

BIBLIOGRAPHIC DATA SHEET

1. CONTROL NUMBER

PN-AAJ-337

2. SUBJECT CLASSIFICATION (100)

PC00-0000-0000

3. TITLE AND SUBTITLE (300)

International Fertility Research Program, annual report, 1979/1980

4. PERSONAL AUTHORS (100)

5. CORPORATE AUTHORS (101)

Int. Fertility Research Program

6. DOCUMENT DATE (110)

1980

7. NUMBER OF PAGES (120)

50p.

8. ARC NUMBER (170)

613.943.I61b-79/80

9. REFERENCE ORGANIZATION (130)

IFRP

10. SUPPLEMENTARY NOTES (500)

11. ABSTRACT (950)

12. DESCRIPTORS (920)

Fertility

Birth control

Family planning

Research

Contraceptives

Sterilization

13. PROJECT NUMBER (120)

932053700

14. CONTRACT NO.(140)

AID/pha-C-1172

15. CONTRACT TYPE (140)

16. TYPE OF DOCUMENT (160)

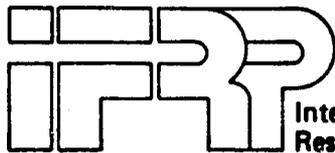
52

613.943
I616
1979/1980

PN-AAJ-33

ANNUAL REPORT
AID/pha-C-1172

August 1, 1979—July 31, 1980



International Fertility Research Program
Research Triangle Park, NC 27709 USA

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I. INTRODUCTION

IFRP research under AID/pha-C-1172 has, as a primary objective, the evaluation of fertility control methods and technology appropriate to the developing world. To meet this specific objective the IFRP carries out a substantial part of its research activities in developing countries. Even those projects that are not conducted in developing country settings yield results and provide information that is important to the future of family planning programs around the world. It is hoped that the IFRP research initiatives under contract 1172 will continue to provide answers to questions on the efficacy, safety and benefits of contraception vital to effective family planning activities.

This report on contract AID/pha-C-1172 covers the period from August 1, 1979 through July 31, 1980. The contract was initiated August 3, 1977 and amended to extend through July 31, 1981. During the period covered by this report, the IFRP continued its work related to the evaluation of the safety and efficacy of new and existing methods of contraception in clinical Phase III and IV (postmarketing) field trials. Work on postpartum IUDs and the further simplification of female voluntary sterilization was especially productive. The organization also placed emphasis on the risks and benefits of family planning and long-term safety issues. The IFRP's efforts in disseminating information related to contraception were intensified with good results. As anticipated, studies of long-term contraceptive risks and benefits required a larger share of contract resources. Projects encompassing multiple research areas

made the IFRP's work more varied and are better utilizing its considerable professional resources.

II. RESEARCH AREAS

Projects in the six major areas of IFRP clinical research (male and female sterilization, pregnancy termination, intrauterine devices, systemic contraception and barrier contraception) continued during the year. Work in these areas included the development of study strategies, forms and protocols, the initiation of studies, and the collection, processing and analyses of data. It also included the reporting of research findings through appropriate publications, reports to the investigators or presentations at scientific meetings. Appendix A lists completed documents in the various clinical research areas and Appendix B lists the completed computer programs and systems. Appendix C lists the type and number of forms processed within each research area.

A. Surgical Female Sterilization

Voluntary sterilization is now the single most important method of family planning worldwide. However, access to female sterilization often remains limited due to the complexity of the current operation and the need for specialist training.

Throughout the contract year, the IFRP continued the collection of data on laparator studies which include four studies of open laparoscopy with room air insufflation, four of suprapubic

endoscopy (modified minilap with the Hasson trocar and blunt cannula), one of open laparoscopy with topical tubal anesthesia and one of suprapubic endoscopy with topical tubal anesthesia.

Preliminary analysis of the lapractor studies, based on 1511 procedures (1026 laparoscopies and 485 suprapubic endoscopies), indicated that there have been 25 technical failures, 7 in the open laparoscopy series and 18 in the suprapubic endoscopy series. The rate of surgical difficulties was 3.8% with open laparoscopy and 3.6% with suprapubic endoscopy. The most common surgical difficulties encountered involved entering the peritoneum and visualizing, grasping and occluding the tubes. There were 12 surgical injuries in the laparoscopy series and 4 in the suprapubic endoscopy series, the most common being tubal injury (0.7% and 0.4%, respectively) and uterine perforation (0.3% and 0.2%, respectively).

Some investigators participating in the lapractor studies reported equipment problems to the IFRP. As a result, all investigators are now requested to submit written reports evaluating the lapractor.

Another major research emphasis in the surgical female sterilization area was the collection of data from four Rocket Clip studies. Analysis of preliminary data from one study comparing the Rocket Clip to the tubal ring revealed 11 technical failures, ten with the ring and one with the Rocket Clip. Ring failures were due to thick tubes, ovarian cysts, obesity and

adhesions; the one clip failure was caused by bilateral abscesses. Surgical difficulties were encountered in 29.3% of the tubal ring procedures and 24.3% of the Rocket Clip procedures. In both groups, the most frequently encountered difficulty was visualization of the tubes. Surgical injuries occurred in 9.3% of the ring patients and 2.9% of the clip patients; all were tubal injuries. Most of the early follow-up complications were related to incision problems. There were no pregnancies reported within six months after sterilization.

In addition to the evaluation of the short-term complications for surgical female sterilization, the IFRP continues to collect long-term follow-up data on women sterilized by different occlusive techniques and using different approaches to the fallopian tubes. The data now available in the IFRP's substantial data bank have made possible a more extensive and accurate analysis of accidental pregnancy following voluntary sterilization. Several IFRP publications on this topic are found in Appendix E.

Plans for future clinical trials include evaluation of the Bleier Clip, the Filshie Clip and potentially reversible methods of sterilization such as the Teflon Sleeve and the Fimbrial Hood.

B. Nonsurgical Female Sterilization

The follow up of women in clinical trials of the transcervical insertion of quinacrine pellets continues. Pellets were inserted in 262 women at three clinics. Five pregnancies were reported; three before completion of the insertion schedule and two after completion of the insertion schedule.

Blood and saliva samples were obtained from 11 women who underwent pellet insertion; samples are being analyzed to determine the amount of quinacrine in the saliva and blood within 48 hours after insertion of the pellets.

In an effort to further simplify nonsurgical sterilization and occlude the tubes with a simple procedure, the IFRP conducted a study of quinacrine-loaded IUDs (TCu-220 Cs over which a mixture of 80% quinacrine and 20% polyethyleneoxide was molded) as a means of permanent sterilization. The quinacrine mixture goes into solution within four hours. These IUDs were inserted in 25 menstruating women awaiting hysterectomy for uterine prolapse. Extirpated uteri were examined to determine the presence of sclerosing lesions in the intramural portion of the tubes. The first 8 devices had 75 mg of quinacrine at the end of each arm and a bolus of 150 mg on the stem. In an effort to find out if the bolus contributed to occlusion, the next 17 cases had only 75 mg per arm. These IUDs produced results similar to those found with the larger dose. As with quinacrine pellets, the IUDs were not uniformly effective in delivering

the quinacrine to the uterotubal junction. The erratic occlusion seemed to be a function of the placement of the IUD. The IUDs were inserted with the arms bent upward.

Under subcontracts from the IFRP, investigators at the Johns Hopkins University are currently conducting research on the toxicology and teratology of quinacrine that will provide information to be used in obtaining a Claimed Investigational Exemption for a New Drug (IND) for the use of quinacrine hydrochloride as a sclerosing agent. After an IND is obtained, the IFRP expects to conduct additional limited clinical trials of quinacrine using several different IUD configurations as carriers for the quinacrine.

