI continued publication of its quarterly newsletter, Network, with the aim of keeping FHI's network of investigators, policymakers and other significant developments in the field. After substantial trimming of the distribution list in FY 1983, Network now reaches about 2,300. The subscription list is continuously updated. Four issues were produced in FY 1984. A tendency for slight delay in publication was corrected in this year, so that issues now appear by the end of the first month of the appropriate quarter. The year also saw an increasing tendency for discussion of general themes in FHI research in addition to individual projects, and use of outside contributors.

In addition to these two regular publications, FHI provides for wide distribution of FHI research findings published in journals and as monographs. Significant studies implemented by other agencies are also shared in this manner with FHI's international collaborating network. During FY-84, a series of four articles published by the CDC in Family Planning Perspectives and the Journal of the American Medical Association on the risks and benefits associated with hormonal contraception were translated into French and distributed to over 500 of FHI's francophone colleagues. A Spanish translation of these publications is currently underway.

International meetings provide another useful mechanism for sharing of research findings. During the past year, FDT sponsored the participation of many colleagues to attend such meetings, giving them an opportunity to present data from their FHI-supported work to the international research community and allowing them to benefit from similar presentations of other researchers.

FHI sponsored the participation of Mr. Joseph Tunde Taylor-Thomas, Executive Secretary of the Gambia Family Planning Association to the First Annual Meeting of the Society for the Advancement of Contraception held in Cairo in November 1983.

A symposium on Contraception: Issues and Controversies was held March 14-16, 1984 in San Juan, Puerto Rico. This conference was sponsored by the College of Physicians and Surgeons of Colombia University and the University of Puerto Rico. FHI sponsored the

participation of Ms. Fernando Sanchez, Dr. Sergio Correu, Dr. Imelda Marquez and Dr. Lorenzo Garibaldi, all from Mexico. This seminar was intended for physicians involved in the provision of family planning services.

Support was provided to the Mexican Academy of Research in Reproductive Biology (AIBIR) for their IX Annual Meeting in March, 1984. The annual symposium included New Directions in Contraception and Recent Advances in Reproductive Biology.

In addition to major activities in information dissemination described elsewhere in this report, funds were set aside to meet certain small-scale, ad hoc needs information dissemination. One typical activity is distribution of articles or monographs whether produced at FHI or elsewhere, deserving of widespread distribution. Included for distribution last year were a series of articles relating to the relationship between oral contraceptives and neoplastic disease; the book, Research on the Regulation on Human Fertility; the FHI monograph, Childbirth in Developing Countries; Family Planning Methods and Practice: Africa; and Contraceptive Technology. Some activities providing information about FHI are supported from these funds, such as FHI's publications list and exhibits at two particularly important conferences.

FHI is currently contacting Mr. Winfield Best, of Communication Resources Foundation, Inc., to develop a revised and unified information dissemination strategy.

## **VI. MANAGEMENT**

### **Protection of Human Subjects Committee (PHSC)**

Three meetings of the Protection of Human Subjects Committee (PHSC) were held at FHI on December 16, 1983; March 30 and June 1, 1984 to review 36 research proposals, inclusive of amendments. The policy governing the purpose of the committee was amended to enlarge the committee classification of social sciences. The committee adopted a text of "Operating Guidelines for the Protection of Human Subjects Committee" governing the operation and responsibilities of the committee. Written to comply with the Helsinki Declaration and the Federal regulations (45 CFR 46, revised as of March 8, 1983), the document will serve as a guide as well as an orientation tool.

Two members of the committee were reappointed for three-year terms:

Ms. Betty H. Dennis, Assistant Professor of Clinical Pharmacy, University of North Carolina/School of Pharmacy, Chapel Hill, NC

Dr. Dorothy N. Glenn, an obstetrician/gynecologist consultant to JHPIEGO, the UNFPA and the World Bank; a retired Federal employee who served as Chief of Population for AID in Pakistan and Korea, in addition to having served as Chief of OB/GYN at Gaston Memorial Hospital, Gastonia, NC.

Dr. John Shelton Reed, Jr., as sociologist, was appointed for a three-year term, replacing Dr. Steve N. London, who relocated to

Texas. Dr. Reed, a 1983-84 Fellow of the National Humanities Center, is a Professor of Sociology as well as an Adjunct Professor of American Studies at the University of North Carolina at Chapel Hill, NC.

#### **Technical Advisory Committee (TAC)**

The Technical Advisory Committee (TAC) held its annual meeting at FHI on July 12, 1984. Three new members were appointed to the committee:

Kit Abdala, MD (obstetrician/gynecologist, Director of the Hospital  
Kit Abdala located in Francisco Beltrao, Brazil)

Daniel R. Mishell, Jr., MD (obstetrician/gynecologist, Professor/  
Chairman, Dept. of OB/GYN, University of Southern California,  
Los Angeles; Chief of Professional Services, Women's Hospital,  
Los Angeles County; Editor-in-Chief, CONTRACEPTION)

Lourens JD Zaneveld, DVM, PhD (reproductive biology, Professor,  
Depts. of OB/GYN and Biochemistry; Director of Research, Dept. of  
OB/GYN; Unit Director of Endocrine Laboratories/Office of  
Consolidated Laboratory Resources at Rush Medical College, Chicago)

replacing Drs. Joseph Davis, Theodore King, Allan Rosenfield and  
Gebhard Schumacher, whose terms expired July 1984.

## **Board of Directors**

The Board of Directors held the following meetings in Research Triangle, Park, NC:

Annual meeting, September 25/26, 1983

Spring meeting, April 29/30, 1984

Annual meeting, September 23/24, 1984

The Executive Committee of the Board met at FHI on December 2, 1983.

At the 1983 annual meeting, three of the four incumbent Directors were reelected for three-year terms (1983-86):

Dr. Torrey C. Brown, Secretary, Department of Natural Resources,  
State of Maryland

Dr. Sharon L. Camp, Vice-President, Population Crisis Committee,  
Washington, DC

Mr. Donald A. Collins, President, International Services Assistance  
Fund, San Francisco, CA

At the 1984 annual meeting, five of the incumbent Directors were reelected for three-year terms (1984-87):

Gen. Alexander B. Andrews, US Air Force (ret.) Raleigh, NC

Mr. Fred A. Coe, Jr., President, Research Triangle Foundation and retired Chairman and President, Burroughs Wellcome, Research Triangle Park, NC

Mr. William N. Hubbard, Jr., recently retired from Upjohn as President, Kalamazoo, MICH

Dr. Roger Short, Professor, Department of Physiology, Monash University, Clayton, Victoria, Australia

Mr. R. Peyton Woodson, III, Chairman, McM Corporation, Raleigh, NC

The Corporate officers were reelected in 1983 and in 1984:

Dr. Roger Short, Chairperson

Dr. Sharon Camp, Vice Chairperson

Dr. Malcolm Potts, President/COO

Mr. John Ganley, Executive Vice-President

Gen. Alexander Andrews, Secretary

Mr. Fred A. Coe, Jr., Treasurer

The Board of Directors took action on the following:

- 1) Established a Facilities Management Committee (special committee), chaired by Dr. Torrey Brown.
- 2) Established a satellite office in Seattle, Washington; renewable in two years.

3) Established practice of annually appointing a Board observer to each of FHI's external advisory committees. The appointees for 1984/85 are: Dr. Torrey Brown, Protection of Human Subjects Committee; Dr. Arthur Christakos, Technical Advisory Committee; and Dr. Roger Short, Natural Family Planning Advisory Committee.

