ANNUAL REPORT
DPE-0537-C-00-1028-00

16 September 1981 - 15 September 1982

Family Health International • Research Triangle Park, NC 27709 USA

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I. Introduction

This annual report on AID contract DPE-0537-C-00-1028-00 covers the period from 16 September 1981 through 15 September 1982. This is the first year of contract 1028, follow on to AID/pha-C-1172.

In the field of contraceptive safety, FHI is conducting two Reproductive Age Mortality Surveillance studies (RAMOS), one in Menoufia, Egypt and the other in Bali, Indonesia. The studies are progressing well and preliminary analysis is being conducted.

FHI is proceeding with additional animal studies before initiating prehysterectomy studies of quinacrine hydrochloride for use in nonsurgical female sterilization. LD-50 studies in rats are being conducted.

In the field of health and demography, the longitudinal breastfeeding study in Mexico is nearly complete and the analysis will be done as soon as all follow up data are received. There are plans for similar studies in Thailand (initiated this summer under the Thailand Fertility Research Association subgrant) and in Egypt (planned for December of this year).

FHI continues to investigate possible sites for studies of natural family planning methods. Although the large study in Brazil did not materialize, studies are in the planning stage for other sites.

In clinical trials, studies of two new vaginal foaming tablets--Emko Vaginal Tablet and Ortho Vaginal Tablet--were initiated b[illegible] in the

US and overseas. A new strategy for studies of low-dose oral contraceptives was developed and studies are being initiated.

In training and transfer of technology, programs for microcomputers in the clinical research areas are being developed. A workshop on Contraceptive Technology with ten participants from as many different countries was conducted at FHI.

II. Clinical Trials

FHI conducts clinical trials in the major research areas (sterilization, intrauterine devices, systemics and barrier contraception). A listing of the number and type of forms received and loaded into the computer for the contract period is found in Appendix A. Appendix B lists the major computer programs developed to aid in the analysis of research data and new forms, manuals and protocols.

A. Surgical Female Sterilization

Data collection in the comparative studies of the Rocket clip versus the tubal ring is nearly complete. A total of 663 procedures have been performed in three studies. There were five (1.5%) technical failures in the Rocket clip group and 25 (7.5%) in the tubal ring group, almost all these failures due to changes in the planned occlusion technique or two techniques used. The rates of surgical difficulties in the Rocket clip and tubal ring groups were 12.7% and 16.6%, respectively. The rate of surgical complications was also somewhat higher in the tubal ring procedures, 4.2% (mainly tubal injuries with or without

bleeding), compared to 2.1% in the Rocket clip group (mainly tubal injuries without bleeding). More than 80% of the women in each occlusion group returned for 6-month follow-up and more than 60% of each group had a 12-month follow-up visit. Two intrauterine pregnancies have been reported in each group, and there have been eight abdominal or pelvic surgeries reported, including six in the tubal ring group (one herniorrhaphy, two conizations, two hysterectomies for cervical cancer, one D and C for heavy bleeding) and two in the Rocket clip group (one hysterectomy for cervical cancer, one repair of a vaginal fistula).

FHI is evaluating the hypothesis that application of topical anesthesia to the fallopian tubes before tubal occlusion reduces the pain experienced by women during the operation. One comparative study of topical anesthesia versus no topical anesthesia utilizing the suprapubic endoscopy approach is complete, and another study using open laparoscopy is continuing. Preliminary analysis indicates that topical anesthesia does reduce pain experienced by the women during the procedure. In both studies, the proportion of women reporting no pain during the procedure was approximately twice as great among women receiving topical anesthesia as among those who did not receive topical anesthesia.

Data have been received from one comparative study of the Secuclip versus the tubal ring. In 23 procedures, no surgical difficulties or injuries were reported.

B. Nonsurgical Female Sterilization

FHI has obtained a Claimed Investigational Exemption for New Drug (IND) for the use of quinacrine as a sclerosing agent designed to secure tubal occlusion when placed in the uterus after insertion through the cervix. A series of animal studies have been undertaken. The Phase I prehysterectomy study will begin after completion of the annual studies. Results follow:

Monkey and Rat Teratology Studies. These studies were conducted to get a broad assessment of the effects of quinacrine on the fetus when accidentally administered in early pregnancy. The rat teratology studies were negative. Of the three monkeys given 30 mg intrauterine quinacrine, one delivered a normal fetus. The second delivered a fetus with multiple skeletal and neurological malformations including a neural tube defect. However, the defect was not judged to be quinacrine induced since the monkey was administered quinacrine on day 42 while closure of the neural tube is complete by day 29. (The other malformations were thought to be related to the neural tube defect.) The third monkey died of unknown causes two days after the administration of quinacrine. This is not an uncommon occurrence in monkey populations.

Monkey and Pig Simulated Uterine Perforation Studies. These studies were undertaken to determine what happens if uterine perforation occurs and quinacrine enters the peritoneal cavity.

Using a dose comparable to the human dose, quinacrine was instilled directly into the peritoneal cavity of three monkeys. One animal showed extensive adhesions typical of what might occur after a uterine perforation. The other two animals either had no problem or any intraperitoneal changes were resolved by the time of autopsy.

Quinacrine pellets containing considerably more quinacrine than the human dose were placed in the peritoneal cavities of two pigs. One had no symptoms; the other died, but autopsy revealed the cause of death to be chronic extensive bilateral hydronephrosis.

In a non-FHI funded study, quinacrine, at twenty times the anticipated human dose for accomplishing tubal closure, was inserted in the peritoneum of cynogamous monkeys. Two of the three monkeys died within two hours and the third had a seizure. These reactions appear to have been caused by rapid peritoneal absorption producing a high blood level of quinacrine, up to x10 that found in the toxicology experiments conducted by Johns Hopkins under contract to FHI.

FHI will not implement work under the IND granted by the USFDA until additional animal studies are completed. These studies are aimed at further improving the therapeutic ratio when the drug is placed intraperitoneally, by slowing the release rate and will determine the LD-50 for different release rates in rats.

Follow-up of Quinacrine Pellet Cases

The follow-up of women in ongoing clinical trials of the transcervical insertion of quinacrine pellets continues. Pellets have been inserted in 440 women at three clinics. For those women receiving three administrations of quinacrine, the pellet method is a marked improvement over the quinacrine solution method both from the point of view of safety as well as efficacy.

Gross Cumulative Life-table Pregnancy Rates (per 100 Women) For Women Who Completed Three Administrations of Quiracrine Hydrochloride

	6-month rate	12-month rate	18-month rate
Quinacrine Solution (N = 124)	6.5	9.9	11.7
Quinacrine Pellets with Sodium Thiopenthal (N = 147)	1.4	4.3	6.5
Quinacrine Pellets without Sodium Thiopenthal (N = 293)	1.0	1.0	3.4

Quinacrine-releasing IUDs

In an effort to develop a one insertion method of delivery with a high rate of effectiveness, FHI continues to explore the use of the No Gravid Ypsilon-shaped IUD to deliver quinacrine. Progestational adjuncts may have the ability to inhibit epithelial regeneration in the tubal ostia and an oral dose of 80 mg

of Megace, a progestational agent, was administered five days pre and post IUD insertion in selected prehysterectomy cases. Of the 12 tubes examined from these women, ten had lesions that appeared to be definitive, one had a lesion that could have ended in occlusion or healing and the last tube was untouched despite the fact that it was in a specimen in which the lumen of the other tube was obliterated.

The next phase of prehysterectomy insertions tested the efficacy of a sustained release, extended exposure to quinacrine capsules (13-20 hour release) with a dose of 100 mg per arm and adjunct progestational agents were not used. Two of the four specimens examined showed less damage than for previous release rates while third and fourth had extensive damage in spite of the dislodgement of one of the IUDs. Currently, IUDs containing a combination of short and long acting pellets are being studied to evaluate the effect of a combined delivery system. Adjunct progestational agents are not being used.

The pathologic examination of the specimens has been improved by taking three blocks from each tube at the ostial, mid-intramural and serosal portions of the tube. A scoring system is being developed to improve the evaluation of damage. Future cases should retain the IUD 21-30 days to demonstrate scar formation.

International Workshop

Several FHI staff members participated in an International Workshop on Nonsurgical Methods for Female Tubal Occlusion,

June 22-24 1982, in Chicago, Illinois. The workshop was sponsored by the Program for Applied Research on Fertility Regulation (PARFR). FHI presented data on quinacrine pellets and the quinacrine loaded IUD.

In the next year, FHI will attempt to determine the optimal dosage-release rate composition for quinacrine pellets and further explore adjunctive therapies in a series of prehysterectomy studies. FHI will monitor work being conducted elsewhere on tetracycline as a candidate substance for non-surgical tubal occlusion.

C. Male Sterilization

Vasectomy has been proven to be safe, effective and inexpensive. FHI is currently conducting a large study of vas excision and ligation in Brazil. Preliminary analysis of 940 procedures reveals that no technical failures occurred and the total complication rate due to all causes at follow-up was in 11.9% of the men returning.

The percutaneous vas injection technique of male sterilization is undergoing testing outside FHI using three prototype clamps developed in collaboration with FHI. If the procedure shows promise in this early study, FHI may conduct more extensive clinical trials. Percutaneous vas cautery, a second nonsurgical technique, may soon be ready for expanded human trials.

D. Intrauterine Devices

Ongoing IUD clinical trials at FHI include evaluation of the postpartum Delta devices, stringless IUDs that may reduce the risk of pelvic infection, the TCu 380 Ag IUD that has a silver-cored copper wire, and levonorgestrel-releasing IUDs.

FHI has demonstrated the practicality of postpartum IUD use and data collected in FHI-sponsored clinical trials have been the basis of a nationwide postpartum IUD program.

FHI clinical trials, which are now drawing to a close, have demonstrated:

a. Postpartum IUD insertion is safe and unassociated with any measured risk of perforation or infection.

b. Immediate insertion (within minutes of placental expulsion) is simpler and associated with fewer expulsions than later (hours after delivery) insertion. Among 609 insertions in the Delta Loop studies, the expulsion rate at three months for immediate insertions was 8.0 compared to 21.0 for early insertions ($p < .05$), suggesting that the timing of insertion may play an important role in device retention during the puerperium.

c. Postpartum insertion is associated with an expulsion rate that is higher than for interval insertion but low enough to make it a worthwhile choice for the woman and a cost-effective procedure for health professionals.

d. Expulsion rates can vary widely between centers, suggesting insertion technique is an important variable. Adequate training, appropriate monitoring and where necessary retraining are important if a postpartum IUD program is to be successful.

e. The physical design of the device is important. The addition of biodegradable sutures to the standard TCu 220C and Lippes Loop D IUDs, is a device modification intended to lower high expulsion rates associated with immediate postpartum insertions. The Delta (sutured) T and Delta Loop were compared with their unsutured counterparts and with each other in a multicenter trial. The following table is based on seven comparative studies of the Delta Loop and plain LLD, five comparative studies of the Delta T and TCu 220 C and seven studies comparing the two Delta devices.

f. Specific devices have optimum insertion techniques. In four studies of 1030 insertions of the Delta Loop inserted by hand versus an inserter there were no differences in any life-table event rates. In the only study of the Delta T, the inserter method was associated with significantly less pain at insertion among the women and fewer removals for bleeding/pain than hand insertions, 4.2 per 100 insertions compared to 11.8, respectively. In addition, physicians participating in this study stated that they were more confident of proper fundal placement when the inserter was used. Two studies each of the Delta Loop and Delta T were

conducted to determine the effect of the timing of insertion on expulsion rates.

Life-table Event Rates by Device (per 100 women)

	LLD (N = 733)	Delta Loop (N = 771)	TCu (N = 778)	Delta T (N = 783)	Delta Loop (N = 798)	Delta T (N = 828)
Expulsion						
1 month	14.3	11.4	7.1	7.6	4.7	5.9
3 months	19.0	15.5	11.0	10.2	9.6	8.1
6 months	23.1	17.7*	11.8	11.8	13.3	9.5
Removal for bleeding/pain						
1 month	0.0	0.2	0.6	0.4	0.3	0.4
3 months	0.5	2.3*	2.0	1.8	1.2	0.9
6 months	1.7	3.4	3.6	5.4	3.9	3.5
Continuation						
1 month	84.7	87.8	91.8	91.3	94.6	92.9
3 months	78.6	80.7	85.3	86.8	88.5	89.5
6 months	72.6	77.0	81.2	81.0	80.4	84.7
Follow-up						
1 month	85.2	84.0	97.0	97.9	85.9	87.5
3 months	65.7	61.4	75.9	77.6	77.6	79.7
6 months	57.5	53.1	63.6	63.5	66.2	69.3

*$p < .05$

The Delta Loop has lower expulsion rates than the standard LLD, but results from the comparative studies of the standard TCu versus the Delta T were nearly identical.

Delta devices for all of FHI's international research studies were manufactured at PIACT de Mexico. FHI wishes to thank PIACT for the support given to this research program over the last few years.

FHI is seeking to determine whether stiffer, molded projections would improve postpartum retention rates significantly better than the suture projections. This study is being proposed to decide whether to proceed with development of injection molded biodegradable projections for the Delta devices. US centers studying the Delta T and Delta Loop under the IND and IDE continue, but new studies will not be initiated until the current evaluations have been completed.

Nationwide postpartum IUD programs have been initiated or are in the pilot stages in two countries. In Tunisia, 13 centers have participated and there were 471 postpartum insertions of the Delta T and 60 insertions of the Delta Loop; follow up at one month was 51.0% and 21.7%, respectively. The 1-month expulsion rate was 10.6 for the Delta Loop and 6.0 for the Delta T. Ten Turkish centers have contributed data on 1429 postpartum insertions of the Delta Loop, with an overall expulsion rate of 31.4 and follow up of 35.4% after three months. A training program and additional data collection to evaluate the success of the program are planned for the coming year.

In an attempt to examine the effect of device size on IUD-related dysfunctional bleeding, FHI conducted a study of the Copper I IUD. Data on 98 insertions of this device, jointly developed by Dr. Jaime Zipper of Chile and FHI, have shown that while the device may be effective in reducing the number of removals due to bleeding, pain or other medical reasons, the pregnancy and expulsion rates tend to be unacceptably high. With

a 12-month follow up of 54.5%, the pregnancy rate was 9.1, expulsion rate 16.0 and bleeding/pain removal rate 1.1.

Although increased risk of pelvic inflammatory disease (PID) is a serious side effect of IUD use, the role of the IUD string in the etiology of PID is uncertain. To examine this relationship FHI has initiated a comparative study of TCu 200B devices with and without strings. Preliminary analysis of 389 acceptors among four centers with 63.5% follow up at one year reveals no differences in reports of infection or inflammation. There were no differences in the reporting of bleeding and pain side effects but there was a significantly higher removal rate for bleeding/pain among women wearing devices with strings, most likely due to the relative ease of removing these devices compared to the stringless IUDs.

Under a subcontract from FHI, Southern Research Institute has developed a fibrous delivery system for povidone-iodine, an antimicrobial agent, to be attached to the IUD alongside the regular string. This biodegradable, polycaprolactone thread will slowly release the povidone-iodine, which may reduce the incidence of PID immediately following IUD insertion. Work continues on optimizing the thread to increase its tensile strength.

FHI is collaborating with the Population Council in funding studies of levonorgestrel-releasing IUDs. Two studies have been initiated in a comparative clinical trial of the levonorgestrel-

releasing IUD and the TCu 380 Ag. Over 700 acceptors have been admitted and follow up is good. There has been one pregnancy with each device. The 6-month life-table rates do not indicate any important differences between the devices.

Clinical evaluations of the TCu 380 Ag are almost complete. This device consists of a plastic T with copper collars on the cross-bar and silver-cored copper wire wound around the vertical stem; the silver core is designed to prevent the copper wire from fragmenting as easily and prolong the life of the device in vivo. The following results, based on 328 interval insertions in two centers comparing the TCu 380 Ag with the Copper 7 and 1403 interval insertions in five centers comparing the TCu 380 Ag with the Multiload Cu 375, indicate no difference between the TCu 380 Ag and either the Cu 7 or Multiload Cu 375.

