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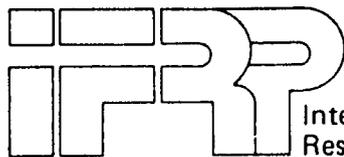
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PN-AAH-512

**SEMIANNUAL REPORT**  
**AID/pha-C-1172**

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**August 1, 1979—January 31, 1980**



**International Fertility Research Program**  
**Research Triangle Park, NC 27709 USA**

## Table of Contents

	Page
I. INTRODUCTION.....	1
II. CLINICAL RESEARCH.....	1
A. SURGICAL FEMALE STERILIZATION.....	2
B. NONSURGICAL FEMALE STERILIZATION.....	3
C. MALE STERILIZATION.....	5
D. ABORTION, MENSTRUAL REGULATION AND PREGNANCY TESTING.....	6
E. SYSTEMIC CONTRACEPTION.....	7
F. BARRIER CONTRACEPTION.....	8
G. INTRAUTERINE DEVICES.....	9
III. OTHER RESEARCH ACTIVITIES.....	12
IV. SUBCONTRACTS.....	13
V. DISSEMINATION OF INFORMATION.....	14
VI. MANAGEMENT.....	17
VII. FUTURE DIRECTIONS.....	19
APPENDIX A: COMPLETED DOCUMENTS	
APPENDIX B: COMPLETED MAJOR COMPUTER PROGRAMS	
APPENDIX C: FORMS RECEIVED AND LOADED INTO THE COMPUTER	
APPENDIX D: COMPLETED CONSULTANT REPORTS (CR)	
APPENDIX E: PUBLICATIONS	

## I. INTRODUCTION

Contract AID/pha - C - 1172 became effective August 3, 1977 and has since been amended and extended through July 31, 1981. This report covers the period of August 1, 1979 through January 31, 1980. The focus of the IFRP's work under the Contract remains the evaluation of the safety and efficacy of new, existing or modifications of existing contraceptive methods in clinical Phase III and IV (postmarketing) field trials. During the six months covered by this report, the IFRP continued its work to identify new projects it may undertake related to the safety of contraceptive methods. In addition, the IFRP also continued its efforts to disseminate information related to all aspects of contraception to wide and varied audiences.

## II. CLINICAL RESEARCH

Comprehensive work in all major IFRP areas of clinical research (sterilization, hormonal contraception, abortion, intrauterine contraception and barrier contraception) continued during the first six months of the Contract year. This work includes the development and initiation of studies, the collection, processing and analyses of data and the reporting of research findings. Appendix A lists the new forms, protocols, strategies and computer program specifications developed for each of the research areas. Appendix B lists completed computer programs and systems. Appendix C shows the number of research forms processed within each research area.

The IFRP continually monitors its research studies, reassesses their importance to AID objectives, and closes out those studies that are

no longer pertinent or that are not providing data of appropriate research quality. During the first six months of the Contract, 51 studies were closed, 39 were approved and 25 became active (first batch of forms received).

Clinical trials are conducted throughout the network of research centers. The following table gives the number of active research centers in each geographic region.

<u>Region</u>	<u>Number of Centers</u>
Latin America	14
Middle East and Africa	11
Far East	28
Europe and the United States	<u>23</u>
Total	76

#### A. SURGICAL FEMALE STERILIZATION

Data collection for the ten laproscator studies continues. Preliminary analysis of this data is based on over 1,100 procedures (983 laparoscopies and 175 minilaparotomies). There have been only three technical failures reported, all in the open laparoscopy series. The rate of surgical difficulties was 3.5% with open laparoscopy and 7.4% with minilaparotomy. The most common surgical difficulties encountered involved entering the peritoneum and visualizing, grasping and occluding the tubes. There were only seven surgical injuries and complications in the two series of studies, the most common being tubal injury or uterine perforation. As a result of equipment problems reported by the investigators to the IFRP, all investigators are now requested to submit written reports evaluating the laproscator.