In addition, another quinacrine hydrochloride related subcontract was awarded to the University of North Carolina School of Pharmacy to prepare quinacrine tablets of different strengths that will dissolve at varying rates. The data obtained will also be used in the preparation of the IND for submission to the US Food and Drug Administration.

C. Male Sterilization

Vasectomy has been proven to be safe, effective and inexpensive. At present, the IFRP is not conducting trials of any new method of male sterilization. However, the IFRP plans to prepare a document describing the experience and current status of the use of paramedical personnel for delivery of vasectomy

services around the world. It is significant because the use of paramedical personnel to perform vasectomies could prove to be more productive than the use of improved techniques of vasectomy.

In addition, the IFRP is continuing to follow the developments made on two percutaneous methods of male sterilization currently funded by PARFR, with a view toward conducting Phase II clinical trials in the future. Contacts have also been made with the Peoples Republic of China with regard to work in that country on percutaneous male sterilization.

The IFRP awarded a subcontract to the Kaiser Research Foundation for a retrospective cohort study that will examine the association between prior vasectomy and a number of hospitalized illnesses. The objectives of this study are to examine the rates of hospitalized illnesses and relative risks of individual diseases grouped by organ systems and by underlying pathophysiologic mechanisms in relation to vasectomy, duration of vasectomy, and age at vasectomy. The research is relevant because there is increasing concern over possible serious unanticipated adverse effects of vasectomy. The project was initiated toward the end of the contract year.

D. Abortion, Menstrual Regulation and Pregnancy Testing

An evaluation of two pregnancy tests, the capillary tube and Dri Dot, is 75% complete. A report, based on data of 556 women

in three separate clinics, was prepared for AID. The women were classified by the number of days from onset of last menstrual period (LMP) to day of pregnancy test. Preliminary analysis shows that the pregnancy tests were less accurate in the ≤ 42 days LMP group for the true positive rates and the overall accuracy rates than in the later groups. In the ≤ 42 days LMP group there was no difference in the overall accuracy rate for the Dri Dot test and the capillary tube test.

The IFRP has been negotiating with Schering AG, Upjohn and May and Baker to obtain prostaglandin (PG) analogues to evaluate their use for uterine evacuation within two weeks of the first missed menstrual period.

Work in other aspects of the field of abortion has been highly selective. In response to requests by physicians working in countries where abortion is available, research has been initiated in an attempt to further reduce the dangers of abortion when done with limited medical facilities. The use of an intraamniotic injection of 10% saline is being evaluated in Yugoslavia. Another study is being conducted in which the insertion of laminaria is followed by the intraamniotic injection of 80 gm of urea and 5 mg of $\text{PGF}_{2\alpha}$.

Although recruitment of centers has not yet been completed, a multicenter trial of a modification of the gynecological syringe using a double valve that accepts 12 mm cannulae has been initiated.

A newly devised synthetic osmotic cervical dilator is being evaluated in a 50-case multicenter trial. This synthetic dilator, composed of a polyvinyl alcohol sponge saturated with magnesium sulfate and compacted, promises to be not only easier and cheaper to manufacture but also to offer a wider range of well controlled clinical uses than natural laminaria.

E. Intrauterine Devices

The IFRP is evaluating several types of IUD modifications which should result in improved IUD performance and acceptability. Modifications include: postpartum IUDs that reduce the risk of expulsion, medicated IUDs to reduce bleeding without reducing the device's effectiveness against pregnancy and tailless IUDs to reduce the risk of infection.

The IFRP continued the clinical trial of the postpartum insertion of modified IUDs. The modification consists of adding biodegradable extensions of #2 chromic gut sutures to Lippes Loop D and TCU-220C IUDs. An Investigational Device Exemption (IDE) and a Claimed Investigational Exemption of a New Drug (IND) were prepared and submitted to the Food and Drug Administration (FDA) during the contract year for the modified devices. As a result of an objection from the FDA, the names of the postpartum IUDs were changed from Sutured-Loop and Sutured-T to Delta-Loop and Delta T.

Thirty centers have been recruited in twenty countries for the 9,000 case clinical trial of the Delta IUDs. Preliminary data show the following results from comparative studies:

Comparative Studies	Three-month (Life Table) Expulsion Rates (per 100 women)
Lippes Loop D vs Delta Loop	21.4
TCu 220C vs Delta T	15.5
Delta Loop vs Delta T	14.4
	9.8
	6.5
	7.4

The IFRP is also recruiting centers in the United States to conduct studies of the Delta IUDs under the approved IND and IDE. Studies will be initiated during the coming year.

If results of the Delta IUD clinical trials continue to be satisfactory, they will represent a major step forward in IUD use, as postpartum insertion is socially acceptable and logistically achievable in countries with limited, overstrained medical resources. Several national programs have already inquired about the possibility of incorporating the devices into their family planning services.

The most common drawback of IUDs still relates to increased uterine bleeding. In the IFRP's trials of medicated IUDs, preliminary data on 89 insertions from a comparative study of a Lippes Loop D containing Trasylol versus a standard Lippes

Loop D show a slightly higher continuation rate for the nonmedicated devices. Several approaches to the same problem are being tried; for example, quantitative blood loss studies are being conducted to evaluate the Lippes Loop D containing amino caproic acid (AMCA) or Trasylol. No data are yet available at the IFRP for analysis.

Requests were received for an AMCA-releasing IUD in the "T" configuration. In response, the IFRP produced experimental IUDs using a TCU-220C IUD in which all but one of the copper sleeves have been replaced with a sleeve that provides a sustained release of AMCA for approximately one year.

The IFRP is collaborating with the Population Council in funding studies of levonorgestrel-releasing IUDs. These studies will provide information and aid in determining the effect of the release of levonorgestrel on the endometrium and the concentration of levonorgestrel in tissues. A three-center comparative clinical trial of the levonorgestrel-releasing IUD and the Nova T will provide the necessary data for a clinical evaluation of the benefits of the slow release of levonorgestrel from an IUD. A subcontract with the Population Council for these trials has been prepared and is awaiting approval. Another subcontract with the Steroid Research Laboratories in Helsinki, Finland, to study the local effects of a levonorgestrel-releasing IUD in the endometrium and on the genital organs in the human has also been prepared. Both should be initiated within the next few months.

It is usually thought that the addition of copper to an IUD increases its effectiveness, but it has been suggested that the surface area of a device may, in fact, be the prime factor in preventing pregnancy. The IFRP is concerned with obtaining a better understanding of this factor in the hope of uncovering new approaches in this field. Two studies comparing the Nylon T (a T-shaped IUD wound with nylon rather than copper) and the TCU-200B have been initiated to determine whether the effectiveness of the copper IUD is due to the increase in surface area or from the addition of the copper itself. To date, data on only 61 insertions have been received at the IFRP.

A clinical trial to evaluate the Population Council's TCU-380 Ag has been initiated. The TCU-380 Ag has a tightly wound copper wire with a silver core on the vertical stem. The silver core prevents the wire from fragmenting as the copper dissolves, increasing the effective lifetime of the device. Two centers have been supplied with devices, studies in two other centers are pending approval and an additional four centers are being recruited. The TCU-380 Ag is being compared to the Multiload and the Cu-7.

The IFRP continued to support research activities in the IUD area at the Institute for Population Studies in the University of Exeter, England. This was the second year of support in a three-year subcontract.

