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INTERNATIONAL FERTILITY RESEARCH PROGRAM
Research Triangle Park
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I. INTRODUCTION

This nine-month reporting period includes significant accomplishments both in the development of the International Fertility Research Program (IFRP) and the use of the IFRP research by AID. Landmarks in our development were:

1. Moving to offices in Research Triangle Park
2. Purchase and installation of a Burroughs 6700 computer
3. Affiliation with the International Federation of Gynecology and Obstetrics (FIGO) for:
 - a. joint publication of the INTERNATIONAL JOURNAL OF GYNAECOLOGY AND OBSTETRICS
 - b. joint sponsorship of a pretest of the Maternity Record
4. Establishment of the Bangladesh Fertility Research Programme and appointment of IFRP as Official Consultant to the Peoples Republic of Bangladesh
5. Completion of first study in IFRP's sixth study area--Systemic Contraceptive Study
6. Pretest of the Family Planning Clinic Record by the government of Iran
7. Agreement by the International Planned Parenthood Federation (IPPF) to use the Family Planning Clinic Record on a trial basis in several affiliate clinics
8. Initiation of a Household Distribution of Contraceptives Study for the government of Tunisia

9. Provision of training in female sterilization at eight medical schools at the request of the Peoples Republic of Bangladesh

10. Completion of staffing of all approved positions of IFRP

AID is making increasing use of IFRP capabilities for specific tasks. A very close working relationship was established with the Research Division in delineating relative side effects of three oral contraceptives procured in large numbers by AID. Assistance to the government of Tunisia in studying the feasibility of Household Distribution of Contraceptives was also a joint effort with the Research Division. IFRP processed data for the Family Planning Services Division to evaluate their minilap equipment distribution program.

Increasingly, IFRP is providing services to other AID contractors to evaluate equipment designed by Battelle Northwest, to test a new IUD for PARFR, and to provide data collection and processing services for the Southwest Foundation for Research and Education.

Results of many IFRP field trials are needed to provide a firm foundation for important programmatic decisions of AID, such as the safety of minilaparotomy for female sterilization or the effectiveness of the tubal ring for tubal occlusion.

What are less obvious, but possibly the most important accomplishments for the future contribution of IFRP, are its growing computer data base and wide geographic distribution of its highly skilled field trial clinic network. Before long, it should be possible to conduct case control epidemiological studies off the IFRP computer data base to answer present and future questions regarding the safety of methods of fertility control. At this stage in development, clinics in the IFRP contributor network can now be referred to as Research and Training Centers. Each has linked to its center several service programs into which newer developments in fertility control can be rapidly diffused. IFRP can now exploit this natural extension into training and service of the methods documented as safe and effective in contributor centers.

We look forward with optimism to the final year of our contract, confident that an organization has been developed that can significantly influence adoption of improved methods in family planning programs, and thereby, slow the too rapid rates of population growth.

FIELD ACTIVITIES

Field activities during this reporting period were essentially the same as in the preceding year (see Annual Report for 1975), but the amount of data collected and the number of geographic areas covered were considerably expanded. A number of studies were initiated as a part of the IFRPs regionalization program, in Bangladesh, other Asian countries (especially in the Inter-Governmental Coordinating Committee countries), the Sudan, Colombia, and Egypt. Also a number of special studies of scientific and/or programmatic importance, such as induction of abortion by prostaglandin suppositories, evaluation of the Lau and other pregnancy tests, IGCC collaborative studies of anesthesia for female sterilization, nonsurgical (Quinacrine) female sterilization, evaluation of the "Vaseal" and "Vasector" units for male sterilization, study of the durability of menstrual regulation equipment, evaluation of the Battelle Hand Pump for first trimester abortion and testing of the FIGO minilap kits, were begun. A group of studies related to family planning program evaluation, for example Female Sterilization and Pregnancy Termination Surveillance, Household and Community Distribution of Contraceptives, the Family Planning Clinic Record, and several health-family planning interrelated studies including the Maternity Record; studies of threatened, inevitable and incomplete abortions treated in hospitals; rural penetration project; and a study of abortion sequelae in Singapore were also undertaken.

Because of the increased number and variety of forms received and the increased need for training Data Collection Coordinators in connection with IFRPs regionalization efforts, it was necessary to appoint an Assistant Data Collection Coordinator. Because of increased activities in Asia, especially in Bangladesh, and in Latin America, Assistant Area Coordinators are being recruited for these two areas. Hopefully, these appointments will be made by the end of the year. With the increasing volume, variety, and complexity of field studies, more detailed record keeping became necessary for study classification, study monitoring, and documentation of committee processes. Correspondingly, the need to expand and broaden the duties of the Field Studies Administrative Assistant into those of a full-time Field Studies Coordinator became apparent. This position is expected to be created and filled in the very near future.

The Area Coordinators Committee continued to serve as the primary review body for study proposals, internationally related travel, and other activities related to field programs. Because adequate review of study proposals frequently required scientific and/or administrative inputs from IFRP staff other than those originally included as members of the Committee, the ACC was declared open to all staff. A representative from Design and Analysis and from Data Processing were asked to attend routinely, and Research Assistants/Associates were asked to be present when study proposals relevant to their areas were being considered. This has improved preparation and review of proposals and reduced delays in processing proposals.

Study Status Lists are appended (Appendix A) for each of the geographic areas with the exception of India, since studies in that country are conducted and analyzed by the India Fertility Research Programme. These lists are updated continuously and are a valuable tool for study monitoring. To date the IFRP has accumulated contributors in a total of 328 centers in 40 countries on all the major continents. During the past nine months, 106 centers in 30 countries have contributed data and negotiations regarding new studies are underway with an additional 53 centers in 25 countries.

Table I provides information on the number of studies by study area and the number of forms by country. Data from centers in India are not included since forms from Indian centers are processed in that country.

The 82,000 forms (exclusive of India*) received during this nine-month period show nearly a 50 percent increase compared to the approximately 87,000 forms received during the entire previous year (which included over 13,000 received in India by the India Fertility Research Programme). The pattern by country is in general similar to that of 1975 except for a marked increase in the number of studies in Chile.

Table II lists the "major contributors", defined as those who have submitted 375 or more forms in one or a combination of study areas. It is noteworthy, however, that compared with 1975, the number of countries represented

*Forms are currently being submitted to the India Fertility Research Program at a rate of nearly 22,000/year.

TABLE I
NUMBER OF CENTERS ACTIVE JANUARY 1 - SEPTEMBER 30, 1976

Country	Number Centers	Number of Studies by Study Area								Total	
		PT	MR	IUD	FS	MS	SYS	Mat Rec	Special Studies	Studies	Forms Received*
USA	11	1	1	1	4	3	3	2	-	15	1 750
England	6	2	-	-	5	-	-	-	-	7	1 008
Yugoslavia	8	3	3	9	-	-	-	-	-	15	5 777
Switzerland	1	-	-	-	-	-	-	1	-	1	358
Sweden	2	-	-	-	-	-	-	2	-	2	314
Hungary	2	-	-	4	-	-	-	1	-	5	1 392
Egypt	10	5	-	11	9	-	-	3	-	28	4 604
Iran	15	1	7	5	5	-	-	-	4	22	2 178
Lebanon	1	-	-	-	2	-	-	-	-	2	65
Nigeria	1	-	1	-	-	-	1	-	-	2	897
Ghana	1	-	-	-	-	-	-	1	-	1	300
Sudan	3	3	-	1	1	-	-	3	-	8	2 162
Zambia	1	-	-	-	-	-	-	1	-	1	300
Philippines	3	1	-	-	4	-	-	1	-	6	1 562
Pakistan	1	-	-	-	2	-	-	-	-	2	153
Singapore	2	3	4	-	2	-	-	1	3	13	17 969
Korea	2	-	-	-	4	-	-	1	0	5	2 385
Indonesia	4	-	1	2	4	-	-	1	-	8	2 179
Thailand	2	-	-	-	3	-	-	-	-	3	642
Malaysia	4	-	1	-	4	-	-	-	-	5	875
Sri Lanka	3	-	1	-	2	-	1	2	-	6	1 840
Bangladesh	4	1	2	-	4	-	-	-	-	7	2 434
Taiwan	1	-	-	-	1	-	-	-	-	1	388
Chile	5	1	2	12	7	-	-	1	-	23	9 805
Colombia	3	-	1	-	2	-	-	-	-	3	2 823
El Salvador	2	-	-	1	9	1	-	1	-	12	4 229
Costa Rica	1	-	-	-	2	-	-	1	-	3	551
Guatemala	1	-	-	-	-	1	-	-	-	1	1 500
Mexico	2	-	-	1	2	-	-	-	-	3	900
Brazil	1	-	-	-	1	-	-	-	-	1	20
Total	103	21	24	47	79	5	5	23	7	211	71 360