Insertion-related Complications and
Life-table Event Rates by Device (per 100 women)

	TCu 380 Ag (N = 162)	Cu 7 (N = 166)	TCu 380 Ag (N = 704)	ML Cu 375 (N = 699)
Failed insertion	1.3	0.0	0.1	0.1
Cervical laceration	1.3	1.2	2.1	1.9
Perforation	0.6	0.6	0.1	0.0
Pregnancy				
1 month	0.0	0.0	0.0	0.0
6 months	0.7	0.9	0.0	0.8
Expulsion				
1 month	4.5	5.1	0.9	1.4
6 months	9.7	10.1	2.4	2.7
Removal for bleeding/pain				
1 month	0.0	0.6	0.0	0.6
6 months	0.0	1.5	3.2	1.6
Continuation				
1 month	95.5	93.7	99.1	97.9
6 months	85.6	84.1	93.5	93.8
Follow up				
1 month	96.9	92.2	92.0	93.4
6 months	63.2	62.8	71.7	70.5

FHI has developed a new IUD string retriever which will be tested in several clinics. Wing Sound II studies have been initiated by PARFR in four centers to determine the relationship between uterine cavity measurements and IUD performance. FHI will conduct the data analysis. Results are not yet available.

E. Systemic Contraception

FHI clinical trials of oral contraceptives continue.

Standard- and Low-dose Oral Contraceptives

Results of studies comparing standard-dose and low-dose pills are shown in Tables I and II. Pregnancy rates are low for all pills. Menstrual problems lead to more discontinuations among Brevicon users than among other contraceptive users. Nordette has consistently higher overall continuation rates. Lo-ovral did well at the one center where it was evaluated.

A multicenter trial of Norinyl 1/35 is being initiated to compare the acceptability of this oral contraceptive with Norinyl 1/50, Brevicon, and Lo-ovral. The FHI also plans to collect one-year continuation data from centers offering oral contraceptives and injectables in their programs.

Table I

Cumulative 6-month Life-table Rates
Low- vs Standard-dose Comparative Study

	Bangladesh			Bangladesh			Philippines		Thailand		
	Brevicon (.5/35) (N=199)	Nordette (.15/30) (N=196)	Norinyl (1/50) (N=202)	Brevicon (.5/35) (N=198)	Nordette (.15/30) (N=197)	Norinyl (1/50) (N=199)	Nordette (.15/30) (N=154)	Norinyl (1/50) (N=142)	Brevicon (.5/35) (N=79)	Loestrin (1.5/30) (N=81)	Norinyl (1/50) (N=79)
Accidental pregnancy	3.1	0.0	0.0**	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Menstrual problems	4.5	1.4	2.9	3.2	0.0	2.2	1.0	2.3	14.1	1.7	0.0***
Side effects	3.5	5.1	5.2	6.7	3.7	6.6	10.5	19.6	9.5	5.4	13.2
Other medical	0.0	0.7	0.6	0.6	0.0	0.0	3.7	1.4	0.0	0.0	0.0
Planned pregnancy	0.6	1.3	0.5	1.2	1.1	0.6	0.0	4.3	9.3	7.7	1.8
Personal reasons	1.3	2.9	5.8	3.5	1.6	2.7	3.4	3.2	9.4	0.0	5.7
Method unrelated	1.5	2.1	2.9	0.6	2.6	1.2	0.8	1.3	13.2	17.5	12.0
Continuation rate	86.4	87.2	83.7	85.1	93.3	87.3**	81.7	70.7	55.4	70.8	70.7
Follow-up rate	57.9	65.4	59.0	92.4	96.7	92.7	63.2	55.2	67.2	74.2	81.5
Months of use	750	792	766	949	1017	961	535	452	303	347	353

**p < .05

***p < .01

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Table II

Cumulative 6-month Life-table Rates

Low-dose Comparative Oral Contraceptive Studies

	Argentina		Egypt		Malaysia	
	Lo-ovral (.3/30) (N = 225)	Brevicon (.5/35) (N = 225)	Brevicon (.5/35) (N = 114)	Loestrin (1.5/30) (N = 114)	Nordette (.15/30) (N = 45)	Loestrin (1.5/30) (N = 51)
Accidental pregnancy	0.0	0.0	3.0	3.2	0.0	0.0
Menstrual problems	0.5	14.7*	0.0	0.9	2.4	3.0
Side effects	0.5	0.0	0.0	0.0	0.0	5.3
Other medical	0.0	0.0	0.0	0.0	2.4	2.5
Planned pregnancy	0.0	0.0	0.0	0.0	0.0	0.0
Personal reasons	0.5	0.7	0.0	2.1	2.9	2.1
Method unrelated	0.0	0.0	2.0	0.0	2.9	2.1
Continuation rate	98.5	84.8*	95.0	93.9	89.8	85.9
Follow up rate	83.3	65.2	85.0	81.5	68.3	73.9
Months of use	1085	856	557	552	192	227

*$p < .001$

Progestogen-only Oral Contraceptives

A clinical trial of progestogen-only oral contraceptives (Microval, .03 mg levonorgestrel) in lactating women has been initiated in India, Malaysia, Argentina and Egypt. The primary objectives of the study are to determine:

1. the initial acceptance and continued use of progestogen-only OCs among breast-feeding women,
2. any significant differences over time in the weight of breast-fed infants whose mothers are using progestogen-only OCs, compared to the weight of control infants whose mothers are not using hormonal contraceptives, and
3. side effects of progestogen-only oral contraceptives experienced by the women, with particular emphasis on those side effects which result in discontinuation of pill use.

Preliminary results from the center in Argentina show that:

1. three pregnancies (1.2%) have been reported among progestogen-only OC users and 5 (2.0%) among women using non-hormonal methods, mainly the IUD and barriers. Thirteen (5.2%) progestogen-only users and 24 (9.6%) non-hormonal users discontinued from the study for various reasons; decrease in milk production accounted for 4 (1.6%) discontinuations for progestogen-only users and 11 (4.4%) for non-hormonal users.
2. no differences occurred between the progestogen-only group and the non-hormonal group with respect to the physical

condition and growth of infants. Infants gained an average of 613 gm per month during the first 9 months following delivery and most physical problems reported were gastrointestinal in nature.

3. more than 30% of the women in both groups reported some intermittent bleeding early in the study, but less than 2.0% of all women terminated from the study because of bleeding problems. No changes were evident over time in maternal weight or other medical problems.

Data from the other centers is not yet sufficiently complete for analysis.

F. Barrier Contraception

FHI continues to evaluate several barrier contraceptives--the contraceptive sponge, the diaphragm with spermicide, Neo Sampoon, Emko Vaginal Tablets (EVT), Ortho Vaginal Tablets (OVT) and spermicidal foam. The following table summarizes results from nine active or completed comparative studies of these methods for which pooled six-month life-table rates are available (four comparing the contraceptive sponge and Neo Sampoon, two comparing the contraceptive sponge and the diaphragm and three comparing Neo Sampoon and foam).

Six Month Gross Life-table Rates per 100 Women

	Contraceptive Sponge (N = 653)	Neo Sampoon (N = 643)	Foam (N = 320)	Neo Sampoon (N = 328)	Contraceptive Sponge (N = 202)	Diaphragm (N = 208)
Terminations						
Accidental pregnancy	6.5	7.0	3.0	3.3	14.1*	5.7
Planned pregnancy	1.4	1.1	0.0	0.6	1.9	3.5
Discomfort	4.0	3.8	3.0	6.7	0.0	6.9*
Other personal	17.5*	4.9	13.5	12.0	23.3	21.3
Medical	1.7	1.0	2.0	2.4	9.5*	1.8
Continuation	71.8	83.3	79.7	77.3	58.5	65.5
Follow-up	73.9	77.3	43.1	41.8	54.5	50.3

*Significantly greater termination rate ($p < 0.05$).

In addition to these studies, trials are now underway comparing Neo Sampoon and OVT, OVT and EVT, the contraceptive sponge and foam, and Neo Sampoon versus OVT versus EVT. Numbers are small and no statistically significant differences ($p < 0.05$) in termination rates have been observed in these studies to date.

FHI evaluated a second sponge for PARFR, the collagen sponge, in three centers. The majority of the 130 women admitted to the trials reported product-related complaints and insertion, retention and removal problems were also common. There were 15 accidental pregnancies and the three-month total termination rate was 46.6.

Data from a Phase II clinical trial in London, England, involving a small, single-size diaphragm to be used without adjunctive spermicide are being collected by FHI.

On 12 March 1982, the FHI hosted an Expert Meeting on Sexually Transmitted Diseases (STD). The meeting focused on the prevalence of STDs both internationally and in the US. STDs are a major cause of infertility in Africa and some other parts of the world. Most spermicides are also active against STD organisms and results of studies previously conducted were presented and research in STD prevention was discussed. Designs for possible future research studies were reviewed by the experts present. The list of participants and the minutes from the meeting are found in Appendix C.

III. Contraceptive Safety

Two Reproductive Age Mortality Surveillance (RAMOS) studies are presently underway; the one in Indonesia for almost two years (data collection will terminate at the end of September) and the one in Egypt has been collecting data on deaths since 1 January 1981 and will continue through 1983.

Coverage (the percentage of deaths located) continues to be excellent in Egypt but uneven in Indonesia. The percentage of deaths for which a cause can be assigned is good in both sites. In both sites maternal deaths constitute a large fraction of all deaths, followed by accidents. In Egypt, deaths from rheumatic heart disease are a

significant fraction of all deaths. In both sites, the percentage of the deceased women who were contracepting at the time of death is far less than the percentage of women in the population who are known to be contracepting demonstrating the health benefits of distributing modern contraceptives in traditional societies, with weak medical services and where most deliveries are performed by traditional birth attendants.

The progress of these studies was evaluated at an expert meeting in June that was attended by the in-country project directors of both studies, experts in contraceptive safety (some of whom have been associated with the RAMOS studies since their conceptualization), experts in other specialized fields (e.g. Indonesian demography, tropical infectious diseases) and the Acting Head of the Research Division, AID Office of Population. Minutes of the meeting and the list of participants are found in Appendix D.

The leading cause of death in both areas was complications of pregnancy, (including abortion), childbirth and the puerperium. This accounted for 27% of the deaths in Bali, and 21% in Menoufia. The next most common cause of death was chest infections (18%) in Bali, and trauma (12%) in Menoufia. In both populations, slightly more than 7% of the deaths were attributed to cancer. Given the relative stages of development of the two countries, and their available medical facilities, it is not surprising that infections should comprise a larger proportion of all deaths in Bali than in Menoufia; maternal deaths are also more prevalent in Bali, in spite of lower birth rates. Menoufia, on the other hand, shows a greater

percentage of deaths attributed to all forms of heart disease (but especially rheumatic heart disease), and cerebrovascular disease including strokes.

In Bali, about 50% of the women of reproductive age use modern methods of family planning, but only 28% of the women who died were contracepting at the time of death. The mean age of the deceased contraceptors was 33.3 years and of the noncontraceptors was 32.3 years. In Menoufia 20%-25% of the women practice family planning, and 9% of the women who died were contracepting. The deceased contraceptors were 3 years older on the average than the noncontraceptors (38.8 years and 35.6 years). This implies that when death rates to all women of reproductive age are examined, the noncontracepting women have a considerably higher death rate than contracepting women. Future analysis will focus on this issue.

One of the goals of this research was to see if any deaths could be directly attributed to contraception. In developed countries a number of rare but potentially lethal hazards associated with the use of IUDs, oral contraceptives and contraceptive sterilization have been established, although exact measurement of the risks remains difficult. In the analysis of the current data, a systematic attempt is being made to look for any deaths which might be attributed to the use of modern methods of contraception, such as PID among IUD users, or cardiovascular disease in oral contraceptive users. In Bali, where IUDs are the most popular method of family planning, during the study period no deaths to contraceptors could be attributed to pelvic inflammatory disease or to possible ectopic

pregnancies.* However, before the study began (during the training period) a death occurred that can probably be attributed to acute pelvic infection following an IUD insertion. The attached table shows that in Menoufia, where oral contraceptives are the preferred method of most contraceptors, among deaths that are attributed to myocardial infarction, other heart and circulatory diseases, cerebrovascular disease including stroke and to thromboembolic disorders, the percentage that occurred to contraceptors is higher than the percentage of contraceptors among the women who died, but lower than the percentage of contraceptors in the population.

Although the present analysis is preliminary and deals only with small numbers, the data strongly suggest that the practice of family planning in these areas is safer than its nonuse, and it is not expected that larger numbers or more refined analysis will change this. Not only do the number of deaths from causes unrelated to reproduction (such as infectious diseases, or trauma) far exceed those known (in developed countries) to be related to contraception, but deaths from abortion, pregnancy and delivery exceed all other causes, and this is especially true among the high parity women who might be expected to have preferred to avoid pregnancy. It is expected that the final result will be of considerable value to public health workers, obstetricians and those interested in family planning.

*Not all the data have yet become available for analysis.

Table II

Contraceptive status at time of death, by cause of death; Bali, Indonesia and Menoufia, Egypt

Cause of death	INDONESIA						EGYPT					
	Contra-cepting		Not contra-cepting		Total		Contra-cepting		Not contra-cepting		Total	
Chest infections	30	44.1	38	55.9	68	100.0	6	12.8	41	87.2	47	100.0
Other infectious diseases	3	13.6	10	86.4	13	100.0	1	5.9	16	94.1	17	100.0
Heart failure involving chest infection	1	8.3	11	91.7	12	100.0	4	8.2	45	91.8	49	100.0
Rheumatic heart disease	0	-	2	100.0	2	100.0	3	4.2	69	95.8	72	100.0
Myocardial infarction	0	-	0	-	0	-	2	11.1	16	88.9	18	100.0
Other heart and circulatory diseases	7	41.2	10	58.8	17	100.0	8	12.1	58	87.9	66	100.0
Cerebrovascular disease, including stroke	4	57.1	3	42.9	7	100.0	5	16.7	25	83.3	30	100.0
Thromboembolic disorders	0	-	0	-	0	-	1	25.0	3	75.0	4	100.0
Diabetes	0	-	0	-	0	-	3	15.8	16	84.2	19	100.0
Pelvic inflammatory diseases	0	-	0	-	0	-	-	-	2	100.0	2	100.0
Cancer	8	28.6	20	71.4	28	100.0	2	3.6	53	96.4	55	100.0
Trauma	19	57.6	14	42.4	33	100.0	13	14.6	76	85.4	89	100.0
Maternal causes*	1	1.9	102	98.1	103	100.0	0	-	151	100.0	151	100.0
Other	17	4.7	20	54.1	37	100.0	15	19.2	63	80.0	78	100.0
Unknown (symptoms only)	16	33.3	342	66.7	48	100.0	0	-	29	100.0	29	4.0
Total	106	28.0	272	72.0	378	100.0	63	8.7	663	91.3	726	100.0

*Includes abortion, direct obstetric, indirect obstetric and nonobstetric deaths.

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The subcontract with the Emory/Grady Family Planning Program in Atlanta for the study, "Association between contraceptive methods and health outcomes," was completed April 2, 1982. A data file created under the subcontract contains diagnostic information on approximately 30,000 hospitalizations accrued to more than 57,000 women clients who attended the Grady Family Planning Clinic at least once during the period 1967-1976. During that period women between the ages of ten and forty-nine accumulated 71,496 woman years of oral contraceptive use, 28,090 woman years of IUD use, 9718 woman years of DMPA use and 5824 woman years of barrier contraceptive use. Based on the data collected under the subcontract, a paper "The risk of breast, uterine corpus, and ovarian cancer in women using Depo Medroxyprogesterone Acetate" has been prepared jointly by FHI, the CDC and Emory University. In summary, it is concluded in the paper that DMPA users in the Grady Family Planning Clinic were not at an increased risk of these cancers. In addition, the data are being used for a comprehensive investigation of hospitalized morbidity among the family planning clients which will be specific to diagnosis, age and contraceptive use. The CDC will continue to collaborate with FHI in this study and the publication of results.

So far 664 volunteers have been enrolled to participate in the study on the effects of Depo Provera in long-term users being conducted in Bandung, Indonesia. Of these, 480 women are current users of Depo-Provera, 86 are previous users and 98 are never users (the comparison group). The never users, composed primarily of sterilized women, are older and of greater parity than the other two groups.

The prevalence of amenorrhea and scanty/infrequent periods is 41.5% and 53.8% respectively in the current user group. The corresponding prevalences are 16.3% and 14.0% in the previous user group and 2.0% and 1.0% in the never user group. Mean values of serum hemoglobin (gm/100 ml), white blood cells (1000/cu mm) and glucose (mg/100 ml) differ slightly among the groups, but the significance of these differences is unclear.

Mean changes in both systolic and diastolic blood pressure among current and previous users from the first Depo injection to the survey physical exam are less than 5 mm Hg. The current users gained, on average, 2.2 kilograms in this period.