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

AID-DPE-0537-C-00-1028-00

Expenditures

1 October 1983 - 30 September 1985

Salaries & Fringe Benefits	\$ 1,338,541
Service Centers	501,560
Consultant & Professional Fees	91,543
Contracted Labor	20,307
Travel - domestic	66,104
Travel - foreign	322,137
Supplies - office	17,091
Supplies - medical	16,778
Printing & Reprints	32,136
Equipment Rental	1,204
Equipment Maintenance & Repair	8,465
Office Equipment	15,932
Medical Equipment	27,000
Freight	4,163
Computer Software Lease	5,373
Dues & Registration Fees	5,550
IJGO Subscriptions	22,500
IJGO Royalties	(8,214)
Other Purchased Services	112,235
Duplicating Services	133
Other Expenses & Bank Service Charges	3,221
Fixed Fees	68,974
Data Purchases	126,430
Subcontracts	552,785
General and Administrative Costs	1,014,873
	<u>4,366,821</u>

## VII. FUTURE PLANS

FHI's divisions will be working on the many projects developed last year and developing additional ones for future funding. A new initiative will be launched in contraceptive development. In Clinical Trials, studies of the NORPLANT® implants will get underway early in 1985. A number of barrier contraceptives and contraceptives studies will also continue.

Contraceptive Safety has developed studies of risk factors affecting the development of cancers. Studies of STDs are also being initiated.

Program Evaluation will initiate studies in Natural Family Planning (NFP) and Reproductive Health (RH). NFP will initiate additional studies of breast-feeding and return to ovulation and also those of NFP methods developed during the past year. RH is completing studies of follow-up of sterilization users and attitudes of physicians towards contraception and collecting data on a couple of large surveys of family planning methods.

Field Development and Training will fund one or two research methodology/clinical trials workshop, continue to sponsor collaborators to international meetings, and proceed with the development of a solid information dissemination scheme that will fully utilize FHI data.

The coming year will be one in which many previously developed FHI initiatives will become active projects.

ANNUAL1

Completed Consultant Reports (CRs)

1 October 1984 - 30 September 1984

Title	Prepared for	Center#	Study#
Comparison of the Copper T 380AG and the Multiload Cu375 in Interval Women in Mehalla-Kubra, Egypt	S. Etman	340	544
Comparative Study of the Copper R 380Ag and the Multiload Cu 375 in San Jose, Costa Rica	C. Aranda	831	544
Long-term Follow-up of Female Sterilization in Winchester, England	A. Letchworth	290	620,636
Copper-T 200B vs Lippes Loop D in Postabortion Women in Lima, Peru	M. Acousta	101	5538
Comparative Study of the Neo Sampoo Tablets vs Emko Tablets in Accra, Ghana	P. Lamptey	043	786
Comparative Study of Neo Sampoo Tablets vs Emko Vaginal Foam in Alexandria, Egypt	H. Youssef	368	785
Comparative Study of Norinyl 1+50 vs Nordette in Cebu City, Philippines	E. Dacalos	066	850
A Comparison of Two Insertion Methods of the Delta Loop	L. Albuquerque	8003	5531
A Comparative Study of Standard vs Low-Dose Oral Contraceptives in Cebu City, Philippines	E. Dacalos	066	850
Interval Insertions of the Copper T vs Lippes Loop D: An Evaluation	C. Guzman	102	5538
A Comparative Study of Minilaparotomy Female Sterilization by the Rocket Clip vs the Tubal Ring	C. Aranda	831	6252
Evaluation of Lippes Loop D Insertions in Interval Women in Lima, Peru	J. Nagahata F. Romero	110	5507
Postpartum Delta Copper T Insertions: An Evaluation in Alexandria, Egypt	S. El Shawi	357	5527
A Comparative Study of Closed vs Open Laparoscopy with the Tubal Ring	Hospital de Seguro Social	824	638

Title	Prepared for	Center#	Study#
A Study of Depo Provera in Thailand	Hospital de Seguro Social	695	820
A Comparison of the Delta Copper T and the Copper T 200 in Bolgna, Italy	C. Flamigni C. Melega	264	5562
Nationwide Postpartum IUD Study in Turkey	General Directorate of Population Planning	Multi-center	5531
A Study of Depo Prover in Thailand	P. Amornwicheit	690	820
A Comparative Study of Loestrin vs Nordette in Kelatan, West Malaysia	H. Arshat	770	825
A Crossover Study from Standard-Dose to Low-Dose Oral Contraceptives in Khartoum, Sudan	A. Geraiis	048	835
A Comparative Study of the Collatex Sponge vs Neo Sampoos Tablets in Dhaka, Bangladesh	S. F. Begum	704	782
Long-term Follow-up in Taipei, Taiwan	F. M. Chen	781	670
Surveillance of Female Sterilization in Karawa, Zaire	D. Sambe	430	6900
Interval Copper T 200 Insertions in Ankara, Turkey	M. Erdwan	304	5526
A Comparative Study of Neo Sampoos Tablets vs Emko Tablets in Zagazig, Egypt	A. Abelsalaam	365	786
Surveillance of Female Sterilization in Dhaka, Bangladesh	S. Rahman	721	6960
Postpartum Delta T Insertions in Karawa, Zaire	G. Nelson	430	5527
Laparoscopic Sterilization in Post-abortion Women	T. A. Sinnathuray	791	627
The Multiload Cu 250 vs the Copper T 200 in Rangpur, Bangladesh	A. Bhuiyan	786	5544
A Comparative Study of Culdoscopy vs Minilaparotomy with Modified Pomeroy Occlusion	R. Khan	721	675

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Title	Prepared for	Center#	Study#
A Comparative Study of Minilaparotomy Female Sterilization by the Modified Pomeroy Technique vs Tubal Ring	T.R. Chowdhury	160	6902
A Comparative Study of the Contraceptive Sponge vs Diaphragm with Spermicide in Montreal, Canada	Y. Lefebvre	272	783
A Comparative Study of the Lippes Loop D and the Delta Loop in Manila,	R. Apelo	600	560
A Comparison of Two Insertion Methods of the Delta Lippes Loop	P. Stumpf	919	528
Surveillance of Female Sterilization in Dhaka, Bangladesh	S. Ahmed	723	6960
A Comparative Study of the Copper T 380Ag and the Copper 7 in Manila, Philippines	R. Apelo	600	521
A Comparative Study of Emko and Ortho Vaginal Tablets in Houston, Texas	A. Poindexter	225	793
A Comparative Study of the TCU 380Ag and Copper 7 IUDs in Winchester, England	M. Thomas	018	521
The Delta T vs the Copper T 200 in Postpartum Women in Santiago, Chile	P. Lavin	852	562
Surveillance of Female Sterilization in Korea	Multitple Investigators	Multi-center	694
Surveillance of Female Sterilization in Santa Maria, Brazil	R. Bossemeyer	865	6900
Surveillance of Female Sterilization Sterilization in Dhamrai, Bangladesh	M. Bareque	163	6960

STUDY STATUS LIST FOR PROGESTOGEN-ONLY PILLS IN LACTATING WOMEN

DATE: 1 OCTOBER 1984

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
					IDATE	CASE	ADM	2MO	6MO	12MO	SHIP				
084	DELGADO	MEXICO	SYS 84/034		112/86	200									PLANNED
102	GUZMAN	PERU	SYS 84/018	07/23/84	9/86	200	47	13			7/84	09/17/84	07/84 EW	ACTIVE	
110	ROMERO	PERU	SYS 84/014		6/86	200							01/84 MW	PLANNED	
400	ADNAN	SUDAN	SYS 84/033		9/86	200							10/84 LK	PLANNED	
422	BROQUET	RWANDA	POC 84/004		3/87	200								PLANNED	
452	DOH	CAMEROON	SYS 84/030		6/86	200								PLANNED	
453	WRIGHT	NIGERIA	SYS 84/035		1/87	200							09/84 SM	PLANNED	
483	NDIAYE	SENEGAL	SYS 84/004		3/86	200							10/84 NB	PLANNED	
831	ARANDA	COSTA RICA	SYS 84/019	09/13/84	9/85	200					9/84	09/13/84		PLANNED	
840	SERRATOS	MEXICO	SYS 84/029		9/86	200								PLANNED	
851	SANTISO	GUATEMALA	SYS 84/031		10/86	200								PLANNED	
853	ARAUJO	BRAZIL	SYS 84/036		4/87	200								PLANNED	
855	CHAGAS	BRAZIL	SYS 84/038		4/87	200								PLANNED	
869	CETINA	MEXICO	SYS 84/015	07/24/84	6/86	200	56	21			7/84	09/06/84	06/84 MW	ACTIVE	
871	MOGGIA	ARGENTINA	SYS 84/020	08/08/84	9/86	200	25					08/08/84	10/84 MW	PLANNED	
893	CZERESNIA	BRAZIL	SYS 84/037		4/87	200								PLANNED	
8014	LECOIN	HAITI	SYS 84/016	08/14/84	6/86	200	144	7	77		6/84	09/17/84	04/84 KJ	ACTIVE	
8056	OLIVERA C	BRAZIL	SYS 84/039		4/87	200								PLANNED	
8058	ANDRADE	BRAZIL	SYS 84/041		4/87	200								PLANNED	
8059	NUNES	BRAZIL	SYS 84/040		4/87	200								PLANNED	

