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INTERNATIONAL FERTILITY RESEARCH PROGRAM

I. INTRODUCTION

This annual report marks the establishment of the International Fertility Research Program (IFRP) as an independent research organization. We are grateful to the University of North Carolina at Chapel Hill for providing a base for this program in its formative years and to our sponsors for their confidence in our ability to carry out the scope of work of this contract.

During 1975, development work was completed to conduct studies in all six study areas, the last being systemic contraceptives. IFRP's comprehensive field trial capabilities are now an important and recognized asset in the international population field.

The ability of IFRP to respond to newer developments in methods of fertility control is well illustrated by its studies in female sterilization this year. The safety and effectiveness of the tubal ring is now established. In the process of conducting trials to document this fact, the methodology has been widely spread in less developed countries.

Other promising technical advances are on the horizon and we pledge a maximum effort to be equally responsive to them. There are also serious questions being raised about well established contraceptives. IFRP will play its role in providing the answers to these questions.

The desire of couples in both developed and developing countries to control their fertility has never been so great. While the delivery of services remains the primary deterrent to demographic and health transitions in rural areas of poor countries, it must also be recognized that improved methods of fertility control can markedly ease the task of weak delivery systems. Never before have technological improvements had such potential for improving the quality of life than in this case of better methods of fertility control and their ability to accelerate an existing and desirable trend toward lower fertility and less rapid population growth.

II. FIELD STUDIES DIVISION

In 1974, its first full year in operation, the Field Studies Division (FSD), emphasized development and expansion, especially of its contributor network. Although growth continued during 1975, the FSD placed more emphasis on consolidating and scientifically upgrading studies. Fewer surveillance and straight studies were started in preference for a larger number of comparative studies. This emphasis is evident in Table I. Because comparative studies are more complicated, time-consuming, and costly than surveillance or straight studies, the number of forms decreased slightly from 90,973 in 1974 to 87,054 in 1975 while costs increased. However, the scientific value of the data also increased. A number of new contributors and cooperating centers from several additional countries were added to the contributor network.

TABLE I
TYPES OF STUDIES BY YEARS*

	1971-72	1973	1974	1975
Surveillance	9	15	24	23
Straight	62	114	211	218
Comparative	1	9	23	57

* A study in progress for several years is included for each year that it was active.

In its position as the generator of data on which the activities of the other divisions largely depend, the Field Studies Division is in the difficult position of having to consider the interests of each contributor and his institution, the impact of IFRP studies on population activities within each country, and their scientific and programmatic value to the IFRP and its funding agencies particularly USAID. Therefore it is especially important that the Area Coordinators know and be culturally attuned to their areas of responsibility in addition to being highly competent professionally and knowledgeable regarding IFRP (and USAID) objectives, procedures, and priorities. These objectives are furthered by, in most cases, having as area coordinators natives of the area for which they are responsible.

In the only major change in FSD personnel in 1975, Dr. Alfredo Goldsmith resigned as head of the Division so that he could concentrate primarily on Latin America. His resignation also enabled him to take a more active role in the development of forms and protocols, to interact to a greater extent with the Design and Analysis Division in developing Spanish translations of forms and protocols. On July 1, Dr. R. K. Anderson succeeded Dr. Goldsmith as Division Head. Dr. Anderson has been involved almost entirely in population-related activities during the past dozen years and has had technical assistance responsibilities in many parts of the world, including Asia, Africa, and Latin America.

In addition to Dr. Goldsmith for Latin America, the Area Coordinators included Dr. Anjali Saha for Asia (exclusive of India), Dr. Poursu Bhiwandiwalla for India, Ms. Helen Compton for Europe and sub-Saharan Africa, Dr. Javad Vakilizadeh for Iran, and Dr. Khairia Omran for North Africa and the Middle East exclusive of Iran. In addition, Dr. Omran coordinated female sterilization studies and Dr. Vakilizadeh all other IFRP studies in the USA; Helen Compton served as Administrative Assistant to FSD; and Dr. Bhiwandiwalla served as staff gynecologist. Betsy Drew continued as data collection coordinator throughout the year and from time to time acted for an Area Coordinator when he/she was traveling on IFRP business. Dale Flexner, formerly Assistant to the head of the FSD, is now assistant for regionalization in the Field Development Division headed by George Stathes. The Studies Manager position, formerly held by George Stathes and considered a service of the FSD, is now held by Peggy Morrow and is a part of Administration. The FSD continued to work closely with the Field Development Division in planning and implementing regionalization programs and with the Studies Manager in improving study monitoring and providing and listing clinical equipment. The FSD staff also cooperated with the Design and Analysis Division in developing data collection forms and in analyzing data.

The Area Coordinators Committee (ACC) continued to serve as the primary reviewing board for study proposals, travel requests, and other activities related to field programs. The head of the FSD chairs this committee, which includes all Area Coordinators, the Data Collection Coordinator, the Studies Manager, a representative from Administration, and from time to time the Director of IFRP and the Head of the Field Development Division. When their special skills and knowledge are relevant to proposals under consideration, other staff members are also requested to participate in ACC discussions. Proposals considered

by the ACC, usually on Monday morning, are considered by the Studies Review Committee, usually on Thursday morning, and then referred back to ACC for final action the following Monday. This system ensures a thorough review of each study together with minimizing the time between its initial proposal and initiation. An improved Study Proposal Form has been developed and has been in regular use for several months.