Another major research emphasis has been the collection of data for the six Rocket clip studies. Initial difficulties with either broken equipment or slower than expected caseloads have prevented the expedient completion of these studies.

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.

A study to examine the obstacles to obtaining sterilization was initiated at a large maternity hospital in Brazil. In this study, 2,000 obstetric patients will be interviewed over a three-month period.

The IFRP began an evaluation of samples from four lots of tubal rings provided by AID. Stress and other physical tests to determine ring integrity are being performed on the rings and a preliminary report is being prepared.

#### B. NONSURGICAL FEMALE STERILIZATION

In the past six months, the following work has been completed on the use of quinacrine as a nonsurgical method of female sterilization:

1. Quinacrine pellets have been inserted in 223 women at three clinics; five pregnancies have been reported; three before completion of the insertion schedule and two after completion of the insertion schedule.

2. Blood and saliva samples have been obtained from eight women who have undergone pellet insertion; samples will be analyzed to determine the amount of quinacrine in the saliva and blood for up to 48 hours after insertion of the pellets.
  
3. The TCU-220C IUD, with a total of 300 mg of quinacrine hydrochloride in a polyethylene oxide (PEO) matrix, has been inserted into the uteri of twelve women scheduled for hysterectomy for medical conditions such as uterine prolapse. Specimens from seven cases have been evaluated at the Johns Hopkins University. In one case, the tissue was totally autolyzed. Evidence of tubal fibrosis was confirmed throughout the intramural portions of the tube in all other cases, but for some of the specimens, only one tube in each uterus was affected. Since the device must be inserted with the arms flexed upward, the clinicians thought that the unaffected tubes resulted from a failure of one of the T arms to deploy once the device was in place. In no instance was there any damage beyond the lamina propria. The tubal muscularis was intact and untouched.

In January 1980 a meeting was held between the scientific staffs of the AID Research Division and the IFRP to discuss the future directions of the IFRP in relation to the development of the use of quinacrine as a nonsurgical method of female sterilization. The following course of action was unanimously agreed to by the IFRP and AID:

- a) The IFRP will not recruit additional subjects into the quinacrine pellet studies. Although the insertion of quinacrine pellets appears to be an effective method of sterilization, the administration schedule, as presently conceived, has limited applicability in the developing world.
- b) The IFRP will fund two subcontracts with the Johns Hopkins University for preclinical studies of quinacrine. These studies will provide the necessary data for the IFRP to apply to the FDA for an IND under which pre-hysterectomy studies of quinacrine could be performed.
- c) Once an IND is obtained (probably in late 1980), the IFRP will submit to AID a test plan under which additional clinical studies of quinacrine will be performed.

#### C. MALE STERILIZATION

Current research in male fertility has not provided any new ideas that are ready for clinical trial testing. The IFRP will be able to conduct trials once the appropriate technology has been developed. The idea that paramedical personnel can be trained to perform vasectomies has already been implemented in some areas of the developing world. The evaluation of the operator, rather than the technique, may prove to be the best way to promote vasectomy in less developed countries. Trials focusing on this evaluation are being planned by the IFRP.

#### D. ABORTION, MENSTRUAL REGULATION AND PREGNANCY TESTING

Two midtrimester abortion studies have been initiated. The midtrimester abortion procedure using an intraamniotic injection of 10% saline for women at 16 to 18 weeks' gestation is being evaluated in Yugoslavia. A replication of the Johns Hopkins technique, starting with the insertion of laminaria and following with the intraamniotic injection of 80 gm of urea and 5 mg of PGF<sub>2α</sub> for women at 16 to 20 weeks' gestation, is being evaluated in Bangladesh.

The development of a double valve hand syringe which accepts 12 mm cannulae presented the IFRP with the opportunity to evaluate the syringe for abortions in women at 10 to 12 weeks' gestation. A multicenter study has been initiated. The IFRP continues to evaluate MR procedures performed by trained midwives with the initiation of one more study.