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STUDY STATUS LIST FOR BFRP THREE-WAY DOUBLE BLIND PILL TRIAL

STUDY NUMBER: 8851

DATE: 1 OCTOBER 1984

FCO: 1203

CTN	INVESTIGATOR	COUNTRY	INDEX	EXP		CASE	ADM	1MO	3MO	6MO	12MO	LST SHIP	LST SITE	STATUS
				FST SHP	DATE									
I 721	I RAHMAN	I BANGLADESH	I 84/021	I 7/84	I	I 300	I 61	I 48	I	I	I	I 09/13/84	I 10/84 SK	I ACTIVE
I 744	I MALAKAR	I BANGLADESH	I 84/022	I 7/84	I	I 300	I 50	I 36	I	I	I	I 09/13/84	I 10/84 SK	I ACTIVE
I 782	I IMAFAKHARL ISLAMI	I BANGLADESH	I 84/023	I 7/84	I	I 300	I 53	I 43	I	I	I	I 09/13/84	I 10/84 SK	I ACTIVE
I 7017	I RAHMAN KHAN	I BANGLADESH	I 84/024	I 7/84	I	I 300	I 37	I 14	I	I	I	I 09/13/84	I 10/84 SK	I ACTIVE

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FAMILY HEALTH INTERNATIONAL  
STUDY STATUS LIST

ORAL CONTRACEPTIVES

ACTIVE COMPARATIVE STUDIES

OCTOBER 1984

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
8825	0081	82/013	Dr. Jose Moreno Hospital Santo Tomas Panama City, Panama	Comparative Study Norinyl 1/35 vs Brevicon	x	FCO 3107	2/83	07/02/84	300	208	166	115	73	57
8825	0356	83/015	Dr. Hany Abdel Rahman El-Shatby Mat. Hosp. Alexandria, Egypt	Comparative Study Norinyl 1/35 vs Brevicon	x	FCO 3107	8/84	08/07/84	300	75	41	16		
8825	0890	82/010	Dr. Nunez ASHONPLAFA Tegucigalpa, Honduras	Comparative Study Norinyl 1/35 vs Brevicon	x	FCO 3107	11/82	05/17/84	300	143	93	58	37	27
8825	8003	82/014	Dr. L. A. Albuquerque Centro Medico EPF Rio Claro, Brazil	Comparative Study Norinyl 1/35 vs Brevicon	x	FCO 3107	3/83	09/11/84	300	208	179	149	84	44
8825	0040	83/027	Dr. E. O. Otolorin Univ. Of Ibadan Ibadan, Nigeria	Comparative Study Norinyl 1/35 vs Lo-Ovral	x	FCO 3107	7/84	07/16/84	150	20	6			
8825	0370	83/016	Dr. Samir Nada Ahmed Maher Hospital Cairo, Egypt	Comparative Study Norinyl 1/35 vs Lo-Ovral	x	FCO 3107	6/84	08/07/84	300	206	126			
8825	0436	83/028	Dr. O. Ayangade Univ. Medical Center Ile-Ife, Nigeria	Comparative Study Norinyl 1/35 vs Lo-Ovral	x	FCO 3107	8/84	08/20/84	100	HELD				
8825	0841	82/011	Dr. Santiso APROFAM Guatemala City, Guatemala	Comparative Study Norinyl 1/35 vs Lo-Ovral	x	FCO 3107	11/82	08/28/84	300	300	117	149	120	99
8825	0871	82/015	Dr. Angel Moggia Jose Penna Hospital Buenos Aires, Argentina	Comparative Study Norinyl 1/35 vs Lo-Ovral	x	FCO 3107	10/82	08/08/84	300	300	284	239	199	160
8825	0919	83/022	Dr. Paul Stumpf Penn State Univ. Hershey, Pa, USA	Comparative Study Norinyl 1/35 vs Lo-Ovral	x	FCO 3107	7/83	07/24/84	300	288	249	198	70	

FAMILY HEALTH INTERNATIONAL  
STUDY STATUS LIST

ORAL CONTRACEPTIVES

ACTIVE COMPARATIVE STUDIES

OCTOBER 1984

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					
										ADM	ML	1 mo FU	4 mo FU	8 mo FU	12 mo FU
8850	0024	83/004	Dr. Branko Behlilovic Dom Zdravlja Belgrade, Yugoslavia	Comparative Study Norinyl 1/35 vs Norinyl 1/50	x	FCO 3107	4/83	09/05/84	300	299		280	282	271	172
8850	0358	83/002	Dr. Mamdouh Shaaban Mabarrah Hospital Assuit, Egypt	Comparative Study Norinyl 1/35 vs Norinyl 1/50	x	FCO 3107	7/83	08/28/84	300	300		192	137	46	29
8850	0440	83/032	Dr. Caossou Traore Ministry of Health Bamako, Mali	Comparative Study Noriday vs Norminest	x	FCO 3114	9/84	09/04/84	100	9					
8850	0703	83/014	Dr. Sriani Basnayake FPA of Sri Lanka Colombo, Sri Lanka	Comparative Study Norinyl 1/35 vs Norinyl 1/50 vs Norinyl 1/50FE	x	FCO 3107	7/83	08/16/84	500	499		421	324	159	54
8850	0821	83/013	Dr. Argueta ADS San Salvador, El Salvador	Comparative Study Norinyl 1/35 vs Lo-Ovral vs Norinyl 1/50FE	x	FCO 3107	6/83	08/06/84	450	321		297	235	130	69
8850	0831	82/009	Dr. Cecilio Aranda Caja Costarricense Del Seguro Social San Jose, Costa Rica	Comparative Study Norinyl 1/35 vs Norinyl 1/50	x	FCO 3107	11/82	07/24/84	300	299		297	296	246	155
8850	0869	82/012	Dra. Thelma Cetina Centro de Investigaciones Hideyo Noguchi Merida, Yucatan, Mexico	Comparative Study Norinyl 1/35 vs Norinyl 1/50	x	FCO 3107	11/82	08/06/84	300	200		167	155	108	50

## STUDY STATUS LIST

DEPO PROVERA

ACTIVE COMPARATIVE STUDIES

OCTOBER 1984

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					
										ADM	ML	1 mo FU	3 mo FU	6 mo FU	12 mo FU
8880	0340	83/025	Dr. Sayed Etman MISR Spinning & Weaving Hosp Mahalla El Kubra, Egypt	Retrospective Depo Provera vs Combined OCs	x	FCO 3107	6/84	08/07/84	300	122					118
8880	0703	83/025	Dr. Sriani Basnayake FPA of Sri Lanka Colombo, Sri Lanka	Retrospective Depo Provera vs Combined OCs	x	FCO 3107	9/83	09/17/84	600	599					245
8880	0709	84/003	Dr. Mongkol na Songkhla Provincial Health Office Chiang Mai, Thailand	Retrospective Depo Provera vs Combined OCs	x	FCO 3107	2/84	07/16/84	300	299					291
8880	0869	83/023	Dra. Thelma Cetina Centro de Investigaciones Hideyo Noguchi Merida, Yucatan, Mexico	Retrospective Depo Provera vs Combined OCs	x	FCO 3107	1/84	07/31/84	300	71					10
8880	089	83/001	Dr. Carlos Czereania R-i Hospital Das Clinicas Sao Paulo, Brazil	Depo Surveillance Monthly vs 3-Month injections	x	FCO 3114	4/84	08/03/84	100	61	34	23	8	1	
8880	4010	84/017	Ms. Adama Dabo Gambia FPA Kanifing, Banjul, Gambia	Retrospective Depo Provera vs Combined OCs	x	FCO 3114	7/84	07/23/84	400	50					