The Studies Status list, usually updated every three months, continues to be a valuable monitoring tool but is being supplemented by an "Administrative Computer Printout" developed by the Data Processing Division. This will help make continuous monitoring possible, in addition to providing other useful information.

The IFRP has to date accumulated contributors in a total of 299 centers in 38 countries on all the major continents. During the past year 145 centers in 29 countries have contributed data. Thirty-three new centers in 17 countries were added during the year, and data is expected from an additional 46 centers where studies have been recently negotiated and approved.

Table II provides a breakdown of studies active during 1975 by country, study area, and total number of forms received. Data from centers in India are included, but forms from Indian centers are processed in that country under the auspices of the India Fertility Research Programme. Costs of the Indian program are being met primarily by other than USAID funds.

Table III lists the major active contributors (defined as those who have submitted 500 or more forms in one or a combination of study areas). Not included are forms being developed and tested in conjunction with the Maternity Record System. Considerable interest has been evidenced in this apparently promising system, but additional funds must be received and further testing and adaptation will be required before it can be widely utilized.

Table IV summarizes data on the number of forms received by study area from 1971 to 1974 and during the year of 1975. Pregnancy termination, intrauterine device and female sterilization study areas show the greatest activity.

TABLE II
NUMBER OF CENTERS ACTIVE JANUARY 1, 1975-DECEMBER 31, 1975
NUMBER STUDIES BY STUDY AREA AND NUMBER OF FORMS BY COUNTRY

Country	Number of Centers	Number of Studies by Study Area						Special Studies	Total Number	
		PT	MR	IUD	FS	MS	SYS		Studies	Forms Received
USA	12	5	4	2	9	—	1	—	21	7 877
England	5	1	—	2	2	—	—	—	5	2 029
Yugoslavia	8	5	—	13	—	—	—	—	18	7 341
Hungary	2	—	—	6	—	—	—	—	6	4 157
Egypt	9	5	2	11	8	—	—	—	26	10 547
Iran	16	3	6	16	3	—	—	—	28	2 768
Lebanon	2	—	—	—	4	—	—	—	4	753
Nigeria	1	—	1	—	—	—	1	—	2	350
Ghana	1	—	1	—	—	—	—	—	1	249
Sudan	9	8	—	—	—	—	—	4	12	4 256
India*	31	30	18	2	21	1	2	—	74	13 108
Philippines	7	—	3	1	6	—	—	—	10	4 045
Pakistan	1	—	1	—	—	—	—	—	1	18
Singapore	2	5	2	—	2	—	—	2	11	8 138
Korea	2	—	—	—	4	—	—	—	4	4 408
Nepal	1	—	—	—	1	—	—	—	1	51
Indonesia	7	—	4	2	4	—	—	—	10	2 093
Thailand	3	1	—	1	7	—	—	—	9	3 823
Malaysia	3	—	—	—	3	—	—	—	3	297
Sri Lanka	4	—	—	—	4	—	1	—	5	1 047
Bangladesh	2	1	2	2	—	—	—	—	4	650
Taiwan	1	—	—	—	1	—	—	—	1	121
Chile	4	1	1	4	2	—	—	—	8	4 246
Colombia	6	6	—	—	—	—	—	—	6	294
El Salvador	2	1	—	1	6	1	—	—	9	2 351
Costa Rica	1	—	—	—	2	—	—	—	2	652
Guatemala	2	2	—	—	—	1	—	—	3	989
Mexico	1	—	—	—	1	—	—	—	1	44
Jamaica	1	—	—	—	1	—	—	—	1	352
Totals	146	74	45	63	91	3	5	6	286	87 054

* India forms received by the India Fertility Research Programme.

TABLE III
MAJOR* CONTRIBUTORS
JANUARY 1-DECEMBER 31, 1975

Country	Center	Study Area(s)	Total Forms Received
USA	001	FS	987
	903	PT, IUD, FS	629
	944	PT	1 248
	970	PT	4 023
England	219	IUD	1 721
Yugoslavia	020	PT, IUD	2 203
	021	PT	778
	022	PT, IUD	1 567
	241	IUD	1 876
Hungary	026	IUD	1 302
	221	IUD	2 855
Egypt	030	PT, MR, IUD	9 474
Iran	311	PT, MR	592
Sudan	048	PT	567
	049	PT	731
Philippines	060	FS	746
	600	FS	2 822
Singapore	070	PT, MR, FS, Special	9 113
Korea	750	FS	3 958
Indonesia	074	IUD, FS	745
	739	MR, IUD, FS	541
Thailand	075	PT, FS	1 851
	741	IUD, FS	1 572
Chile	088	MR, IUD, FS	3 694
El Salvador	821	FS, MS	1 288
	823	PT, IUD, FS	1 063
Costa Rica	831	FS	652
Guatemala	841	PT, MS	938

* Defined as those submitting 500 or more forms in one or a combination of study areas.