In the area of IUD safety, the IFRP will conduct a clinical trial of the TCU-200B with and without strings. The purpose of these studies is to evaluate the incidence of pelvic inflammatory disease associated with the use of IUDs, in an effort to determine the role of the monofilament IUD strings in the development of upper genital tract infections. Two centers have been recruited and studies will be initiated in September 1980. Recruitment for additional centers with the facilities to conduct the necessary tests continues.

F. Systemic Contraception

Oral Contraceptives

The direction of research in the area of oral contraceptives is changing from innovation toward assessment of rare adverse side effects and studies of special topics such as the needs of lactating women.

Four studies evaluating the effects of progestogen-only oral contraceptives in lactating women have been initiated. Preliminary data from these studies indicate no pregnancies have occurred among the women admitted. However, there have been problems associated with slow recruitment and follow up.

Studies of the long-term effects of oral contraceptive use are difficult, especially in the developing world. However, the IFRP is undertaking a pioneer effort in attempting to assess the risks and benefits of contraceptive use, including those of

pill use, in a developing country situation. These Reproductive Age and Mortality Studies (RAMOS) are further explained in sections III and VII.

Comparative and crossover studies of various combined oral contraceptives are ongoing. Contributors have reported difficulties with slow recruitment of patients. Preliminary analyses of data are being performed, but results are not yet available.

Among other planned studies of systemics, a feasibility study is being developed to study the proportion of congenital abnormalities among the offspring of oral contraceptive users as compared to IUD users. The proposed retrospective study will use data from the Asociacion Pro-Salud Maternal in Mexico.

Injectables and Implants

Two subcontracts for studies of long-term Depo-Provera users in Indonesia and Thailand were signed during the contract year. The IFRP did not supply the Depo-Provera, but is anxious to obtain data on what appears to be a popular contraceptive in many parts of the world and one which is presently the object of a great deal of controversy.

The objectives of these studies are to collect information on the health status of current and previous Depo-Provera users, and determine whether any association exists between Depo-Provera use and endometrial changes.

The interviewers and staff participating in the Indonesian study have been trained and the project is ongoing. By the end of 1980, the IFRP will begin analyzing preliminary data.

The initiation of the study in Thailand was delayed due to a number of problems, but the Ministry of Health, Thailand, is very anxious to proceed with the study, which is expected to start in the near future. The training of the staff is complete.

A subcontract was signed with Emory University to study the Association between Contraceptive Methods and Negative Health Outcomes and is now ongoing. The primary purpose of this study is to determine if women who have ever used Depo-Provera are at an increased risk of severe adverse effects compared to women who have used other contraceptive methods. The project is utilizing the records at Grady Memorial Hospital Family Planning Clinic. This clinic previously had an active Depo-Provera program and therefore has available the largest data set of Depo-Provera users in the United States.

Negotiations have been initiated with the Population Council to conduct a multicenter trial of contraceptive implants.

G. Barrier Contraception

Data from Phase II studies of the Collatex sponge and Neo Sampoo foaming tablet are being analyzed. One completed 12-month study of Neo Sampoo in Bangladesh showed that the

regularity of use and acceptability of this foaming tablet appears high when compared to other barrier methods. Selected data on effectiveness and discontinuation are presented in the following tables.

Cumulative gross life-table rates per 100 women

	3-month Rate \pm SE	6-month Rate \pm SE	12-month Rate \pm SE
Pregnancy	2.8 \pm 1.4	4.2 \pm 1.7	6.5 \pm 2.1
Discontinuation	4.0 \pm 1.6	9.0 \pm 2.4	24.8 \pm 3.7
Total terminations	6.7 \pm 2.0	12.8 \pm 2.7	29.6 \pm 3.8
Continuation	93.3 \pm 2.0	87.2 \pm 2.7	70.4 \pm 3.8
Women at risk of termination	144.0	133.0	115.0
Woman-months of use	440.0	849.5	1589.5

Reasons for Termination

Reason	No.	%
Unplanned pregnancy	9	20.9
Burning sensation	10	23.3
Partner objection (reasons for objection not specified)	9	20.9
Planning pregnancy	7	16.3
Male discomfort	2	4.7
Not needed	1	2.3
Other personal reasons (not specified)	5	11.6
Total terminations	43	100.0

Sufficient data from comparative studies of barrier contraceptives will be available by the end of 1980 for analysis. At that time, all planned studies in this research strategy will have been initiated.

Two new strategies related to vaginal contraception are being developed. These include a comparative trial involving a small, single-sized diaphragm to be used with and without adjunctive spermicide, and studies to investigate vaginal chemoprophylaxis and sexually transmitted diseases.

H. Fertility Awareness Methods

The IFRP, in response to interest in the ovulation method expressed by investigators from Guatemala, Nigeria, Pakistan and Rwanda, is developing a research strategy for a study of the efficacy and acceptance of this method in a Phase II clinical trial.

III. OTHER RESEARCH PROJECTS

During the contract year, the IFRP identified and developed several major research projects. Some of these have been initiated and others are either awaiting approval or are still in the planning stages. Most of these projects represent a new emphasis for the IFRP, provide effective utilization of the professional staff's scientific skills and will help obtain answers to research issues, especially in the area of contraceptive safety.

Some of these research projects, such as the evaluation of the long-term users of Depo-Provera in Indonesia and Thailand, the study of the toxicology and teratology of quinaquine hydrochloride and the evaluation of the association between negative health outcomes and

contraceptive use were detailed in the previous section. Others are discussed below.

A research project to study Reproductive Age and Mortality was designed and developed during the year. The project will examine all deaths to women of reproductive age in Bali, Indonesia, and assign a cause of death to each. The information obtained will help establish a relationship between the use or nonuse of contraceptive methods and mortality. Due to delays in obtaining field approvals, the initiation date was postponed until September 1980.

The first phase of a research study to identify the best method of cold sterilization of copper IUDs was completed during the year. The next phase will determine if the methods identified in the laboratory are effective under actual field conditions.

A report on the mechanical properties of Falope rings is being printed. In general, the report concluded that tubal rings purchased by AID were of a uniform high quality. One by-product of the test was to recommend a modification of the ring applicator. This change is being adopted by the supplier.

Analysis of a study on Infant Mortality, which began under a separate AID contract, is being completed with Contract 1172 funds. Findings from the study show that (1) pregnancy intervals are longer for women whose last child survived than for women whose last child did not survive (pregnancy ended in other than a live birth or the child subsequently died), (2) part of this difference is related to the higher probability that women will use contraceptives and breast-feed if the

child survives than if it does not, and (3) planned contraceptive use is higher for women, proportional to the number of surviving children.

A report on the findings of the study on access to sterilization in Campinas, Brazil, was completed. A second paper, using some of the data from the study, was also written. Findings indicate that the way women pay for medical care is an important determinant of whether they are sterilized postpartum. Among women who plan to be sterilized, the percentage of women who are actually sterilized increased along the continuum--indigent, government insured, privately insured, private. Moreover, even the percentage who plan to be sterilized increases along this same continuum, and virtually all sterilizations are performed at the time of cesarean section. In general, all cesarean sections, not just those concurrent with sterilization, are associated with how women pay for their care. It may be concluded that initial access to cesarean section is an important determinant of access to sterilization.

In Egypt, the IFRP is sponsoring a survey to evaluate the knowledge of and attitudes toward contraception, family planning and practices of a sample size of 450 pharmacists. The survey will be conducted in cosmopolitan Cairo and two governorates, one in upper and one in lower Egypt. The data obtained from the survey will be used in the development of a bulletin that will provide information on family planning to pharmacists. Since pharmacists are the most accessible source of family planning information, improvement of their knowledge is important to the delivery of family planning services.