The synthetic osmotic cervical dilator, composed of a polyvinyl alcohol sponge saturated with magnesium sulfate and compacted, has been tested in vitro and a 50 case multicenter evaluation has been initiated. The increasing demand to use natural laminaria for cervical dilation has depleted the existing supply, and the production of inexpensive and effective synthetic dilators would satisfy a definite need.

Developing countries continue to need a simple and accurate pregnancy test. The re-evaluation of the Capillary Tube Pregnancy

Test, developed by Dr. L. Lau of the Johns Hopkins University, is about 50% completed.

During the past six years, the IFRP has collected extensive data on incomplete abortions treated in countries where elective abortion is usually illegal except for a few indications. During the first six months of the Contract year, a major effort was undertaken to prepare an extensive report on the IFRP's incomplete abortion studies in Latin America. The report will be available by the end of the next reporting period.

#### E. SYSTEMIC CONTRACEPTION

Analyses of data from comparative and crossover studies of various combined oral contraceptives (OCs) are being performed. Some of the results will be available before the end of the Contract year. These results will assist AID in choosing the type of pills that should be purchased for distribution.

Two studies evaluating the effects of progestogen-only OCs in lactating women were initiated during the reporting period; two others will be initiated shortly. The objectives of these studies are to determine the acceptability of low-dose progestogen-only OCs among breast-feeding women and to determine how changes in the weight of breast-fed infants whose mothers are using progestogen-only OCs compare with changes in the weight of a group of infants whose mothers are not using hormonal contraceptives. Preliminary results from these studies should be available by the end of the next reporting period.

In addition, studies are being developed to evaluate the volume, composition and steroidal content of the breast milk of women using different combined OCs and progestogen-only OCs.

The safety of long-term use of the injectable contraceptive, Depo-Provera, is being investigated in two projects--one in Bandung, Indonesia and the other in Chiang Mai, Thailand. A third study is being developed to examine the possible association between Depo-Provera and carcinomas of the breast, endometrium and cervix and other major diseases among women in Atlanta, Georgia.

Data collected from clinics in Bangladesh, Honduras, Hong Kong and the Philippines are being evaluated to study factors leading to the discontinuation of Depo-Provera. The report will be available by the end of the Contract year.

#### F. BARRIER CONTRACEPTION

Analyses of data from Phase II, straight studies of the Collatex sponge and Neo Sampoo foaming tablet, are being performed. Preliminary results indicate six-month pregnancy rates (life table) of 4.2 per 100 women and 6.9 per 100 women for the Collatex sponge and Neo Sampoo foaming tablet, respectively. Use of either of these barrier contraceptives appears to be acceptable in many cultures. Comparative studies are being conducted of various barrier methods, including Collatex sponge, Neo Sampoo, spermicidal foam and the diaphragm with spermicide. These

studies were initiated during the reporting period, and it is still too early to report any results.

A study is being developed to examine the clinical effectiveness of a vaginal contraceptive preparation, Conceptrol<sup>R</sup> cream (containing nonoxynol-9), as a prophylaxis against gonorrhea and other sexually transmitted diseases.

#### G. INTRAUTERINE DEVICES

The IFRP has pursued evaluations of IUD modifications and their acceptability. Following are some highlights of the recent results of these evaluations.

1. To reduce the risk of expulsion when IUDs are inserted immediately postpartum, the IFRP has added biodegradable extensions (#2 chromic gut sutures) to the Lippes Loop (Sutured-Loop) and TCu-220C IUDs (Sutured-T). The Sutured-Loop has been evaluated in eight studies and the Sutured-T in four. Data on 490 insertions of the Sutured-Loop and 376 insertions of the Sutured-T gave the following life table expulsion rates:

	Expulsion Rates (per 100 women)	
	1 mo.	3 mo.
Sutured-Loop	4.7	6.3
Sutured-T	5.3	7.5

A large scale clinical trial (about 11,000 insertions) of the postpartum devices is being conducted. Preliminary data on 136 insertions from a comparative study of the Sutured-Loop

and the standard Lippes Loop inserted by the hand technique gave the following results:

	One-Month Expulsion Rates (per 100 Women)
Lippes Loop D	19.4
Sutured-Loop	14.1

2. IUDs containing Trasylol or AMCA may reduce IUD-related menorrhagia and dysmenorrhea. Two quantitative blood loss studies have been initiated for the Lippes Loop D with AMCA and one for the Lippes Loop D with Trasylol. No data from these studies have been reported to the IFRP as of January 1980.