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DATE - OCTOBER 1, 1984

VAGINAL CONTRACEPTIVE STUDY STATUS LIST

5 NONOXYMOL-9) STUDY # 780

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE SCH	CASE	ADM	1MO	3MO	6MO	12MO	1ST SHIP	LST SHIP	STATUS
0359	FL MAGHOUB	EGYPT	FB 83/007	06/06/83	200	60	17	3			10/03/83	10/13/83	ACTIVE
8002	COFAC	MEXICO	FR 83/010	06/10/83	50	10					12/07/83	12/07/83	ACTIVE

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

TOTAL NUMBER OF CASES - 1700

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE SCH	CASE	ADM	1MO	3MO	6MO	12MO	1ST SHIP	LST SHIP	STATUS
023	BORKO	YUGOSLAVIA	FR 79/008	10/03/79	450	450	561	319	424	350	12/02/80	11/82	CR 386
024	BEHLILVIC	YUGOSLAVIA	FR 79/002	06/19/80	350	351	378	212	335	342	11/29/79	01/20/82	CR 454
099	SUN	TAIWAN	FR 79/009	03/06/80	350	153	160	79	89	54	07/24/80	04/19/83	CR 484
104	BEGUM	BANGLADESH	FR 79/004	01/17/80	350	348	320	142	187	168	06/04/80	04/19/80	CR 483
186	NIUIYAN	BANGLADESH	FR 82/005	FCO 1103	200	102	101	61	55		06/10/82	08/30/83	CR LIST

DESCRIPTION OF STUDY - SPONGE VS. DIAPHRAGM STUDY # 783

TOTAL NUMBER OF CASES - 550

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE SCH	CASE	ADM	1MO	3MO	6MO	12MO	1ST SHIP	LST SHIP	STATUS
72	LEFEBVRE	CANADA	FR 81/006	06/01/82	300	240	300	159	153	77	11/17/81	01/05/84	CR 502
198	GUILLEBAUD	ENGLAND	FR 79/006	06/04/81	250	251	253	177	199	164	07/25/80	01/09/84	CR 485

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DESCRIPTION OF STUDY - SPONGE VS. FOAM STUDY # 784

TOTAL NUMBER OF CASES - 700

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 0332	I GOLDMAN	I ISRAEL	I FB 81/015	I 06/22/81	I 350	I 350	I 515	I 103	I 334	I 157	I 01/20/82	I 08/29/84	I CR LIST
I 0698	I APICHART	I THAILAND	I FB 81/001	I 08/07/81	I 350	I 17	I 6	I 1	I	I	I 04/22/82	I 04/22/82	I CLOSED

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

TOTAL NUMBER OF CASES - 1050

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 0020	I ANDOLSEK/KOZUMI	I YUGOSLAVIA	I FB 81/014	I 06/22/81	I 350	I 194	I 181	I 116	I 89	I 49	I 04/02/82	I 09/25/84	I ACTIVE
I 0360	I MAHRAH	I EGYPT	I FB 80/012	I 12/06/79	I 350	I 330	I 79	I 27	I 19	I 15	I 01/05/81	I 09/19/83	I CR LIST
I 0368	I YOUSSEF	I EGYPT	I FB 80/013	I 04/16/80	I 350	I 349	I 360	I 195	I 308	I 248	I 02/18/81	I 02/02/83	I CR 468

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

TOTAL NUMBER OF CASES - 900

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 0043	I CYAMFI	I GHANA	I FB 81/013	I 06/23/81	I 200	I 146	I 132	I 69	I 59	I 42	I 11/11/81	I 03/14/84	I CR 467
I 0365	I ABDELSALAAM	I EGYPT	I FB 81/021	I 09/21/81	I 200	I 200	I 256	I 64	I 185	I 83	I 05/10/82	I 05/25/83	I CR 489
I 0841	I APROFAN	I GUATEMALA	I FB 81/023	I 11/12/81	I 200	I 67	I 37	I 10	I 14	I	I 06/10/82	I 03/21/83	I CLOSED
I 8022	I LARRANAGA	I PERU	I FB 81/016	I 07/30/81	I 300	I 39	I 14	I 8	I 6	I 6	I 03/11/82	I 07/14/83	I CLOSED

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

TOTAL NUMBER OF CASES - 340

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE	SGN	CASE	ADM	1MO	3MO	6MO	12MO	1ST SHIP	LST SHIP	STATUS
US90	ASHCEPLAFA	HONDURAS	FR 82/007	03/21/82		200	25	4	3			06/23/82	05/17/83	CLOSED

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

TOTAL NUMBER OF CASES - 200

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE	SGN	CASE	ADM	1MO	3MO	6MO	12MO	1ST SHIP	LST SHIP	STATUS
0721	RAHMAN	BANGLADESH	FR 81/002	02/03/81		200	170	123	54	58	43	12/07/82	09/07/84	ACTIVE

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

TOTAL NUMBER OF CASES - 620

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE	SGN	CASE	ADM	1MO	3MO	6MO	12MO	1ST SHIP	LST SHIP	STATUS
0222	FOREMAN	MINN. USA	FR 82/002	??/??/??		160	32	3	9	10	8	07/08/82	08/20/84	CR LIST
0225	POINDEXTER	TEXAS USA	FR 82/004	02/16/82		160	107	18	34	35	15	06/21/82	04/11/84	CR 510
0314	YOUNIS	EGYPT	FR 83/003	01/11/83		140	140	95	88	115	14	04/12/83	01/25/84	ACTIVE
0907	BERGER	N.C. USA	FR 82/003	12/??/81		160	33	10	9	9	3	03/11/82	02/17/83	CLOSED

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

TOTAL NUMBER OF CASES - 300

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE	SGN	CASE	ADM	1MO	3MO	6MO	12MO	1ST SHIP	LST SHIP	STATUS
0044	KLUFIO	GHANA	FR 81/020	09/03/81		300	300	183	89	229	145	02/25/82	11/02/83	CR LIST

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

TOTAL NUMBER OF CASES - 450

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE	SGN	CASE	ADM	1MO	3MO	6MO	12MO	1ST SHIP	LST SHIP	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 LIST

DESCRIPTION OF STUDY - <sup>(1) (b) (6)</sup> PROPRANOLOL STUDY # 7790

TOTAL NUMBER OF CASES - 200

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE	SGN	CASE	ADM	1MO	3MO	6MO	12MO	1ST SHIP	LST SHIP	STATUS
I 0088	I ZIPPER	I CHILE	I FB 84/002	I 12/16/83	I	I 200	I 40	I 77	I	I	I	I 02/08/84	I 07/24/84	I ACTIVE

DESCRIPTION OF STUDY - OVT (60 MG MENFEGOL) VS. OVT (100 MG MONOXYNOL-9) STUDY # 7798

TOTAL NUMBER OF CASES - 600

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE	SGN	CASE	ADM	1MO	3MO	6MO	12MO	1ST SHIP	LST SHIP	STATUS
I 0365	I ABDELSALAAM	I EGYPT	I FB 83/005	I 06/10/83	I	I 200	I	I	I	I	I	I	I	I PLANNED
I 0044	I KLUFIO	I GHANA	I FB 84/004	I FCO 0550	I	I 150	I	I	I	I	I	I	I	I PLANNED
I 0045	I GUNNEY	I GHANA	I FB 84/005	I FCO 0550	I	I 150	I	I	I	I	I	I	I	I PLANNED
I	I POSSIBLE OPEN	I	I	I	I	I 100	I	I	I	I	I	I	I	I PLANNED