The IFRP is also involved in supporting the data analysis of a survey on female circumcision in the Sudan. The data are currently being processed in the Sudan and will be sent to the IFRP for analysis. Female circumcision is widely practiced in the Sudan but little research on the practice has been conducted to date.

IV. RESEARCH ACTIVITIES

In order to successfully conduct clinical trials in research areas, the IFRP maintains a close relationship with investigators around the world. These researchers form a network of collaborators essential to the success of IFRP research activities. Specified below are the number of centers, by region, presently participating in IFRP research activities.

<u>Regions</u>	<u>Number of Centers</u>
Latin America	26
Middle East and Africa	10
Far East	24
Europe and North America	<u>18</u>
Total	<u>78</u>

Consultant Reports (CRs) are prepared as a service to the investigators. These reports analyze the data of a particular study and provide the investigator with information on pertinent results of his/her project. Appendix D lists the 47 CRs completed this year.

Members of the IFRP staff are in frequent contact with investigators and are working to recruit others who have expressed an interest in participating in IFRP research and have appropriate facilities to conduct the studies. Travel to the centers by both the field and

scientific staff is considered an important element in the success of the IFRP's research program.

A less obvious but essential effect of the close collaboration between the IFRP staff and researchers in the developing world is the impact that IFRP research has on family planning and population programs. The rapid feedback obtained from IFRP-sponsored research aids in the allocation and management of resources. The applicability of IFRP findings to policymaking and development plans within individual countries could be the single most important accomplishment of research conducted under AID/pha-C-1172.

On a number of occasions, the IFRP sponsored the travel of collaborators or potential collaborators to the IFRP to discuss participation in research projects. Two such visitors this year were Dr. Firoza Begum from Bangladesh who discussed future research in postpartum IUDs and systemics, and Dr. Z. Durmus from Turkey whose visit is expected to lead to an expansion of IFRP activities in that country.

In addition, personnel from various research centers travel to the IFRP to obtain training in analysis techniques or computer systems and programming methods that lead to upgrading the research capabilities of centers in their respective countries. This year, Renaldo Araki of the Universidad Estadual de Campinas, Brazil, was trained in computer systems and programming methods that resulted in the successful transfer of various IFRP computer programs. Dr. Ximena Tacla of Barros Luco Hospital, Santiago, Chile, trained at

the IFRP in data analysis techniques. Dr. Taola has successfully participated in a number of IFRP studies.

The IFRP is expanding its collaborative activities with other research organizations. The ongoing subcontracts with Johns Hopkins, Emory University and Kaiser Research Foundation Institute are examples, as is the ongoing and planned collaboration with the Population Council.

There have also been collaborative projects with the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT) and there will be a much closer relationship with the Program for the Adaptation of Research in Fertility Regulation (PARFR). Members of the IFRP will be processing and analyzing data collected through PARFR's limited Phase II trials and will later conduct expanded clinical trials of those devices, methods or techniques considered appropriate for Phase III trials.

V. INFORMATION DISSEMINATION

The IFRP research findings continue to be disseminated through papers published in a variety of major journals. Appendix E lists the papers published and in press during the period covered by this report. The IFRP scientific staff has increased its efforts to utilize data in the IFRP computer data bank to answer research questions that demand more complex analysis. Papers utilizing pooled data resources of the IFRP are identified by asterisks.

Research findings are also disseminated through presentations at scientific meetings. Members of the IFRP staff are often invited to present papers and chair sessions or participate in discussions that aid in the dissemination of IFRP research results. Staff members represented the IFRP in a number of scientific meetings, among them, the Fourth International Congress on Gynecologic Endoscopy, Population Association of America, American Fertility Society, Xth World Congress of Fertility and Sterility and several NIH workshops on aspects of fertility regulation. The medical staff also regularly serve as instructors in training courses such as those sponsored by JHPIEGO. In addition, staff skills are in demand to conduct evaluations of various projects.

Investigators who collaborate in IFRP studies were also sponsored by the IFRP to international and regional meetings. At these meetings they presented results on IFRP-sponsored research. Those collaborators whose travel was funded by the IFRP this year include Dr. Ximena Tacla from Santiago, Chile, who attended the Xth World Congress of Fertility and Sterility and presented a paper based on IUD data collected in IFRP studies; Dr. V. Ruiz Velasco from Mexico who also attended the Xth World Congress and presented a paper on preliminary data from his postpartum IUD study; and Dr. Kamheang Chaturachinda from Thailand who attended the American Association of Gynecologic Laparoscopists and presented a paper on female sterilization technology in Thailand.

The IFRP continues its support of the International Journal of Gynaecology & Obstetrics (IJGO); writes, publishes and distributes

Network, a quarterly newsletter; has initiated a monograph series; and either sponsors or conducts conferences and workshops.

The IJGO continues to develop and advance in the areas of manuscript submissions, scientific content, quality of review, administrative efficiency and cost control. More manuscripts are being submitted for editorial review than previously and the IFRP staff has developed special presentations for a series on Midwifery, features on Maternity Care Monitoring and legal aspects of fertility control that focuses on the question of abortion, and a second International Forum entitled, Pelvic Inflammatory Disease and the Intrauterine Device: A Causal Relationship? A reader service listing, "New Titles," was introduced to help attract advertising from publishing houses and to obtain additional titles for the IFRP library.

Major efforts to reach new readers included the distribution of over 5,000 information packets and subscription cards at FIGO's IXth World Congress of Obstetrics and Gynaecology in October 1979. At the Association of Gynaecological Laparoscopists meeting in November, several hundred sample Journals and subscription cards were presented to participants. In April 1980, a direct mail subscription drive was directed at private Ob/Gyn physicians in Latin America and at medical school libraries, family planning clinics and governmental health agencies throughout the US and Canada. To better contain costs and increase efficiency, the IFRP transferred IJGO subscription and reprint management, mailing list maintenance and inventory control to Waverly Press in January 1980, thereby reducing staff requirements from the equivalent of 4 1/2 to 2 1/2 full-time persons. Further

efforts at cost control have resulted in serious discussions followed by formal negotiations with two other potential publishers of IJGO.

The IFRP's major research results continue to be published in various scientific journals, including IJGO. In the fall of 1979, the IFRP introduced Network, a quarterly newsletter that highlights current IFRP research and projects. The response to Network following its first Volume year, completed in July, has been positive, with new requests for the publication arriving weekly and increasing in number as more issues are distributed. The first issue was mailed to over 4,000 individuals and institutions; the fourth issue was mailed to 4,800 readers and it is anticipated that over 5000 readers will receive Network by the completion of Volume 2.

The IFRP also initiated a monograph series that it hopes will continue to produce at least two special interest publications each year. During the contract year, a monograph, presenting the philosophy behind and the need for the Reproductive Age and Mortality Study (RAMOS), was produced.

The IFRP continues to sponsor conferences and workshops focusing on fertility control. In December 1979, the IFRP cosponsored a seminar in Sao Paulo, Brazil, with PARFR and two Brazilian medical groups. The seminar was well attended and enthusiastically received by the participants. The seminar generated ideas for similar seminars in Brazil and other Latin American countries. Plans for these seminars are currently being formulated.

In May of 1980, the IFRP cosponsored a seminar with Tulane University entitled "High-Risk Pregnancy: Diagnosis, Treatment and Prevention-- a Major Update for Spanish-Speaking Health Professionals."

The seminar was attended by over 100 Latin American physicians who expressed interest in attending future seminars on this topic.