The IFRP has received data on 52 insertions in a comparative study of the Trasylol device vs a standard Lippes Loop D in which bleeding calendars are being used by the subjects.

There have been two expulsions and one removal for bleeding and pain of the Trasylol LLD, compared with one expulsion of the standard LLD.

In vitro studies of the sustained release of Trasylol from several materials indicated an instability problem. In the freeze-dried form, Trasylol is stable and heat resistant, but when fabricated into a sustained release system, much of the fibrinolytic activity of the drug is lost. On the other hand, IUDs containing AMCA have released clinically useful amounts of the drug for over a year during in vitro tests.

The ongoing clinical trials of Trasylol- and AMCA-releasing IUDs will be closely monitored in view of the results of the in vitro tests.

3. Two comparative studies of the Nylon T (a T-IUD wound with nylon instead of copper) and the TCu-200LB have been initiated to determine if the effectiveness of the copper IUD is due to the increase in surface area or from the addition of copper itself.
4. Photoreduced and tapered Lippes Loop D IUDs were developed to reduce the rates of expulsion and bleeding/pain removal. Analysis of data from these comparative studies did not indicate improved performance:

Six-Month Life Table Rates  
(per 100 Women)

	Photoreduced Lippes Loop (N = 338)	Standard Lippes Loop (N = 340)	Tapered Lippes Loop (N = 250)	Standard Lippes Loop (N = 250)
Expulsion	7.3	8.0	2.6	5.4
Removal for bleeding/pain	8.6	6.1	2.5	2.9

An application to the FDA for the fabrication, testing and evaluation of the Sutured-T intrauterine device in clinical trials was approved by the FDA in December 1979 (IND #16952). During the Contract year, the IFRP will prepare an IDE application to the FDA for the Sutured-Loop.

The IFRP is currently evaluating the best and most effective way to sterilize or resterilize copper-bearing IUDs. In this project, emphasis is being given to methods of cold sterilization that would be applicable for clinics in developing countries.

### III. OTHER RESEARCH ACTIVITIES

Although all IFRP activities related to Maternity Care Monitoring are now funded under the Grant, in the previous Contract year some Maternity Care Monitoring activities were funded through Contract 1172, especially those activities relating to the analyses of maternity data relating to contraception. The results from some of these analyses were presented at meetings and/or published during the first half of the current Contract year. A list of the papers is given in Appendix L.

The IFRP has continued to optimize use of the extensive data collected under contract to AID on the safety, effectiveness and acceptability of different contraceptive methods. Published papers based on an examination of the total experience reported to the IFRP are indicated in Appendix E by asterisks. Analyses of specific aspects of contraception continue to be performed by the scientific staff using the extensive data of the IFRP.

Under Contract 1172 the IFRP provides support for investigators to travel to meetings to present the results of their studies. More importantly, investigators or persons designated by them come to the IFRP for an extended visit for training in data collection procedures

and analysis techniques as well as selected aspects of computer programming. Dr. Ximena Tacla of the Barros Luco Hospital, Santiago, Chile spent three weeks at the IFRP for training in data analysis techniques. Training in the use of the IFRP computer systems and programming methods were also provided to Renaldo Araki, Universidad Estadual de Campinas, Brazil. One of the principal benefits obtained from this training is that some IFRP computer programs were able to be transferred to Brazil where they are now operational. Such transfers significantly upgrade local capabilities including those of the regional fertility research programs.