Of those Pap smears obtained, approximately half were interpreted as negative, slightly less than half were termed reactive and 1.6% were atypical. The endometrial biopsies were read by histopathological teams in Indonesia and Boston and there was no statistical difference between these independent results. Among the current users, seven out of te nad atrophic endometria, one third of the previous users had endometrial atrophy and one in 14 of the never users had atrophic endometria. There were no precancerous changes recorded by either of the evaluation teams in any of the women studied.

A project to examine the health effects of vasectomy has been completed through a subcontract with the Kaiser Foundation Research Institute. The study included nearly 4400 vasectomized men, of whom one third had a duration of vasectomy of ten or more years. Two papers based on these data have been published; a third and final

report is also expected to be published. "Physiologic measures in men with and without vasectomies" was published in Fercility and Sterility and "A Survey of Personal Habits, Symptoms of Illness, and Histories of Disease in Men With and Without Vasectomies" was published in the American Journal of Public Health. No association was found between vasectomy and any diseases that are manifestations of atherosclerosis or any other significant disease pattern. FHI staff have found that wide reporting has been given to the possibility of artherosclerotic changes in monkeys following vasectomy and believes the above papers will be important for family planning program managers and physicians in several countries. As the result of work supported under AID contract AID-1028, FHI has received support from the Ford Foundation, New York, to conduct a follow-up of vasectomized men in Korea.

A long-term follow-up of women who underwent sterilization procedures has been completed in one center that participated in four FHI trials in the 1970s. Of the 1434 women in the original studies, a total of 389 (27.1%) were contacted.

Those women with and without long-term follow-up were quite similar sociodemographically. In addition, women with long-term follow-up are representative of the original sample in terms of the distribution of occlusion techniques used. One pregnancy following laparoscopic tubal ring occlusion was reported. Three women sterilized by electrocoagulation reported subsequent hysterectomies--one for irregular menses, one for fibroma and one for an unspecified reason.

Long-term follow-up data have been received recently from another center, and additional studies are planned in other locations.

Of the two subcontracts with the Steroid Research Laboratories in Helsinki, Finland, to evaluate the long-term effects on the endometrium of the continuous release of small amounts of levonorgestrel and to measure the accumulation of levonorgestrel in specific tissues four to eight weeks following insertion of the levonorgestrel releasing IUD, one is complete and the second one is nearing completion. FHI is awaiting receipt of the final report on the results.

IV. Health and Demography

In the field of health and demography FHI is giving considerable priority to natural family planning (NFP) studies and is working in three main areas. Firstly, FHI intends to record and evaluate the dissemination and use of NFP in selected countries. A project to evaluate a nationwide NFP program in Brazil was prepared and endorsed by the cooperating institution (MOBRAL), which has the support of the Brazilian National Council of Bishops (CNBB). Unfortunately, the Ministry of Education and Culture refused permission for the use of overseas money and the project has been cancelled. Follow-up visits have been conducted in brazil and Peru and plans are being prepared for evaluation of NFP programs elsewhere in Latin America and in Africa.

Secondly, FHI is conducting preliminary studies on a possible modification of the cervical mucus method depending on an objective

self measurement of vaginal secretions. Finally, FHI is studying patterns of breast-feeding and the return of ovulation in lactating women.

Longitudinal studies of breast-feeding are being conducted to determine the time of first ovulation, and in some cases return to fertility, after childbirth in women who are breast-feeding, and to study its relationship to patterns of infant feeding and hormonal parameters.

Admissions to the breast-feeding study in Durango, Mexico have been completed and follow-up continues. Preliminary results indicate that the number of suckling episodes seems to be the crucial factor to maintain suppression of ovulation in lactating women. The number of suckling episodes in a 24-hour period required to inhibit ovulation is probably ten. Ovulation will return if the number of suckling episodes is reduced (which often occurs with the introduction of supplementary food). Low or brief rises in pregnanediol have been observed in some of the early menstrual cycles after delivery probably indicating luteal insufficiency.

The second study, in Bangkok, Thailand, was initiated in July of this year under the Thailand Fertility Research Association. Recruitment of study subjects has been excellent. As in Durango, the recruitment of control subjects has been more difficult, but remains on schedule. A third study will be initiated later this year in Assuit, Egypt. Discussions are underway for a similar study to be conducted in Nigeria.

Consideration will be given to studying cervical mucus changes as a marker of the return of ovulation in breast-feeding women.

FHI is studying access to sterilization services as well as the clinical outcome of operations. A final phase of a project to investigate the factors limiting access to female voluntary sterilization is now underway in Honduras. In this phase, women who reported that they were interested in obtaining a tubal ligation both at the time they were hospitalized for delivery and three months following delivery will be interviewed to determine whether they were sterilized in the past year and, if not, why not. The impact of travel time, difficulty in arranging for laboratory tests, scheduling appointments, etc. will be investigated.

The first two phases of the project demonstrated that the percentage of women sterilized when hospitalized for delivery is low and dominated by whether the woman has perceived indications for voluntary sterilization and 2) that over the following year more women who wanted to be sterilized but failed to get an operation had an unwanted pregnancy then succeeded in obtaining access to voluntary sterilization.

A survey of program managers and clinicians in five developing countries was carried out to determine their relative preferences for standard and low-dose pills. This study was carried out at the request of AID in order to provide information concerning whether it should add the low-dose pill or substitute the low-dose for the

standard pill in making supplies available for family planning programs.

Results showed that all respondents favored receiving both types of pills but if they had to receive only one pill, they preferred the standard pill. The standard pill was preferred because of its greater perceived efficacy even though repondents felt that it led to more immediate side effects and a greater likelihood of more long-term problems than did the low-dose pill.

With technical assistance from FHI, efforts have just been initiated to conduct a survey of distributors and promoters in the Honduran family planning program. The survey will cover the knowledge of workers concerning possible contraindications and side effects of orals, procedures followed if women report side effects and recommendations concerning appropriate methods. Of particular interest is the wide array of orals sold by these distributors including one low-dose pill. Consequently, the questionnaire will cover knowledge of differences in these two pills, recommendations made concerning the choice of standard vs low-dose pills, and, if in the event of supply problems for one pill, what recommendations are made to the woman concerning family planning.

FHI is planning to collaborate with the International Nutrition Communications Service (INCS) in obtaining information from hospitals concerning policies and practices in the area of infant feeding. To date, a draft questionnaire has been designed. Current plans are to

carry out the project in three countries including Jamaica and Honduras.

During the past year, two papers derived from the study of infant mortality, breast-feeding and contraceptive use have been accepted for publication. The first, "Child Survivorship and Pregnancy Spacing in Iran," to be published in the Journal of Biosocial Science, discusses the relative influences of mortality, breast-feeding and contraceptive use in affecting the length of the pregnancy interval and concludes that all of these factors have important effects on the interval.

The second paper, "Child Survivorship and Contraceptive Use in the Closed Pregnancy Interval," to be published in Social Science and Medicine, explores the link between the survival status of past pregnancies and the use of family planning in the last pregnancy interval. Results show that the survival status of previous outcomes, especially the penultimate, affects contraceptive use, with contraceptive use highest among women with the most successful outcomes controlling for the number of pregnancies.

A third paper, "Desire for Additional Children and Contraceptive Plans," is now in draft form. In that paper, the impact of the survival status of previous pregnancy outcomes on both the desire for additional children and on contraceptive plans is determined. Results show that the impact of an improvement in pregnancy outcome has a greater impact on both desire for additional children and on contraceptive plans the lower the parity of the woman.

V. Training and Transfer of Technology

In September 1982, FHI conducted a two week workshop on contraceptive technology and clinical research skills. A grant from the Noyes Foundation funded the airfare and per diem of the participants. AID contract 1028 covered all in-house staff costs. The list of participants is attached as Appendix E. The workshop focused on clinical trials, contraceptive technologies, data analysis and contraceptive safety. A questionnaire on the workshop was completed by participants. The participants considered the workshop most helpful to their work as developing country physicians, improving their research capability and enhancing the understanding and cooperation between FHI and the investigators in the field.

The computer programming staff at FHI is continuing with the development of data analysis programs in the research areas for microcomputer use.

VI. Information Dissemination

The list of papers published during the reporting period is found in Appendix F.

FHI published a report, Meeting the Family Planning Needs of the Urban Poor. The report summarized discussions from a 1980 workshop in Juarez, Mexico. The workshop was attended by 14 professionals who evaluated the most appropriate ways to deliver family planning services to the people of the rapidly expanding cities of the developing world.

Proceedings from the FHI-sponsored IUD seminar that took place in Salvador, Brazil, were translated into Portuguese and distributed to attendees at the seminar.

FHI sponsored an experts meeting on Sexually Transmitted Diseases (STDs) in March 1982. The focus of the meeting is discussed in the section on barrier contraception (II.F.), and details appear in the minutes (Appendix C). A second experts meeting on the RAMOS studies took place in June 1982. A summary of the meeting can be found in Appendix D. FHI took the opportunity of having experts in contraceptive safety who were attending the RAMOS meeting, and held a meeting on contraceptive safety following the RAMOS meeting. A summary of the discussion can also be found in Appendix D.

In June, several FHI staff members participated in a PARFR-sponsored meeting on chemical female sterilization. More details on the meeting are found in the section on nonsurgical female sterilization.

FHI staff presented papers in many professional meetings, including the Association of Planned Parenthood Physicians (APPP), the American Public Health Association (APHA) and the American College of Obstetrics and Gynecology (ACOG).

VII. International Investigator Network and Other Research Activities

The number of active* research centers by geographic region participating in FHI studies are listed below:

Latin America	26
Middle East	23
Far East	19
Africa (subSaharan)	4
Europe and North America	13
Total	83

Study status lists for ongoing and planned studies are found in Appendix G. Consultant Reports (CRs) are prepared by the research staff for each study completed. Data analyses are done as a service to the investigator. Appendix H lists the 47 CRs completed during the reporting period.

During the contract year, FHI made major steps to ensure the quality of data collected. In addition to standard procedures for routine editing of data, improved procedures of design control, field visit procedures and random data checks were instituted. Careful selection and training have been used to improve the quality of investigators. There is now a section on data quality included routinely in consultant reports. In the coming year, the Office of Quality Assurance will produce a complete quality assurance manual.

Several FHI investigators and prospective investigators visited the Research Triangle Park office to discuss ongoing studies and areas of possible collaboration. Among them were Dr. Mateja Kozuh-Novak

*Active centers are those from which FHI is receiving forms. It does not include centers from which FHI has not received a first forms shipment.

from Yugoslavia, who discussed the analysis of ten year IUD retrospective data from which monographs are to be written and Dr. A.A. Bruce-Tagoe from Ghana, who discussed possible collaboration on researching hormonal contraception in sickle cell patients. In addition, Dr. Gerson Naronha and Dr. Elena Lewin from MOBRAL, Brazil, came to FHI to develop a proposal to evaluate MOBRAL's natural family planning program. Other investigators from Egypt, Indonesia, People's Republic of China and several African countries were also among those visiting FHI.

The President and Staff Epidemiologist visited the People's Republic of China in May 1982 and have established an especially close scientific liaison with the Guandong Research Institute of Family Planning, Guangzhou, China, and in the long term it is hoped FHI will be able to assist in the possible usefulnesss of some of the Chinese innovations in family planning technology for other Third World countries.

VIII. Management

Initiatives taken during the first half of the reporting period with respect to making the corporate operating committees more representative of the organization and placing new emphasis on the role of the Task Forces continued yielding good results.

The Board of Directors met on 25-26 April 1982 and 12-13 September 1982. The By-laws were amended to a) increase the number of Directors from nine to fifteen; b) change the name of the organization to

Family Health International; c) eliminate ex-officio, nonvoting class of Directors and d) create additional corporate officer positions. The Board is reviewing long-term (5 years and more) directions for the organization. New Corporate Officers appointed were: Dr. Roger V. Short, Chairperson, Dr. Sharon Camp, Vice Chairperson, Dr. Malcolm Potts, President/Chief Operating Officer, Gen. Alexander Andrews, Secretary and Mr. Fred Coe, Treasurer. Three new directors were elected to the Board:

Mr. Fred Coe, Jr., President/Treasurer of the Research Triangle Foundation; retired President/Chairman of the Board of Directors, Burroughs Wellcome (1981), Research Triangle Park, NC.

Arthur C. Christakos, MD, Professor, Obstetrics/Gynecology; Dean, Undergraduate Medical Education, Duke University Medical Center, School of Medicine, Durham, NC.

Mr. R. Peyton Woodson, III, Woodson Associates of Raleigh, NC; Chairman/President of British-American Insurance Co.; Chairman of the Board of Occidental Life Insurance Co. of NC and Peninsular Life Insurance Co.

The Protection of Human Subjects Committee (PHSC) met on 18 September 1981. The annual review meeting was held 18 December 1981. The Committee also met on 23 April 1982 and will meet again in December 1982. Two new members, Dr. Dorothy Glenn and Ms. Betty Dennis, were added to the Committee at the December 1981 meeting, and Rev. Timothy Kimrey was added at the April meeting.

Scientific Directions 1982 was completed during the reporting period. This document, updated each year, provides an overview of ongoing, planned and possible scientific initiatives for FHI.

FHI expended a total of $2,360,170 from 16 September 1981 through 15 September 1982. Expenditures are summarized in the following table.

Contract 1028
Expenditures from 16 September 1981-15 September 1982

Item	Expenditure
Salaries	$ 617,406
Fringe benefits	132,435
Consultant and professional fees	10,875
Contract labor	15,019
Domestic travel	23,060
Foreign travel	90,193
Supplies	18,377
Equipment	--
Foreign office expense	--
Freight and postage	13,118
Data purchases	135,562
Subcontracts	229,192
Printing	13,765
Other purchased services	5,292
Other direct expenses	3,256
Text Processing charges	98,514
Computer charges	240,783
Data Entry charges	29,248
Graphics charges	34,064
Home department expenses	191,127
Fixed fee	58,434
General administrative	400,450
Total costs	$2,360,170

IX. Future Directions

During the next contract year, FHI plans to commence evaluation of at least one NFP program and to pursue the study of possible improvements of the mucus method. Carefully controlled work will continue on non-surgical sterilization, including further investigation of doses, rates of release and candidate substances in animals

and, when appropriate, human volunteers awaiting hysterectomy. FHI will continue to give priority to analyzing data from its barrier studies and on initiating studies of low-dose oral contraceptives. The investigation of microencapsulated steroids as long-acting contraceptives, currently being conducted by PARFR, is producing promising results and it is hoped that FHI will plan and initiate expanded human trials in the coming year. Information is also being accumulated on work done in the past on the toxicology and clinical performance of once-a-month oral contraceptives and, following careful review, work in this field may be made. FHI, using non-AID resources, has completed Phase I studies of the use of B blocking agents as a potential new class of spermicides. Interesting results have been obtained and it is hoped to follow-up this potentially important breakthrough by launching Phase II and III clinical trials in the coming year.

FHI is increasing its commitment to work in contraceptive safety. Data from the RAMOS studies will be analyzed and published and other studies on reproductive health and the impact of contraception will be initiated. FHI has had preliminary discussions on the possibility of studying the interaction of contraceptive use (especially steroidal contraceptives) and sickle cell disease.

FHI has also developed a plan to conduct a variety of studies that will serve as training for possible collaborators. In this manner, FHI will increase and strengthen its network of investigators to be used for more complex clinical trials.

Appendix A

Forms Received and Loaded Into the Computer
16 September 1981 - 15 September 1982

Intrauterine Devices	Admission	6,569
	Follow-up	16,062
	Method List	1,686
	Other	881
	Total	25,198
Systemic Contraception	Admission	864
	Follow-up	2,813
	Physical	791
	Total	4,468
Female Barrier	Admission	1,756
	Follow-up	4,049
	Total	5,805
Progestogen-only	Admission	660
	Follow-up	2,926
	Total	3,586
Male Sterilization	Admission	1,171
	Follow-up	823
	Other	1 118
	Total	3,112
Female Sterilization	Admission	183
	Follow-up	947
	Method List	147
	Other	2
	Total	1,279
Chemical Female Sterilization	Admission	76
	Follow-up	200
	Instillation	217
	Total	493
Depo Provera (Bandung, Indonesia)	Admission	319
	Phys. Exams	212
	Histopathologies	416
	Total	947
Breast-feeding (Mexico)	Admission	38
	Follow-up	1,227
	Termination	8
	Total	1,273
RAMOS (Bali, Indonesia)	Questionnaires	303
	Birth reports	16,403
	Death reports	8,048
		24,754

Appendix B

AID Contract 1028 Projects: 16 September 1981 - 15 September 1982

Longitudinal Breast-feeding Loading Program

Automated Data Archiving System

Generalized Data Variable Range Checking Program

Major Revision of "New-Old" FS Tables Program

IUD Patient Summary Record Control Block Revision - Data, Load, Tables

Generalized Delete User Interface Preprocessor Program

FS Data Record Revision for Long-term Follow-ups - Data, Load, Tables

DP Forms Processing Training Guide

SHERLOCK Data Manipulation Program Enhancements

FSPS Data Record Revision - Data, Load, Tables

Magnetic Tape Data Management Utility

APPENDIX C

Summary for Expert Meeting on Sexually Transmitted Diseases

International Fertility Research Program

Summary of the Meeting of
The Panel of Experts on Sexually Transmitted Diseases
12 March 1982

Malcolm Potts opened the meeting and explained the nature of the IFRP's role in STD research--a new adventure for the organization.