**TABLE IV
IFRP DATA FORMS RECEIVED
BY STUDY AREA**

Study Area	July 1971- December 1974		January- December 1975		Total	
	No.	%	No.	%	No.	%
Pregnancy Termination	52 010	22.22	20 777	8.88	72 787	31.10
Menstrual Regulation	10 915	4.66	8 336	3.56	19 251	8.22
Intrauterine Device	54 118	23.12	24 409	10.43	78 527	33.55
Female Sterilization	24 871	10.63	23 173	9.90	48 044	20.52
Male Sterilization	1 591	0.68	611	0.26	2 202	0.94
Systemic Contraceptives	3 520	1.50	884	0.38	4 404	1.88
Special Studies	0	0.00	8 864	3.79	8 864	3.79
TOTAL	147 025	62.81	87 054	37.20	234 079	100.00

**TABLE V
PERCENT DISTRIBUTION OF FORMS
BY STUDY AREA**

Study Area	Jan-Dec 1974	Jan-Dec 1975
Pregnancy Termination	24.5	23.87
Menstrual Regulation	9.0	9.58
Intrauterine Device	47.5	28.04
Female Sterilization	17.4	26.62
Male Sterilization	0.3	0.70
Systemic Contraceptives	1.2	1.02
Special Studies	0.0	10.18

Table V shows the percentage of forms submitted by study areas during 1975 compared with 1974. The notable changes have been an increase in data on female sterilization and a decrease in data on IUDs. The change in IUD testing does not represent a decrease in emphasis but rather problems in manufacturing some of the newer IUDs and in initiating new studies. Several new IUDs and several new approaches are being developed under the new IFRP IUD development contract, and activity in this study area is already increasing. Research in male sterilization has been minimal but will increase rapidly with implementation of the Vaseal electrocoagulation unit testing program.

Highlights of developments in the several geographical areas include the following:

Latin America

The contributor network continued to develop as planned in Latin America. With the exception of the Asociación Salvadoreña Clínica in San Salvador and the APROFAM clinic in Guatemala, this network consists entirely of contributors from University Hospitals. At this time Latin America is the only IFRP geographic area that has operational computer programs for all five major areas of IFRP research. Contributors are developing new techniques and devices (e.g., the Madrigal speculum, a modified minilaparotomy technique, the copper/zinc "F" IUD, and nonsurgical methods of female sterilization) in addition to conducting studies of good quality.

IFRP pregnancy termination, IUD, female sterilization, pregnancy confirmation, and minilaparotomy data collection forms have been translated into Spanish, and working drafts of the male sterilization and the maternity records have been prepared in Spanish.

Five IFRP Contributors visited Chapel Hill in 1975: Dr. Jaime Zipper (Chile), Dr. Guillermo Lopez Escobar (Colombia), Dr. German Riaño (Colombia), Dr. Rafael Viada (Chile), Dr. Gaston Delard (Chile), and Dr. Vernon Madrigal (El Salvador).

Travels of the Latin American Coordinator within his area included visits to El Salvador and Costa Rica to initiate comparative studies and monitor the

on-site testing of the Wolfe Spring Clip prototype and the development of a new minilaparotomy technique. He attended the USAID Population Officers' Meeting in San Salvador, the Fifth Guatemalan Congress of Obstetrics and Gynecology and the Eleventh Colombian Congress of Obstetrics and Gynecology. The First Latin American IFRP Contributors' Conference was held in conjunction with the latter. He also visited the Pathfinder Fund, the IPPF/WHO, and IPAVS to discuss relationships with IFRP Latin American interests.

USAID selected the Area Coordinator to evaluate an IPAVS (International Program of the Association for Voluntary Sterilization) program in Taiwan and Thailand. He is still a member of the Latin American Program Advisory Committee of the Carolina Population Center at UNC-CH and was a short-term consultant for WHO/PAHO in Guatemala and the Pathfinder Fund. During this period, 12 IFRP papers were prepared in Spanish. A leaflet describing the IFRP was prepared in Spanish to facilitate answering requests for information from prospective contributors or interested persons in Latin America. In addition, as requested by AID/El Salvador, a newsletter was prepared and distributed in that country.

It is believed that data generated by the IFRP contributed to the acceptance of postabortion IUD insertions and female sterilization procedures in El Salvador's family planning program and to Colombia's proposal to amend its abortion law. Studies were initiated in Mexico and Brazil during 1975. The IFRP hopes to expand these programs in 1976.

During 1976 the number of contributors and countries represented can be expected to increase, and more sophisticated research designs will be developed. Plans are being made to transfer some of the computer tasks to one of the cooperating centers in Colombia and to create a Colombia Fertility Research Programme.

North Africa and the Middle East

In North Africa and the Middle East (exclusive of Iran), a well-established network of IFRP collaborators, primarily in universities, continued to conduct significant fertility studies in 1975. Prospective new centers are developing in Kuwait, Jordan, and Tunisia. Unfortunately, studies at the American University in Beirut, where an established culdoscopy center existed, are at a standstill because of the civil war.