* Admission and follow-up only.

TABLE II
MAJOR CONTRIBUTORS*
JANUARY 1 – SEPTEMBER 30, 1976

Country	Center	Study Area(s)	Total Forms Received	Country	Center	Study Area(s)	Total Forms Received
USA	970	PT	4 911	Indonesia	739	IUD, FS, Mat R	1 301
	909	PT	5 683		796	FS	384
England	016	FS	484	Thailand	075	FS	626
Yugoslavia	020	MR, IUD	1 995	Taiwan	781	FS	388
	022	PT, IUD	997	Malaysia	791	MR, FS	634
	024	IUD	657				
	241	IUD	1 075	Sri Lanka	700	SYS	1 058
			737	FS, Mat R			
Hungary	026	IUD, Mat R	573	Bangladesh	721	PT, MR, FS	1 279
Egypt	221	IUD	819	723	FS	FS	827
	030	PT, IUD	2 618				
	035	PT, Mat R, FS	5 523				
	358	PT, Mat R, FS	487				
Iran	305, 306**	MR, FPCR	527	Chile	086	IUD	751
	321	MR, IUD, FS	489		087	MR, IUD, FS	1 301
					088	IUD, FS	6 932
			850	FS, Mat R	548		
Nigeria	040	MR, SYS	899	Colombia	810	FS	654
Sudan	047	PT, IUD, Mat R	787		811	FS	2 126
	048	PT, Mat R	467	El Salvador	821	FS, MS	2 338
	049	PT, FS, Mat R	908				
Philippines	600	FS, Mat R	1 317	Costa Rica	831	FS	551
Singapore	070	PT, MR, FS	2 204	Guatemala	841	MS	1 500
Korea	750	FS, Mat R	1 955	Mexico	860	FS	514
					861	IUD	386

* Centers submitting 375 or more forms in one or a combination of study areas.
 ** One contributor submits data from these two centers.

by major contributors was increased from 16 to 23 by the addition of Bangladesh, Colombia, Malaysia, Mexico, Nigeria, Taiwan, and Sri Lanka. It should be emphasized, however, that an arbitrary number of forms received is not necessarily a valid criteria for defining "major contributors" since this criteria does not necessarily measure the complexity of studies or the quality of the data submitted. There are excellent contributors whose research produces a relative low volume of forms, but data of major significance and of high quality. Such contributors may not be represented in such a table, while others who produce a high volume of lesser quality data may be.

Table III summarizes by study area data received for 1971 to 1974, during 1975, and during the first nine months of 1976. Pregnancy termination, intrauterine device, and female sterilization studies continue to be the most active, but there is a noteworthy increase in special studies, including the Maternity Record.

TABLE III
IFRP DATA FORMS RECEIVED BY STUDY AREA

Study Area	July 1971 – Dec 1974		Jan – Dec 1975		Jan – Sept 1976		Total	
	No.	%	No.	%	No.	%	No.	%
Pregnancy Termination	52 010	16.41	20 777	6.55	3 113	0.98	75 900	23.94
Menstrual Regulation	10 915	3.44	8 336	2.63	5 647	1.78	24 898	7.85
Intrauterine Device	54 118	17.07	24 409	7.70	18 899	5.96	97 426	30.73
Female Sterilization	24 871	7.84	23 173	7.31	18 519	5.84	66 563	21.00
Male Sterilization	1 591	0.50	611	0.19	1 883	0.59	4 085	1.29
Systemic Contraception	3 520	1.11	884	0.28	2 038	0.64	6 442	2.03
Maternity Record	0	0.00	2 301	0.73	6 362	2.01	8 663	2.73
Special Studies	0	0.00	6 563	2.07	26 490	8.36	33 053	10.43
Total	147 025	46.37	87 054	27.46	82 951	26.17	317 030	100.00

Table IV records the percentage of forms submitted by study area during 1974 and 1975 and during the first nine months of 1976. Notable changes are a marked decrease in pregnancy termination forms and a marked increase in special studies forms including the Maternity Record. There was a moderate percentage decrease in IUD and FS forms received and a moderate increase in MS and systemic forms. However, on the basis of total forms flow corrected for the time period (see Table III), there was an actual increase in both IUD and FS forms and an approximately four-fold and three-fold increase in MS and Systemic forms, respectively, although the totals remain rather small in both instances. Forms flow in both study areas is expected to increase in the future.

TABLE IV
ANNUAL PERCENT DISTRIBUTION OF FORMS
BY STUDY AREA

Study Area	1974 Jan-Dec	1975 Jan-Dec	1976 Jan-Sept
Pregnancy Termination	24.5	23.87	3.75
Menstrual Regulation	9.0	9.58	6.81
Intrauterine Device	47.5	28.04	22.78
Female Sterilization	17.4	26.62	22.33
Male Sterilization	0.3	0.70	2.27
Systemic Contraception	1.2	1.02	2.46
Maternity Record	0.0	2.64	7.67
Special Studies	0.0	7.54	31.93

Highlights in the several geographic areas include the following:

Latin America

Latin America continued to be an active, expanding study area during the first nine months of calendar year 1976. A program that started in late 1973 and submitted hardly more than three hundred forms in that year, has now provided a total of nearly 20 percent of all the forms received by the IFRP since its beginning.

At present there are 33 active IFRP studies in Latin America, 30 have been completed and 29 are pending. Latin America is active in all major areas of IFRP research and Latin American contributors, in addition to conducting good quality studies, are also active as IFRP technical consultants, as well as in evaluating new equipment and procedures (Zipper, Madrigal, Guzmán Serani, Quiñones) and in pretesting new data collection instruments (Quan, Riaño). Some have also developed new techniques, such as Quinacrine for female sterilization the Cu-7 IUD, and modifications of the Cu-Zn 7 IUD.

Two Latin American contributors visited IFRP headquarters during the first nine months of 1976--Dr. Jaime Zipper (Chile) and Dr. Rodolfo Quiñones (México). During 1976, the Area Coordinator for Latin America traveled to Chile, Brazil, Bolivia, Colombia, Panamá, El Salvador, and Guatemala to monitor studies and contact new contributors. All but two of the Latin American contributors were personally contacted during this nine-month period. The Area Coordinator attended, as a special lecturer, The Pathfinder Fund meeting in Airlie, Virginia, served as a Faculty member at the PIEGO Seminar in Panamá, and acted as a consultant for the Ministry of Public Health in El Salvador. A visit was made to AID/W and IPPF/WHR to discuss coordination of Latin American Projects.