The IFRP sponsored a session on "Contraceptive Development: 1980 and Forward" at the Xth Congress of Fertility and Sterility in July 1980. Among the speakers participating in the session was Dr. Liu Guo-zhen of the Chinese Academy of Medical Sciences in Peking who presented a paper on "Family Planning in the People's Republic of China". Subsequently, Dr. Liu visited the IFRP and met with staff members to explore a research relationship between the IFRP and scientists in China.

Plans are being made for several conferences to take place during the next year. Arrangements are in progress for meetings of African health professionals dealing with various issues related to contraceptive use and development. These initiatives represent an important IFRP activity in the African continent.

Initiatives are also being made to sponsor a conference in Brazil on IUDs, scheduled for April or May 1981. This conference would be a collaborative effort among the Instituto de Maternidade in Brazil, PARFR and the IFRP.

Plans are also being finalized for a meeting, to be held in Mexico, to discuss the status, problems and opportunities of family planning services in the poor urban areas of the world. The planned date is

September 1980 and participants are all actively involved in family planning programs. The outcome of the meeting will be reported upon in a monograph that should prove useful to family planning programs.

VI. MANAGEMENT

As of July 31, 1980, the staff of the IFRP numbered 99, including four part-time persons. During the reporting period, the IFRP hired a Senior Program Development Associate for Latin America to strengthen the field personnel, and a scientist to strengthen statistical professional skills. The position of Deputy Director was defined and recruitment is ongoing. IFRP personnel transactions are shown in the table below.

IFRP Personnel Transactions:

August 1, 1979 - July 31, 1980

Position Grade	Number of Employees		
	Hired	Departed	On Staff*
10	0	3	6
9	1	1	4
8	1	0	8
7	0	2	7
6	2	2	7
5	4	8	18
4	1	1	8
3	8	5	27
2	7	2	8
1	4	2	6
	<u>28</u>	<u>26</u>	<u>99</u>

*as of July 31, 1980

The IFRP management structure continues to operate efficiently and effectively. During the reporting period, the IFRP's Associate Director for Administration died suddenly. Although it was a difficult and sad loss, staff at the IFRP filled the void with reasonable speed and proficiency.

The IFRP Board of Directors met at the following times during the year:

September 23-24, 1979 -- Annual Board Meeting
January 20-21, 1980 -- Executive Committee Meeting
February 2-3, 1980 -- Special Meeting
April 14, 1980 -- Executive Committee Meeting
June 16, 1980 -- Executive Committee Meeting
July 5, 1980 (morning) -- Joint Board and IFFH Executive
Committee Meeting
July 5, 1980 (afternoon) -- Board Meeting

At the time of the September 23-25 meeting, Dr. Lise Fortier, a practicing gynecologist, and Dr. Torrey Brown, Director of the Office of Health Care Projects at Johns Hopkins, were added to the Board. During the special meeting, February 2-3, 1980, General Alexander Andrews, attorney and prominent local businessman, was added to the Board.

The IFRP Protection of Human Subjects Committee met three times during the contract year, September 14 and December 14, 1979 and May 30, 1980. The December meeting included the annual review of all IFRP studies.

The IFRP Technical Advisory Committee met May 2, 1980 and reviewed research plans for the coming year. Efforts are being made to use this committee more effectively in the coming year.

At the beginning of 1980, the IFRP prepared a broad document that included ongoing, planned and possible scientific initiatives for the IFRP. Based on that document, the IFRP has set goals for calendar year 1980 that will be reviewed at the end of the year when accomplishments during 1980 are evaluated and directions for 1981 are set.

The IFRP continued its streamlining of accounting procedures and is in the process of investigating the possibility of transferring the payroll to the IFRP's computer. A modification of IFRP's fringe benefits plan was completed, leading to a slight decrease in the cost of the plan. In addition, the IFRP will initiate, in the new contract year, a more detailed accounting of expenditures, especially personnel, under the AID contract.

The IFRP expended a total of \$2,883,268 during the contract year.

Expenditures are summarized in the following table.

IFRP Expenditures, Contract 1172:
August 1, 1979 - July 31, 1980

Category	Amount
Salaries	\$ 665,584
Fringe benefits	225,924
Consultants	17,542
Travel (domestic)	32,875
Travel (foreign)	113,122
Material and supplies	37,929
Subcontracts	59,057
Other direct costs	
Service centers	560,566
Direct department indirect	253,501
Other	<u>214,679</u>
Subtotal	2,210,779
General and administrative	600,972
Fixed fee	<u>71,517</u>
Total	<u>\$2,883,268</u>

VII. FUTURE DIRECTIONS

In the coming contract year, the IFRP plans to monitor closely the research projects implemented as well as finalize those projects now in the development stage. Among the major projects still to be finalized and implemented is a second Reproductive Age and Mortality Study (RAMOS), modeled after the Bali project, to be conducted in Egypt. This project will complement the Bali RAMOS because orals rather than IUDs are the prevalent form of contraception in Menoufia and the mortality rate is lower in Egypt than in Indonesia.

Another initiative will be the development and finalization of studies of breast-feeding and ovulation. The primary purpose of the research will be to study the effects of lactation on fertility. The research will be based on a study conducted in Edinburgh, but it will be replicated in several sites in the developing world.

The RAMOS subcontract in Bali will be initiated and other projects already developed but pending final approval should also be ready for implementation. Ongoing projects in the area of contraceptive safety should yield important results.

Centers for studies of the Delta IUDs that are to be conducted in the United States will be recruited, and data received from the ongoing overseas studies will be sufficient to draw more definitive conclusions. Initiatives on the part of the IFRP's professional staff in countries such as Tunisia are broadening the scope of the Delta IUD studies by providing the opportunity to collect and later analyze a large number of cases from one location.

Follow up on women sterilized with quinaorine pellets will continue and data from the Johns Hopkins studies should make it possible to prepare the required documentation for submission of an IND to the Food and Drug Administration.

In the coming year, the IFRP will also explore the possibility of providing regional research centers in selected developing countries with microcomputers that have been adapted to use IFRP analysis and loading programs. This will encourage research activities in those centers selected, increase analysis capabilities and simplify the transfer and modification of IFRP-developed computer loading and analysis programs.

During the coming year, with funds from AID/pha-C-1172, the IFRP will obtain results from clinical trials that will answer questions relating to fertility control methods and technology applicable to the developing world, and see some of its more ambitious projects implemented.

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APPENDIX A

COMPLETED DOCUMENTS

INTRAUTERINE DEVICES

Strategies

Copper T 200LB with and without strings
Copper T 380 Ag

Forms

Quantitative Blood Loss Form
Medical Exam Form (Copper T 200LB with and without strings study)
French translation of IUD Patient Summary Admission and Follow-up
Forms

Protocol

Copper T 200LB with and without strings

Instruction Manual

French translation of IUD Patient Summary Forms Instruction Manual

MENSTRUAL REGULATION

Strategies

Menstrual Regulation with Double Valve Hand Syringe and
8mm, 10mm and 12mm Cannulae
Cervical Osmotic Dilator Study

FEMALE STERILIZATION

Loading and Analysis Specifications

Follow-up Table Specifications

MALE STERILIZATION

Strategy

Percutaneous Vas Injections Strategy

SYSTEMIC CONTRACEPTION

Forms

Study of Progestogen-Only Oral Contraceptives in Lactating Women -
Admission Form (Spanish)
Study of Progestogen-Only Oral Contraceptives in Lactating Women -
Follow-Up Form (Spanish)