#### IV. SUBCONTRACTS

University of Exeter. This three-year subcontract awarded to the Institute of Population Studies (formerly the Family Planning Research Unit) is in its second year. Under the contract the Institute continues to assess a number of aspects of IUD usage, including issues related to safety and acceptability. The IFRP support to the Institute will progressively diminish, and by August 1981 the Institute is expected to be totally self-supporting and IFRP funding will terminate.

Hasan Sadikin Hospital, Bandung, Indonesia. The purpose of this subcontract is to evaluate the long-term safety associated with the use of Depo-Provera. Ever users of Depo-Provera at the Hasan Sadikin Hospital will be contacted and their health status evaluated. The study will also include a "control" group of women who have never used Depo-Provera.

The following subcontracts have been prepared by the IFRP and forwarded to AID. No action has yet been taken.

Study of Long-Term Depo-Provera Users, Thailand. Under a subcontract with the Ministry of Health, Thailand, a study is planned for Northern Thailand to evaluate possible adverse effects associated with the long-term use of Depo-Provera. The study will include women who have used Depo-Provera for ten or more years and a "control" group of never users of Depo-Provera.

Reproductive Age and Mortality Study (RAMOS). Under a subcontract with the National Family Planning Board of Indonesia (BKKBN), a study will be conducted to evaluate the cause of death to all women of reproductive age on the island of Bali. These data, combined with the excellent records on contraceptive practice, should provide good estimates of the risks of death associated with the use of different contraceptive methods including the use of no method.

Johns Hopkins University. Two subcontracts with the Johns Hopkins University will evaluate specific aspects of the toxicology and teratology of quinacrine hydrochloride in laboratory animals (monkeys and rats). The data from these studies should be sufficient for the IFRP to obtain an IND for the evaluation of the intrauterine administration of quinacrine hydrochloride for permanent female sterilization.

#### V. DISSEMINATION OF INFORMATION

The IFRP is committed to providing the widest practicable distribution of its research findings. To this purpose, the IFRP supports

the International Journal of Gynaecology & Obstetrics (IJGO), writes, publishes and distributes Network, a quarterly newsletter, 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. The backlog of press-ready manuscripts for Volume 17 has enabled the IFRP staff to develop special presentations for a series on Midwifery, a feature on Maternity Care Monitoring and "New Titles," a regular reader service listing also designed to help attract advertising from publishing houses. A second International Forum was prepared and is in press for a later issue, as is a special series on legal aspects of fertility control.

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. Additional exposure at this Congress was provided by the Wyeth International, Ltd. commercial exhibit which was devoted to a recent issue of IJGO. At the Association of Gynaecological Laparoscopists meeting in November, several hundred sample Journals and subscription cards were presented to participants. The third major effort will involve a direct mail subscription drive to over 15,000 potential readers.

The Journal staff has been reduced from the equivalent of 4 1/2 full-time staff to the equivalent of 2 1/2 full-time staff. Subscription and reprint management, mailing list maintenance and inventory control have been transferred to Waverly Press.

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 has been positive. The first issue was mailed to over 4,000 individuals and institutions, and IFRP receives new requests for the publication every week. Approximately 4300 copies of the second issue were mailed and an even greater number of copies are scheduled for the third mailing.

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. Plans were finalized for the IFRP to cosponsor a seminar with Tulane University entitled "High-Risk Pregnancy: Diagnosis, Treatment and Prevention--a Major Update for Spanish-Speaking Health Professionals." The IFRP-sponsored sessions at this seminar will deal with issues related to contraceptive use. The seminar will be held in May 1980 immediately following the annual meeting of the American College of Obstetricians and Gynecologists.

Approvals were obtained and arrangements made for the IFRP to sponsor a special session on contraceptive development at the IXth World Congress of Fertility and Sterility in July 1980. Arrangements are in

progress for a meeting in Liberia for health professionals dealing with various issues related to contraceptive use and development.