During this period, eight papers prepared in 1975 were published, five of them in the Colombian Obstetrics and Gynecology Journal. An additional seven papers were prepared in the first nine months of 1976 (all are already accepted for publication), and six papers are in preparation for October and November meetings.

All basic IFRP forms are in a final or near final Spanish translation. The Area Coordinator for Latin America was also partially involved in the development of the incomplete abortion form, maternity record form, Quinacrine female sterilization form and protocol, and the revised IUD forms.

A Regional Program, the Programa Regional de Investigaciones en Fecundidad (PRIF), was established in cooperation with the Corporación Centro Regional Población (CCRP) and is now managing three active studies. The IFRP computer programs for female sterilization studies have already been partially transferred. Special agreements were reached with IPPF/LONDON for evaluating Depo Provera cases in Honduras, with IPPF/WHR for developing a Family Planning Clinic Record Evaluation System for El Salvador, and with the Ministry of Public Health, El Salvador for pretesting data collection instruments to be used in Rural Health Penetration Programs

The location of centers, the names of contributors, the types of studies, and the flow of forms are indicated on the Study Status Lists for Latin America (Appendix A).

North Africa and the Middle East (Exclusive of Iran)

Jordan and Tunis are new additions to the network of active contributors in this region which now includes major universities in Egypt and Sudan. Unfortunately, studies at the American University in Beirut, Lebanon, have been halted by the civil war there.

Female sterilization is the most active area of research in Egypt and Jordan. Straight and comparative studies utilizing various approaches to the Fallopian tubes and means of tubal occlusion are being evaluated. At Cairo University, a straight study evaluating the tubal ring has been completed including six-month follow-up data. A comparative study of the tubal ring and electrocoagulation is currently underway, and a new approach, a combination of a minilap incision and laparoscopic visualization of the tube, is being evaluated.

At Ain-Shams University in Cairo, two centers are evaluating a new vacuum cup (Vacu-lap) technique to deliver the tube and apply the tubal ring; both

centers use a minilap incision. At Al-Azhar University, minilap and standard laparotomy are frequently used.

The University of Alexandria, Egypt, and AUB, Lebanon (unfortunately disrupted by the civil war) are well established culdoscopy training centers. The tantalum clip is the usual method of tubal occlusion, but recently, the tubal ring has been added in Alexandria.

Posterior colpotomy is the main approach at the Misr Weaving Company Hospital in Mahalla El-Kobra, Egypt, and Khartoum North Hospital, Sudan, as well as the new center in Jordan. Laparoscopic sterilization by tubal ring and electrocoagulation are well established techniques at Assiut University where Dr. Fathalla, the President of the World Federation of Voluntary Sterilization, offers laparoscopic training to local and Middle Eastern physicians.

A series of major straight and comparative IUD studies are well underway at Al-Azhar University in Cairo, utilizing different designs of plain and copper Lippes Loops, the Cu-T, and medicated IUDs such as the U-coil loaded with progesterone and the Lippes Loop loaded with amino-methyl cyclohexanecarboxylic acid (AMCA). Patients are monitored to assess systemic as well as local effects of the medicated IUDs. Uterine measurements using the Battelle and Hasson sounds are made before insertion, and hystero-graphic studies are recorded. In all patients, the amount of menstrual blood loss is carefully measured by the atomic absorption technique. Such careful monitoring may increase our knowledge of the mode of action of IUDs as well as provide more accurate bleeding and expulsion rates.

New IUD designs, including the TR-10 and Soonawala devices, are currently being evaluated at Ain-Shams University. One study has been initiated at Alexandria University and another is underway at Ain-Shams University to test the effect on bleeding and expulsion rates of endometrial aspiration by a MR syringe prior to Lippes Loop insertions.

The newly modified tapered Lippes Loop IUD and the T device with polyethylene thread of the same dimension as on the Cu-T will soon be tested in Cairo University. A comparative study of the Cu-7 and the Lippes Loop D is currently underway at the Omdurman Maternity Hospital in Sudan.

The most recent and significant ongoing pregnancy termination studies are the evaluation of prostaglandin analogues at Ain-Shams, Alexandria, and Assiut Universities and a comparative study of induction of abortion by saline vs prostaglandin $E_2\alpha$ under paracervical block anesthesia also at Ain-Shams. One study evaluating vacuum aspiration and D&C has been completed at Cairo University. Two other studies to evaluate the Battelle hand pump and the Lau pregnancy test are underway at the same center.

A new menstrual regulation study has been initiated at Assiut University.

A new comparative study of the effects on liver function of Lo-Ovral and Neogynon is well underway at Khartoum General Hospital, Sudan. The IFRP is also involved in the design and analysis of the Household Distribution Study being conducted by the ministry of health in Tunis.

Five major universities in Egypt--Cairo, Ain-Shams, Al-Azhar, Alexandria, and Assiut--are also involved in the pretest of the Maternity Record. The Sudanese involvement in pretesting the Maternity Record constitutes the largest series in this study area to date.

Studies of inevitable, incomplete, and septic abortions have been recently expanded to 6000 cases in three major hospitals in Sudan. Data from these Sudanese studies currently constitute the largest series at IFRP from one study area and will be the subject of several publications.

A "National Sterilization Registry" has been established within the Egyptian Fertility Control Society. IFRP female sterilization forms have been adopted to assure uniform reporting. As a preliminary step toward regionalization in Egypt, emphasis will first be directed to FS studies and then expand to other fertility regulation areas.

The Sudan Fertility Control Association has also been making substantial progress toward regionalization.

Iran-Pakistan

Two field visits were made to this area, one during February 1976 and the other during May-June 1976.

Several studies in Iran have produced excellent quality data and have been expanded; a number of others have been discontinued because of poor progress or lack of need for further data. Partial success was achieved in having certain Iranian centers absorb local costs, and several new studies were initiated with no obligation on the part of IFRP for forms payments. Efforts are underway to expand this trend, and ways are being explored by which IFRP can be compensated for studies at certain centers. Ongoing studies include two large (1000 cases each) menstrual regulation studies, a comparative study of menstrual regulation performed by physicians and nurse-midwives, and comparative and straight female sterilization studies.

Two new study areas received special emphasis in the Iranian program. The Family Planning Clinic Record is being pretested at three major centers within the Ministry of Health. In depth analysis is underway on data from one of these pretest studies, and a formal presentation will be made to the Ministry of Health in February 1977. It is hoped that the Ministry of Health will adopt the system for its National Family Planning Program. Emphasis was also given to the use of paramedical personnel, especially in performing menstrual regulation procedures and IUD insertions. One contributor has also developed a program to train nurse-midwives to perform female sterilizations via suprapubic laparotomy (minilap). The IFRP is encouraging centers to record the experiences of paramedical personnel on IFRP forms.

Responsibility for developing a research network to coordinate studies in Pakistan was assumed during 1976 by the Area Coordinator for Iran, and a field trip to Pakistan was made in June. Four female sterilization studies and one maternity record study have been initiated and several additional studies are under consideration. Further expansion of the network is anticipated during the coming year.

Initial contacts were made in Dubai, United Arab Emirates (UAE) in the course of a field trip to Iran in June. The Iranian Red Lion and Sun Health Facilities organization, which has a rather sizable network in the UAE, has been the IFRP's key contact there. A pretest study of the Maternity Record is underway at the Dubai Medical Center. The IFRP will make no commitment for data

collection costs in these studies. Moreover, as our research involvement grows in the UAE, it is expected that the IFRP will be compensated for its total study cost.

Asia (Exclusive of India)

This extensive, heterogeneous area, along with India, continued to be the most active in terms of total number of active centers and volume of forms flow. Important developments included the following. The year started with the InterGovernmental Coordinating Committee (IGCC) Contributor's Conference, held in Kuala Lumpur in early January. Participants from Nepal, Thailand, Malaysia, Singapore, Indonesia, and the Philippines showed great interest in research in fertility control. New equipment was discussed, and the needlescope was demonstrated. The IGCC decided to conduct comparative anesthesia studies to evaluate the various types of anesthesia being used by the member countries for female sterilization.