Straight and comparative female sterilization studies using several methods of tubal occlusion were initiated in many centers. At Cairo University, two centers are evaluating laparoscopic tubal band and electrocoagulation techniques, as well as minilaparotomy, a combination of minilaparotomy and laparoscopy. At Al Azhar University, minilaparotomy and laparoscopy techniques are being studied. At Boulak El-Dakroor Hospital, a comparative study of El-Kadi's tubectomy vs. tubal band occlusion (using the needlescope) is being conducted and the reversible "Hood Technique" is being evaluated. Alexandria has become an established culdoscopy center. A new "vacu-lap" technique is under study at Ain Shams University. Posterior Colpotomy is the main approach at Misr Weaving Company Hospital in Mahalla El-Kobra in Egypt and in Khartoum North in Sudan. Assuit University has become an established center for laparoscopic tubal band sterilization.

The development of the Egyptian Fertility Control Society and the establishment of the new "National Sterilization Registry" within that society is furthering regionalization in Egypt. It is planned that all female sterilizations performed in Egypt be uniformly recorded and reported on IFRP Female Sterilization Forms.

A series of major IUD studies has been initiated using various designs of plain, copper, and progesterone-loaded IUDs. Hystero-graphic studies, measurements of the uterus with either the wing of the Battelle Uterine Sound, and quantitative determinations of menstrual blood loss (using the atomic absorption technique) are being conducted at Al Azhar. A comparative study to evaluate endometrial aspiration prior to Lippes Loop insertion is under way at Alexandria University. An IUD hystero-graphic study has been initiated at Cairo University.

A new system of prostaglandin $F_{2\alpha}$ instillation to reduce induction time in second trimester pregnancy termination was evaluated at Ain Shams University. Vacuum aspiration versus D&C in incomplete abortion management is being evaluated at Cairo University.

In the Sudan studies on 5,000 incomplete abortions are nearing completion in three urban centers, and reporting of incomplete abortions in rural centers

has been initiated. Maternity Record forms are being pretested in four Sudanese hospitals to evaluate the management of labor, pregnancy outcome and postpartum programs. Khartoum University, Omdurman Hospital, Khartoum North Hospital, and satellites of 12 rural centers representing the North, South, East, and West of the Sudan are major IFRP contributors. Preparations have been made for comparative contraceptive field studies at Khartoum University. The establishment of the Sudan Fertility Control Association is a major step toward regionalization.

The Area Coordinator visited new and prospective centers in Egypt and Sudan in January 1975 and in Egypt and Kuwait in June-July. Staff members attended the Sudanese Congress of Obstetrics and Gynaecology in February, and a second conference on voluntary sterilization of the Egyptian Fertility Control Society in Alexandria in June. Papers by IFRP contributors and staff were presented at both meetings. The Area Coordinator made presentations on fertility regulation in Khartoum, Cairo, and Kuwait, gave lectures at the UN-CH School of Public Health and at NCSU, conducted a series of workshops on various aspects of fertility management for the North Carolina Department of Human Resources, and spoke at the Fifth Annual Conference of the North Carolina Nurses Association of the American College of Obstetricians and Gynecologists.

Iran

The IFRP network in Iran having been well established by 1974, major efforts during 1975 were directed toward solidifying the research network through continued contacts with the field, follow-up of on-going studies to assure their successful completion, development of new studies that would be of mutual interest and benefit to the Iranians and the IFRP, and a study of ways of obtaining support for some or all of the project costs.

During a field visit in May-June 1975, the Area Coordinator initiated three new comparative studies and five straight studies. In addition, three pretest studies of the IFRP Family Planning Clinic Record have been initiated at three Ministry of Health clinics in order to evaluate the usefulness of this data collection system. The Family Planning Clinic Record Form has been translated into Farsi, and pretest studies with this form are expected to be underway soon at one clinic of the Institute for Protection of Mothers and Newborn in Teheran, as well as at the Central Family Planning Clinic in Shiraz.

Given its significant economic and political position in the Middle East Iran can be expected to play an increasingly important role in developing regional networks and programs.

During the year, the Area Coordinator for Iran attended the International Conference of Andrology in Detroit in April, the Seventh Annual Meeting of the International Family Planning Research Association in Palm Springs in October, a seminar on Population and Family Planning of Iran in Isfahan in May, and the Second Conference on Voluntary Sterilization in Alexandria, Egypt, in June, 1971.

Asia (Exclusive of India)

Not surprisingly, this vast, widely dispersed area currently has the largest number of centers actively engaged in IFRP-related projects.

Noteworthy developments during the year include the following: Professor Lean of Kandang Kerbau Hospital in Singapore has conducted a study of the effect of an exogenous estrogen-progesterone combination on withdrawal bleeding in menstrual regulation cases. The findings indicate that the estrogen-progesterone combination does not help to minimize the need for menstrual regulation in non-pregnant women with delayed menses.

Professor Lean is conducting three studies to evaluate the relative durability of menstrual regulation kits manufactured by Rocket, Burnett, and IPAS. He has also done a study to determine the sensitivity and specificity of a new pregnancy test designed by Dr. Lorrain Lau of Johns Hopkins. Present findings indicate that the Lau test is possibly more sensitive than the Pregnosticon Dri-Dot test for pregnancy. Additional studies are being planned in several countries of Asia to test the transportation and storage capabilities of the test materials under varying climatic conditions.