The IFRP's scientific staff continues to disseminate research findings through many different channels. During the reporting period, Consultant Reports (Appendix D) were prepared for IFRP investigators and papers were published in a variety of journals, conference proceedings and other publications (Appendix E).

The IFRP staff were invited to participate in scientific meetings in the United States and abroad. These meetings included an NIH meeting on LH-RH analogues, Association of Gynecological Laparoscopists, and the World Congress of Gynaecologists and Obstetricians.

## VI. MANAGEMENT

As of January 31, 1980, the staff of the IFRP numbered 103, including six part-time employees. Contract AID/pha - C - 1172 funded 75.1% of the salaries of all direct employees during the reporting period. During this period the IFRP has been actively recruiting qualified scientists and field personnel.

No major changes have been made to the IFRP management structure or systems. Changes made during the last reporting period have been effectively implemented and the IFRP's operating efficiency has improved. The new management structure of the IFRP has allowed it to respond quickly and effectively to new research opportunities and projects.

IFRP PERSONNEL TRANSACTIONS  
August 1, 1979 - January 31, 1980

Position Grade	Hired	Departed	Number of Employees as of 1-31-80
10	0	1	8
9	0	1	3
8	1	0	8
7	0	1	7
6	2	2	7
5	3	4	20
4	1	0	9
3	5	3	23
2	4	1	11
1	<u>4</u>	<u>1</u>	<u>7</u>
	20	14	103

The Administrative Committee (Executive Director and Associate Directors) continues to implement policy and new management directions effectively, and to facilitate interdepartmental administration.

The IFRP Board of Directors met once during the reporting period (September 23-24, 1979). At the time of this meeting, the Board added two new members: Dr. Lise Fortier and Dr. Torrey Brown. The IFRP's Protection of Human Subjects Committee met twice during the six months: on September 14, 1979 and on December 14, 1979. The second meeting included the annual review of all IFRP studies.

Efforts continue to be made to broaden IFRP's funding base.

Unrestricted grants totalling \$20,315 were made to the IFRP. Two proposals were submitted to NIH and other proposals submitted to NIH earlier totalling over \$660,000 will be funded before the end of the

Contract year. One benefit to AID that results from the IFRP's broader funding base is a lowering to all funding sources of the overhead costs, a significant component of which is fixed expense.

The IFRP expended a total of \$1,449,072 during the first six months of the Contract year. Expenditures are summarized in the following table.

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

<u>Category</u>	<u>Amount</u>
Salaries	\$ 353,853
Fringe benefits	140,153
Consultants	9,253
Travel - domestic	14,778
Travel - foreign	89,634
Material and supplies	8,902
Subcontracts	29,008
Other direct costs	
a. Service centers	258,235
b. Direct department indirect	110,910
c. Other	<u>85,575</u>
Subtotal	\$1,100,301
General and Administrative	317,022
Fixed Fee	<u>31,749</u>
TOTAL	<u>\$1,449,072</u>

VII. FUTURE DIRECTIONS

During the second half of the Contract year, the IFRP will emphasize the implementation of recently approved, or shortly to be approved, contracts to evaluate further the safety of Depo-Provera and quina-craine hydrochloride and to evaluate the interrelationships of contraception and mortality.

The IFRP will also initiate comparative trials to evaluate the TCu-380Ag IUD versus the Multiload or Cu-7 IUD. Trials to evaluate IUDs with and without tails will also be initiated during the next six months. Data from additional comparative barrier studies will be submitted to the IFRP.

A continuing emphasis will be placed on studies of the laproclator, the side effects of different oral contraceptive formulations and trials of postpartum IUDs (the Sutured-T and Sutured-Loop). The IFRP will continue to screen, by way of its scientific committees, new contraceptive developments and eventually evaluate those methods which appear most appropriate for the developing world. Among the methods/products which may be evaluated by the IFRP are: a reformulation of the barrier contraceptive CCC, hormonal releasing implants and vaginal rings, and a norgestrel-releasing IUD.