Dr. G. M. Antal of WHO outlined the scope of the problem worldwide. The current problem is heightened by the spreading resistance to drug therapy as well as the increasing cost. The failure by an increasing number of patients to respond to treatment and subsequent extended periods of disease activity and infectivity will not only result in a higher proportion of disease complications but also in increased disease transmission. This situation underlines the importance to further develop the "prevention and control" practice in dealing with STD.

Dr. James Curran of CDC narrowed the focus of STD to the national (U.S.) level. He stated that the numbers are deceiving for the U.S.--stable rates for reported diseases, but a large problem for the unreported diseases, such as herpes and chlamydial infections. The problem on a national level is that the most frequent consequences are the least detected--PID, cervical cancer (if this proves to be sexually transmitted) and effects on the neonate. The problem of STD within the gay male community is one of increasing importance as well.

Dr. John Cutler of the University of Pittsburgh reviewed the literature and history of VD research in the U.S., mainly relating the military to prevention done through World Wars I and II. Chemoprophylaxis is once again coming to the forefront. An old technology needs to be updated and applied to the new problems of resistance. Dr. Cutler stressed the point that "we must deal with human beings as they are, not as we would like them to be" in studying STD.

Dr. Clifford Cole of the State Health and Rehabilitative Services of Florida discussed the Tampa-Orlando Lorophyn study as an example of past research. The advantage of the study was that it was done through local programs, thus cutting costs and avoiding red tape. A reduction in the rate of gonorrhea reinfection was demonstrated as the use of prophylactic suppositories was advocated among the study population.

Dr. Leonard Laufe reviewed new technology in this area. Vaccinations are on the way but will be costly. The biggest drawback may be social--what parent will want to have their child vaccinated? Another new approach is fiber research. Slow release agents, such as iodine, could be incorporated into tampons, IUD strings, suppositories, etc. for prevention of many vaginal diseases. The fibers need to be optimized to increase tensile strength and to document sustained release over a minimum of three months. It was pointed out that germicide impregnated IUD strings would combat two problems--STD and PID. However, it was also emphasized that the useful life of iodine impregnated fibers would be limited, expensive teratological investigations would be necessary and the the FDA was reviewing all iodine containing compounds. Once-a-month slow release spermicides in diaphragms are also under investigation.

Marketing was discussed as a problem for a combined chemoprophylaxis and contraceptive agents. Education of the public in the current wave of conservatism is difficult in any medium. Promotion of contraceptive and advertising a lowered STD rate could be construed as promotion of promiscuity. However, the increased incidence of sexually transmitted diseases may defuse the morality issue.

Introduction of an IFRP proposed current study design and requests for suggestions of alternative designs were made by Dr. Potts. Dr. James Higgins of the IFRP discussed the proposed sampling scheme, sample size determination and methods of analysis. Sociological factors as well as chemical effects and FDA regulations were included in the group discussion.

The conclusion was that gonorrhea, trichomoniasis, clamydia and herpes cultures would be taken at entry and exit and the volunteers should be monitored regularly. The active product (containing nonoxynol-9) and placebo vaginal agent would be compared. The advantages and disadvartages of a third control group with no use of vaginal agents were discussed. Approximately two hundred women would be tested every two weeks over a six-month period.

The consensus of the group was that there exists a genuine need for research in this area, which can be applied to the public health, medical and marketing fields.

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APPENDIX D

Participants and Summaries
for
RAMOS and Contraceptive Safety
Expert Meetings

(14 June 1982)

APPENDIX D

SUMMARY OF THE MEETING OF THE PANEL OF EXPERTS ON THE RAMOS STUDIES

14 June 1982

The present status of the two RAMOS studies was reviewed: the Bali project has been underway since September 1980 and data collection is scheduled to continue through September 1982. Three hundred eight death questionnaires have been received. Under-registration of deaths remains the primary concern. Quality of the data is extremely good and the non-medical personnel are doing an excellent job of collecting medical data. Data collection in Egypt began in January 1981 and 726 questionnaires have been tabulated for that year. Registration of deaths is exceeding the proposed estimates (which were calculated from lifetable rates for all of Egypt) and the interviewers, who are county social workers, are now readily accepted by the community as word about the project has spread.

Findings

Preliminary review of deaths by causes (Table 1 and 2) reveal a rich data set that:

- provides one of the best insights available into mortality patterns among women in a traditional society.
- for the first time, will permit a broad analysis of the risks and benefits of contraceptive use in two developing countries with a relatively high prevalence of the use of modern methods of contraception, but with simple systems of medical supervision.
- is likely to provide a good deal of detailed information on certain important aspects of mortality, including deaths due to pregnancy,

childbirth and abortion (about 20% of all deaths), heart disease and even such causes as suicide.

- it is possible, but by no means certain, that the data may provide insight into rare adverse effects of pill, IUD and surgical methods of family planning.

Recommendations

The material that is being accumulated does not differ in quality from conventional death certification in a more developed society. The Panel recommended that the data be analyzed by case rather than by cause of death and where multiple causes have been specified, a standardized classification scheme, such as the National Center for Human Statistics' rules for death classification should be used. It was also suggested to classify never, ever and current contraceptive users separately.

The Panel thought that the Bali districts which were designated as target areas deserve further review. The provision of additional Kelian training sessions and doubling the transportation costs of the PLKBs had not demonstrated significant increases in registration of deaths in these areas, suggesting that under-registration may not be as serious as once thought. It was also pointed out that the registration may be biased by an increased surveillance among elcos (eligible couples). The interviewers are so used to dealing with currently fertile women that we may be losing cases of post menopause, 50 or younger women. At the same time, it was recognized that there is a lack of data to estimate mortality in Bali. Mortality rates will be compared for contraceptors and noncontraceptors, as

will the patterns of mortality for the two groups. Comparison of the rates will, however, have to be interpreted with caution.

It was suggested that data collection in Bali stop ahead of the scheduled September 1982 completion date. Approximately one-third of the completed interviews remain in Bali to be diagnosed and it may be worthwhile to consider using any time saved to allow more consolidation of data.

Reliability

The Panel suggested that a sample of death reports be resubmitted to the Egyptian Advisory Committee for re-diagnosis and that a medical panel in the United States be convened to further review a sample of Egyptian and Balinese forms to measure reliability and reproducibility of data.

Publications

In regard to publications, it was agreed:

- separate publications in Egypt and Indonesia.
- prepare paper for international audience (eg, Lancet) providing an overview of causes of mortality to women (15-50) in a traditional society and of risks and benefits of contraceptive use.
- submit a paper on methodology perhaps to the American Statistical Association.
- prepare papers on various categories of disease, eg, maternal mortality, infectious diseases, etc.
- the IFRP might consider publishing a monograph on the methodology and some of the findings.

Implications

The data is of a consistently high quality. All reasonable steps have been taken to review and improve the level of registration. Both studies are proceeding with relatively few unanticipated problems and will be completed according to schedule.

It is felt the results will be of significance to policy makers, and have an international as well as a national impact. It seems that any proven or suspected risk of contraceptive use will be considerably less than those of childbearing. The studies, however, may direct attention to certain groups (such as the relatively large number of women who have rheumatic heart disease) who may require special attention to some wider public health issues in the prevention and treatment of adult infectious diseases.

On behalf of the meeting, Dr. Potts expressed the appreciation of everyone in IFRP and of the outside experts to Dr. Inne Susanti and Dr. Saneya Saleh for their painstaking and persistence over so many months and sometimes under difficult conditions.

PARTICIPANTS

Panel of Experts

Dr. Elizabeth Connell, APHA

Dr. Herbert Peterson, UNC - Chapel Hill

Dr. Diana Petitti, Kaiser Research Foundation

Dr. Roger Rochat, Center for Disease Control

Ms. Saneya Saleh, American University in Cairo

Dr. James Shelton, AID

Dr. Alan Spanos, UNC - Chapel Hill

Dr. Jeremiah Sullivan, POPLABS

Dr. Inne Susanti, BKKBN Bali

Dr. Bradley Wells, Wake Forest University

Dr. Nicholas Wright, Rutgers University

IFRP

Dr. David Edelman

Dr. Judith Fortney

Dr. Patrick Friel

Mr. John Ganley

Dr. James Higgins

Mr. Peter Miller

Dr. Malcolm Potts

Ms. Susan Rogers - rapporteur

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Summary of the Meeting of the Panel of Experts
on Contraceptive Safety
June 14, 1982

The purpose of the meeting was to discuss IFRP's role in the field of contraceptive safety - what areas need to be explored, what questions need to be answered and how the IFRP can best assist in resolving current problems.

Priorities for research in the various contraceptive methods were reviewed.

With regard to female sterilization, the incidence of ectopic pregnancy was a major issue. Preliminary data suggest a lower incidence of ectopics among women sterilized by quinacrine than among women sterilized by other methods. Possible areas to explore include a more discrete assessment of hormonal status (not menstrual patterns) among women being sterilized, particularly noting the type of procedure and associated endocrinological changes. Surgical methods of female sterilization continue to evolve and improve, necessitating further analysis. It was also suggested to extend the present two year follow-up period in order to investigate the occurence of long-term side effects. (Several ongoing studies have four year follow-up.)

The Panel felt that the area of male sterilization was receiving extensive attention and there was no immediate need for further research at this time.

With regard to injectable contraception, the Panel questioned the applicability of animal experimentation to humans. High doses, several times greater than human dosages, may lead to adverse effects, even death, in animals. A primary issue requiring research is the relation of injectables to endometrial and uterine cancer and PID. Do these associations affect acceptability? Does the use of injectables provide a protective effect against PID in the same manner that oral contracepives appear to? The Panel also agreed that innovations in methods of injectable contraception require review.

The investigation of infection was the major issue in the discussion of IUD safety. The IFRP is currently conducting a four center trial of the tailless CuT-200 in populations with a high prevalence of PID to investigate whether women who use devices with strings are more prone to infection than those who wear devices without strings. The use of antiseptic-releasing (providine - iodine) fibers for IUD tails deserves further research. The Panel felt review of other variables associated with IUD use, i.e., timing of insertion, operator skill, duration of use and center variability in assessing PID would be useful in determining the relation between IUD use and PID. Further information on uterine measurements, removals with subsequent reinsertions and infertility are also needed.

With respect to pill safety, several issues were discussed. The question of protection against ovarian cancer was raised. A case-control study in an area with a high incidence of ovarian cancer was suggested. Long term consequences of pill use and use of the pill in lactating women are presently under investigation. Other high priority areas of research include heart disease and sickle cell anemia with oral contraceptive use. An effort will be made to collect more information on the attitude of policy makers, physicians and pill users and their preferences for different formulations of pills.

Participants

Dr. Arthur Christakos, Duke University Medical Center
Dr. Elizabeth Connell, APHA
Dr. Herbert Peterson, University of North Carolina School of Medicine
Dr. Diana Petitti, Kaiser Research Foundation
Dr. Roger Rochat, Center for Disease Control
Ms. Saneya Saleh, American University in Cairo
Dr. James Shelton, AID
Dr. Jeremiah Sullivan, POPLABS
Dr. Inne Susanti, BKKBN-Bali
Dr. Hugh Tilson, Burroughs Wellcome
Dr. Bradley Wells, Bowman Gray University
Dr. Nicholas Wright, Rutgers University

IFRP

Dr. Pouru Bhiwandiwala
Dr. I-cheng Chi
Ms. Lynda Cole
Dr. David Edelman
Dr. Judith Fortney
Mr. John Ganley
Dr. James Higgins
Dr. Leonard Laufe
Dr. Malcolm Potts
Ms. Susan Rogers
Ms. Elena Tomaro
Mr. Robert Wheeler

Appendix E

Contraceptive Technology Workshop

1. Ismail Fouad El Essaily
   Lecturer/Consultant Ob/Gyn, Cairo Univ. (Faculty of Medicine)
   Cairo, Egypt

2. Cecil Adjei Klufio
   Senior Lecturer, Dept. of Ob/Gyn, Univ. of Ghana Medical School
   Accra, Ghana

3. Carlos Eduardo Czeresnia
   Supervisor/Chief of the Family Planning Clinic of the Hospital
   Das Clinicas, Sao Paulo
   Sao Paulo, Brazil

4. John Wreford Nagahata
   Medico Asistente Ginecologia-Obstetricia/Profesor Asociado Ob/Gyn
   Universidad Nacional Mayor San Marcos
   Lima, Peru

5. Jose David Ortiz Mariscal
   Director, ESPLANIFAM
   Nuevo Leon, Mexico

6. Nalo Martinez
   Provincial Minister of Health, Tungurahua Province
   Ambato, Ecuador

7. Herman Susanto
   Medical Doctor, Dept. of Ob/Gyn, Hasan Sadikin Hospital
   Bandung, Indonesia

8. Lin Shing Toa (Mr.)
   Engineer, Guandong Provincial Research Institute on Family Planning
   Guangzhou, China

9. Sopon Chalapati
   Director, Family Health Division, Health Dept.
   Bangkok, Thailand

10. Afroza Kazi
    Deputy Director, National Research Institute of Fertility Control
    Karachi, Pakistan

APPENDIX F

Annual Publications List
16 September 1981 - 15 September 1982

METHODOLOGY

M Potts, P Feldblum; I Chi, W Liao and AF de la Haba. The Puerto Rico Oral Contraceptive Study: An Evaluation of the Methodology and Results of a Feasibility Study. Brit J Fam Plann 7(4):99, 1982. (METH-53)

RG Wheeler and PG Friel. Release of Drugs from IUDs Using an Ethylene Vinyl Acetate Matrix. In: Proceedings of the Seventh International Symposium on Controlled Release of Bioactive Materials, Ft. Lauderdale, Florida, July 27-30, 1980 (New York: Plenum Publishing Corp., 1981), p. 26. (METH-52)

SYSTEMICS

M Potts. Is the Pill Natural? Populi 7(1):12, 1980. Also in Spanish: Es La Pildora Un Metodo Anticonceptivo Natural? (Queretaro, Mexico: PROFAM, 1981). (SYS-24)

MM Shaaban, WA Hammad, MF Fathalla, SA Ghaneimah, MM El-Sharkawy, TH Salim, MY Ali, WC Liao and SC Smith. Effects of Oral Contraception on Liver Function Tests and Serum Proteins in Women with Past Viral Hepatitis. Contraception 26(1):65, 1982. (SYS-30)

MM Shaaban, WA Hammad, MF Fathalla, SA Ghaneimah, MM El-Sharkawy, TH Salim, WC Liao and SC Smith. Effects of Oral Contraception on Liver Function Tests and Serum Proteins in Women with Active Schistosomiasis. Contraception 26(1):75, 1982. (SYS-31)

BARRIER

DA Edelman and S Thompson. Vaginal Contraception-An Update. Cont Deliv Syst 3:75, 1982. (BAR-10)

A Goldsmith and DA Edelman. Metodos Anticonceptivos de Barrera. Reproduccion (in press) (BAR-11)

J Zipper, ME Bruzzone, S Angelo, V Munoz and RG Wheeler. Effect of Topically Applied Andrenergic Blockers on Fertility. Int J of Fertil (in press) (BAR-9)

INTRAUTERINE DEVICES

B Behlilovic, S Etman, LE Laufe and B Dixon. Comparison of the Lippes Loop D and Tapered Lippes Loop D Intrauterine Devices. Contraception 25(3):293, 1982. (IUD-78)

LP Cole, MF McCann, JE Higgins and CS Waszak. Effects of Breast-feeding on IUD Performance. Am J Public Health (in press) (IUD-88)

E Kessel, I Chi and P Feldblum. Postmarketing Surveillance of Intrauterine Contraceptive Devices. Cont Deliv Syst (in press) (IUD-86)