Dr. Agoestina in Bandung, Indonesia, is conducting a study of the latex leaf IUD. In Sri Lanka, a study by Dr. Dassenaik has indicated that a new, simple technique of female sterilization by minilaparotomy has great possibilities for developing countries. Another simple technique of female sterilization--the digital technique--is being evaluated by Dr. Chen of Tri-Service General Hospital in Taiwan.

Extensive planning has been carried out for utilizing in Indonesia the Family Planning Clinic Record System for menstrual regulation. The IFRP menstrual regulation form has been translated into Indonesian and collection of data is expected to start in the near future. Use of the FPCRS is also being planned for Depo Provera cases at McCormick Hospital in Chiangmai, Thailand.

In several important conferences in the area, IFRP staff and Contributors played important roles. At the Conference on Newer Concepts on Voluntary Sterilization and Menstrual Regulation, held in Dacca in February under the auspices of the Bangladesh Association of Voluntary Sterilization, doctors from outside Dacca and Government officials showed keen interest in collaborating with the IFRP in fertility control studies. Several training programs in newer techniques of fertility control were organized for the participants. Before the conference, IFRP staff members visited hospitals and clinics in the districts of Bangladesh to participate in workshops and training sessions. The local chapters of BAVS organized and sponsored all local arrangements.

A number of IFRP Contributors presented their results at the Second International Seminar on Maternal and Perinatal Mortality, Pregnancy Termination and Sterilization held by FIGO in Bombay, March 2-6. Contributors from the IGCC countries were invited to attend the Contributors Conference of the India Fertility Research Programme held in Bombay in conjunction with this meeting. The Contributors Conference enabled the Asian Contributors to interact and exchange technical know-how with the Indian Contributors. Training programs in new technology in fertility control and delivery systems were organized for the Asian Contributors.

The third meeting of the IGCC contributors was held in Kathmandu on March 7-8, 1975. Progress of studies being conducted by the Contributors was reviewed, and decisions were made regarding future collaboration between IGCC Contributors and the IFRP. Regionalization of the Asian program was discussed. An informative demonstration of camp sterilization was also organized. Plans have been completed for the fourth meeting of IGCC contributors in Kuala Lumpur in January, 1976.

It is hoped that this participation in international conferences by doctors from leading hospitals, universities, and private and governmental agencies from various countries will have a positive impact on the family planning programs in their countries.

Sub-Saharan Africa

FSD activities in this area are currently limited to West Africa, specifically to Nigeria and Ghana. However, staff members have had past contact with many centers in Africa, numerous African clinicians visited the IFRP during 1975, and possible cooperative programs have been discussed. Therefore the potential for expanding IFRP activities in Africa appears very good if the necessary funding becomes available.

In Ghana (Accra) and Nigeria (Ibadan), similarly designed studies of menstrual regulation performed on women who are up to 14 days past the expected onset of menses are nearing completion. Further studies, which would spread this method to hospitals in surrounding cities and possibly to adjacent countries, as well as studies on female sterilization, are being planned.

In Ibadan, the Goldzieher, Pill/Nutrition Study is in the early stages of implementation. This complicated study involves the performance, both in Ibadan and in the USA, of blood and other analyses from the study populations. This study is also being conducted in Colombo, Sri Lanka.

Europe

The only IFRP studies involving the Samaritan Clip, developed by Rocket of London in collaboration with Brian Lieberman, were initiated at four British centers under Mr. Lieberman's general direction. Data from these studies can be compared with data on the spring-loaded (Hulka-Clemens) clip from a study conducted by Professor Beard at one of the four hospitals, St. Mary's Hospital in London. Studies of the Samaritan Clip and the tubal ring are now being conducted by Ian Craft at Queen's Charlotte's Hospital.

Also in England, studies on abortion with Prostaglandin E₂ are being conducted at two separate centers near London, one using an intraamniotic and the other an extraamniotic approach. At one of the centers, data are also being

collected on vacuum aspiration, routinely used at that hospital as an out-patient procedure under local anesthesia.

In Yugoslavia, two similar abortion studies, each involving 1,100 cases, comparing the flexible with the non-flexible plastic cannula, for performing vacuum aspiration are nearly complete--one in Ljubljana in northern Yugoslavia and one in Skopje in the south. In northern Yugoslavia a 1,000-case study of menstrual regulation on patients at 4 through 12 menstrual weeks of gestation has been initiated. This study will incorporate field testing of the Lau pregnancy test, a study of postmenstrual regulation, IUD acceptance, and a study of a series of delayed menses cases. Also in Yugoslavia, studies comparing various sizes of the pleated-membrane IUD in nulliparous, interval, and post-abort patients are nearing completion. In Belgrade a baseline study of the U-coil IUD is nearing completion and will be followed up by studies of the U-coil invested with various antihemorrhagic agents. In southern Yugoslavia, under conditions far less advanced than in the North, a comparative study of midtrimester abortion induced by saline and prostaglandin $F_{2\alpha}$ also is under way. Possible sterilization studies are being discussed, following a recent relaxation of the law in Yugoslavia.