Noteworthy was the progress made toward regionalization. Regionalization of the Asia Program was discussed in detail at the IGCC Meeting held in January, 1976. Steps have been taken to facilitate collecting funds for setting up the central office. All member countries reviewed the regionalization proposal. Thailand and Indonesia showed interest in establishing individual country programs.

The agreement establishing the Bangladesh Fertility Research Programme (BFRP) was signed in July by the government of Bangladesh and the IFRP. Since the beginning of 1976 studies in Bangladesh have progressed at a rapid pace and have accelerated markedly since the formation of the BFRP. Ten new studies were initiated in September 1976 alone.

Several Data Collection Coordinators (DCC) were trained to improve data collection, both qualitatively and quantitatively, as well as to further progress toward formation of individual country programs. DCCs for Thailand and Korea were trained at the IFRP for three weeks followed by one week in Calcutta. The Data Collection Coordinator for Bangladesh was trained in Calcutta and will later spend some time at the IFRP. Her training has helped in establishing the

BFRP office and in improving the quantity and quality of data. Additional Data Collection Coordinators from rural centers in Bangladesh were subsequently trained in Calcutta.

Two doctors from Bangladesh were trained in the use of prostaglandins for abortion and in techniques of female sterilization at Kandang Kerbau Hospital, Singapore. One doctor from Bangladesh received training in these techniques in Bombay.

At the request of the government of Bangladesh, an extensive training program was organized by the BFRP with the assistance of IFRP. Drs. Laufe and Tyson visited all the medical schools in Bangladesh conducting training in the minilap technique of female sterilization using the double ring applicator with a light source. Phase II of the program will attempt to evaluate the effectiveness of this training program in stimulating further training of doctors in this technique in Bangladesh. A similar doctors training program is planned in Nepal.

Studies being newly conducted in Asia include:

1. A comparative oral contraceptive study with symptom grids in Bangladesh and in Thailand,
2. A cross-over study of high-dose and low-dose oral contraceptives with symptom grids in Singapore
3. A Depo-provera study in Indonesia
4. Studies of modifications of the Lippes Loop 100 in the Philippines and in Sri Lanka
5. A Battelle Hand Pump study in Sri Lanka
6. Evaluation of the PIEGO double ring minilap applicator in Nepal, Sri Lanka, Malaysia and Singapore

1. Evaluation of Waters Thermocoagulation Unit for female sterilization in Sri Lanka

8. Lau and Roche-Placentex pregnancy test studies and menstrual regulation kit durability studies in Singapore.

In addition, Maternity Record studies were also begun in seven countries in the area.

India

During this period, the emphasis in India was on developing the India Fertility Research Programme as an autonomous research organization. Expansion of new centers was restricted and efforts were focused on consolidating the existing ones. Several comparative studies were initiated in each of the major fields of fertility control. Studies were encouraged in rural areas, since that is where the greatest need exists. New techniques were developed and evaluated for outdoor camp sterilizations. At present, there are 43 active centers conducting 84 straight studies and 48 comparative studies. All data processing and analysis is being done in India; standard tables are prepared by the Delhi University Computer centre, and information of considerable scientific and programmatic significance is being obtained. The current submission rate of study forms to the India Fertility Research Program is nearly 27 000/per year compared to about 13 000 last year.

Research in several new study areas was initiated during the period. Ten centers participated in the pretest of the Maternity Record, and many more are expected to undertake the regular study after the form is finalized. One of the centers collects Maternity Record data from eight rural maternity homes situated in remote villages. Eleven studies are underway on prostaglandin vaginal suppositories. Among the equipment studies, the most prominent are evaluation of the Burnett hand pump, the minilap tubal ring applicator, and locally manufactured uterine vacuum aspirators. Large scale tests of the Lau capillary pregnancy test are being conducted at two centers. A study of community based distribution of contraceptives has been initiated in a rural area of Howrah district, the results of which will be of great significance for the family planning programme in India.

Members of the India Fertility Research Programme are regularly provided with detailed information on the latest international developments and techniques in fertility control. Contributors are supplied with new equipment which they evaluate and subsequently modify to suit local needs. Based on the results of these studies, the India Fertility Research Programme encourages manufacturers to produce the equipment locally at competitive prices and promotes their wide-spread use.

In order to disseminate the knowledge gained by these studies, the contributors have been encouraged and helped to present their findings at Indian and international conferences, and their papers (some 19 during the period) have been published in reputable journals. Indian contributors participated in the First Inter-Congress of the Asian Federation of Gynecology and Obstetrics held at Singapore in April 1976.

Many contributors received support to attend the XIX All India Congress in Obstetrics and Gynaecology at Jamshepur from December 27-30, 1975. The India Fertility Research Programme Contributor's Conference was held on December 31, 1975, at which there was a valuable exchange of ideas and information. Preparations are underway to publish the results. In July 1976, a book entitled the "Second Transaction of Scientific Papers at the India FRP Contributors' Conference", containing papers on studies conducted by the contributors, was published and distributed.

Indian contributors have been enthusiastic about sharing their experiences with other physicians and family planning administrators in India and other developing countries, and the benefits from this exchange have been considerable. The regional office of the India Fertility Research Programme has trained Data Collection Coordinators from Bangladesh, Korea, and Thailand; and physicians from Bangladesh and rural areas of India received clinical training at IFRP-related centers in Bombay.

Sub-Saharan Africa

In Sub-Saharan Africa, new studies were negotiated and initiated in two currently active centers. These centers in Accra, Ghana and Ibadan, Nigeria, are evaluating the Battelle hand pump for uterine vacuum aspiration. A tubal

ring female sterilization study has been approved for a hospital in Kenya, and two Sub-Saharan hospitals are pretesting the Maternity Record. The center in Ibadan has begun to record data on cases of culdoscopic and laparoscopic sterilization in preparation for a comparative study and is continuing the Goldzieher oral contraceptive/nutrition study.

Dialogue and negotiation increased with a number of additional potential contributors. Several African clinicians visited the IFRP, and tentative plans for further exploratory visits by IFRP staff have been made. Dependent on priorities and necessary funding, potential for expanding IFRP activities in Africa appear very good.

Europe and Australia

In 1976 there was a marked increase in activity for centers in England, a decrease in activity for the Yugoslav centers, and increased dialogue with several potential contributors in other parts of Europe and in Australia. There are now 21 active studies in this area, 10 more are ready to initiate studies, and in 11 other centers studies are under negotiation.

In Yugoslavia, where some of IFRPs earliest abortion studies were done, two large comparative abortion studies were recently completed comparing rigid and plastic cannulae. These included data on 2200 cases. A study initiated earlier on plastic versus metal cannulae remains active. Although menstrual regulation, often involving early abortion, is not emphasized in the Yugoslav national program, one small retrospective study from Northern Yugoslavia was initiated.

A study of 1 000 cases was initiated to evaluate the acceptance of IUDs after MR.

Two other MR studies to evaluate the Lau capillary pregnancy test are ready for initiation in England and Australia. In France, a study of induced abortion is under negotiation. For Austria, a study of female sterilization with the tubal ring via colpotomy is being conducted, the only IFRP related study of this kind initiated to date.

During 1976 two prostaglandin studies were initiated in Birmingham and London. One is a retrospective study on extraamniotic instillation of PGE₂ and

oxytocin in midtrimester abortion cases. The same hospital is conducting a study of vacuum aspiration with local anesthesia as an outpatient procedure, a routine practice at that site. The other prostaglandin study is a midtrimester procedure involving intraamniotic instillations of PGE, and urea followed by syntocinon when labor does not ensue.