Health Survey of Women - Interview Questionnaire
Health Survey of Women - Physician Examination and Investigational
Record
Health Survey of Women - Histopathology Findings Record

Loading and Analysis Specifications

Loading specifications for Progestogen-Only Oral Contraceptive Studies

Computer Program Instructions

Specifications for Systemic Contraception Lifetable Procedures

BARRIER CONTRACEPTION

Strategies

Prophylactic-Contraceptive Study

Procedures

Protocol for Comparative Studies of Barrier Contraceptives

Instruction Manual

Female Barrier Contraceptive Study - Instruction Manual for Patient
Record Forms (Revised)

Computer Program Instructions

Specifications for Female Barrier Lifetable Procedures
Specifications for Female Barrier Standard Tables Procedures

APPENDIX B

COMPLETED MAJOR COMPUTER PROGRAMS

August 1, 1979 - July 31, 1980

1. Extended Lifetable Rates Program
2. Female Barrier Long Form Loading Program
3. IUD Patient Summary Form Loading Program
4. Extended FS Lifetable Rates Program
5. Extended CHEMFS Lifetable Rates Program
6. Female Sterilization Master and Demographic Tables Program
7. Unlimited Time Span Generalized Lifetable Program
8. Female Barrier Long Form Lifetable Rates Program
9. Female Barrier Short Form Lifetable Rates Program
10. FS78CHECKER Program (contingency and range checks for FS78 forms)
11. IUD Retrospective to IUD5 Conversion Program
12. FS78 Update Program
13. Systemic Load Program (SEARLE Version modified to run systemic)
14. Lactation Load Program
15. Female Sterilization Clinical Tables Program
16. Female Sterilization Follow-up Tables Program
17. Female Sterilization Rates Tables Program
18. IUD Patient Summary Standard Tables Program
19. Systemic Contraception Lifetable Rates Program
20. Female Barrier Standard Tables Program

APPENDIX C

FORMS RECEIVED AND LOADED INTO THE COMPUTER

August 1, 1979 - July 31, 1980

<u>Intrauterine Devices</u>	Admission	14,496
	Follow up	7,926
	Method List	3,691
	Other	<u>3,422</u>
	Total	29,535
<u>Intrauterine Devices</u>		
<u>Patient Summary</u>	Admission	577
	Follow up	543
	Other	<u>1</u>
	Total	1,121
<u>Systemic Contraception</u>	Admission	579
	Follow up	674
	Physical Exam	70
	Other	<u>55</u>
	Total	1,378
<u>Female Barrier Short Forms</u>	Admission	551
	Follow up	<u>809</u>
	Total	1,360
<u>Female Barrier Long Forms</u>	Admission	538
	Follow up	<u>845</u>
	Total	1,383
<u>Hospital Abortion</u>	Admission	219
<u>Maternity Record</u>	Admission	8,597
<u>Male Sterilization</u>	Follow up	11
<u>Female Sterilization</u>	Admission	2,873
	Follow up	3,555
	Additional information	374
	Method list	2,593
	Pregnancy confirmation	<u>3</u>
	Total	9,398
<u>Chemical Female Sterilization</u>	Admission	249
	Follow up	203
	Instillation	<u>678</u>
	Total	1,130

APPENDIX C cont'd

Female Sterilization
Patient Summary

Admission 38

Family Planning
Clinic Record

Admission 1
Status Report 3,790
Total 3,791

APPENDIX D

COMPLETED CONSULTANT REPORTS (CRs)

August 1, 1979 - July 31, 1980

Title	Prepared for	Center No.	Study No
Evaluation of the Photoreduced Lippes Loop D IUDs, Klinika Za Ginekologiju I Akuserstvo Novi Sad, Yugoslavia	Dr. N. Bregun	202	501
Postabortion Insertion of Lippes Loop at Maribor General Hospital, Slovenja, Yugoslavia	Dr. E. Borko	023	507
Postcoital IUD Insertion	Dr. T. Black	295	315
Management of Incomplete Abortion: Completion by Vacuum Aspiration and by Sharp Curettage Inpatient and Outpatient Procedures	Dr. E. Moran Caceres	824	141
Female Sterilization at the University of Ibadan Hospital, Ibadan, Nigeria	Dr. O. A. Ojo	040	621
A Comparison of the Tapered Lippes Loop D and Lippes Loop D, University of Belgrade, Belgrade, Yugoslavia	Dr. B. Behlilovic	024	502
Female Sterilization at the Thana Health Complex, Kalilati Tangail, Bangladesh	Dr. A. Rahman Khan	730	630
Evaluation of Nylon Wound T Insertions at Cairo University, Cairo, Egypt	Dr. I. Kamal	035	510
Female Sterilization Acceptability Study at Profamilia, Cali, Colombia	PRIF (Programa Regional de Investigaciones en Fecundidad)	897	687
Evaluation of the Postpartum T, Universidad de Nuevo Leon, Monterrey, Mexico	Dr. R. Garcia-Flores	861	555

APPENDIX D (cont'd)

Title	Prepared for	Center No.	Study No.
Evaluation of the Copper T and Sutured Copper T in Hospital Juan Noe, Arica, Chile	Dr. R. Beltran	854	555
Evaluation of Tapered Lippes Loop Insertions at Tegucigalpa, Honduras Appendix D cont'd	Dr. J. Nunez	890	500
Female Sterilization Via Single Puncture Laparoscopy by Either Tubal Ring, Monopolar Cautery or Spring Loaded Clip	Dr. L. Ramirez	864	667
A Comparison of the Copper 7 and the Lippes Loop D, Family Planning Institute, Ljubljana, Yugoslavia	Dr. L. Andolsek	020	411
A Comparison of the Lippes Loop D, the Lippes Loop D with Copper and the Photoreduced Lippes Loop, Apro-fam Clinic, Guatemala City, Guatemala	Dr. Solai V.	792	501
Female Sterilization Via Suprapubic Minilaparotomy by Either Modified Pomeroy Technique or Tubal Ring Technique at the Jose Fabella Memorial Hospital, Manila Philippines	Dr. R. Apelo	600	670
Evaluation of the Postpartum T at the Hospital de Gineco, Guadalajara, Mexico	Dr. L. Uribe	864	555
A Study of Depo-Provera Acceptors at the Bangladesh Family Planning Program Assoc. at the Christian Health Care Project in Dacca, Bangladesh	Mad. Mozammel Hogue	766	FPCR
A Study of Depo-Provera Acceptors at the Bangladesh Family Planning Program Assoc. at the Gandaria Model Clinic in Dacca, Bangladesh	Mad. Mozammel Hogue	766	FPCR

APPENDIX D (cont'd)

Title	Prepared for	Center No.	Study No.
Analysis of Depo-Provera Acceptors Admitted to the Hong Kong Family Planning Assoc. in Hong Kong	Dr. Ho-Kei Ma	734	FPCR
Analysis of Depo-Provera Acceptors at Surigao City Health Department Surigao City, Philippines	Dr. B. T. Mora	617	FPCR
A Study of Depo-Provera Acceptors at the Family Planning Assoc. of Honduras, Tegucigalpa, Honduras	Dr. J. Nunez	890	FPCR
Laparoscopic Sterilization by the Tubal Ring Technique of Tubal Occlusion Using the Open Laparoscopy Approach, Hasan Sadikin Hospital, Padjadjaran University School of Medicine, Bandung, Indonesia	Prof. Sulaiman Sastrawinata	739	6001
A Four-Way Comparative Postpartum IUD Study: Intrauterine Membrane, Lippes Loop D, Copper T and Postpartum T	Dr. P. Lavin	852	551
Evaluation of the Lippes Loop C, the Lippes Loop D, and the one-year Progestasert at Ten Centers in the Federal District of Mexico	Government of Mexico	859	598
A Comparison of the TR-10 and the Copper Soonawalla, Family Planning Institute, Ljubljana, Yugoslavia	Dr. L. Andolsek	020	484
Evaluation of Nylon Wound T Cairo, Egypt	Dr. I. Kamal	035	510
Evaluation of the Finland Copper-T and the Copper T-220C at the Hospital Sotero del Rio, Santiago, Chile	Dr. J. Zipper	088	437 461