United States

Centers in the United States have largely focused on male and female sterilization studies. The female sterilization studies are concentrated at UNC-CH. At this center a series of 500 cases of laparoscopic application of spring-loaded clips for female sterilization with long-term follow-up has been completed, and the use of the needlescope for diagnosis and sterilization has been evaluated. The IFRP has analyzed 1,944 cases of tubal ring sterilizations. A small series of tubal ring sterilizations has been completed at Virginia Medical College in preparation for a comparative study of laparoscopic tubal ring and spring-loaded clip application for female sterilization.

Detailed discussion and planning have preceded the initiation of male sterilization studies using the Vaseal electrocoagulation unit developed by the Battelle Memorial Institute and the Electro Medical Systems, Inc. (EMS) utilizing the Schmidt technique. Much time and effort were spent working with Battelle, the EMS, and potential contributors to get the Vaseal unit to the field.

testing level. Units were finally delivered during December 1975, and plans are being made to test these units on 200 to 300 cases in five to six centers in the US. It is hoped that studies with six-month follow-up will be completed in 15 to 18 months and those without follow-up in 8 to 10 months. Several centers have agreed to conduct studies without the usual forms payments.

III. DESIGN AND ANALYSIS DIVISION

In 1975 a research associate, a research assistant, and two studies clerks were added to the Design and Analysis Division (D&A) staff. Resumes are included in Appendix A for two of the new staff members--Prem Talwar, research associate in charge of systemic contraceptive studies, and Joy Wood, research assistant for systemic contraceptive and pregnancy termination studies. A new position, Deputy Head of Design and Analysis Division, was created; Dr. David Edelman assumed this position. These changes in staffing were necessary because of the increased responsibilities of the D&A Division in all study areas and a rapidly increasing work load.

A. Preparation of Data Collection Instruments

The Design and Analysis Division has taken primary responsibility for the design of new forms, protocols and manuals that have been required in all study areas to meet the IFRP's expanded research efforts. The following is a list of forms and protocols that were developed during 1975:

- Maternity Record Form
- Protocol for the evaluation of the Lau pregnancy test
- Protocol for the reader reliability study of histopathology slides from MR studies
- Anesthesia study protocol for the IGCC
- Forms for non-surgical female sterilization procedures
- Method list for hysteroscopic electrocoagulation studies
- Minilaparotomy data collection form
- Protocol and forms for evaluation of effects of different systemic contraceptives on lactation
- Fertility survey form for Howrah (Survey III)
- Protocol and forms for the evaluation of the effects of paracervical block anesthesia on the abortifacient efficacy of $\text{PGF}_{2\alpha}$ and hypertonic saline
- Protocol and forms for the study of 15(S)-15-Methyl- $\text{PGF}_{2\alpha}$ (Tham) in vaginal suppositories for the induction of abortion
- Comparative study of IUD insertion techniques--evaluation of endometrial aspiration prior to IUD insertion

Instruction manual for the Male Sterilization Study Patient Record Form
Method list for evaluating the Vaseal unit
Protocol and forms for studying the durability of MR equipment
Revision of the comparative systemic contraceptive protocol
Method lists for selected IUD and abortion studies
Family planning clinic record system forms
Household distribution form (draft)

The following manuals and forms were translated into Spanish:

Pregnancy termination manual
Minilaparotomy form
Maternity record form
Pregnancy confirmation form

The following analysis systems were finalized and sent to the Data Processing Division for implementation:

Loading system for systemic contraceptive and maternity record studies
Demographic, clinical, and follow-up standard tables for male sterilization studies
Standard tables for the long-term follow-ups in female sterilization studies
Demographic standard tables for the maternity record studies

For all study areas the responsibility for coding the open-ended questions been moved from the Data Processing Division to the D&A Division. This has resulted in an increased reliability in the coding of the open-ended questions and has reduced the need for periodic revisions to the code lists in all study areas.

In March 1975, the Design and Analysis Division prepared for each study area (menstrual regulation, pregnancy termination, IUDs, male and female sterilization, and systemic contraceptives) status reports that (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.

B. Summary of Research Findings

The following summaries highlight the major findings for 1975 from research done in each IFRP study area.

Menstrual Regulation

In all menstrual regulation (MR) studies, the MR procedure is vacuum aspiration, except in one completed study in which prostaglandin $F_{2\alpha}$ was used to induce uterine bleeding.

In one study in which nurse-midwives had been trained to perform MRs, high complication and failure rates were initially obtained. After additional training in the appropriate procedures for handling the MR equipment and in performing the procedure, the complication and failure rates declined. In another study there was no difference in the complication rates when MRs were performed by a physician and by a nurse-midwife.

2. The principal findings in a study of 7,956 MR procedures include:

- a. The proportion of patients documented to be pregnant progressively increased from 40.5 percent at 32-33 days of amenorrhea to 87.1 percent at 46-49 days of amenorrhea.
- b. The complication rate of MR was significantly higher for patients documented to be pregnant (3.0%) than for patients not pregnant at the time of MR (1.2%).

The failure rate of MR to terminate pregnancy is less than 2 percent.

3. Findings similar to those summarized in 2 above were obtained from a pooled study of 9,564 MR procedures. This study indicated a two-fold higher incidence of complications among women documented to be pregnant than among those who were not pregnant when adjusted for differences in age, parity, duration of amenorrhea, and clinic where the procedures were performed.