In England, six hospitals have formed a testing network to give IFRP the only data being collected on the Rocket-made spring-loaded clip for female sterilization. During 1976, straight studies were completed and comparative studies involving the tubal ring were initiated. Two hospitals will soon undertake an evaluation of the PIEGO Minilap Kit. Also in England, a new hospital is testing the Waters low-voltage thermocoagulation unit, a study which may be followed by female sterilization studies comparing this new method with standard methods.

There are several continuing IUD studies in Hungary and Yugoslavia. Follow up is still being done on previously initiated studies of the Copper-7, U-Coil, Antigon, and Szontagh devices, as well as the IUM in standard, hydron, and soft (EVA) versions. New Studies of the TR-10 and Soonawalla IUDs have been initiated in 1976. Some of the Belgrade centers are now considering both straight and comparative studies of the photo-reduced and tapered Lippes Loop. In Germany, the IFRP has initiated a PARFR-funded study of bleeding patterns of a Lippes Loop device treated with EACA (epsilon-amino caproic acid). At the same center, a study of an IUD treated with AMCA (amino-methyl cyclohexanecarboxylic acid) is planned, as well as retrospective and prospective collections of data on the Multiload Copper IUD.

Four European Centers are providing pretest data on 300 Maternity Records. It is hoped that approximately a dozen large studies covering consecutive maternity cases for one year will later be initiated in Great Britain, Denmark, Sweden, Austria, Germany, Hungary, Italy, and Yugoslavia.

United States

Studies in the USA have continued to focus largely on male and female sterilization. An evaluation of 500 laparoscopic spring-loaded clip sterilizations with six-month and one-year follow-ups was completed at the University of

North Carolina and a smaller service is continuing in Philadelphia. The tubal ring is being evaluated in a straight study at Johns Hopkins University and in a comparative study versus the spring-loaded clip at the Medical College of Virginia. In both studies the approach is laparoscopy.

A great deal of detailed coordination with the Battelle Institute, the Electro-Medical System (EMS), and various contributors led to bringing the Vaseal unit for male sterilization to the field testing level. Five studies were initiated during early and mid-1976. The EMS is also developing a new prototype electrode needle. Findings relative to the Vaseal unit are inconclusive at this date. Intensive monitoring of these studies is being maintained.

Three comparative studies, each involving an evaluation of three oral contraceptives, are underway in cooperation with Planned Parenthood in Seattle; menstrual regulation studies are ongoing in Hawaii and Vermont; two USA centers--the University of North Carolina at Chapel Hill and Johns Hopkins--are currently participating in pretesting the Maternity Record; and three pregnancy termination surveillance studies are being conducted--two in Washington, D.C. and one in Minneapolis.

The pattern of having most of the ongoing and new studies in the USA conducted at no data collection cost to the IFRP has continued.

III. DESIGN AND ANALYSIS

A number of changes have been necessary in the Design and Analysis (D&A) staff to meet increased responsibilities, the rapidly increasing work load, and the expanded research efforts of the IFRP. On January 1, 1976, Dr. David Edelman became Head of D&A, a position which was vacated by Dr. Saroj Pachauri in June 1975. Additional staffing within D&A includes: a research analyst, three research assistants, and a studies clerk. Resumes are included in Appendix B for the new staff member.

A. Preparation of Data Collection Instruments

The following is a list of forms and protocols that have been developed since January 1, 1976:

- Maternity record instruction manual
- Non-surgical female sterilization procedures instruction manual
- Revised protocol for comparative IUD studies
- Instruction manual and protocol (revised) for systemic contraceptive studies
- Systemic contraceptive studies symptom grid form that can be optically read
- Forms for the household distribution study in Tunisia
- Protocol for an epidemiologic study on the possible relationship between use of oral contraceptives and thromboembolic disorders in Asian women
- Instruction manual for pregnancy termination surveillance studies
- Protocol to evaluate the postcoital insertion of IUDs in preventing pregnancy
- "Incomplete" abortion data collection form
- Method lists for selected IUD, abortion, menstrual regulation, and male and female sterilization studies
- Protocol for the evaluation of the Battelle hand pump
- Form for the evaluation of second trimester surgical evacuation procedures

Specifications for the following analysis systems were finalized and given to the Data Processing staff for implementation:

- Loading system and clinical standard tables for the maternity record studies
- Revised clinical and follow-up standard tables for male sterilization studies
- Loading and data cleaning systems for the long-term sequelae of abortion study
- Tunisia household distribution load system
- Loading system for the minilaparotomy data collection form

The following manuals and forms have been translated into Spanish:

- Female sterilization instruction manual
- Male sterilization study forms
- Systemic contraceptive forms
- Family planning clinic record form

B. Other D&A Activities

In March 1976, D&A prepared status reports for each study area. These reports (1) summarized the progress of surveillance, straight, and comparative studies, (2) summarized the principal research findings to date, and (3) proposed recommendations for future studies.

D&A assumed primary responsibility for the development of the bilingual forms (French and Arabic) and protocol, and for the implementation of the household distribution study that is being conducted in Sfax, Tunisia. The study will test the hypothesis that contraceptive use can be increased among rural women if contraceptives are readily available and easily accessible.

Selected D&A personnel participated in initiating studies including a pretest of the Family Planning Clinic Record and the Rural Health Aide Program in San Salvador.

D&A personnel have attended a number of professional meetings including the following: Population Association of America, International Family Planning Research Association, IXth International Conference on Health Education, American Statistical Association, and ACOG meeting.

Another activity of D&A is the development and evaluation of different analytical techniques for use in evaluating and comparing various methods of contraception. Methods for use in analyzing bleeding calendar data and discriminant analysis methods for use in evaluating contraceptive acceptance patterns are being evaluated.

C. Summaries of Research Findings

The following summaries highlight the major findings from research conducted through the IFRP since January 1, 1976.

Menstrual Regulation

1. Further studies have shown that menstrual regulation by vacuum aspiration is a safe and effective procedure. If performed within 14 days of delayed menstruation, the incidence of complications is about 3% and the incidence of failed procedures is about 2%. The incidence of complications is about twice as high among patients documented to be pregnant as it is among those who are not pregnant.

2. Based on the results of one study, menstrual regulation performed by nurse-midwives is as safe and effective as menstrual regulation performed by physicians.

3. A study of intrauterine instillation of 5 mg prostaglandin $F_{2\alpha}$ for menstrual regulation showed that this technique is no more effective than vacuum aspiration and that the incidence of side effects is substantially higher.

4. Intramuscular injection of an estrogen/progesterone mixture to induce menses was no more effective than no treatment. A similar study with progesterone alone has been completed but not yet analyzed.

5. A study of the durability of menstrual regulation kits (hand syringe and cannulae) has shown IPAS kits to be usable for more procedures than kits made by other manufacturers (Rocket and Burnett).

Pregnancy Termination

1. One study reported no significant differences in complication rates or surgical times between the metal and flexible plastic (Karman type) cannulae for terminating pregnancies of 7-10 weeks' gestation by vacuum aspiration. However, the metal cannula was associated with higher rates of cannula obstruction and retention of tissue. Other studies of metal and flexible plastic cannulae reported no differences between the two types of cannulae with respect to all criteria of performance.

2. Both the 50 mg and repeated 25 mg prostaglandin $F_{2\alpha}$ ($PGF_{2\alpha}$) dose schedules have shorter instillation-to-abortion times than 200 ml of 20% hypertonic saline (median, 26.3 hours), higher rates of incomplete abortion, and

higher rates of gastrointestinal side effects. The 50 mg PGF_{2α} dose schedule is associated with higher rates of side effects than the repeated 25 mg PGF_{2α} dose schedule.