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DESCRIPTION OF STUDY - OVT (60 MG MEFENEGOL) VS. OVT (100 MG MONOXYPOL-9) STUDY # 7799

TOTAL NUMBER OF CASES - 300

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE	SGN	CASE	ADM	1MO	3MO	6MO	12MO	1ST SHIP	LST SHIP	STATUS
0220	RUDOF	MICHIGAN USA	FR 84/003	04/11/84	50	5	3					08/20/84	09/17/84	ACTIVE
0930	PHARMACO D.	TEXAS USA	FR 84/006	06/13/84	50									PLANNED
0957	BERNSTEIN	CALIF USA			50									PLANNED
	POSSIBLE OPEN				100									PLANNED
	POSSIBLE OPEN				50									PLANNED

DESCRIPTION OF STUDY - VAGINAL RINGS (58 MM POP COUNCIL) VS. LO-OVRAL OCS STUDY # 856

TOTAL NUMBER OF CASES - 1500

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE	SGN	CASE	ADM	1MO	3MO	6MO	12MO	1ST SHIP	LST SHIP	STATUS
0023	BREZNIK	YUGOSLAVIA	SYS 84/002			300							10/21/83	ON HOLD
0101	ACOSTA	PERU	SYS 84/012			300							02/02/84	ON HOLD
0102	GUZMAN	PERU	SYS 84/001			300							02/03/84	ON HOLD
0223	SCHULTZ	MEX. USA	SYS 84/013			300								ON HOLD

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FAMILY HEALTH INTERNATIONAL  
STUDY STATUS LIST

FEMALE STERILIZATION

PLANNED STRAIGHT STUDIES

SEPTEMBER 1984

STUDY NO.	CENTER NO.	INDEX NO.	INVESTIGATOR NAME & ADDRESS	DESCRIPTION OF STUDY	PATIENT CATEGORY			DATE SA SIGNED	NO. CASES APPROVED	COMMENTS
					INT	PA	PP			
6900	0703	84/001	Dr. Sriani Basnayake FPA of Sri Lanka Colombo, Sri Lanka	Surveillance of Minilap	x	x	x	FCO 1124	500	No data to be received in-house; microcomputer analysis
6906	0437	84/021	Dr. Alex Omu Univ. of Benin Hosp. Benin, Nigeria	Minilap; Pomeroy	x		x	FCO 2231 Subcontract 609	200	Initiation scheduled 7/84

FAMILY HEALTH INTERNATIONAL  
STUDY STATUS LIST

FEMALE STERILIZATION

PLANNED COMPARATIVE STUDIES

SEPTEMBER 1984

STUDY NO.	CENTER NO.	INDEX NO.	INVESTIGATOR NAME & ADDRESS	DESCRIPTION OF STUDY	PATIENT CATEGORY			DATE SA SIGNED	NO. CASES APPROVED	COMMENTS
					INT	PA	PP			
0670	0723	84/002	Dr. Salahuddin Ahmed BAVS Clinic Dhaka, Bangladesh	Long-term FU: Minilap: Ring vs Pomeroy	x			01/84 FCO 2126	200	Initiation letter needed
6264	0836	84/011	Dr. John Nagahata Hosp. San Juan de Dios Lima, Peru	Minilap: Ring vs Filshie Clip	x			05/17/84 FCO 2126	200	Initiation visit 8/84. To start after Filshie vs. SecuClip admissions.
6264	0865	84/010	Dr. Ronald Bossemeyer Inst. of Reprod. Health Santa Maria, Brazil	Minilap: Ring vs Filshie Clip	x			*06/27/84 FCO2126	300	Study will begin after inves- tigator completes Filshie vs. SecuClip admissions
6264	0083	84/019	Dr. Contreras Hosp. Jose de Obaldia David, Panama	Minilap: Ring vs. Filshie Clip	x			06/18/84 FCO 2126	300	Initiation visit 8/84
6264	0825	84/009	Dr. R. Rivera Durango, Mexico	Minilap: Filshie vs Ring	x			05/23/84 FCO 2126	200	May need to cancel due to low caseload of interval women requestion sterilization.
6265	0075	84/015	Dr. Suporn Koetsawang TFRA Bangkok, Thailand	Laparoscopy: Ring vs Filshie Clip	x			Subgrant 1225	300	Dr. Suporn to deliver forms 9/84. Monitoring visit 8/84.
6960	0786	84/014	Prof. Talukoler Rangpur Med Coll. Hosp. Rangpur, Bangladesh	Minilap: w/ vs w/o antibiotics	x	x	x	FCO 1203	200	Initiation scheduled 5/84
6960	7019	84/013	Dr. Syed Ahmed Comilla BAVS Clinic Comilla, Bangladesh	Minilap: w/ vs w/o antibiotics	x	x	x	FCO 1203	200	Initiation scheduled 5/84

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FAMILY HEALTH INTERNATIONAL  
STUDY STATUS LIST

FEMALE STERILIZATION

ACTIVE STRAIGHT STUDIES

SEPTEMBER 1984

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	ML	1 mo FU	3 mo FU	6 mo FU	12 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 2126	12/83	02/20/84	500						113
6101	0255	84/017	Prof. Franco Gaspari Florence Univ. Hosp. Florence, Italy	Intra-tubal device	x			in-house FCO 2126	05/84	05/17/84	25	10		1		7	
6101	0258	84/018	Prof. Ettore Cittadini Clinica Ob/Ginec Palermo, Italy	Intra-tubal device	x			in-house FCO 2126	05/84	05/14/84	25	5				5	
6101	0279	84/016	Dr. Jacques Hamon Tenon Hospital Paris, France	Intra-tubal device	x			In-house FCO 2126	07/84	08/08/84	50	40		17		19	
6900	multi	84/008	Div.d'Hygiene Familiale Dept. de Sante Pub. Port-au-Prince, Haiti	Surveillance: all approaches, all techniques	x		x	FCO 2140	03/05/84	05/15/84	1500	135		55	28		
6900	8020	81/007	Dr. H. Aguinaga CPAIME Rio de Janeiro, Brazil	Laparoscopy: Tubal Ring	x			FCO 2140	02/11/82	07/12/84	2000	2048		1927	1491		1548

FAMILY HEALTH INTERNATIONAL  
STUDY STATUS LIST

FEMALE STERILIZATION

ACTIVE COMPARATIVE STUDIES

SEPTEMBER 1984

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	ML	1 mo FU	3 mo FU	6 mo FU	12 mo FU	24 mo FU
0630	0730	77/209	Dr. Rahman Khan Thana Health Complex Tangali, Bangladesh	Long-term FU: minilap: Pomeroy vs Tubal Ring	x			FCO 1203	03/22/83	06/12/84	300	312						257
6256	0739	81/012	Dr. J. Thouw Hasan Sidikin Hosp. Bandung, Indonesia	Minilap: SecuClip vs Tubal Ring	x			07/13/81 FCO 2126	05/18/82	06/26/84	200	200	176	137		102	44	18
6258	0825	83/008	Dr. Roberto Rivera Inst. Invest. Scienti. Durango, Mexico	Minilap: Filshie Clip vs SecuClip	x			09/15/83 FCO 2126	04/24/84	07/12/84	200	12	9		1			
6258	0836	84/005	Dr. John Nagahata Hosp San Juan de Dios Lima, Peru	Minilap: Filshie Clip vs SecuClip	x			01/12/84 FCO 2126	07/05/84	07/05/84	200	72	71					
6258	0865	84/004	Dr. Ronald Bossemeyer Inst of Reprod Health Santa Maria, Brazil	Minilap: Filshie Clip vs SecuClip	x			12/29/83 FCO 2126	08/20/84	08/29/84	300	9	9					
6260	0600	83/009	Dr. Ruben Apelo Jose Fabella Mem Hosp Manila, Philippines	Minilap: Filshie Clip vs Pomeroy			x	12/07/83 FCO 2126	04/24/84	08/15/84	300	148	147	102		3		
6260	0781	84/003	Dr. Jaw-shong Yan Tri Service Gen Hosp Taipei, Taiwan	Minilap: Filshie Clip vs Pomeroy			x	12/21/83 FCO 2126	04/13/84	07/16/84	200	31	31	4				
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 2126	02/28/84	08/20/84	300	249	247	233				
6960	0704	83/004	Dr. S.F. Begum Dhaka Medical College Dhaka, Bangladesh	Minilap: w/ vs w/o antibiotics	x			FCO 1203	09/83	06/12/84	200	96		94	2			