Studies of the long-term risks and benefits of contraceptive methods will continue to be evaluated by the IFRP. The IFRP will be selective in its choice of these studies since they might require considerable contract resources. Projects will be undertaken which utilize the IFRP's unique data bank and its considerable professional resources.

The IFRP will seek the widest possible dissemination of its research findings and share its expertise with other organizations. Also, the IFRP will continue to review its management systems to ensure that its resources are used as wisely and effectively as possible.

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APPENDIX A  
COMPLETED DOCUMENTS

INTRAUTERINE DEVICES

Strategies

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

Forms

Quantitative Blood Loss Form

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

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)

Loading and Analysis Specifications

Loading specifications for Progestogen-Only Oral Contraceptive Studies

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 Life Table Procedures

APPENDIX B

COMPLETED MAJOR COMPUTER PROGRAMS

August 1, 1979 - January 31, 1980

1. Extended Life Table Rates Program
2. Female Barrier Long Form Loading Program
3. IUD Patient Summary Form Loading Program
4. Extended FS Life Table Rates Program
5. Extended CHEMFS Life Table Rates Program
6. Female Sterilization Master and Demographic Tables Program
7. Unlimited Time Span Generalized Life Table Program
8. Female Barrier Long Form Life Table Rates Program
9. Female Barrier Short Form Life Table 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)

APPENDIX C

FORMS RECEIVED AND LOADED INTO THE COMPUTER

August 1, 1979 - January 31, 1980

<u>Intrauterine Devices</u>	Admission	6,565
	Follow-up	4,351
	Method List	538
	Other	<u>65</u>
	Total	11,519
<u>Systemic Contraception</u>	Admission	172
	Follow-up	116
	Physical Exam	70
	Other	<u>55</u>
	Total	413
<u>Family Planning Clinic Record</u>		
(Depo-Provera Studies)	Admission	0
	Status	<u>3,790</u>
	Total	3,790
<u>Female Barrier Short Forms</u>	Admission	433
	Follow-up	<u>476</u>
	Total	909
<u>Female Barrier Long Forms</u>	Admission	370
	Follow-up	<u>559</u>
	Total	929

APPENDIX C (cont'd)

FORMS RECEIVED AND LOADED INTO THE COMPUTER

August 1, 1979 - January 31, 1980

Female Sterilization

Admission	1,949
Follow-up	2,227
Additional Information	351
Method List	1,756
Pregnancy Confirmation	<u>1</u>
Total	6,284

Chemical Female Sterilization

Admission	206
Follow-up	105
Installation	<u>509</u>
Total	820

APPENDIX D

COMPLETED CONSULTANT REPORTS (CR)

August 1, 1979 - January 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. Moran Caceres	824	141
Female Sterilization at the Univer- sity 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

## APPENDIX D (cont'd)

Title	Prepared for	Center No.	Study No.
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
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	Dr. J. Nunez	890	500

## Appendix E

### International Fertility Research Program

#### Publications

August 1, 1979 - January 31, 1980

#### PREGNANCY TERMINATION

Berger GS, Edelman DA, Keith LG: Auxology: human growth in health and disorder. In Proceedings of the First International Congress of Auxology, Rome, April 12-16, 1977. 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: Avoidance of late abortion (editorial). Lancet 2(8152):1113, 1979. (PT-122)

#### MENSTRUAL REGULATION

Laufe L: Menstrual regulation--international perspectives. In Proceedings of the PARFR International Workshop on Pregnancy Termination, Nassau, Bahamas, May 23-26, 1978. Harper & Row, Hagerstown, MD (in press). (MR-44)

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

#### 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)

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 quirurgicos 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 Poblacion, 1979. (FS-105)

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 (in press). (FS-110)\*\*

Hulka JF, Omran K, Lieberman B, Gordon A: Laparoscopic sterilization with the spring clip and current clinical experience. Am J Obstet Gynecol (in press). (FS-113)