3. Since the interval from intraamniotic administration to abortion has been reported to depend on the time of day PGF_{2α} was instilled, a study was undertaken to determine if there was a periodicity in response to the intraamniotic instillation of 200 ml of 20% hypertonic saline. In this study of 4000 hypertonic saline abortion cases, no significant differences in instillation to abortion times were found after controlling for the known effect of oxytocin infusion.

4. The repeated extraamniotic administration of 1.17 mg PGF_{2α} every 10 minutes over a 2.5- to 4-hour period resulted in shortened instillation-to-abortion times compared to those reported by other investigators. Compared to the intraamniotic administration of a repeated 25 mg dose or a single 50 mg dose of PGF_{2α}, the extraamniotic procedure reduced the amount of PG necessary to effect abortion, was associated with shortened instillation-to-abortion times, and similar rates of side effects and incomplete abortion.

5. In a comparative study (1100 subjects) of flexible (Karman type) and rigid plastic cannulae for performing first trimester abortions by vacuum aspiration, the flexible cannula was associated with significantly higher rates of retained tissue and cannula obstruction. There were no significant differences between the two types of cannulae with respect to all other criteria of evaluation: frequency of a second procedure to complete the abortion, procedure time, and frequency of specific complications.

Female Sterilization

1. The following results were obtained from a pooled study of 8568 laparoscopic sterilization procedures performed in 16 countries and including 4928 electrocoagulation, 1696 spring-loaded clip, and 1944 tubal ring procedures. Nearly 84% percent of the laparoscopies were performed as interval procedures.

a. Problems with equipment occasionally caused difficulties with all three methods of tubal occlusion, but problems were most frequent with prototype spring-loaded clip equipment. Failure to complete the planned procedure occurred less frequently among electrocoagulation cases (0.2%) than among spring-loaded clip (0.8%) or tubal ring (0.6%) cases.

b. For various reasons, laparotomy was required for five cases (0.1%). Bowel injuries occurred in five patients (0.1% of electrocoagulation cases); for four of these, no surgical treatment was required. Bleeding of the tubes and/or mesosalpinx was reported for a higher proportion of electrocoagulation (1.0%) and tubal ring (1.2%) patients than spring-loaded clip (0.2%) patients.

11.2. Comparative studies of interval sterilization via laparoscopy with electrocoagulation and division of the tubes or the application of spring-loaded clips, in which the technique of tubal occlusion was randomly assigned to a total of 600 subjects, indicated:

a. Technical difficulties were more frequent with the spring-loaded clip (7.3%) than with electrocoagulation (4.1%), primarily as a result of mechanical problems with the laparoscope.

b. Rates of surgical and early postoperative complications were similar for the two techniques.

c. Moderate or severe pain during the procedure was reported by a significantly higher proportion of the cautery (19.6%) than clip (7.3%) patients. However, postoperative pain was more frequent after the application of spring-loaded clips than after cautery both before discharge (33.2% and 22.4%, respectively) and at the 7-21 day follow-up visit (15.6% and 9.0%, respectively).

3. Pregnancy rates based on pooled data from comparative and straight studies of laparoscopy were significantly higher for the spring-loaded clip than for electrocoagulation and the tubal ring. The six-month rates were 1.3 per

hundred women for clip patients, 0.2 for cautery, and 0.2 for ring; twelve-month rates were 2.1, 0.2, and 0.3, respectively.

4. The following results were obtained from an analysis of long-term follow-up data from 14 Asian institutions on 2925 women sterilized by laparoscopic electrocoagulation (1526 cases); laparoscopic application of spring-loaded clips (286 cases) or tubal rings (422 cases); laparotomy with Pomeroy tubal ligation (342 cases); and culdoscopy with Pomeroy ligation (349 cases):

a. The incidence of menstrual irregularities within six months of sterilization and the incidence of gynecological abnormalities and the need for pelvic surgery within 12 months of sterilization were infrequent for all procedures.

b. Some changes in menstrual cycle parameters were reported for all sterilization procedures evaluated. For each of the procedures similar proportions of women reported an increase or a decrease in the severity of dysmenorrhea and in the duration and amount of menstrual flow.

5. In a study of culdoscopy in an outpatient setting at three institutions involving 525 patients:

a. The procedure could not be completed in seven (1.3%) patients. Although technical difficulties occurred in 16.6% of the procedures, none necessitated a change in the planned technique.

b. Complications at the time of surgery were reported for 2.1% of the patients.

6. An analysis of 398 cases of posterior colpotomy gave the following results:

a. Failure to complete the sterilization procedure occurred in 9 cases (2.3%).

- b. Potentially serious complications occurred in 10 cases (2.6%). This included two cases of bowel perforation and 8 cases of blood loss in excess of 100 ml, 4 of which required transfusion.

7. Based on an evaluation of 189 patients, laparoscopic sterilization with the application of tubal rings does not appear to result in increased rates of complications when performed 4 to 48 hours after treatment of a "spontaneous" (probably illegally induced) abortion

8. Three questions on the standard IFRP female sterilization forms that relate to the decision to be sterilized were analyzed for 1948 interval patients from three institutions.

- a. When asked why they preferred sterilization to other family planning methods, the majority of women at each center expressed concern about the side effects of other methods.
- b. Within each center, more highly educated women said that they were most important in the decision to be sterilized, while less educated women named a friend or relative as the most important person.
- c. Responses to the question about referral source indicated that more highly educated women sought information about sterilization from physicians and other health workers, while less educated women relied on their own knowledge of available services and that of their peers.

Male Sterilization

1. One study of 986 vasectomy procedures in Guatemala indicated that vasectomy is probably an acceptable method of contraception. Complications were infrequent with the resection and ligation procedure, and most men resumed intercourse within two weeks of the vasectomy

2. Multi-clinic trials of the Vaseal (an electrocoagulation device for vasectomy designed by Battelle Northwest) have been initiated in the United States. Preliminary reports from one contributor have indicated a higher than acceptable failure rate when the Vaseal is used in conjunction with the Schmidt

technique of vas occlusion. The trials are continuing and the results are being closely monitored.

Intrauterine Devices

1. In a study of 286 acceptors of the fluid-filled Tecna IUD, one-year rates of pregnancy, expulsion and bleeding/pain removal were higher than those for any of eight previously tested devices at the Family Planning Research Center in Ljubljana, Yugoslavia. Nearly 10% of the devices were spoiled because of difficulties related to inflation of the bag at the time of insertion.

2. Results from a study of a hydron-coated, soft material, and standard Intrauterine Membranes suggested that calcification of hydron devices leads to stiffness and a subsequent increase in bleeding/pain removals and expulsion. Use of a too-soft material led to expulsions for over half the women.

3. In a comparison of a small Copper-7 and a small Copper-Zinc-7 with the standard Copper-7, it was found that the addition of 47 sq mm of zinc in the superior position of the vertical arm led to a significant decrease in the rate of pregnancy compared to the rate for the standard Cu-7. There was also a significant decrease in rates of expulsion using a small 7 vector with the 200 sq mm of copper.

4. The long-term use effectiveness of the Cu-7 200, (based on 514 Cu-7 users who were followed up for up to 63 months) indicated that the yearly rates of pregnancy, expulsion, and removal for medical reasons did not increase with increasing duration of use. Five-year bleeding and/or pain removal rates in this study were significantly lower than corresponding rates in a study of the Lippes Loop C and D. Pregnancy rates were, however, significantly higher.