LE Laufe. Chemical Sterilization With an IUD. Cont Deliv Syst 2:343, 1981. (IUD-82)

LE Laufe and RG Wheeler. Quinacrine IUDs. In: Female Transcervical Sterilization. (Chicago: PARFR) (in press) (IUD-99)

P Lavin, C Bravo and C Waszak. Evaluation of the TCu 200 and the Progestasert IUDs. Cont Deliv Syst (in press) (IUD-85)

P Lavin, C Waszak and C Bravo. Preliminary Report on a Postpartum CuT 200 Study, Santiago, Chile. Int J Gynaecol Obstet (in press) (IUD-84)

M Potts and L Cole. Wider Opportunities for IUD Insertion. IPPF Med Bull (in press) (IUD-94)

ZS Wen, L Lin, LE Laufe and B Dixon. The Introduction of Postpartum IUDs in the People's Republic of China. Int J Gynaecol Obstet (in press) (IUD-89)

MALE STERILIZATION

S Mumford, J Davis and M Freund. Considerations in Selecting a Post-vasectomy Semen Examination Regimen. Nephrology (in press) (MS-5)

MENSTRUAL REGULATION

DA Edelman and GS Berger. Menstrual Regulation. In: Abortion and Sterilization: Medical and Social Aspects, JE Hodgson, ed. (London: Academic Press Inc. Ltd., and New York: Grune & Stratton, 1981), p. 209. (MR-27)

PREGNANCY TERMINATION

JA Fortney. The Use of Hospital Resources to Treat Incomplete Abortions: Examples from Latin America. Public Health Rep 96(6):574, 1981. (PT-124)

FEMALE STERILIZATION

RV Bhatt, KM Jariwala, P Bhiwandiwala and LE Laufe. Chemical Female Sterilization Using Quinacrine Pellets. In: Proceedings of the Third International Seminar on Maternal and Perinatal Mortality, Pregnancy Termination and Sterilization, New Delhi, India, October 3-5, 1980, V Hingorani, RD Pandit and VL Bhargara, eds. (New Delhi: Federation of Obstetrics and Gynaecological Societies of India, 1981), p. 370. (FS-172)

P Bhiwandiwala, S Mumford and P Feldblum. A Comparison of Different Laparoscopic Sterilization Occlusion Techniques in 24,439 Procedures. Am J Obstet Gynecol (in press) (FS-147)

P Bhiwandiwala, S Mumford and P Feldblum. Menstrual Pattern Changes Following Laparoscopic Sterilization: A Comparative Study of Electrocoagulation and the Tubal Ring in 1025 Cases. J Reprod Med 27(5):249, 1982. (FS-167)

P Bhiwandiwala, S Mumford and P Feldblum. Menstrual Pattern Changes Following Laparoscopic Sterilization with Different Occlusion Techniques: A Review of 10004 Cases. Am J Obstet Gynecol (in press) (FS-163)

I Chi and P Feldblum. Laparoscopic Sterilizations Requiring Laparotomy. Am J Obstet Gynecol 142(6):712, 1982. (FS-157)

I Chi, P Feldblum and S Balogh. Previous Abdominal Surgery as a Risk Factor in Interval Laparoscopic Sterilization. Am J Obstet Gynecol (in press) (FS-162)

I Chi, S Mumford and S Gardner. Failure Rates Higher for Postpartum Postabortion Sterilizations Than for Interval Procedures. Summary in Fam Plann Perspect 14(2):100, 1982 and Int Fam Plann Perspect 8(2):78, 1982. (FS-122)

B Janowitz, DL Covington, ML Brown and MS Nakamura. Interval Sterilizations: A Substitute for Postpartum Procedures, An Example from Southeast Brazil. Soc Sci Med (in press) (FS-158)

B Janowitz, JE Higgins, DC Clopton, MS Nakamura and ML Brown. Access to Postpartum Sterilization in Southeast Brazil. Med Care 20(5):526, 1982. (FS-149)

B Janowitz, JH Lewis, DC Clopton and MS Nakamura. Postpartum Sterilization in Sao Paulo State, Brazil. J Biosoc Sci 14:179, 1982. (FS-148)

B Janowitz and J Nunez. Access to Sterilization in Two Hospitals in Honduras. Bull Pan Am Health Organ 15(3):226, 1981. (FS-131) Also in Spanish: Acceso A La Ligadura Tubaria En Dos Hospitales De Honduras. Bol of Sanit Panam 92(4):303, 1982.

E Kessel and S Mumford. Potential Demand for Voluntary Female Sterilization in the 1980s: The Compelling Need for a Nonsurgical Method. Fertil Steril 37(6):725, 1982. Sterilization: New Techniques to Meet Demand. Summary in People 9(3):36, 1982. Summary in Obstet Gynecol (in press) (FS-159)

AR Khan, HH Akhtar, HA Ali and B Dixon. Female Sterilization: A Comparison of Minilaparotomy and Culdoscopy. Sing J Obstet Gynecol 13(1):31, 1982. (FS-145)

S Koetsawang, S Srisupandit, O Kiriwat, S Apimas and P Feldblum. Three Neuroleptanalgesia Schedules for Laparoscopic Sterilization by Electrocoagulation. Int J Gynaecol Obstet (in press) (FS-154)

S Mumford, P Bhiwandiwala and I Chi. In Developing World, Fewer Pregnancies, Greater Safety with Minilap/Ring than with Laparoscopy (Summary). Int Fam Plann Perspect 7(2):65, 1981. Also, Laparoscopic and Minilaparotomy Female Sterilization Compared in 15,167 Cases (Summary). Obstet Gynecol Surv 36(7):363, 1981. (Summary) Fam Plann Perspect 13(6):278, 1981. (FS-126)

R Guzman-Serani and L Cole. Clinical Report--Quinacrine-Fused Pellets. In: Female Transcervical Sterilization. (Chicago: PARFR) (in press) (FS-175)

S Sheth, A Verke, S Pachauri, P Bhiwandiwala, ND Motashaw and VN Purandare. A Comparison of Tubal Ring and Madlener's Techniques of Tubal Ligation in Postpartum Cases. J Obstet Gynaecol India 31(1):43, 1981. (FS-178)

RG Wheeler. Delivery Systems for Quinacrine Applications as a Tubal Closing Agent. In: Female Transcervical Sterilization. (Chicago: PARFR) (in press) (FS-169)

J Zipper, D Edelman and L Cole. Overview of Clinical Trials with Quinacrine. In: Female Transcervical Sterilization. (Chicago: PARFR) (in press) (FS-176)

EVALUATION

P Bhiwandiwala and K Minor. Common Sense and Technology. People (in press) (EVAL-83)

P Donaldson, D Nichols and EH Choe. Abortion and Contraception in the Korean Fertility Transition. Pop Studies 36(2):227, 1982. (EVAL-80)

DA Edelman. Contraceptive Research in the 1980s. In: Proceedings of Symposium Internacional Sobre Avances En Planificacion Familiar, Mexico City, Mexico, Novémber 3-7, 1981, sponsored by Direccion General De Salud Materno Infantil Y Planificacion Familiar, p. 54. (EVAL-84)

DA Edelman. Family Planning Programs in the United States. In: Proceedings of Symposium Internacional Sobre Avances En Planificacion Familiar, Mexico City, Mexico, November 3-7, 1981, sponsored by Direccion General De Salud Materno Infantil Y Planificacion Familiar, p. 31. (EVAL-85)

JT Hanlon, SM Caiola, LH Mulbaier, BH Dennis, DA Edelman and JR Dingfelder. An Evaluation of the Sensitivity of Five Home Pregnancy Tests to Known Concentrations of Human Chorionic Gonadotropin. Am J Obstet Gynecol (in press) (EVAL-88)

M Potts. International Overview of Contraceptive Research. Adv Plann Parent 16(3):85, 1981. (EVAL-76)

M Potts and RG Wheeler. Quest for a Magic Bullet. Fam Plann Perspect 13(6):269, 1981. (EVAL-74)

JD Shelton and JE Higgins. Contraception and Toxic Shock Syndrome: A Reanalysis. Contraception 24(6):631, 1981. (EVAL-77)

SPECIAL PUBLICATIONS

M Potts. Contraception--More Research is Needed. Population: UNFPA Newsletter 7(9):3, 1981. (SP-60)

M Potts. Family Planning Without Doctors. Chapter in Fertility Control, SK Chaudhuri, ed. (in press) (SP-57)

M Potts and P Bhiwandiwala. Meeting the Family Planning Needs of the Urban Poor. (Research Triangle Park, North Carolina: International Fertility Research Program) Published 1981, reprinted 1982. (SP-50)

NE Williamson. Who is Practicing Family Planning? Comparing Survey and Clini: Reports in Bohol, Philippines. In: The Role of Surveys in the Analysis of Family Planning Programs, Proceedings of Seminar, Bogota, Colombia, October 28-31, 1980, AI Hermalin, ed. (Liege, Belgium: International Union for the Scientific Study of Population (IUSSP), 1982), p. 171. (SP-66)

NE Williamson. Sex Preference and Excess Fertility. Draper Fund Report (in press) (SP-67)

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APPENDIX G

Study Status Lists

(Planned and Ongoing)

INTERNATIONAL FERTILITY RESEARCH PROGRAM

STUDY STATUS LIST

STUDY AREA (circle one) PT MR FS MS (IUD) SYS

TYPE OF STUDY (circle one) (COMP) STRAIGHT

Planned

DATE September 1982

STUDY NO	CLINIC NO	NO	CONTRIBUTOR NAME CLINIC LOCATION	DESCRIPTION OF STUDY	PATIENT CATEGORY INT	PP	PA	Date Active	DATE SA SIGNED	NO CASES APPROVED	Date Closed	FORMS RECEIVED ADM	FU 1	FU 2	FU 3	FU 4	FU 5	ML	Paper/CR
530	020	IUD 82/ 002	L. Andolsek Family Planning Inst. Ljubljana, Yugoslavia	CuT 200 B With vs Without Strings	x				500 Sub-contract	500									
544	103	IUD 81/ 064	TFRA Mangrong District Hosp Buriram Province Thailand	Multiload Cu 375 vs TCu 380 Ag	x				0725 Subgrant	220									
544	618	IUD 81/ 065	TFRA MCH Center Chiang Mai, Thailand	Multiload Cu 375 vs TCu 380 Ag	x				0725 Subgrant	220									
544	695	IUD 81/ 066	TFRA MCH Center Khon Kaen, Thailand	Multiload Cu 375 vs TCu 380 Ag	x				0725 Subgrant	220									
560	332	IUD 82/ 010	J. Goldman Hasharon Hospital Petah Tikua, Israel	Delta LLD vs LLD Hand		x			2-10-82	200									
560	695	IUD 81/ 063	TFRA MCH Center Khon Kaen Prov. Thailand	Delta LLD vs LLD		x			0725 Subgrant	300									
5544	161	IUD 82/ 006	S. Jahan Khulna Sader Hospital Khulna, Bangladesh	Multiload Cu 250 vs CuT	x				0703 Subgrant	200									

INTERNATIONAL FERTILITY RESEARCH PROGRAM
STUDY STATUS LIST

STUDY AREA (circle one) PT MR FS MS (IUD) SYS

TYPE OF STUDY (circle one) COMP (STRAIGHT)

Planned DATE September 1982

STUDY NO	CLINIC NO	NO	CONTRIBUTOR NAME CLINIC LOCATION	DESCRIPTION OF STUDY	PATIENT CATEGORY INT	PP	PA	Date Active	DATE SA SIGNED	NO CASES APPROVED	Date Closed	FORMS RECEIVED ADM	FU 1	FU 2	FU 3	FU 4	FU 5	ML	Paper/CR
527	952	IUD 82/ 003	V. Georges Hufnagle Cedar - Sinai Los Angeles, CA, USA	Delta CuT		x			1-4-82	100									
594	100	IUD 82/ 011	I. Zighelboim Maternidad Concepcion Palacios Caracas, Venezuela	Wing Sound II	x					100									
594	218	IUD 82/ 008	R. Snowden Univ. of Exeter Exeter, England	Wing Sound II	x				1-15-82	600									
594	363	IUD 82/ 009	M. Toppozada Shatby Mat. Hosp. Alexandria, Egypt	Wing Sound II	x				1-15-82	150									
5507	0110	IUD 81/ 062	F. Romero Hosp. San Juan de Dios Lima, Peru	LLD		x	x		0960 Subgrant 1-4-82	400									
5527	0357	IUD 81/ 053	S. El Sahwi El Shatby Mat. Hosp. Alexandria, Egypt	Delta CuT Inserter		x			7-8-81	100									
5527	0777	IUD 81/ 056	B. Affandi Raden Saleh Clinic Jakarta, Indonesia	CuT 200B		x			10-8-81	300									
5531	0865	IUD 81/ 010	R. Bossemeyer Inst. of Rep. Health Santa Maria, Brazil	Delta LLD		x			12-1-80	250									

INTERNATIONAL FERTILITY RESEARCH PROGRAM

STUDY STATUS LIST

STUDY AREA (circle one) PT MR FS MS (IUD) SYS

TYPE OF STUDY (circle one) (COMP) STRAIGHT Active DATE September 1982

STUDY NO	CLINIC NO	NO	CONTRIBUTON NAME CLINIC LOCATION	DESCRIPTION OF STUDY	PATIENT CATEGORY INT	PP	P.	Date Active	DATE SA SIGNED	NO CASES APPROVED	Date Closed	FORMS RECEIVED ADM	FU 1	FU 2	FU 3	FU 4	FU 5	ML	Paper/CR
521	018	IUD 80/ 020	M. Thomas Hampshire Area Winchester, England	CuT 380 Ag vs Cu7	x			3-16-81	8-19-80	150		166	143	88	77	37	4		
521	609	IUD 80/ 014	R. Apelo Jose Fabella Hosp. Manila, Philippines	CuT 380 Ag vs Cu7	x			5-13-81	8-28-80	200		167	145	121	104	36	3		
528	704	IUD 79/ 036	F. Begum Dacca Medical College Dacca, Bangladesh	Delta LLD Hand vs Forceps		x		5-6-80	0703 Subgrant	240		240	239	201	175	70		234	
528	836	IUD 80/ 002	J. Nagahata Hosp. San Juan de Dias Lima, Peru	Delta LLD Hand vs Forceps		x		11-9-80	1-10-80	500		499	495	240	235				
528	848	IUD 80/ 001	A. Neto Hosp. de Cruz Vermelha Belo Horizonte, Brazil	Delta LLD Hand vs Forceps		x		7-15-80	1-09-80	240		214	175	155	154				
528	919	IUD 79/ 031	P. Stumpf Penn. State U. Hershey Medical Center Hershey, PA, USA	Delta LLD Hand vs Forceps		x		12-5-79	9-7-79	200		77	61	28	20	11	4	70	
530	086	IUD 81/ 013	X. Tacla Hosp. Barros Luco Santiago, Chile	CuT 200 B With vs Without Strings	x			8-7-81	1-27-81	100		60	57	48	49	27			
530	299	IUD 81/ 003	J. Cohen Clinique Marionan Paris, France	CuT 200 B With vs Without Strings	x			7-31-81	11-3-80	100		38	30	26	14				
544	022	IUD 80/ 007	L. Randic Family Planning Unit Rijeka, Yugoslavia	Multiload Cu 375 vs CuT 380 Ag	x			12-18-80	3-18-80	300		300	218	193	203	171	45		