APPENDIX D (cont'd)

Title	Prepared for	Center No.	Study No.
Female Sterilization Via Double Incision Laparoscopy Using the Semms Endocoagulator for Tubal Occlusion	Dr. D. Van Lith	266	690
Female Sterilization Via Single Puncture Laparoscopy by the Tubal Ring Technique of Tubal Occlusion	Government of Mexico	859	6901
A Comparison of the Copper T and the TR-11, Family Planning Institute, Ljubljana, Yugoslavia	Dr. L. Andolsek	020	514
Female Sterilization Via Minilap with Either the Rocket Spring-Loaded Clip or the Tubal Ring for Tubal Occlusion in Postabortion Patients	Dra. D. Badia	823	6252
Evaluation of the Lippes Loop D and the Delta Lippes Loop D Mexico City, Mexico	Dr. V. Ruiz-Velasco	966	560
Pomeroy Sterilization Via Mini-laparotomy Employing Two Different Anesthesia Schedules, Dr. Jose Fabella Memorial Hospital, Manila Philippines	Dr. R. Apelo	600	614
Acceptors of IUD and Oral Contraceptors Admitted to the Asociacion Demografica Salvadorena Family Planning Program in Santa Ana	ADS	822	FPCR
Acceptors of IUDs and Oral Contraceptives Admitted to the Asociacion Demografica Salvadorena Family Planning Program in San Salvador	ADS	821	FPCR
Acceptors of IUDs and Oral Contraceptives Admitted to the Asociacion Demografica Salvadorena Clinic in Santa Tecla	ADS	820	FPCR

APPENDIX D (cont'd)

Title	Prepared for	Center No.	Study No.
Electrocoagulation Via Laparoscopy Employing Two Different Anesthesia Schedules	Dr. Kamheang Chaturachinda	740	614
Evaluation of the TR-11 IUD in Kasreleini Hospital, Cairo, Egypt	Dr. I. Kamal	035	513
Evaluation of Two Intrauterine Membrane Devices: The Standard and the Modified Wishbone Compared with the Lippes Loop D, Hospital Sotero del Rio, Santiago, Chile	Dr. M. Medel	087	490 491
Comparison of Interval and Post-abortion Insertions of the Lippes Loop C and the Copper T-220C, Model Outpatient Clinic, Dacca, Bangladesh	Dr. A. R. Khan	721	462 463
Analysis of Collatex Sponge in London, England	Dr. J. Guillebaud	298	781
Evaluation of the Copper T 200 at the Family Planning Institute Ljubljana, Yugoslavia	Dr. L. Andolsek	020	417
Evaluation of the U-Coil, Misr Spinning and Weaving Co. Hosp. Mahalla-El-Kobra, Egypt	Dr. S. Etman	340	445
Inevitable and Incomplete Abortions Treated at the Department of Ob/Gyn Univ. of Assiut, Assiut, Egypt	Dr. M. Shaadan	358	140
Evaluation of the Delta LLD Dacca Medical College Dacca, Bangladesh	Dr. F. Begum	704	556
A Comparison of the Lippes Loop D, the Lippes Loop D with Copper and the Photoreduced Lippes Loop Aprofam Clinic, Guatemala City, Guatemala	Dr. L. F. Galich	841	503

APPENDIX E

International Fertility Research Program

Publications

August 1, 1979 - July 31, 1980

PREGNANCY TERMINATION

Berger GS, Edelman DA, Terwey ER, Keith LG: Fetal growth in early pregnancy. In Auxology: human growth in health and disorder. In Proceedings of the First International Congress of Auxology, Rome, April 12-16, 1977. p 495. Academic Press, New York, 1978. (PT-104)

Potts M: Changing medical attitudes to abortion. West J Med 131(5):455, 1979. (PT-117)

Potts M, Lewis JH: Social factors in abortion. In Proceedings of the IXth World Congress of Gynecology and Obstetrics, Tokyo, Japan, October 25-31, 1979. Excerpta Medica, Amsterdam (in press). (PT-119)

Potts M: Population growth and abortion. In Pregnancy Termination: Procedures, Safety and New Developments (ed GI Zatuchni, JJ Sciarra, JJ Speidel), Chapter 35, p 416. Harper & Row, Hagerstown, MD, 1979. (PT-123)

MENSTRUAL REGULATION

Edelman DA, Berger GS: Menstrual regulation. In Techniques of Abortion and Sterilization (ed P Huntingford). Academic Press Inc, Ltd, London (in press). (MR-27)**

Laufe L: Menstrual regulation--international perspectives. In Pregnancy Termination: Procedures, Safety and New Developments (ed GI Zatuchni, JJ Sciarra, JJ Speidel), Chapter 9, p 79. Harper & Row, Hagerstown, MD, 1979. (MR-44)

Kessel E: Menstrual regulation. In Birth Control: An International Assessment (ed DM Potts, P Bhiwandiwalla), Chapter 11, p 187. University Park Press, Baltimore, 1979. (MR-46)

Fortney JA, Vengadasalam D: Disposable menstrual regulation kits in a non-throw-away economy. Contraception 21(3):235, 1980. (MR-47)

FEMALE STERILIZATION

Chi I-c, Cole LP: Incidence of pain among women undergoing laparoscopic sterilization by electrocoagulation, the spring-loaded clip and the tubal ring. Am J Obstet Gynecol 135(3):397, 1979. (FS-99)**

Laufe L: Suprapubic endoscopy for interval female sterilization. Am J Obstet Gynecol 136(2):257, 1980. (FS-101)

- Kwak HM, Moon YK, Song CH, Ahn DW, Chi I-c: Timing of laparoscopic sterilization in abortion patients. *Obstet Gynecol* 56:85, 1980. (FS-102)
- Zipper J, Rivera M, Cole LP, Goldsmith A, Wheeler RG: Quinacrine hydrochloride pellets: a nonsurgical method of female sterilization. *Int J Gynaecol Obstet* (in press). (FS-103)
- Cole LP, Colven CE, Goldsmith A: Tubal occlusion by laparoscopy in Latin America: an evaluation of 8186 cases. *Int J Gynaecol Obstet* 17(3):253, 1980. (FS-104)**
- Cole LP, Goldsmith A: Métodos no quirúrgicos de esterilización femenina, p 7. In *Proceedings of An International Course in Advances in Gynecology and Obstetrics*, Bogotá, Colombia, October 4-5, 1978, Vol 14, p 7. Corporación Centro Regional de Población, 1979. (FS-105)
- Kwak HM, Chi I-c, Gardner S, Laufe L: Menstrual pattern changes in laparoscopic sterilization patients whose last pregnancy was terminated by therapeutic abortion--a two-year follow-up study. *J Reprod Med* (in press). (FS-106)
- Swenson IE, Jahan FA, Khan AR: A follow-up of tubectomy clients in Bangladesh. *Int J Gynaecol Obstet* 17(1):47, 1979. (FS-107)
- Chi I-c, Laufe LE, Gardner S, Tolbert M: An epidemiologic study of risk factors associated with pregnancy following female sterilization. *Am J Obstet Gynecol* 136:758, 1980. (FS-110)**
- Hulka JF, Omran K, Lieberman BA, Gordon AG: Laparoscopic sterilization with the spring clip: instrumentation development and current clinical experience. *Am J Obstet Gynecol* 135:1016, 1979. (FS-113)
- Shatt RV, Aparicio A, Laufe LE, Parmley T, King TM: Quinacrine-induced pathologic changes in the Fallopian tube. *Fertil Steril* 33:566, 1980. (FS-114)
- McCann MF, Cole LP: Laparoscopy and minilaparotomy: a revolution in female sterilization. *Stud Fam Plann* 11:4, 1980. (FS-115)**
- Chi I-c, Laufe LE, Gardner S: The history of pregnancies that occur following female sterilization. *Int J Gynaecol Obstet* 17(3):265, 1980. (FS-117)**
- Mumford SD, Bhiwandiwalla P: The silastic ring device for tubal occlusion: experience of 10,086 cases. *Obstet Gynecol* (in press). (FS-120)**
- Arqueta G, Henriquez E, Amador MN, Gardner SD: Comparison of laparoscopic sterilization via spring-loaded clip and tubal ring. *Int J Gynaecol Obstet* (in press). (FS-12#)
- Diaz MO, Atwood R, Laufe LE: Laparoscopic sterilization with room-air insufflation: preliminary report. *Int J Gynaecol Obstet* (in press). (FS-125)