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FAMILY HEALTH INTERNATIONAL  
STUDY STATUS LIST

FEMALE STERILIZATION

ACTIVE COMPARATIVE STUDIES

SEPTEMBER 1984

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	ML	1 mo FU	3 mo FU	6 mo FU	12 mo FU	24 mo FU	
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	08/20/84	200	38		38					

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FAMILY HEALTH INTERNATIONAL  
STUDY STATUS LIST

FEMALE STERILIZATION

PLANNED STRAIGHT STUDIES

SEPTEMBER 1984

STUDY NO.	CENTER NO.	INDEX NO.	INVESTIGATOR NAME & ADDRESS	DESCRIPTION OF STUDY	PATIENT CATEGORY			DATE SA SIGNED	NO. CASES APPROVED	COMMENTS
					INT	PA	PP			
6900	0703	84/001	Dr. Sriani Basnayake FPA of Sri Lanka Colombo, Sri Lanka	Surveillance of Minilap	x	x	x	FCO 1124	500	No data to be received in-house; microcomputer analysis
6906	0437	84/021	Dr. Alex Omu Univ. of Benin Hosp. Benin, Nigeria	Minilap; Pomeroy	x		x	FCO 2231 Subcontract 609	200	Initiation scheduled 7/84

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FAMILY HEALTH INTERNATIONAL  
STUDY STATUS LIST

FEMALE STERILIZATION

PLANNED COMPARATIVE STUDIES

SEPTEMBER 1984

STUDY NO.	CENTER NO.	INDEX NO.	INVESTIGATOR NAME & ADDRESS	DESCRIPTION OF STUDY	PATIENT CATEGORY			DATE SA SIGNED	NO. CASES APPROVED	COMMENTS
					INT	PA	PP			
0670	0723	84/002	Dr. Salahuddin Ahmed BAVS Clinic Dhaka, Bangladesh	Long-term FU: Minilap: Ring vs Pomeroy	x			01/84 FCO 2126	200	Initiation letter needed
6264	0836	84/011	Dr. John Nagahata Hosp. San Juan de Dios Lima, Peru	Minilap: Ring vs Filshie Clip	x			05/17/84 FCO 2126	200	Initiation visit 8/84. To start after Filshie vs. SecuClip admissions.
6264	0865	84/010	Dr. Ronald Bossemeyer Inst. of Reprod. Health Santa Maria, Brazil	Minilap: Ring vs Filshie Clip	x			*06/27/84 FCO2126	300	Study will begin after investigator completes Filshie vs. SecuClip admissions
6264	0083	84/019	Dr. Contreras Hosp. Jose de Obaldia David, Panama	Minilap: Ring vs. Filshie Clip	x			06/18/84 FCO 2126	300	Initiation visit 8/84
6264	0825	84/009	Dr. R. Rivera Durango, Mexico	Minilap: Filshie vs Ring	x			05/23/84 FCO 2126	200	May need to cancel due to low caseload of interval women requesting sterilization.
6265	0075	84/015	Dr. Suporn Koetsawang TFRA Bangkok, Thailand	Laparoscopy: Ring vs Filshie Clip	x			Subgrant 1225	300	Dr. Suporn to deliver forms 9/84. Monitoring visit 8/84.
6960	0786	84/014	Prof. Talukoler Rangpur Med Coll. Hosp Rangpur, Bangladesh	Minilap: w/ vs w/o antibiotics	x	x	x	FCO 1203	200	Initiation scheduled 5/84
6960	7019	84/013	Dr. Syed Ahmed Comilla BAVS Clinic Comilla, Bangladesh	Minilap: w/ vs w/o antibiotics	x	x	x	FCO 1203	200	Initiation scheduled 5/84

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FAMILY HEALTH INTERNATIONAL  
STUDY STATUS LIST

MALE STERILIZATION

ACTIVE STRAIGHT STUDIES

SEPTEMBER 1984

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	ML	1 mo FU	3 mo FU	6 mo FU	12 mo FU
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 2126	12/83	02/20/84	500							113
01 0255	84/017	Prof. Franco Gaspari Florence Univ. Hosp. Florence, Italy	Intra-tubal device	x			in-house FCO 2126	05/84	05/17/84	25	10		1			7	
01 0258	84/018	Prof. Ettore Cittadini Clinica Ob/Ginec Palermo, Italy	Intra-tubal device	x			in-house FCO 2126	05/84	05/14/84	25	5					5	
01 0279	84/016	Dr. Jacques Hamon Tenon Hospital Paris, France	Intra-tubal device	x			In-house FCO 2126	02/84	08/08/84	50	40		17			19	
00 multi	84/008	Div.d'Hygiene Familiale Dept. de Sante Pub. Port-au-Prince, Haiti	Surveillance: all approaches, all techniques	x		x	FCO 2140	03/05/84	05/15/84	1500	135		55	28			
00 8020	81/007	Dr. H. Aguinaga CPAIMC Rio de Janeiro, Brazil	Laparoscopy: Tubal Ring	x			FCO 2140	02/11/82	07/12/84	2000	2048		1927	1491			1548

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John  
Lew

STATUS LIST FOR IUD5 STUDIES

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

DATE: 1 OCTOBER 1984

TOTAL CASES: 1100

FCO: 3101

CTR	INVESTIGATOR	COUNTRY	INDEX	EXP				LST SHIP	LST SITE	STATUS					
				FST SHP	DATE	CASE	ADM				1MO	3MO	6MO	12MO+	
841	GALICHI	GUATEMALA	IUD 80/009	9/80	1/82	300	299	163	113	149	243	5/21/84	10/82	MWI	CLOSED
090	ANDOLSEK	YUGOSLAVIA	IUD 80/002	3/83	12/83	500	239	206	188	149	71	9/24/84	10/83	SBI	ACTIVE
086	TACLA	CHILE	IUD 81/013	8/81	1/83	100	68	66	60	63	56	1/12/84	3/83	MWI	CLOSED
09	COHEN	FRANCE	IUD 81/003	7/81	6/85	100	94	81	71	60	48	8/15/84	5/84	CWI	ACTIVE

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

TOTAL NUMBER OF STUDIES: 2

FCO: 3101

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	21					9/18/84	4/84	CSWI	ACTIVE
721	SABERA RAHMAN	BANGLADESH	IUD 84/002	9/84	12/85	150	22					9/18/84	4/84	CSWI	ACTIVE