INTERNATIONAL FERTILITY RESEARCH PROGRAM
STUDY STATUS LIST

STUDY AREA (circle one) PT MR FS MS (IUD) SYS

TYPE OF STUDY. (circle one) (COMP) STRAIGHT Active DATE September 1982

STUDY NO.	CLINIC NO	NO.	CONTRIBUTOR NAME CLINIC LOCATION	DESCRIPTION OF STUDY	PATIENT CATEGORY INT	PP	PA	Date Active	DATE SA SIGNED	NO CASES APPROVED	Date Closed	FORMS RECEIVED ADM	FU 1	FU 2	FU 3	FU 4	FU 5	ML	Paper/CR
544	081	IUD 80/ 048	J. Moreno Hosp. Santo Tomas Panama City, Panama	Multiload Cu 375 vs CuT 380 Ag	x			5-13-81	10-28-80	300		300	265	222	194	99			
544	340	IUD 81/ 025	S. Etman Misr Spinning and Weaving Hospital Mehalla-Kubra, Egypt	Multiload Cu 375 vs TCu 380 Ag	x			7-21-81	1-27-81	300		265	238	197	117	1			
544	831	IUD 80/ 047	C. Aranda CCSS San Jose, Costa Rica	Multiload Cu 375 vs CuT 380 Ag	x			8-7-81	11-17-80	300		265	230	185	146	21			
560	600	IUD 79/ 011	R. Apelo Jose Fabella Hospital Manila, Philippines	Delta LLD vs LLD Inserter		x		10-16-79	5-9-79	250		249	166	128	130	95	39	247	
562	852	IUD 79/ 024	P. Lavin Hosp. Barros Luco Santiago, Chile	Delta CuT vs CuT 220 Hand		x		6-17-80	5-31-79	300		258	246	97	63	6		256	
565	365	IUD 79/ 007	F. Abdel Salam Zagazig University Zagazig, Egypt	Delta LLD vs Delta CuT Hand		x		9-29-80	4-13-79	220		92	84	73	70	64	3	91	
565	739	IUD 79/ 009	T. Agoestina Hasan Sadikin Hosp. Bandung, Indonesia	Delta LLD vs Delta CuT Forceps and Inserter		x		9-11-79	4-11-79	220		129	97	70	48	20	2	129	
565	795	IUD 79/ 014	B. Mehra General Hospital Kuala Lumpur, Malaysia	Delta LLD vs Delta CuT Hand		x		10-23-80	4-13-79	220		152	63	52	25	24	2	106	
568	277	IUD 79/ 028	M. Thiery Univ. of Ghent Ghent, Belgium	Delta LLD vs Delta CuT vs CuT Inserter		x		12-17-79	6-29-79	1000		893	768	502	440	268	37	889	

INTERNATIONAL FERTILITY RESEARCH PROGRAM

STUDY STATUS LIST

STUDY AREA (circle one): PT MR FS MS (IUD) SYS

TYPE OF STUDY (circle one): (COMP) STRAIGHT

Active

DATE: September 1982

STUDY NO	CLINIC NO.	NO	CONTRIBUTOR NAME CLINIC LOCATION	DESCRIPTION OF STUDY	PATIENT CATEGORY INT	PP	PA	Date Active	DATE SA SIGNED	NO. CASES APPROVED	Date Closed	FORMS RECEIVED ADM	FU 1	FU 2	FU 3	FU 4	FU 5	ML	Paper/CR
584	600	IUD 78/ 009	R. Apelo Jose Fabella Hosp. Manila, Philippines	IPCS 52mg vs CuT Hand vs Inserter		x		10-18-79	6-22-78	200		200	157	132	132	90	12	198	
584	852	IUD 78/ 087	P. Lavin Hosp. Barros Luco Santiago, Chile	IPCS 52mg vs CuT Hand vs Inserter		x		12-26-78	6-22-78	400		400	328	223	212	189	161	366	CR 269 IUD 85
5527	356	IUD 81/ 030	H. Abdul Rahman El-Shatby Mat.Hosp. Alexandria, Egypt	Delta CuT Hand vs Inserter		x		3-9-82	2-10-81	150		147	107	56	54				
5527	371	IUD 81/ 031	S. El-Sadek Al-Zahra Hospital Cairo, Egypt	Delta CuT Hand vs Inserter		x		8-12-81	2-10-81	200		84	36						
5531	8003	IUD 81/ 024	L. de Albuquerque Materno Infantil de Rio Claro Rio Claro, Brazil	Delta LLD Hand vs Forceps		x		6-29-81	1-15-81	240		174	159	123	90				
5538	101	IUD 81/ 057	M. Acosta Maternidad de Lima Lima, Peru	TCu 200B vs LLD			x	2-11-82	0960 Subgrant 9-11-81	300		210	152	56	1				
5538	102	IUD 81/ 058	C. Guzman Med.Ctr. Carmen de la Legua Lima, Peru	TCu 200B vs LLD	x			3-15-82	0960 Subgrant 9-11-81	200		91	70	38	6				
5538	771	IUD 80/ 004	P.A.C. de Silva Health Unit Dehiwala, Sri Lanka	CuT vs LLD	x			9-19-80	0960 Subgrant 4-15-80	300		282	277	240	157	74	13		

INTERNATIONAL FERTILITY RESEARCH PROGRAM

STUDY STATUS LIST

STUDY AREA (circle one) PT MR FS MS (IUD) SYS

TYPE OF STUDY (circle one) (COMP) STRAIGHT Active

DATE: September 1982

STUDY NO	CLINIC NO.	NO	CONTRIBUTOR NAME CLINIC LOCATION	DESCRIPTION OF STUDY	PATIENT CATEGORY INT	PP	PA	Date Active	DATE SA SIGNED	NO. CASES APPROVED	Date Closed	FORMS RECEIVED ADM	FU 1	FU 2	FU 3	FU 4	FU 5	ML	Paper/CR
5544	704	IUD 80/ 039 82/ 004	F. Begum Dacca Med. College Dacca, Bangladesh	Multiload Cu 250 vs CuT	x		x	11-17-80	0703 Subgrant	300		300	300	293	275	253	3		
5544	721	IUD 80/ 032	F. Khanum Mohammadpur Model Clinic Dacca, Bangladesh	Multiload Cu 250 vs CuT	x		x	10-13-80	0703 Subgrant	300		298	262	198	153	120	2		
5544	786	IUD 82/ 005	A.B. Bhuiyan Rangpur Med.Coll.Hosp. Rangpur, Bangladesh	Multiload Cu 250 vs CuT	x			4-30-82	0703 Subgrant	200		50	49						
5562	264	IUD 81/ 037	C. Flamigni Univ. of Bologna Bologna, Italy	Delta CuT vs TCu 220C			x	1-22-82	4-14-81	200		109	71	7	2				
5565	8000	IUD 81/ 020	E. Darze Mat. Climerio Oliveira Salvador, Brazil	Delta LLD vs Delta CuT Inserter		x		9-16-81	1-8-81	300		275	239	135	87	15	2		

INTERNATIONAL FERTILITY RESEARCH PROGRAM

STUDY STATUS LIST

STUDY AREA: PT MR FS MS (IUD) SYS (circle one)

TYPE OF STUDY: COMP (STRAIGHT) (circle one)

Active

DATE: September 1982

STUDY NO	CLINIC NO.	NO.	CONTRIBUTOR NAME CLINIC LOCATION	DESCRIPTION OF STUDY	PATIENT CATEGORY			Date Active	DATE SA SIGNED	NO. CASES APPROVED	Date Closed	FORMS RECEIVED							Paper/CR
					INT	CP	PA					ADM	FU 1	FU 2	FU 3	FU 4	FU 5	ML	
527	916	IUD 81/ 038	J. Stryker Wayne State Univ. Detroit, MI, USA	Delta CuT		x		2-16-82	9-21-81	100		5	5	3					
527	957	IUD 80/ 017	P. Brenner USC Los Angeles, CA, USA	Delta CuT		x		4-8-81	8-11-80	100		95	89	60	52			89	
566	360	IUD 79/ 008	M. Mahran Ain-Shams Univ. Cairo, Egypt	Delta LLD Immed. and Early Forceps		x		5-7-79	4-11-79	260		353	146	96	36			264	
566	778	IUD 79/ 029	B. Laddawan Rasavithi Hospital Bangkok, Thailand	Delta LLD Immed. and Early Forceps		x		3-23-80	11-2-79	260		256	174	154	141	8		243	
594	850	IUD 82/ 007	R. Guzman-Serani Univ. Austral de Valdivia Valdivia, Chile	Wing Sound II	x			8-12-82	1-15-82	300		64	13					62	
5522	088	IUD 79/ 051	J. Zipper Hosp. Sotero del Rio Santiago, Chile	CuI	x			1-14-81	NA	100		98	88	69	53	37	16		
5526	304	IUD 81/ 032	K. Ustay Hacettepe Univ. Ankara, Turkey	CuT 200B	x			10-16-81	0960 Subgrant 2-10-81	200		154	154	144	104	46			
5526	354	IUD 81/ 033	M. El-Kholi Tanta Univ. Tanta, Egypt	CuT 200B	x			7-20-81	0960 Subgrant 2-10-81	200		84	84	83	19				
5527	309	IUD 81/ 028	E. Ezzeldin Hassan Menoufia Univ. Cairo, Egypt	Delta CuT Inserter		x		3-9-82	2-10-81	200		124	92	59	25				

INTERNATIONAL FERTILITY RESEARCH PROGRAM
STUDY STATUS LIST

STUDY AREA (circle one) PT MR FS MS (IUD) SYS

TYPE OF STUDY (circle one) COMP (STRAIGHT)

Active

DATE: September 1982

STUDY NO	CLINIC NO	NO.	CONTRIBUTOR NAME CLINIC LOCATION	DESCRIPTION OF STUDY	PATIENT CATEGORY INT	PP	PA	Date Active	DATE SA SIGNED	NO CASES APPROVED	Date Closed	FORMS RECEIVED ADM	FU 1	FU 2	FU 3	FU 4	FU 5	ML	Paper/CR
5527	333	IUD 81/ 026	A.M. El-Kady Baulak-El-Dakrour Cairo, Egypt	Delta CuT Midwife and Physician Hand		x		3-9-82	2-10-81	300		38							
5527	430	IUD 81/ 027	G. Nelson C.E.U.M. Hosp. Karawa, Zaire	Delta CuT: Inserter		x		4-22-81	1-23-81	250		142	124	70	36	7			
5531	303	IUD 81/ 042	Z. Durmus Ankara Maternity Hosp. Ankara, Turkey	Delta LLD Forceps		x		9-11-81	507 Sub-contract	600		194	103	34	12				
5531	304	IUD 81/ 043	H. Kisnisci Hacettepe Univ. Ankara, Turkey	Delta LLD Forceps		x		11-10-81	507 Sub-contract	600		360	231	104	26	1			
5531	322	IUD 81/ 044	B. Ustunel Zeynep Kamil Mat.Hosp. Istanbul, Turkey	Delta LLD Forceps		x		8-4-81	507 Sub-contract	600		233	163	59	23	2	1		
5531	323	IUD 81/ 045	Egean Univ. Hosp. Izmir, Turkey	Delta LLD Forceps		x		8-4-81	507 Sub-contract	600		217	167	42	16	1			
5531	324	IUD 81/ 046	Family Planning Clinic of Izmir Izmir, Turkey	Delta LLD Forceps		x		8-4-81	507 Sub-contract	600		85	48	12	2				
5531	325	IUD 81/ 047	Y. Tarikahya Zubeyde Hanim Mat.Hosp Ankara, Turkey	Delta LLD Forceps		x		12-11-81	507 Sub-contract	600		88	60	7	4				
5531	326	IUD 81/ 048	Afyon Mat. Hosp. Afyon, Turkey	Delta LLD Forceps		x		8-4-81	507 Sub-contract	600		72	53	11	2				

INTERNATIONAL FERTILITY RESEARCH PROGRAM

STUDY STATUS LIST

STUDY AREA (circle one) PT MR FS MS (IUD) SYS

TYPE OF STUDY (circle one) COMP (STRAIGHT)

Active

DATE September 1982

STUDY NO	CLINIC NO	NO	CONTRIBUTOR NAME CLINIC LOCATION	DESCRIPTION OF STUDY	PATIENT CATEGORY			Date Active	DATE SA SIGNED	NO CASES APPROVED	Date Closed	FORMS RECEIVED							Paper/CR
					INT	PP	PA					ADM	FU 1	FU 2	FU 3	FU 4	FU 5	ML	
5531	334	IUD 81/ 049	D. Ogur Suleymanive Mat.Hosp. Istanbul, Turkey	Delta LLD Forceps		x		8-4-81	507 Sub-contract	600		108	60	25	7				
5531	338	IUD 81/ 050	Saifi Basu Haseka Hospital Istanbul, Turkey	Delta LLD Forceps		x		8-4-81	507 Sub-contract	600		43	22	1					
5531	339	IUD 81/ 051	OB/GYN Dept. Ankara Univ. Hosp. Ankara, Turkey	Delta LLD Forceps		x		12-11-81	507 Sub-contract	600		53	20	4					
5531	817	IUD 82/ 001	D. Mendez Ministry of Health Hosp San Salvador, El Salvador	Delta LLD Forceps		x		3-2-82	12-12-81	130		23	9	3					
5531	825	IUD 81/ 014	R. Rivera Univ. Juarez Durango, Mexico	Delta LLD Hand		x		8-19-81	12-5-80	110		73	58	29	11	2			
5531	832	IUD 80/ 022	L. de la Vega Complejo Hosp. Metro. Panama City, Panama	Delta LLD Hand		x		2-9-81	10-1-80	150		153	144	100	68	2	2		
5531	861	IUD 81/ 036	R. Garcia Flores Univ. de Nuevo Leon Monterrey, Mexico	Delta LLD Forceps		x		9-17-81	4-15-81	110		69	27	7	1				
5531	886	IUD 81/ 035	J. Septien Private Practice Mexico City, Mexico	Delta LLD with Ring Forceps			x	8-20-81	4-15-81	110		108	106	72	39				

INTERNATIONAL FERTILITY RESEARCH PROGRAM
STUDY STATUS LIST

ACTIVE

Study Area: (circle one) (Sys) FB

Date: October 1, 1982

Study No.	Clinic No.	SP No.	Contributor Name Clinic Location	Description of Study	Patient Category			Ship Date 1st / Last	Date SA Signed	No. Cases Approv.	Date Closed	Forms Received/Loaded										PRESENT STATUS
					Int	PP	PA					ADM	FU	MON 1	MON 2	MON 3	MON 4	MON 5	MON 6	Symptom Grids	Phy. Exams	
807	075	76/351 R-6	Suporn Bangkok, Thailand	Comparative: Norinyl vs Brevicon vs Loestrin	x			6-10-80 / 7-9-82	4-30-79	300		267 / 267	768 / 738	1-2 / 237	3-4 / 198	5-6 / 166	7-8 / 4	9-10 / 4	11-12+ / 129		1018 / 978	A
825	358	78/107 R-3	Shaaban Assuit, Egypt	Comparative: Brevicon vs Loestrin	x			7-23-80 / 4-22-82	8-21-79	300		238 / 228	394 / 390	1	13	190	2	10	174	676 / 582		A
825	770	79/007 R-4	Hamid (Matron Sulaiman) Kelantan, Malaysia	Comparative: Nordette vs Loestrin	x			6-13-80 / 6-10-82	2-11-81	300		96 / 96	485 / 357	1-2 / 108	3-4 / 69	5-6 / 61	7-8 / 14	9-10 / 49	11-12+ / 56	223 / 212		Closing
835	048	79/012 R-1	Gerais (SFCA) Khartoum, Sudan	Crossover: Noriday vs Nordette	x			10-6-80 / 6-24-82	1-12-81	300		158 / 157	141 / 134	1	26	45	5	17	40	28 / 0	95 / 83	A
835	739	79/010 R-1	Agoestina Bandung, Indonesia	Crossover: Noriday &Neogynon to Brevicon & Nordette	x			9-11-80 / 5-18-82	2-12-79	600		324 / 273	341 / 236		27	105		25	79	479 / 400		A
850	066	79/004 R-4	Dacalos Cebu City, Philippines	Comparative: Norinyl vs Nordette	x		x	8-21-79 / 4-29-82	2-11-81	300		299 / 296	408 / 366	24	123	58	11	93	57	599 / 580		A
850	705	79/014	Jabeen Dacca, Bangladesh	Comparative: Noriday vs Brevicon vs Nordette	x			7-16-80 / 9-14-82	10-10-79	600		600 / 595	1086 / 1067	1	147	401		64	454	1665 / 1455		Closing

INTERNATIONAL FERTILITY RESEARCH PROGRAM
STUDY STATUS LIST

ACTIVE

Study Area: (circle one) (Sys) FB

Date: October 1, 1982

Study No.	Clinic No.	SP No.	Contributor Name Clinic Location	Description of Study	Patient Category			Ship Date 1st / Last	Date SA Signed	No. Cases Approv.	Date Closed	Forms Received/Loaded									PRESENT STATUS
					Int	PP	PA					ADM	FU	MON 1	MON 2	MON 3	MON 4	MON 5	MON 6	Symptom Grids	Phy. Exams	
350	706	79/002 R-2	S. Firoza Begum Dacca, Bangladesh	Comparative: Norinyl vs Brevicon vs Nordette	x			2-25-80 / 4-22-82	5-31-79	600		586 / 555	1068 / 1017		2	529	3	11	472	1653 / 1592		Closin
350	787	80/021 R-1	Khan Dacca, Bangladesh	Comparative: Norinyl vs Brevicon vs Nordette	x			4-10-81 / 9-8-82	8-11-80	600		599 / 597	856 / 846	2	2	435	10	4	393	1426 / 825		A