Laufe LE: Challenges for the First National Congress on Gynecological Endoscopy. First National Congress on Gynecological Endoscopy, Bombay, India, October 1979. (FS-128)

Chi I-c, Mumford SD, Laufe LE: Technical failures in tubal ring sterilization: incidence, perceived reasons, outcome and risk factors. Am J Obstet Gynecol (in press). (FS-129)

Potts M: El porqué de la esterilización femenina. In Avances en Obstetricia y Ginecología, Vol 14, p 59. Corporación Centro Regional de Población, Bogotá, 1979. (FS-132)

Bhiwandiwalla P: Female sterilization. In Birth Control: An International Assessment (ed M Potts, P Bhiwandiwalla), Chapter 10, p 173. University Park Press, Baltimore, 1979. (FS-135)

Parikh MN, Patel D, Bhiwandiwalla P: The laprocator--a new instrument for female sterilization. In The Sixth Transactions of Scientific Papers, Proceedings of the Contributors Conference of the India Fertility Research Programme, Bombay, India, March 3, 1979 (ed S Pachauri), p 60. India Fertility Research Programme, Calcutta, 1979. (FS-135)

Jabeen S, Abdullah AQM, Nazmul S, Ahmad N: Female sterilization at Sir Salimullah Medical College Hospital. In Proceedings of the Fourth Contributors Conference of the Bangladesh Fertility Research Programme, Dacca, Bangladesh, November 8, 1979, p 177. Bangladesh Fertility Research Programme, Dacca, 1980. (FS-141)

Khan AR, Ahmed G, Ahmad N: Client characteristics of Pomeroy and tubal ring--the two types of tubectomy in Kalihati Thana Health Centre, Tangail. In Proceedings of the Fourth Contributors Conference of the Bangladesh Fertility Research Programme, Dacca, Bangladesh, November 8, 1979, p 205. Bangladesh Fertility Research Programme, Dacca, 1980. (FS-142)

MALE STERILIZATION

Khan AR, Swenson IE, Rahman A: A follow-up of vasectomy clients in rural Bangladesh. Int J Gynaecol Obstet 17(1):11, 1979. (MS-4)

Mumford SD, Davis J: Flushing of the distal vas during vasectomy: current status and review of literature. Urology 14(5):433, 1979. (MS-6)

Rhodes DB, Mumford SD, Free MJ: Vasectomy: efficacy of placing the cut vas in different fascial planes. Fertil Steril 33(4):433, 1980. (MS-7)**

Lo C, Mumford SD, Atwood R: Postvasectomy residual sperm pregnancy: a case report. Fertil Steril 33:668, 1980. (MS-8)

Potts M: Contracepção masculina sem prescrição. In Temas de Contracepção, p 71. Almed Editora & Livraria Ltda, São Paulo, 1980. (MS-12)

INTRAUTERINE DEVICES

Goldsmith A, Young AB, Colven CE: The intrauterine device: its role in the population program of the developing world. Proceedings of the Medicated IUDs and Polymeric Delivery Systems International Symposium, Amsterdam, Holland, June 27-30, 1979 (ed ESE Hafez, WAA van Os). Martinus Nijhoff BV, The Hague, Holland (in press). (IUD-61)

Batár I, Taylor R Jr, Lampe L: Can inert IUDs be further improved? Proceedings of the Medicated IUDs and Polymeric Delivery Systems International Symposium, Amsterdam, Holland, June 27-30, 1979 (ed ESE Hafez, WAA van Os). Martinus Nijhoff BV, The Hague, Holland (in press). (IUD-63)

Wheeler RG: IUD decisions guide: determinants and IUD continuation. Proceedings of the Medicated IUDs and Polymeric Delivery Systems International Symposium, Amsterdam, Holland, June 27-30, 1979 (ed ESE Hafez, WAA van Os). Martinus Nijhoff BV, The Hague, Holland (in press). (IUD-64)**

Tacla X, Young B, Lavin P, Baeza R, Seaman V: The IUD and anemia: a study of hematocrit. Contraceptive Delivery Systems: An International Journal 1:49, 1980. (IUD-67)

Laufe LE, Friel PG: Improving IUD performance with biodegradable materials. Proceedings of the Medicated IUDs and Polymeric Delivery Systems International Symposium, Amsterdam, Holland, June 27-30, 1979 (ed ESE Hafez, WAA van Os). Martinus Nijhoff BV, The Hague, Holland (in press). (IUD-68)

Berger GS, Keith LG, Edelman DA: IUDs and ectopic pregnancies. Proceedings of the Medicated IUDs and Polymeric Delivery Systems International Symposium, Amsterdam, Holland, June 27-30, 1979 (ed ESE Hafez, WAA van Os). Martinus Nijhoff BV, The Hague, Holland (in press). (IUD-59)

Kamal I, Ezzat R, Zaki S, Shaaban H, Kessel E: Immediate postpartum IUD insertion of a sutured Lippes Loop. Int J Gynaecol Obstet 18:25, 1980. (IUD-70)

Batár I: Fertility after IUD removal. Proceedings of the Medicated IUDs and Polymeric Delivery Systems International Symposium, Amsterdam, Holland, June 27-30, 1979 (ed ESE Hafez, WAA van Os). Martinus Nijhoff BV, The Hague, Holland (in press). (IUD-71)

Cole LP, Edelman DA: A comparison of the Lippes Loop and two copper-bearing intrauterine devices. Int J Gynaecol Obstet 18:35, 1980. (IUD-72)**

Edelman DA, Berger GS, Keith L: Intrauterine Devices and Their Complications. G. K. Hall & Co Publishers, Boston, 1979. (IUD-74)

Goldsmith A, Ruiz-Velasco V: Aplicación DIU ML Cu250 postalumbramiento: reporte preliminar. Ginecol Obstet Mex 45:359, 1979. (IUD-77)

Edelman DA (ed): Pelvic inflammatory disease and the intrauterine device: a causal relationship? *Int J Gynaecol Obstet* 17:504, 1980. (IUD-79)

SYSTEMIC CONTRACEPTIVES

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**Papers utilizing pooled data resources of the IFRP.