5. For 93 nulliparous IUD acceptors, immediate and early responses to IUD insertions were documented. After the IUD insertion, cramps were experienced by 95% of the cases. Bleeding and cramps at the time of or immediately after insertion were more frequent among Lippes Loop A or B and Dalkon Shield users than among Cu-7 users. However, among Copper-7 users such complaints occurred

more frequently, at one hour or more after insertion. The reported duration and amount of bleeding and the severity of cramps were not significantly different for the three types of IUDs.

6. The relationship of endometrial cavity length to IUD performance was evaluated in 319 women wearing different IUDs. Pregnancy, expulsion, and medical removal rates increased significantly when the length of the IUD, regardless of the type, equaled, exceeded, or was shorter by two or more centimeters than the length of the endometrial cavity. Total uterine cavity length was found to be a less accurate indicator of IUD performance than endometrial cavity length.

Systemic Contraceptives

1. Two oral contraceptive studies have been completed. In the first study (Pretest), patients were given either Ovral or Norinyl 1/50 for three cycles and were switched to Norlestrin 1 for the next three cycles. Symptom grids were completed for all six cycles by contacting women by telephone twice in a cycle. In the second study, three oral contraceptives (OCs)--Ovral, Norinyl 1/50 and Norlestrin 1--were compared during the first three cycles, and women were then either switched to another of the three OCs or remained on the same OC for the next three cycles; thus, 9 study groups were formed. Symptom grids were completed during the study period. The following are the important findings:

- a. The incidence of various side effects in these studies were higher than generally reported in the literature. The incidence of breakthrough bleeding (excluding spotting), for instance, obtained in this study was 18% to 26% compared to about 11% reported in the literature. This difference may be attributed to the method in which information was collected; women in these studies were contacted every two weeks by telephone and were asked about various signs and symptoms related to the use of the OC.
- b. Changes in the amount of menstrual flow (either an increase or decrease) were reported by most women during the study. Of the Ovral, Norinyl, and Norlestrin users, 60, 80 and 90% reported changes in menstrual flow.

The incidence of breast discomfort was higher for Norinyl users (43.0%) than for Ovral (25.8%) or Norlestrin users (28.6%).

d. The incidence of breakthrough bleeding was lower in the first cycle for Ovral users but increased in subsequent cycles. For Norinyl and Norlestrin users, the trend was reversed.

e. The incidence of nausea was higher for Ovral users than for users of the other OCs.

f. The side effects were generally of longer duration for Ovral users than the Norinyl or Norlestrin users.

g. Withdrawal bleeding occurred about one day later for Ovral users than for Norinyl or Norlestrin users.

h. After three cycles of OC use, the mean systolic blood pressure for users of all three OCs declined significantly (about 4 mm Hg) compared to the mean systolic blood pressure before OC use. Similarly, diastolic blood pressure declined significantly (by 2.5 mm Hg) only for Norinyl users; for the other two OCs a decline was also indicated but it was not large enough to be statistically significant.

Effect of Crossover

a. A switch from Ovral to Norinyl or vice versa resulted in an increased incidence of nausea. When Norlestrin users were switched to Ovral, they reported a higher incidence of nausea; no significant changes were reported when Norlestrin users were switched to Norinyl.

b. There was a significant increase in the incidence of abdominal bloating when Norlestrin users were switched to Ovral.

c. When switched to Norinyl, Norlestrin users reported a higher incidence of acne.

d. The incidence of breakthrough bleeding increased significantly when Ovral users switched to either Norinyl or Norlestrin. When Norinyl or Norlestrin users switched to Ovral, the incidence of breakthrough bleeding declined.

2. The following summarizes the results of the Depo Provera program at the Family Welfare Centre, Nairobi, Kenya. Of the 2577 participants 0.19% became pregnant while on Depo Provera. The cumulative continuation rates were 70.9, 55.0, 42.6, 32.4, and 25.5 percent at the end of 1, 2, 3, 4, and 5 years, respectively. The only acceptor characteristics associated with program continuation were previous contraceptive use of orals and IUDs and no child loss. Only 312 of the 1464 women who dropped out of the program (21.3%) cited specific reasons for doing so. Seventy-eight women gave menstrual irregularities as the reason. Increases in blood pressure may have influenced the decision for women to drop out of the program.

D. Preparation of Papers and Reports

The D&A staff participated in the analyses of data and/or writing of over 60 publications and/or presentations. A list of all IFRP publications is given in Appendix C. In addition the following Consultant Reports were prepared and sent with standard tables to the Contributors:

CONSULTANT REPORTS - JANUARY 1, 1976 TO SEPTEMBER 30, 1976

Consultant Report for Center 088, Study 302

Analysis of 384 Pregnancy Termination Cases, Lokmanya Tilak Municipal General Hospital, Bombay, India - Center 528, Study 001

A Comparison of Ragab Vacuum Cannulae With and Without Jet Stream on 298 Abortion Patients at the Maribor General Hospital, Slovenja, Yugoslavia - Center 023, Study 003

The Lau Capillary Pregnancy Test - for Dr. Lorrin Lau

Menstrual Regulation at University College Hospital, Ibadan, Nigeria - Center 040, Study 302

An analysis of 383 Sterilization Procedures at Ramathibodi Hospital, Bangkok, Thailand - Center 740, Study 621

Menstrual Regulation at the Vermont Women's Health Clinic, 1973-1975 -Center 944, Study 305

A Report on Dalkon Shield and Lippes Loop Insertions, Tehran, Iran -Center 032, Study 401

Evaluation of Dalkon Shield Insertions at Three Centers in Hong Kong -Centers 734-736, Study 407

Menstrual Regulation at the Eastern Women's Center New York City, 1974 -Center 906, Study 305

Lippes Loop Insertions at Isfahan, Iran, May to November 1973 - Centers 305-308, Study 410

Menstrual Regulation by Vacuum Aspiration at the Cebu City General Hospital in the Philippines 1974-1975 - Center 068, Study 302

Lippes Loop Insertions in Iran, November 1973 to October 1974 - Centers 316-320, Study 401

A Comparison of Metal and Flexible Plastic Cannulae for Performing First Trimester Vacuum Aspiration Abortions - Center 070, Study 006

Use of the Samaritan Clip Applicator and Spring-loaded Clips for Female Sterilization in England - Centers 016, 290, 291, Study 620

Vacuum Aspiration and D&C for 344 Patients at Model Outpatient Clinic, Dacca, Bangladesh - Center 721, Study 001

Female Sterilization in Indonesia - Center 074, Study 621

Female Sterilization at the Model Clinic Mohammadpur - Center 721, Study 611

Female Sterilization at Kandang Kerbau Hospital - Center 070, Study 621

Analysis of the Depo Provera Program, Family Welfare Center, Nairobi, Kenya, 1970-1974 - Center 340

Menstrual Regulation With the Karman Cannula and the Ragab Vented Cannula Center 303, Study 311

IV. DATA PROCESSING

Personnel

There was no change in the authorized staff size during 1976. Promotions and resignations resulted in the replacement of two programmers and six data processors from April through August. Performance was not seriously affected by this turnover.

Hardware

The IBM keypunches were replaced by four TAB Products Model 510 Punch/Verifiers. An increase in machine efficiency at a lower overall monthly cost was obtained by this change. A ninth Perry Electronics PE9000 Data Terminal was added to eight already in use. The installation of the B6700 computer will be discussed in a separate section.