12/80

DESCRIPTION OF STUDY: WING SOUND-STUDY # 594

TOTAL NUMBER OF STUDIES: 4

DATE: 1 OCTOBER 1984

FCO: 3101

					EXP																									
I	CTR	I	INVESTIGATOR	I	COUNTRY	I	INDEX	I	FST SHP	I	DATE	I	CASE	I	ADM	I	1MO	I	3MO	I	6MO	I	12MO+	I	LST SHIP	I	LST SITE	I	STATUS	I
I	00	I	ZIEGELBOIM	I	VENEZUELA	I	IUD 82/011	I	9/82	I	3/84	I	100	I	100	I	78	I	64	I	68	I	82	I	6/11/84	I	-	I	ACTIVE	I
I	218	I	SNOWDEN	I	ENGLAND	I	IUD 82/008	I	1/82	I	3/84	I	600	I	508	I	41	I	78	I	78	I	270	I		I	-	I	ACTIVE	I
I	363	I	TOPPOZADA	I	EGYPT	I	IUD 82/009	I	10/82	I	8/83	I	150	I	150	I	117	I	103	I	81	I	162	I	8/7/84	I	-	I	ACTIVE	I
I	850	I	GUZMAN-SERANI	I	CHILE	I	IUD 82/007	I	1/82	I	2/84	I	300	I	301	I	227	I	29	I	159	I	177	I	4/9/84	I	-	I	CLOSED	I

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John  
Lewes

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

DATE: 1 OCTOBER 1984

TOTAL NUMBER OF STUDIES: 7

FCO: 3101

CTR	INVESTIGATOR	COUNTRY	INDEX	EXP				LST SHIP	LST SITE	STATUS				
				FST SHP	DATE	CASE	ADM				1MO	3MO	6MO	12MO+
024	BEHLILOVIC	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	RANDIC	YUGOSLAVIA	IUD 80/007	12/80	11/84	300	300	219	193	203	581	7/23/84	10/83	ACTIVE
018	THOMAS	ENGLAND	IUD 80/020	1/81	8/83	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	293	5/21/84	-	ACTIVE

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STUDY STATUS LIST FOR IUDPS STUDIES

DATE: 1 OCTOBER 1984

DESCRIPTION OF STUDY - POSTPARTUM INSERTION OF THE LIPPES LOOP D IN TURKISH CENTERS-STUDY # 5531

TOTAL NUMBER OF STUDIES: 5

FCO: 2161

CTR	INVESTIGATOR	COUNTRY	INDEX	EXP			FST					LST SHIP	LST SITE	STATUS
				DATE	ACT DATE	CASE	ADM	1MO	3MO	6MO	12MO			
I 322	I ZEYNEP KAMIL	I TURKEY	I IUD 81/044	I 12/83	I 7/84	I 141	I 24	I 8	I 10	I 12/83	I 4/16/84	I 6/83	SB	I CLOSED
I 323	I EGE UNIVERSITY	I TURKEY	I IUD 81/045	I 4/84	I 7/84	I 40	I	I	I	I 4/84	I 4/16/84	I 6/83	SB	I CLOSED
I 324	I IZMIR MAT HOS	I TURKEY	I IUD 81/046	I 12/83	I 7/84	I 35	I 8	I 2	I	I 12/83	I 2/17/84	I 6/83	SB	I CLOSED
I 325	I ZUBEYDE HANIM	I TURKEY	I IUD 81/047	I 12/83	I 7/84	I 14	I 3	I	I	I 12/83	I 12/5/83	I 6/83	SB	I CLOSED
I 326	I AFYON MATERN.	I TURKEY	I IUD 81/048	I 7/83	I 7/84	I 150	I 41	I 12	I 7	I 7/83	I 4/16/84	I 6/83	SB	I CLOSED

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

TOTAL NUMBER OF STUDIES: 4

FCO: 3114

CTR	INVESTIGATOR	COUNTRY	INDEX	EXP			FST					LST SHIP	LST SITE	STATUS	
				DATE	ACT DATE	CASE	ADM	1MO	3MO	6MO	12MO				
I 033	I EL-ESSAILY	I EGYPT	I IUD 83/006	I 10/83	I 5/85	I 300	I 300	I 193	I 170	I 89	I 14	I 8/7/84	I 2/84	SB	I ACTIVE
I 741	I DAMRONG	I THAILAND	I IUD 83/001	I 3/84	I 5/85	I 300	I 120	I 94	I 2	I	I	I 9/17/84	I 3/84	MR	I ACTIVE
I 4000	I AKUSE	I NIGERIA	I IUD 83/013	I 9/84	I 5/85	I 150	I 15	I	I	I	I	I 9/21/84	I 9/84	SN	I ACTIVE
I 042	I EKWEMPU	I NIGERIA	I	I	I	I 150	I	I	I	I	I	I	I 9/84	SN	I PLANNED

DESCRIPTION OF STUDY: SURVEILLANCE IN MALI- STUDY # 5538

FCO: 1166

CTR	INVESTIGATOR	COUNTRY	INDEX	EXP			FST					LST SHIP	LST SITE	STATUS	
				DATE	ACT DATE	CASE	ADM	1MO	3MO	6MO	12MO				
I 441	I TOUNKARA	I MALI	I IUD 84/001	I 10/83	I 8/85	I 150	I 286	I 303	I 79	I 43	I 12	I 9/13/84	I 12/84	NB	I ACTIVE

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STUDY STATUS LIST FOR IUDPS STUDIES

DATE: 1 OCTOBER 1984

DESCRIPTION OF STUDY - POSTPARTUM INSERTION OF THE LIPPES LOOP D IN TURKISH CENTERS-STUDY # 5531

TOTAL NUMBER OF STUDIES: 5

FCO: 2161

CTR	INVESTIGATOR	COUNTRY	INDEX	DATE ACT	EXP			FST				STATUS	
					DATE	CASE	ADM	1MO	3MO	6MO	SHIP		LST SHIP
I 322	I ZEYNEP KAMIL	I TURKEY	I IUD 81/044	I 12/83	I 7/84	I 141	I 24	I 8	I 10	I 12/83	I 4/16/84	I 6/83 SB	I CLOSED
I 323	I EGE UNIVERSITY	I TURKEY	I IUD 81/045	I 4/84	I 7/84	I 40	I	I	I	I 4/84	I 4/16/84	I 6/83 SB	I CLOSED
I 324	I IZMIR MAT HOS	I TURKEY	I IUD 81/046	I 12/83	I 7/84	I 35	I 8	I 2	I	I 12/83	I 2/17/84	I 6/83 SB	I CLOSED
325	I ZUBEYDE HANIM	I TURKEY	I IUD 81/047	I 12/83	I 7/84	I 14	I 3	I	I	I 12/83	I 12/5/83	I 6/83 SB	I CLOSED
326	I AFYON MATERN.	I TURKEY	I IUD 81/048	I 7/83	I 7/84	I 150	I 41	I 12	I 7	I 7/83	I 4/16/84	I 6/83 SB	I CLOSED

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

TOTAL NUMBER OF STUDIES: 4

FCO: 3114

CTR	INVESTIGATOR	COUNTRY	INDEX	FST SHIP	DATE	CASE	ADM	EXP				LST SHIP	LST SITE	STATUS
								1MO	3MO	6MO	12MO			
I 033	I EL-ESSAILY	I EGYPT	I IUD 83/006	I 10/83	I 5/85	I 300	I 300	I 193	I 170	I 89	I 14	I 8/7/84	I 2/84 SB	I ACTIVE
I 741	I DAMRONG	I THAILAND	I IUD 83/001	I 3/84	I 5/85	I 300	I 120	I 94	I 2	I	I	I 9/17/84	I 3/84 MR	I ACTIVE
I 4000	I AKUSE	I NIGERIA	I IUD 83/013	I 9/84	I 5/85	I 150	I 15	I	I	I	I	I 9/21/84	I 9/84 SM	I ACTIVE
I 042	I EKWEMPU	I NIGERIA	I	I	I	I 150	I	I	I	I	I	I	I 9/84 SM	I PLANNED

DESCRIPTION OF STUDY: SURVEILLANCE IN MALI- STUDY # 5538

FCO: 1166

CTR	INVESTIGATOR	COUNTRY	INDEX	FST SHIP	DATE	CASE	ADM	EXP				LST SHIP	LST SITE	STATUS
								1MO	3MO	6MO	12MO			
I 441	I TOUNKARA	I MALI	I IUD 84/001	I 10/83	I 8/85	I 150	I 286	I 303	I 79	I 43	I 12	I 9/13/84	I 12/84 NB	I ACTIVE