McCann MF, Cole LP: Laparoscopy and minilaparotomy: a revolution in female sterilization. Stud Fam Plann (in press). (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)\*\*

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

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

#### 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 S: Flushing of the distal vas during vasectomy: current status and review of literature. Urology 14(5), 1979. (MS-6)

#### 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)

Batar 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. 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-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-69)

Batar 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)

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)

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Bhiwandiwalla P: Involving the community--Howrah. In Birth Control: An International Assessment (ed DM Potts, P Bhiwandiwalla) Chap 6, p 93. University Park Press, Baltimore, 1979. (SYS-23)

#### EVALUATION

Goldstein MS, Donaldson PJ: Exporting professionalism: a case study of medical education. J Health Soc Behav, p 322, 1980. (EVAL-36)

Laufe LE: Obstetric forceps. In Gynecology and Obstetrics, Vol 3 (ed JJ Sciarra). Harper & Row, Hagerstown, MD (in press). (EVAL-40)

Peng JY: Family planning services by traditional birth attendants. In Proceedings of the Joint IGCC/IFRP East and South East Asia Seminar on Regional Fertility Research, Bangkok, July 18-20, 1979, p 130. IGCC, Kuala Lumpur, 1979. (EVAL-44)

Edelman DA: Prospective studies on the risks and benefits of contraception. In Proceedings of the Joint IGCC/IFRP East and South East Asia Seminar on Regional Fertility Research, Bangkok, July 18-20, 1979, p 98. IGCC, Kuala Lumpur, 1979. (EVAL-45)

Potts M: Retrospective Studies Specially on Depo-Provera. In Proceedings of the Joint IGCC/IFRP East and South East Asia Seminar on Regional Fertility Research, Bangkok, July 18-20, 1979, p 100. IGCC, Kuala Lumpur, 1979. (EVAL-47)

McDaniel EB, Potts M: International Forum update: depot medroxyprogesterone and endometrial carcinoma. Int J Gynaecol Obstet 17(3):297, 1980. (EVAL-57)

Derman R, Edelman DA, Berger GS: Current status of immunologic pregnancy tests. Int J Gynaecol Obstet 17(2):190, 1979. (EVAL-53)

## METHODOLOGY

Kim Su, Donaldson PJ: Dealing with Seoul's population growth: government plans and their implementation. *Asian Survey* 19(7):660, 1979. University of California Press, Berkeley, CA, 1979. (METH-41)

Peng JY: The role of traditional birth attendants in family planning programs in Southeast Asia. *Int J Gynaecol Obstet* 17(2):108, 1979. (METH-46)

## BARRIER CONTRACEPTION

Taylor RN Jr, Goldsmith A, Behlilovic B, Stanojlovic B, McCann MF: Preliminary results of a multiclinic trial of a polyurethane-spermicide contraceptive sponge. In *Vaginal Contraception: New Developments. Proceedings of an International Workshop on New Developments in Vaginal Contraception, Guatemala City, Guatemala, April 25-27, 1979* (ed GI Zatuchni, AJ Sobrero, JJ Speidel, JJ Sciarra), p 119. Harper & Row, Hagerstown, MD, 1980. (BAR-1)\*\*

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López-Escobar G, Fortney JA, Riaño-Gamboa G, Daza L: Maternity record: initial report on a national experience (Colombia). *Int J Gynaecol Obstet* 17(1):40, 1979. (MAT-15)

López-Escobar G, Riaño-Gamboa G, Stewart K: La embarazada adolescente. In *Avances en Obstetricia y Ginecología, Vol 14*, p 109. Corporación Centro Regional de Población, Bogotá, 1979. (MAT-16)

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López-Escobar G: Breech presentations in a sample of Colombian hospitals. *Int J Gynaecol Obstet* 17(3):284, 1980. (MAT-19)

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Kessel E: Maternity care monitoring. Commemorative Souvenir Golden Jubilee Publication of the Nowrosjee Wadia Maternity Hospital, Bombay, India. (MAT-24)

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