INTERNATIONAL FERTILITY RESEARCH PROGRAM
STUDY STATUS LIST

ACTIVE

Study Area: (circle one) (Sys) FB

Date: October 1, 1982

Study No.	Clinic No.	SP No.	Contributor Name Clinic Location	Description of Study	Patient Category			Ship Date	Date SA Signed	No. Cases Approv.	Date Closed	Forms Received/Loaded												PRESENT STATUS
					Int	PP	PA	1st / Last				ADM	FU	Mo 1	Mo 2	Mo 3	Mo 4	Mo 5	Mo 6	Mo 7	Mo 8	Mo 9	Mo 10	Mo 11	Mo 12	
875	340	80/024	Etman Mehalla-Kubla, Egypt	Lactation Progestogen-Only OCs		x		6-3-81 / 8-10-82	6-30-80	500		212 / 197	739 / 670	134	120	99	73	62	60	47	45	29	1			A
875	501	79/008	Patel Bombay, India	Lactation Progestogen-Only OCs		x		6-20-80 / 12-15-80	5-29-79	500		229 / 224	84 / 81	32	11	8	5	4	6	8	5	2				A
875	792	79/006	Yuliawiratnam (NFPB) Kuala Lumpur, Malaysia	Lactation Progestogen-Only OCs		x		6-27-80 / 7-9-82	10-15-79	500		193 / 185	380 / 368	56	57	47	44	41	40	29	33	21				A
875	871	80/023	Moggia Buenos Aires, Argentina	Lactation Progestogen-Only OCs		x		4-21-81 / 9-14-82	6-1-80	500		502 / 501	2454 / 2365	362	340	323	282	278	246	220	177	134	3			A
876	828	80/028	D. Betancourt Villa Hermosa, Mexico	Lactation Progestogen-Only OCs (IPAS-Organon)		x		7-2-80 / 9-27-82		225		232 / 217	1274 / 1176	173	176	193	185	184	193	59	4	9				Closin
876	885	80/027	L. Benitez Juarez, Mexico	Lactation Progestogen-Only OCs (IPAS-Organon)		x		4-6-81 / 3-10-82		225		181 / 180	1054 / 1053	179	180	180	180	61	165	6	1	101				Closin

INTERNATIONAL FERTILITY RESEARCH PROGRAM

STUDY STATUS LIST

Planned

Study Area: (circle one) (Sys) FB

Date: October 1, 1982

Study No.	Clinic No.	SP No.	Contributor Name Clinic Location	Description of Study	Patient Category			Ship Date	Date SA Signed	No. Cases Approv.	Date Closed	Forms Received/Loaded								Present Status
					Int	PP	PA	1st / Last				ADM	FU	Cycle 1 mo	Cycle 3 mo	Cycle 6 mo	Cycle 12 mo			
850	104	81/007	MCH Region 9, 'ALA Thailand	Comparative: Standard vs Low-dose OCs	x				7-2-81	200										P
850	105	81/008	Pimai District Hosp. Nakornrajasima, Thailand	Comparative: Standard vs Low-dose OCs	x				7-2-81	200										P
850	106	81/009	Prabhuddabaht Hosp. Saraburi, Thailand	Comparative: Standard vs low-dose OCs	x				7-2-81	200										P
850	107	81/010	Panasnikom Dist.Hosp. Chonburi, Thailand	Comparative: Standard vs low-dose OCs	x				7-2-81	200										P
850	686	81/006	Suan Dok Hospital Chiang Mai, Thailand	Comparative: Standard vs low-dose OCs	x				7-2-81	200										P

Planned

INTERNATIONAL FERTILITY RESEARCH PROGRAM
STUDY STATUS LIST

Study Area: (circle one) (Sys) FB

Date: October 1, 1982

Study No.	Clinic No.	SP No.	Contributor Name Clinic Location	Description of Study	Patient Category			Ship Date 1st / Last	Date SA Signed	No. Cases Approv.	Date Closed	Forms Received/Loaded								Present Status
					Int	PP	PA					ADM	FU	Cycle	Cycle	Cycle	Cycle			
8825	081	82/013	J. Moreno A. Hospital Santo Tomas Panama City, Panama	Comparative: Norinyl 1/35 vs Brevicon	x				-	300										P
8825	841	82/011	APROFAM Guatemala City, Guatemala	Comparative: Norinyl 1/35 vs Lo-Ovral	x				8-17-82	300										P
8825	871	82/015	Angel Moggia Jose Penna Hospital Buenos Aires, Argentina	Comparative: Norinyl 1/35 vs Lo-Ovral	x				8-24-82	300										P
8825	890	82/010	ASHONPLAFA Tegucigalpa, Honduras	Comparative: Norinyl 1/35 vs Brevicon	x				9-16-82	300										P
8825	8003	82/014	L. A. Albuquerque Rio Claro, Brazil	Comparative: Norinyl 1/35 vs Brevicon	x				8-20-82	300										P
8850	831	82/009	Cecilio Aranda San Jose, Costa Rica	Comparative: Norinyl 1/35 vs Norinyl 1/50	x				8-17-82	300										P
8850	869	82/012	Thelma Cetina Merida, Yucatan, Mexico	Comparative: Norinyl 1/35 vs Norinyl 1/50	x				7-28-82	300										P

INTERNATIONAL FERTILITY RESEARCH PROGRAM
STUDY STATUS LIST

Study Area: (circle one) Sys (FB) ACTIVE (NIH)

Date: October 1, 1982

Study No.	Clinic No.	SP No.	Contributor Name Clinic Location	Description of Study	Patient Category			Ship Date 1st / Last	Date SA Signed	No. Cases Approv.	Date Closed	Forms Received/Loaded												PRESENT STATUS
					Int	PP	PA					ADM	FU	Mo 1	Mo 2	Mo 3	Mo 4	Mo 5	Mo 6	Mo 7	Mo 8	Mo 9	Mo 10	Mo 11	Mo 12	
789	211	Sub # 195-2	Gary Stewart Planned Parenthood of Sacramento Sacramento, CA	Comparative: Sponge vs Diaphragm with Spermicide	x			6-15-81 / 9-9-82	12-23-81	200		199 / 199	385 / 356	29	49	74	33	40	20	18	27	24	13	16	13	A
789	226	Sub # 195-3	Richard Soderstrom The Mason Clinic Seattle, WA	Comparative: Sponge vs Diaphragm with Spermicide	x			5-7-81 / 8-16-82	1-28-81	100		96 / 96	198 / 188	8	19	37	17	13	23	7	12	23	7	6	16	A
789	213	Sub # 195-5	Helen Gilbert Central Iowa Family Planning Marshalltown, IA	Comparative: Sponge vs Diaphragm with Spermicide	x			4-21-81 / 8-18-82	1-24-81	60		61 / 61	136 / 132	24	28	19	6	8	16	5	7	6	3	5	5	A
789	919	Sub # 195-7	Paul Stumpf Hershey Medical Center Hershey, PA	Comparative: Sponge vs Diaphragm with Spermicide	x			9-4-81 / 9-15-82	2-2-81	60		59 / 55	100 / 92	3	18	24	10	7	11	4	4	4	2	2	3	A
789	215	Sub # 195-8	Carol Dunn Toledo Medical Services, Inc. Toledo, OH	Comparative: Sponge vs Diaphragm with Spermicide	x			5-7-81 / 8-5-82	1-27-81	60		52 / 51	64 / 63	14	7	13	5	1	4	5	3	5	1	3	2	A
789	223	Sub # 195-9	Martha Schultz P.P.of Minnesota St. Paul, MN	Comparative: Sponge vs Diaphragm with Spermicide	x			4-2-81 / 8-16-82	2-10-81	150		154 / 150	377 / 356	29	17	20	12	52	40	10	56	41	3	35	41	A
789	222	Sub # 195-10	Harry Foreman Minnesota Med. Foundation Minneapolis MN	Comparative: Sponge vs Diaphragm with Spermicide	x			5-13-81 / 6-3-82	2-24-81	150		155 / 150	225 / 223	13	24	39	33	31	24	12	6	4	1	15	21	A
789	225	Sub # 195-11	Alfred Poindexter, III Baylor College of Medicine Houston, TX	Comparative: Sponge vs Diaphragm with Spermicide	x			5-22-81 / 9-9-82	3-23-81	100		102 / 101	214 / 214	7	12	64	9	26	21	10	7	23	12	4	19	A

*Note: Follow-up schedule for study 789 is 3,6,9 and 12 months after admission to the study

INTERNATIONAL FERTILITY RESEARCH PROGRAM
STUDY STATUS LIST

Study Area: (circle one) Sys (FB) ACTIVE (NIH)

Date: October 1, 1982

Study No.	Clinic No.	SP No.	Contributor Name Clinic Location	Description of Study	Patient Category Int	PP	PA	Ship Date 1st / Last	Date SA Signed	No. Cases Approv.	Date Closed	Forms Received/Loaded ADM	FU	Mo 1	Mo 2	Mo 3	Mo 4	Mo 5	Mo 6	Mo 7	Mo 8	Mo 9	Mo 10	Mo 11	Mo 12	PRESENT STATUS
789	227	Sub # 195-12	Lillian Tereskiewicz Alameda-San Francisco PP San Francisco,CA	Comparative: Sponge vs Diaphragm with Spermicide	x			8-5-81 / 8-3-82	3-9-81	60		56 / 56	84 / 79	8	9	23	7	6	13	5	3	3	0	1	1	A
789	214	Sub # 195-13	Norma Goldberger Akron Women's Clinic Akron, OH	Comparative: Sponge vs Diaphragm with Spermicide	x			4-17-81 / 9-9-82	1-27-81	200		200 / 200	344 / 290	43	45	59	35	25	24	13	7	13	8	7	11	A
789	216	Sub # 195-15	Paula Daystar Womanwise Health care Denver, CO	Comparative: Sponge vs Diaphragm with Spermicide	x			4-9-81 / 8-16-82	2-6-81	120		125 / 125	307 / 273	13	36	56	6	26	32	21	16	28	11	9	19	A
789	210	Sub # 195-16	Lise Fortier PP World Population Los Angeles, CA	Comparative: Sponge vs Diaphragm with Spermicide	x			6-25-81 / 9-2-82	3-17-81	100		69 / 66	121 / 100	7	20	21	6	7	10	8	6	9	1	3	2	A
789	209	Sub # 195-17	Barbara North Healthworks, Inc So.Laguna Beach, CA	Comparative: Sponge vs Diaphragm with Spermicide	x			4-21-81 / 8-26-82	7-29-81	160		141 / 141	332 / 317	9	10	42	43	51	37	18	16	21	23	18	29	A

INTERNATIONAL FERTILITY RESEARCH PROGRAM
STUDY STATUS LIST

Study Area: (circle one) Sys (FB) NIH

Completed/Closed
Date: October 1, 1982

Study No.	Clinic No.	SP No.	Contributor Name Clinic Location	Description of Study	Patient Category Int	PP	PA	Ship Date 1st / Last	Date SA Signed	No. Cases Approv.	Date Closed	Forms Received/Loaded ADM	FU	Mo 1	Mo 2	Mo 3	Mo 4	Mo 5	Mo 6	Mo 7	Mo 8	Mo 9	Mo 10	Mo 11	Mo 12	Pape CR
789	212	Sub # 195-14	Sergio Stone California College of Medicine Univ. of Calif. So. Orange, CA	Comparative: Sponge vs Diaphragm with Spermicide	x			7-26 82 / 9-7 82	3-10-81	80		55 / 32	41 / 16	2	3	6	0	1	4							
797	973	Sub # 190-1	Thomas Kerenyi Mt. Sinai Medical Center New York, NY	Straight: Contracap	x			6-11 82 / 8-11 82	2-1-82	100		9 / 8	19 / 19	19												
797	974	Sub # 190-2	Roy Holly P P Assoc. of Wisconsin Milwaukee, WI	Straight: Contracap	x			12-23 81 / 8-26 82	8-31-81	100		95 / 67	102 / 81	42		23			16							
797	210	Sub # 190-3	Lise Fortier P P of Los Angeles Los Angeles, CA	Straight: Contracap	x			4-14 82 / 9-1-82	9-14-82	100		10 / 10	12 / 12	9		3										

INTERNATIONAL FERTILITY RESEARCH PROGRAM
STUDY STATUS LIST

Study Area: (circle one) Sys (FB)

Planned Date: October 1982

Study No.	Clinic No.	SP No.	Contributor Name Clinic Location	Description of Study	Patient Category			Ship Date	Date SA Signed	No. Cases Approv.	Date Closed	Forms Received/Loaded													PRESENT STATUS
					Int	PP	PA	1st / Last				ADM	FU	Mo 1	Mo 2	Mo 3	Mo 4	Mo 5	Mo 6	Mo 7	Mo 8	Mo 9	Mo 10	Mo 11	Mo 12	
782	772	FB 82/006	Khatun, A. Comilla Hospital Comilla, Bangladesh	Comparative: Secure vs NeoSamnoon	x				FCO 1103	200															P
784	619	FB 82/011	Mrs. Sunorn Suan Dok Hosp. Chiang Mai, Thailand	Comparative: Collatex vs Foam	x					100															P
785	309	FB 81/005	Hassan, E. Cairo, Egypt	Comparative: NeoSamnoon vs Foam	x				2-23-81	350															P
787	721	FB 81/002	Rahman, S. Dacca, Bangladesh	Comparative: NeoSamnoon vs Diaphragm	x				2-3-81	350															P
794	332	FB 82/012	Goldman, J. Hasharon Hosp. Petah Tikva, Israel	Comparative: Collatex vs OVT	x					200															P
795	039	FB 82/009	Nagui, A.R. Cairo Univer. Cairo, Egypt	Comparative: NeoSamnoon vs OVT vs EVT	x				8-24-82	210															P
795	315	FB 82/010	Younis, N. El-Galaa Mat. Hosp. Cairo, Egypt	Comparative: NeoSamnoon vs OVT vs EVT	x					210															P
795	359	FB 82/003	El-Maghoub, S. Ain Shams Univ. Cairo, Egypt	Comparative: NeoSamnoon vs OVT vs EVT	x				2-10-82	300															P

INTERNATIONAL FERTILITY RESEARCH PROGRAM
STUDY STATUS LIST

Study Area: (circle one) Sys (FB)

Active

Date: October 1982

Study No.	Clinic No.	SP No.	Contributor Name Clinic Location	Description of Study	Patient Category Int	PP	PA	Ship Date 1st / Last	Date SA Signed	No. Cases Approv.	Date Closed	Forms Received/Loaded ADM / FU	Mo 1	Mo 2	Mo 3	Mo 4	Mo 5	Mo 6	Mo 7	Mo 8	Mo 9	Mo 10	Mo 11	Mo 12	PRESENT STATUS
782	704	79/004	Begum, S.F. Dacca, Bangladesh	Comparative: Collatex vs Neo-Sampoon	x			6-4-80 / 9-14-82	1-17-80	350		348 / 342	438 / 423	184		95			82					62	A
782	786	82/005	Bhuiyan, A.B. Pangpur, Bangladesh	Comparative: Collatex vs Neo-Sampoon	x			6-10-82 / 6-10-82		6m Fup 200		12 / 0	0 / 0												A
783	272	81/006	Lefebvre, J. Montreal, Canada	Comparative: Collatex vs Diaphragm	x			11-17-81 / 9-17-82	6-1-82	300		170 / 164	314 / 285	177		79			38						A
783	298	79/006	Guillebaud, J. London, England	Comparative: Collatex vs Diaphragm	x			7-25-80 / 9-17-82	6-4-81	250		248 / 247	681 / 651	230		156			159					106	A
784	332	81/015	Goldman, J. Petah Tikva, Israel	Comparative: Collatex vs Foam	x			1-20-82 / 9-27-82	6-22-81	350		350 / 350	582 / 499	387		110			2						A
785	020	81/014	Andolsek & Kozuh Ljubljana, Yugoslavia	Comparative: Neo-Sampoon vs Foam	x			4-2-82 / 9-27-82	6-22-81	350		57 / 55	83 / 73	47		26									A
785	360	80/012	Mahran, M. Cairo, Egypt	Comparative: Neo-Sampoon vs Foam	x			1-5-81 / 8-26-82	12-6-79	350		253 / 243	114 / 109	69		24			13					3	A
785	368	80/013	Youssef, H. Alexandria, Egypt	Comparative: Neo-Sampoon vs Foam	x			2-18-81 / 6-23-82	4-16-80	350		349 / 349	925 / 894	354		191			252					97	A