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

TOTAL NUMBER OF STUDIES: 4

DATE: 1 OCTOBER 1984

FCO: 1203

CTR	INVESTIGATOR	COUNTRY	INDEX	FST SHP	EXP				LST SHIP	LST SITE	STATUS				
					DATE	CASE	ADM	IMO				3MO	6MO	12MO	
721	SABERA RAHMAN	BANGLADESH	IUD 83/003	9/83	5/84	200	199	131	72	71		7/6/84	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	ARABINDA	BANGLADESH	IUD 84/004	9/84	6/85	200	26						4/84	CSW	ACTIVE
165	SHAMSUDDIN	BANGLADESH	IUD 83/004		5/85	200							4/84	CSW	PLANNED

DESCRIPTION OF STUDY: TRACKING IUDS IN POSTPARTUM WOMEN WITH ECHOSONOGRAPHY- STUDY # 5562

FCO: 3102

CTR	INVESTIGATOR	COUNTRY	INDEX	FST SHP	EXP				LST SHIP	LST SITE	STATUS				
					DATE	CASE	ADM	IMO				3MO	6MO	12MO	
892	ORTIZ MARISCALI	MEXICO	IUD 83/007	10/83	12/84	100	103	96	81			8/30/84			ACTIVE

FAMILY HEALTH INTERNATIONAL

INVESTIGATOR NETWORK NEEDS

FCO 3114

DATE - September 31, 1984

STUDY STATUS LIST

STRATEGY - DMPA (25 MG PER MONTH) VS DMPA (150 MG PER THREE MONTHS) STUDY # 3819

I CTR	I INVESTIGATOR	I COUNTRY	I INDEX	I DATE	SGN	I CASE	I ADM	I 1MO	I 3MO	I 6MO	I 12MO	I UNSCH	I 1ST SHIP	I LST SHIP	I STATUS
I 0893	I C. CZEPESZKA	I BRAZIL	I SYS83/001	I 03/11/83	I 100	I 61	I 34	I 12	I 8	I 1	I 23	I 04/25/84	I 08/03/84	I ACTIVE	

STRATEGY - DEPO VS PILL STUDY # - 8880

I CTR	I INVESTIGATOR	I COUNTRY	I INDEX	I DATE	SGN	I CASE	I ADM	I 1FU	I 1	I 1	I 1	I 1ST SHIP	I LST SHIP	I STATUS
I 4010	I ADAMA DAPO	I GAMBIA	I SYS84/017	I 03/01/84	I 400	I 50	I	I	I	I	I	I 07/23/84	I 07/23/84	I ACTIVE

STRATEGY - LAPAROSCOPY (TUBAL RING) STUDY # 6900

I CTR	I INVESTIGATOR	I COUNTRY	I INDEX	I DATE	SGN	I CASE	I ADM	I 1MO	I 3MO	I LT	I PC	I 1ST SHIP	I LST SHIP	I STATUS
I 8020	I H. AGUIAGA	I BRAZIL	I FS 81/007	I 06/15/82	I 2000	I 2048	I 1927	I 1491	I 1548	I 21	I	I 02/11/82	I 07/12/84	I ACTIVE

STRATEGY - FS SURVEILLANCE STUDY # 6900

I CTR	I INVESTIGATOR	I COUNTRY	I INDEX	I DATE	SGN	I CASE	I ADM	I 1MO	I 3MO	I	I	I 1ST SHIP	I LST SHIP	I STATUS
I MULT	I DIV D'HYGIENE	I HAITI	I FS 84/008	I 01/17/84	I 1500	I 242	I 155	I 120	I	I	I	I 03/05/84	I 09/05/84	I ACTIVE

STRATEGY - VASECTOMY SURVEILLANCE STUDY # 7001

I CTR	I INVESTIGATOR	I COUNTRY	I INDEX	I DATE	SGN	I CASE	I ADM	I ERLV	I LT/W	I LT/NOI	I	I 1ST SHIP	I LST SHIP	I STATUS
I MULT	I DIV D'HYGIENE	I HAITI	I FS 84/002	I 01/10/84	I 500	I 4	I	I	I	I	I	I 09/06/84	I	I ACTIVE

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STRATEGY - NL 250 VS COPPER T 200 STUDY # 5544

I	CTR	I	INVESTIGATOR	I	COUNTRY	I	INDEX	I	DATE	SCN	I	CASE	I	ADM	I	1MO	I	3MO	I	6MO	I	12MO	I	1ST SHIP	I	LST SHIP	I	STATUS	I	
I	741	I	DANSONG	I	THAILAND	I	IUP83/001	I	05/11/83	I	300	I	120	I	94	I	2	I		I		I		I	03/27/84	I	09/17/84	I	ACTIVE	I

STRATEGY - COPPER T 200 VS LIPPES LOOP D STUDY # 5538

I	CTR	I	INVESTIGATOR	I	COUNTRY	I	INDEX	I	DATE	SCN	I	CASE	I	ADM	I	1MO	I	3MO	I	6MO	I	12MO	I	1ST SHIP	I	LST SHIP	I	STATUS	I	
I	033	I	EL-ESSAILY	I	EGYPT	I	IUP83/006	I	02/23/83	I	300	I	300	I	197	I	170	I	80	I	14	I		I	10/04/83	I	08/07/84	I	ACTIVE	I

STRATEGY - LIPPES LOOP D VS COPPER T 200 STUDY # - 5538

I	CTR	I	INVESTIGATOR	I	COUNTRY	I	INDEX	I	DATE	SCN	I	CASE	I	ADM	I	1MO	I	3MO	I	6MO	I	UNSCU	I	1ST SHIP	I	LST SHIP	I	STATUS	I	
I	4000	I	J. J. AKUSE	I	NIGERIA	I	IUP83/013	I	01/11/83	I	150	I	15	I		I		I		I		I		I	09/21/84	I	09/21/84	I	ACTIVE	I

STRATEGY - MORIDAV VS LO-FEMENAL STUDY # 8850

I	CTR	I	INVESTIGATOR	I	COUNTRY	I	INDEX	I	DATE	SCN	I	CASE	I	ADM	I	1MO	I	4MO	I	8MO	I	12MO	I	1ST SHIP	I	LST SHIP	I	STATUS	I	
I	440	I	G. TRAORE	I	MALI	I	SYS83/032	I	12/19/83	I	100	I	9	I		I		I		I		I		I	09/04/84	I	09/04/84	I	ACTIVE	I

STRATEGY - STRAIGHT STUDY OF LIPPES LOOP

I	CTR	I	INVESTIGATOR	I	COUNTRY	I	INDEX	I	DATE	SCN	I	CASE	I	ADM	I	1MO	I	3MO	I	6MO	I		I	1ST SHIP	I	LST SHIP	I	STATUS	I	
I	042	I	C.C. EKFRU	I	NIGERIA	I		I		I	150	I		I		I		I		I		I		I		I		I	PLANNING	I

STRATEGY - POSTPARTUM INSERTION OF COPPER T 200 STUDY #5526 (COMPLETED)

I	CTR	I	INVESTIGATOR	I	COUNTRY	I	INDEX	I	DATE	SCN	I	CASE	I	ADM	I	1MO	I	3MO	I	6MO	I	12MO	I	1ST SHIP	I	LST SHIP	I	STATUS	I	
I	304	I	K. USTAY	I	TURKEY	I	IUS81/032	I	02/10/81	I	200	I	201	I	112	I	169	I	237	I	212	I		I		I		I	CF 488	I

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Family Health International

ANNUAL PUBLICATIONS LIST

October 1, 1983 - September 30, 1984

Published

- B Janowitz, JA Nunez, DL Covington and CE Colven. Sterilization in Honduras: Assessing the Unmet Demand. *Stud Fam Plann* 14(1):252, 1983. (83-34)
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