4. The results from one comparative study indicate there are no apparent advantages to administering Duogynon Forte (50 mg progesterone and 3 mg estradiol benzoate) to induce uterine bleeding in amenorrheic patients who are no more than 14 days past the due date of expected menses. In the group of patients administered Duogynon Forte and in the group administered

no drug, about one third of the patients had menstruated between the time of the initial clinic visit and a return visit one week later. Also, patients in the treatment groups had a higher incidence of side effects (headaches, nausea) than patients in the group to which no drug was administered.

15. A comparative study of the intrauterine administration of 5 mg $\text{PGF}_{2\alpha}$ and vacuum aspiration for MR indicated there are no apparent advantages to the PG procedure. The administration of the PG required about 30 minutes, all patients were premedicated in order to attenuate undesirable side effects of the PG, and all patients reported from 9 to 18 days (mean 14.5 days) of uterine bleeding subsequent to the PG administration. Thirty percent of the PG patients had one or more episodes of vomiting. Complications of either of the two study procedures were infrequent.

Pregnancy Termination

1. Removal of 100 ml or 150 ml of amniotic fluid prior to instillation of 200 ml of 20% hypertonic saline is associated with similar cumulative abortion rates, complication rates, and rates of placental retention when compared to the instillation of 200 ml of 20% hypertonic saline without removal of amniotic fluid.
2. Compared to the single intraamniotic 50 mg $\text{PGF}_{2\alpha}$ dose schedule, the multiple 25 mg intraamniotic dose schedule results in shortened median instillation-to-abortion times (17.4 vs. 20.8 hours) and similar rates of placental retention, complications, and side effects except for vomiting, based on the pooled results from three comparative studies of two $\text{PGF}_{2\alpha}$ dose schedules and hypertonic saline. Both $\text{PGF}_{2\alpha}$ dose schedules have shorter instillation-to-abortion times than 20% hypertonic saline (median, 26.3 hours). Hypertonic saline is associated with lower rates of incomplete abortion and gastrointestinal side effects.

Similar results were obtained from another comparative study of the above second trimester abortion procedures. Both PG dose schedules appeared to be equally effective for aborting pregnancies at 16-20 weeks' gestation and more effective than the 20% hypertonic saline. Both PG dose schedules

were associated with similar rates of complications similar to those obtained with saline with higher rates of gastrointestinal side effects.

3. Sterilization via laparotomy with a Pomeroy ligation of the tubes does not significantly increase the complication rates after termination of pregnancies at 15 to 20 weeks' gestation with either $\text{PGF}_2\alpha$ (single or multiple dose schedule) or hypertonic saline.
4. Based on the results of three comparative studies, there are no significant differences with respect to all criteria of performance (rates of specific complications, blood loss, frequency of cannula insertion, amount of retained tissue) between the metal and flexible plastic (Karman type) cannulae for terminating pregnancies at 7 to 10 weeks' gestation by vacuum aspiration.
5. Studies on the treatment of incomplete and inevitable septic or aseptic abortions in the Sudan, Iran, and Latin America indicate that the associated morbidity and mortality rates are significantly higher than for artificially induced abortions. While in some institutions it may be feasible to treat incomplete abortions on an outpatient basis, in others it is not since many of the patients are diagnosed as septic at the time of admission. The different proportions of patients diagnosed as septic at the institutions studied probably reflect the differing methods used to illegally induce the abortions.
6. In a study of induced first trimester abortion, no significant relationship was found between the incidence of complications and anemia (hemoglobin <8 gm/100 ml).

Intrauterine Devices

1. The safety and efficacy of interval insertion of the Dalkon Shield were documented in two large retrospective studies of 2,848 first insertions from a single clinic and 1,969 first insertions from a group of three clinics. Pregnancy and expulsion rates in this study were similar to those reported by the University of Exeter in their large-scale field trial of the Dalkon Shield. Of the 107 women who became pregnant, incomplete

information was obtained on the outcome of all pregnancies. However, for the 56 cases where the outcome was known, no instance of septic spontaneous abortion in the second trimester of pregnancy was reported.

2. In a study of 408 postpartum insertions of the Dalkon Shield the one-year pregnancy and expulsion rates were higher than those reported from centers performing intermenstrual and intramenstrual insertions. The one-year removal rates for pain, bleeding, or medical reasons were similar for postpartum and interval insertions of the device.
3. Based on 198 insertions of the Cu-7 and 200 interval insertions of the Cu-T 200 at a single center, higher rates of pregnancy, expulsion, and bleeding/pain removal were obtained with the Cu-7 during the entire study period (24 months). Some of these differences may be in part related to the previous contraceptive practice of the two groups--37.4 percent of the Cu-7 compared to 83.5 percent of the Cu-T patients had previously used an IUD.
4. In a study of 160 IUD insertions among women who had recently undergone treatment for an incomplete abortion, the six-month expulsion rate was 6.6 per 100 users. The corresponding rate for bleeding removals was 1.8 per 100 users. The expulsion rate of this study was higher than corresponding rates reported from an interval insertion study of the same device (2.0 per 100 users). The bleeding removal rate in this postabortion study was however lower than the rate reported from the interval insertion study (5.9 per 100 users).
5. In a two-year follow-up study of 250 first insertions of the Cu-7, the net cumulative pregnancy, expulsion, and bleeding/pain removal rates per 100 users at two years post-insertion were 2.4, 12.8, and 3.7, respectively. These results compare favorably with those reported in other studies of the Cu-7.
6. Compared to baseline data for nine different IUDs, the pregnancy, expulsion, and bleeding/pain removal rates for the fluid-filled Tecna IUD were relatively high based on a study of 290 first insertions. The one-year rates

for the above events were 4.2, 22.0, and 7.3 per 100 users, respectively. Bleeding problems were so persistent that the investigation was terminated and all continuing users were requested to return to the clinic to have the IUD removed.