INTERNATIONAL FERTILITY RESEARCH PROGRAM
STUDY STATUS LIST

Study Area: (circle one) Sys (FB) Active Date: October 1982

Study No.	Clinic No.	SP No.	Contributor Name Clinic Location	Description of Study	Patient Category			Ship Date	Date SA Signed	No. Cases Approv.	Date Closed	Forms Received/Loaded												PRESENT STATUS
					Int	PP	PA	1st / Last				ADM	FU	Mo 1	Mo 2	Mo 3	Mo 4	Mo 5	Mo 6	Mo 7	Mo 8	Mo 9	Mo 10	Mo 11	Mo 12	
786	043	81/013	Gyamfi, A. Accra, Ghana	Comparative: Neo-Sampoon vs EVT	x			11-11-81 / 9-1-82	6-23-81	200		82 / 62	84 / 70	34		19			17							A
786	365	81/021	Abdelsalaam, A.F Zagazig, Egypt	Comparative: Neo-Sampoon vs EVT	x			5-10-82 / 9-22-82	9-21-81	200		100 / 100	179 / 66	66												A
786	841	81/023	APROFAM Guatemala City Guatemala	Comparative: Neo-Sampoon vs EVT	x			6-10-82 / 8-31-82		200		65 / 64	27 / 26	25		1										(on hold) A
786	890	82/007	ASHONPLAFA Tegucigalpa, Honduras	Comparative: Neo-Sampoon vs OVT	x			6-23-82 / 8-16-82		200		17 / 15	10 / 8	6		2										A
786	8022	81/016	Larranaga, A. Lima, Peru	Comparative: Neo-Sampoon vs EVT	x			3-11-82 / 7-15-82	7-30-81	300		34 / 24	0 / 0													A
793	222	82/002	Foreman, H. Minnesota Med. Found. Minneapolis, Minn. USA	Comparative: OVT vs EVT	x			7-8-82 / 9-20-82		160		5 / 5	0 / 0													A
793	225	82/004	Poindexter, A. Baylor Med. College Houston, TX USA	Comparative: OVT vs EVT	x			6-21-82 / 9-9-82	2-16-82	160		23 / 7	2 / 0													A
793	907	82/003	Berger, G. CRH Chapel Hill, NC USA	Comparative: OVT vs EVT	x			3-11-82 / 8-11-82		160		25 / 20	11 / 10	5		5										A

INTERNATIONAL FERTILITY RESEARCH PROGRAM
STUDY STATUS LIST

Study Area: (circle one) Sys (FB) . Active Date: October 1982

Study No.	Clinic No.	SP No.	Contributor Name Clinic Location	Description of Study	Patient Category Int	PP	PA	Ship Date 1st / Last	Date SA Signed	No. Cases Approv.	Date Closed	Forms Received/Loaded ADM / FU	Mo 1	Mo 2	Mo 3	Mo 4	Mo 5	Mo 6	Mo 7	Mo 8	Mo 9	Mo 10	Mo 11	Mo 12	PRESENT STATUS
795	044	81/020	Boohene, E. Accra, Ghana	Comparative: Neo-Sampoon vs OVT vs EVT	x			2-25-82 / 9-1-82	9-3-81	300		233 / 232	81 / 76	67		8		1							A
795	295	82/00	Lavelly, K. Marie Stopes House London, England	Straight: Non-spermicide fit-free diaphragm	x			3-24-82 / 3-24-82	11-3-81	450		15 / 10	7 / 5					5							A

INTERNATIONAL FERTILITY RESEARCH PROGRAM

STUDY STATUS LIST

STUDY AREA (circle one) PT MR (FS) MS IUD SYS

TYPE OF STUDY (circle one) COMP (STHAIGHT) Active

DATE October 1982

STUDY NO	CLINIC NO	NO.	CONTRIBUTOR NAME CLINIC LOCATION	DESCRIPTION OF STUDY	PATIENT CATEGORY INT	PP	PA	Date Active	DATE SA SIGNED	NO CASES APPROVED	Date Closed	FORMS RECEIVED ADM	FU 1	FU 2	FU 3	FU 4	FU 5	ML	Paper/CR
6900	Multi center	FS82/ 001	S. Chater ONPFP Tunis, Tunisia	Surveillance: Laparoscopy, ligation	x			8-9-82	0067 Subgrant	1500		308	124	56					
6900	0023	FS80/ 012	Dr. E. Borko Maribor Gen. Hospital Maribor, Yugoslavia	Seeuclip and Tubal Ring	x	x	x	8-31-82	4-28-80	200		38	35	37					
6900	0370	FS81/ 008	Dr. El Katsha Ahmed Maher Hosp. Cairo, Egypt	Laparoscopy: Tubal Ring	x			3-9-82	0960 Subgrant	300		10		7					
6900	0430	FS81/ 003	Dr. Duale C.E.U.M. Hospital Karawa, Zaire	Surveillance: All approaches, all techniques	x	x		3-15-82	0660 Subgrant	200		35	31	33					
6900	0865	FS81/ 001	Dr. R. Bossenmeyer S.M. Institute of Reproductive Health Santa Maria, Brazil	Surveillance: Laparoscopy, Tubal Ring and Minilap, Pomeroy	x			2-2-82	0960 Subgrant	300		106	104	106					
6900	8020	FS81/ 007	Dr. H. Aguinaga CPAIMC Rio de Janeiro, Brazil	Laparoscopy: Tubal Ring	x			2-11-82	0960 Subgrant	2000		1226	1134	836	205				
6902	0160	FS82/ 002	Dr. T.R. Chaudury MCH Hospital Sylhet, Bangladesh	Surveillance: Minilap	x	x	x	6-9-82	1103 Subgrant	150		81	81	81					
6902	0162	FS82/ 003	Prof. K.R. Choudhury BAVS Clinic Rajshahi, Bangladesh	Surveillance: Minilap	x	x	x	4-30-82	1103 Subgrant	200		199	199	175					
6902	0163	FS82/ 004	Dr. S.M. Aslam Belishwar Mat.Centre Dhamrai, Bangladesh	Surveillance: Minilap	x	x	x	6-24-82	1103 Subgrant	200		157	156	157					

INTERNATIONAL FERTILITY RESEARCH PROGRAM

STUDY STATUS LIST

STUDY AREA (circle one): PT MR (FS) MS IUD SYS

TYPE OF STUDY (circle one): COMP (STRAIGHT)

Active

DATE: October 1982

STUDY NO	CLINIC NO.	NO.	CONTRIBUTOR NAME CLINIC LOCATION	DESCRIPTION OF STUDY	PATIENT CATEGORY			Date Active	DATE SA SIGNED	NO. CASES APPROVED	Date Closed	FORMS RECEIVED							Paper/CR
					INT	PP	PA					ADM	FU 1	FU 2	FU 3	FU 4	FU 5	ML	
6902	0718	78/ 013/3	Dr. J.A. Chowdhury Inst. of Postgrad. Medicine Dacca, Bangladesh	Surveillance: All techniques	x	x	x	9-10-79	1103 Subgrant	300		252	249	3					

INTERNATIONAL FERTILITY RESEARCH PROGRAM

STUDY STATUS LIST

STUDY AREA (circle one) PT MR (FS) MS IUD SYS

TYPE OF STUDY (circle one) (COMP) STRAIGHT Active

DATE October 1982

STUDY NO	CLINIC NO.	NO.	CONTRIBUTOR NAME CLINIC LOCATION	DESCRIPTION OF STUDY	PATIENT CATEGORY INT	PP	PA	Date Active	DATE SA SIGNED	NO CASES APPROVED	Date Closed	FORMS RECEIVED ADM	FU 1	FU 2	FU 3	FU 4	FU 5	ML	Paper/CR
670	781	77/077	Dr. F. M. Chen Tri-Service Gen.Hosp. Taipei, Taiwan	Long-term Fu only Laparotomy: Pomeroy vs. Tubal Ring		x		9-17-82	10-2-81	500							79		
6051	0075	78/007	Dr. Supor . Koetsawang Siriraj Hospital Bangkok, Thailand	Open laparoscopy using laprocator: topical anesthesia vs. no topical anesthesia	x			6-18-79	9-7-78	400		198	193	2				198	
6252	0831	FS79/018.	Dr. C. Aranda Hospital Mexico (CCSS) San Jose, Costa Rica	Minilap: Rocket Clip vs. Tubal Ring	x			1-28-80	6-14-79	300		300	295	298	297	90		300	
6256	0739	FS81/012	Dr. J. Thouw Hasan Sidikin Hosp. Bandung, Indonesia	Minilap: Secuclip vs. Tubal Ring	x			5-18-82	7-13-81	200		23	13	3				23	

INTERNATIONAL FERTILITY RESEARCH PROGRAM

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STUDY AREA (circle one) PT MR (FS) MS IUD SYS

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DATE October 1982

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					INT	PP	PA					ADM	FU 1	FU 2	FU 3	FU 4	FU 5	ML	
Multi	0075	FS81/014	Dr. Suporn Koetsawang Siriraj Hospital Bangkok, Thailand	Long-term follow-up of tubal ring and cautery cases, straight and comparative studies	x					500									

INTERNATIONAL FERTILITY RESEARCH PROGRAM

STUDY STATUS LIST

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					INT	PP	PA					ADM	FU 1	FU 2	FU 3	FU 4	FU 5	ML	
630	730	77/209	Dr. A. Rahman Khan Thana Health Complex Tangali, Bangladesh	Long-term Fu only Minilap: Pomeroy or Tubal Ring	x				7-8-81	300									
6901	0679	FS80/022	TFRA Royal Thai Army Hosp. Bangkok, Thailand	Surveillance: open vs closed laparoscopy	x				0725 Subgrant	200									
6901	0686	FS80/021	TFRA Chiang Mai University Chiang Mai, Thailand	Surveillance: open vs closed laparoscopy	x				0725 Subgrant	200									
6901	0688	FS80/020	TFRA Rajauithi Hospital Bangkok, Thailand	Surveillance: open vs closed laparoscopy	x				0725 Subgrant	200									
6901	0689	FS80/019	TFRA Chulalongkorn Hosp. Bangkok, Thailand	Surveillance: open vs closed laparoscopy	x				0725 Subgrant	200									

INTERNATIONAL FERTILITY RESEARCH PROGRAM

STUDY STATUS LIST

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701	771	MS80/001	P.A.C. de Silva Health Unit Dehiwala, Srl Lanka	Excision and Ligation				12-8-80	0960 Subgrant	500		492	1						
701	858	MS81/003	M. de Castro Propater Vasectomy Clinic Sao Paulo, Brazil	Surveillance of Excision and Ligation including supplemental form				12-3-81	7-8-81	1000		998	725	10					CR 360

Appendix H

Completed Consultant Reports (CRs)
16 September 1981 - 15 September 1982

Title	Prepared for	Center #	Study #
Female Sterilization by Minilaparotomy using the Modified Pomeroy Technique	M.A. Quader	722	6902/6906
A Comparison of the Copper T and Copper 7, Family Planning Institute, Ljubljana, Yugoslavia	L. Andolsek	020	418
Evaluation of the Copper T 200 in Interval Women in Cairo, Egypt	F. Hefnawi	351	460
Evaluation of the Szontagh Intrauterine Device in a Retrospective Study of Interval Women in Szeged, Hungary	J. Annus	221	423
Analysis of the Intravaginal Insert- Univ. of Texas - Health Science Center at San Antonio	M.M. Ahmad	916	788
A Retrospective Evaluation of the Copper T 200 and the Copper T 300 Intrauterine Devices in Bangkok, Thailand	A. Somboonsuk	714	417
Evaluation of the Multiload Cu 250, CuT 200, with vs without Prophylactic Antibiotics	L. Randic	022	542
A Comparative Study of Vasectomy Performed with vs without Prophylactic Antibiotics	Atiqur Rahman Khan	721	730
A Comparative Study of the Standard Intrauterine and the Medium Intrauterine Membrane in Panevo, Yugoslavia	Z. Paravic	240	491
Evaluation of the Spring Coil and Dalkon Shield, Hacettepe University Ankara, Turkey	H. Kisnisci	304	403/407
Evaluation of the Lippes Loop C Southwestern University Cebu City, Philippines	E. Dacalos	066	410

A Comparison of the Lippes Loop C and Lippes Loop D, Centro Investigaciones Regionales, Merida, Mexico	T. Canto de Cetina	0869	0507
Surveillance of Female Sterilization Panama City, Panama	Lasso de la Vega	0832	6900
Female Sterilization vs Minilaparotomy and Suprapubic Endoscopy using Tubal Rings	R. Bhatt	058	6002
Surveillance of Female Sterilization in Khartoum, Sudan	H. Rushwan	0049	6900
Female Sterilization by Minilaparotomy Using the Modified Pomeroy Technique	Nazimuddia Ahmed	702	6902
A Comparative Study of Minilaparotomy Performed with vs without Topical Anesthesia	E. Moran Caceres	824	6052
Surveillance of Female Sterilization by Minilaparotomy	Sufia Khatun	719	6902
Evaluation of the Laprocator with Minilaparotomy	Ruben Apelo	600	6002
Female Sterilization by Minilaparotomy using the Modified Pomeroy Technique, Rangpur, Bangladesh	Bhuiyan	786	6902
A Comparative Study of Minilaparotomy Female Sterilization by the Pomeroy Technique vs Tubal Ring	A. Firoza Begum	704	670
Female Sterilization by Minilaparotomy using the Modified Pomeroy Technique BFRP Model Clinic Chittagong, Bangladesh	Mirza Islam	704	6902
A Comparative Study of the Lippes Loop D and the Delta Loop in Assuit, Egypt	M. Shabaan	047	539
Surveillance of Female Sterilization Dacca, Bangladesh	Suraiya Jabeen	0705	6902
Surveillance of Female Sterilization Yogayakarta, Indonesia	R. Suprono	0767	6900
Surveillance of Female Sterilization in Freetown - Sierra Leone	Jarrett	415	6900
A Comparative Study of Laparoscopy vs Minilaparotomy	A. Letchworth	290	636

Nonsurgical Method of Female Sterilization with Quinacrine Hydrochloride Pellets at the Dacca Medical College Hospital, Bangladesh	S. Firoza	704	666
Nonsurgical Female Sterilization with Quinacrine Hydrochloride Pellets at Sir Salimullah Medical College Hospital Dacca, Bangladesh	Suraiya Jabeen	705	666
Nonsurgical FS with Quinacrine Hydrochloride Pellets at Dacca Medical College Hospital Bangladesh	Prof. Mukhleswr Rahman	714	666
A Comparative Study of Laparotomy Female Sterilization by the Pomeroy Technique vs the Tubal Ring			
A Comparison of the Multiload Copper 375 and Mini Multiload Copper 250 University Hospital, Essen, Germany	Peter Tauber	250	545
A Report on Obstetric Deliveries Chittagong Medical College Hospital Chittagong, Bangladesh	S.N. Bhuiyan	728	903
Male Sterilization by Excision and Ligation at the MCH Model Clinic, Chittagong	S.N. Bhuiyan	701	701
A Comparative Study of Minilaparotomy Female Sterilization by the Rocket Clip vs the Tubal Ring	Dra. D. de Badia	823	6252
Evaluation of the Delta T in Post-partum Women, San Antonio, Texas	Carl Pauerstein	961	527
Evaluation of Post Cesarean-Section Insertion of Copper T 200	P. Lavin	852	599
Surveillance of Female Sterilization Surabaya, Indonesia	M. Harjono	769	6900
Male Sterilization by Excision and Ligation at the Model Clinic, Dacca Bangladesh	Major M.S. Rahman	721	701
Male Sterilization by the Schmidt Technique using the Vaseal Unit at the USC Medical School, Los Angeles, California	G. Bernstein	957	717

Female Sterilization by Minilaparotomy and Suprapubic Endoscopy using the Laprocator	B. Mehra	795	6002
Surveillance of Female Sterilization Moshi, Tanzania	C.P. Semiono	0490	6900
Evaluation of Insertion Technique of the Delta TCu in David, Panama	Julio Contreras	083	527
A Crossover Study from Standard-Dose to Low-Dose Combined Oral Contraceptiives, San Salvador, El Salvador	Asociacion Demografica Salvadorena	821	835
Evaluation of the Collagen Sponge in Three Centers	PARFR	026,298 907	780
Comparative Study of the Copper T 380 Ag and the Multiload Cu 375 in Belgrade, Yugoslavia	B. Behlilovic	024	544
Surveillance of Male Sterilization in Sao Paulo, Brazil	M. de Castro	858	701