Software

Early in this reporting period program codes were converted from IBM FORTRAN to Burroughs FORTRAN. The implementation of these programs on the IFRP's B6700 computer was successful. Also in this reporting period, the following programming systems were completed and implemented on the B6700:

- IUD bleeding calendar loading/editing (research)
- Minilaparotomy loading/editing (automatic correction)
- Maternity record loading/editing--intermediate version (automatic correction)
- Chemical female sterilization loading/editing--temporary (research)
- Female sterilization master tables (major rewrite)
- Female sterilization (chemical) demographic tables
- Male sterilization master tables
- Male sterilization demographic tables
- Maternity record analysis system--intermediate (demographic and clinical)

Systems which are presently under development, are being modified, or are in final testing include:

- Tunisia household distribution loading system (research)
- Long-term sequelae of abortions loading system (research)
- Female sterilization loading/editing (automatic correction)
- Male sterilization clinical tables

Forms Flow

During the move of IFRP to its new quarters, forms processing was effectively stopped for over two weeks. Installation difficulties with the B6700 combined with the move resulted in minimum forms loading from early April through late May. However, beginning early in June processing regained its typical efficiency. Tables I and II present a history of forms available for analysis and of active studies.

B-6700 Installation

The installation and overall effectiveness of the B6746 computer system was and has proven to be just about what was expected. Extensive problems involving the central processor and the maintenance diagnostic processor resulted in minimal available production time during April and May. Once these difficulties were corrected, overall computer processing capability available to the IFRP increased dramatically. Turnaround is almost immediate for short, non setup jobs. Even for the most complex, extended processing tasks, turnaround seldom exceeds two hours. With the increase in data base use brought about by the growth in the Design and Analysis staff, the greater computer processing capability is most welcome.

Six-Month Projection

It is likely that Data Processing will fill an additional programmer position during the first quarter of fiscal 1977. Anticipated tasks to be passed on from the Design and Analysis staff during this time will increase the DP work load to a level not previously experienced. It is not expected that additional Data Processors will be required.

As the performance of the IFRP computer system stabilizes and personnel increase their experience with it, we expect an increase in cost-effectiveness.

TABLE I
FORMS PROCESSED AND AVAILABLE FOR COMPUTER ANALYSIS
BY MAJOR STUDY AREA AND TIME PERIOD

Study Area	1972	1973		1974		1975		1976	Total
	Jan-Dec	Jan-June	July-Dec	Jan-June	July-Dec	Jan-June	July-Dec	Jan-Sept*	
Pregnancy Termination	10 054	8 506	7 440	8 062	12 300	9 004	9 973	12 653	77 992
Menstrual Regulation	0	1 075	518	3 847	4 306	2 964	4 804	5 084	22 598
Female Sterilization									
Admission									
Pretest	1 007	2 880	98	0	0	0	0	0	3 985
Final	0	250	2 443	6 092	6 550	4 519	6 259	9 036	35 194
Follow-Up/Method List	0	0	0	0	2 905	3 088	8 098	9 562	23 653
Intrauterine Device									
Admission	0	0	3 115	4 510	13 324	4 703	4 750	6 726	37 128
Follow-Up/Method List	0	0	3 000	6 445	14 577	6 016	10 656	15 043	55 737
Male Sterilization									
Admission									
Pretest	0	498	0	0	0	0	0	0	498
Final	0	0	0	0	0	0	380	1 240	1 620
Follow-Up/Semen Tests									
Pretest	0	496	0	0	0	0	0	0	496
Final	0	0	0	0	0	0	435	398	833
Systemic Contraception									
Admission	0	0	0	0	0	0	593	390	983
Physical/Symptomology	0	0	0	0	0	0	2 822	1 343	4 165
Follow-Up	0	0	0	0	0	0	1 016	541	1 557
Maternity Record								6 419	6 419
Other Major Studies								15 428**	15 428
Total	11 061	13 705	16 614	28 956	53 962	30 294	49 786	83 863	288 241

* Nine-month period.

** Washington Hospital Second Trimester Abortion Study (5683); Kalyan (Central Railway Hospital) Study (5013); Depo Provera Special Study (2577); MiniLap (2155).

TABLE II
NUMBER OF ACTIVE CENTERS* AND ACTIVE STUDIES
BY STUDY AREA AND TIME PERIOD

	June 30, 1974		Dec 31, 1974		June 30, 1975		Dec 31, 1975		Sept 30, 1976	
	Centers	Studies	Centers	Studies	Centers	Studies	Centers	Studies	Centers	Studies
All Studies										
Pregnancy Termination	66	7	57	6	57	10	65	13	52	13
Menstrual Regulation	34	5	39	6	39	8	46	9	33	6
Female Sterilization	34	7	46	8	55	11	83	15	94	21
Intrauterine Device	34	16	50	22	58	29	65	36	77	39
Male Sterilization	0	0	0	0	0	0	1	1	3	2
Systemic Contraception	0	0	0	0	0	0	1	1	2	3
Maternity Record	0	0	0	0	0	0	0	0	33	2
Minilaparotomy	0	0	0	0	0	0	0	0	32	1
Other Major	0	0	0	0	0	0	0	0	3	3
Total	168	35	192	42	209	58	261	75	329	90
Comparative Studies Only										
Pregnancy Termination	6	2	6	2	13	6	18	6	18	8
Menstrual Regulation	0	0	0	0	2	2	3	3	3	3
Female Sterilization	1	1	1	1	4	3	12	6	14	9
Intrauterine Device	0	0	2	2	6	4	8	6	23	12
Male Sterilization	0	0	0	0	0	0	0	0	0	0
Systemic Contraception	0	0	0	0	0	0	1	1	2	3
Maternity Record	0	0	0	0	0	0	0	0	0	0
Minilaparotomy	0	0	0	0	0	0	0	0	0	0
Other Major	0	0	0	0	0	0	0	0	0	0
Total	7	3	9	5	25	15	42	22	60	35

*Centers for which forms had been processed within 90 days of date were considered active.

V. ADMINISTRATION

During this reporting period the International Fertility Research Program (IFRP) completed its first full year of operation as an independent organization. The main thrust of activity has been to revise systems and procedures and to make adjustments in staffing to more effectively achieve the purposes of contract AID/csd-2979.

Financial Information

Prior to the beginning of fiscal year 1976, \$6 405 610 had been provided under contract AID/csd-2979. Of this amount \$5 988 111 had been used for actual and accrued expenditures. During fiscal year 1976, an additional \$2 695 000 was added to the contract amount. IFRP was authorized to expend \$3 284 868 or \$172 369 more than was available. Actual and accrued expenditures (less obligations made prior to fiscal year 1976, but paid in fiscal year 1976) totaled \$3 140 767 for a deficit of \$28 268. Financial statements are in Appendix D.

Personnel

During the reporting period, six new positions were added to Administration to improve support to the scientific divisions. On September 30, 1976, IFRP had 60.5 authorized positions of which 5 were vacant. The resumes of those persons who joined IFRP as members of either management staff or the scientific staff are in Appendix B.

Publications

The publications capability was upgraded during the reporting period. IFRP is now able to prepare, with in house equipment, all forms for data collection, the necessary charts and graphics for study instruction manuals, and information monographs. Appendix C contains two sample instructional pamphlets and a listing of publications produced during the reporting period.

Significant Problems

The lack of nongovernment funds continues to be the major problem plaguing IFRP. This deficiency significantly reduces the capability of the organization to move expeditiously in new directions to meet the changing needs of population/family planning.

Future Plans

First priority in future planning has been assigned to diversification of funding in order to increase the capabilities of the IFRP. Exploration of possible sources of gifts, contributions, and grants will continue. In addition, exploration has begun of possible ways in which the scientific capabilities of the IFRP can be used by governments other than the USA and by industry.

During fiscal year 1977, a review will be made of publications production needs with a view to upgrading present capabilities to meet the expanding need for high quality publications

Cost reduction possibilities are being intensively explored now. This exploration will continue through fiscal year 1977 particularly for word processing activities and for information services.

The review and revision of systems and procedures will continue throughout fiscal year 1977. As part of this review the system for job classification and salary administration will be carefully scrutinized.