7. One study provided evidence that the addition of tranexamic acid to an IUD may decrease bleeding problems associated with IUD use. In a study of 200 first insertions of the U-coil IUD loaded with tranexamic acid, the six-month removal rate for bleeding was 1.1 per 100 users. The rate was significantly lower than the removal rate for bleeding of 9.9 per 100 users for the U-coil with copper.

Female Sterilization

The following results were obtained from a pooled study of 8,568 laparoscopic sterilization procedures performed in 16 counties and included 4,928 electrocoagulation, 1,696 spring-loaded clip, and 1,944 tubal ring procedures. Nearly 84 percent of the laparoscopies were performed as interval procedures. Highlights of an analysis of these procedures are as follows:

- 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. Laparotomy, for various reasons, was required for five cases (0.1%). Bowel injuries occurred in five patients (0.1% of electrocoagulation cases), four of whom did not require surgical treatment. 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.
- c. The pregnancy rates, at six months, were 0.4 percent for cautery, 1.2 percent for clip, and 0.2 percent for ring cases. Cumulative 12-month rates were 0.7 percent for cautery and 2.5 percent for clips.

Not enough data were available to determine reliable 12-month rates for the tubal ring

2. A study of interval sterilizations via laparoscopy with electrocoagulation (980 cases), spring-loaded clips (991 cases), and tubal rings (312 cases) for tubal occlusion indicated:

- a. Rates of operative and early postoperative complications were similar for the three techniques of tubal occlusion--operative, 1.2 percent; early postoperative, 1.9 percent.
- b. Rates of technical failure, i.e., failure to perform the elected technique, were significantly higher with the spring-loaded clip technique (1.5%) than with electrocoagulation (0.4%) or tubal ring technique (0.0%).

Rates of technical difficulties at surgery not requiring a change in the planned sterilization technique were significantly higher for the spring-loaded clip technique (6.8%) than for electrocoagulation (3.5%) or tubal ring (2.9%) techniques. Mechanical and optical difficulties with the prototype spring-loaded clip applicator were the major sources of technical failure and difficulties.

3. 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 subjects, indicated:

Technical difficulties were more frequent with the spring-loaded clip technique, primarily as a result of mechanical problems with the laparoscope.

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

Pain during the procedure occurred more frequently and was more severe when electrocoagulation was the method of tubal occlusion employed. However, postoperative pain was more frequent after the application of spring-loaded clips.

4. In studies of laparoscopic tubal ring (797 cases) and electrocoagulation (816 cases) conducted simultaneously at the same institution, the results were similar for the two procedures:

1. The rates of surgical difficulties were 1.9 percent for tubal ring and 2.6 percent for electrocoagulation. The rates of surgical complications were 1.3 and 1.4 percent, respectively.

5. In a study of 200 patients undergoing laparoscopic sterilization within five days of an uncomplicated term delivery, the following results were obtained:

- a. Technical difficulties were encountered in two (1.0%) patients.

- b. Operative or early postoperative complications were reported for 9.5 percent of the subjects. Two complications were potentially serious: in one patient, laparotomy was performed because of a suspected bowel burn, and in another, the small intestine was punctured during placement of the Tuohy needle.

6. In a long-term follow-up study of 635 women sterilized via laparoscopy with electrocoagulation and division of the tubes, the following results were obtained based on 86.2 percent of the patients who were seen for at least one follow-up examination 4 to 31 months post-sterilization:

- a. The failure rate (pregnancy rate) of the procedure was 0.7 percent.

- b. Significant gynecological abnormalities occurred in 2.4 percent of the cases within 4 to 8 months, in 3.0 percent of the cases within 15 to 21 months, and 1.4 percent of the cases within 22 to 31 months of sterilization.

Some changes in menstrual function occurred. The proportion of patients who developed irregular menstrual cycles and dysmenorrhea increased over time.

Male Sterilization

None

Systemic Contraceptives

The comparative cross-over study of Norinyl 1/50, Norlestrin 1, and Ovral has been completed, and analysis of the data is nearly complete. A report with detailed results from the study should be available within the next six months.

C. Preparation of Papers and Reports

During the year, 64 publications and presentations were prepared. A list of these is given in Appendix B. In addition, the following Consultant Reports were completed and sent to contributors:

<u>Contributor and Center Number</u>	<u>Title</u>
Dr. B.N. Purandare Center 501	A Comparison of Abortions Performed on an Inpatient and Outpatient Basis at Nowrosjee Wadia Hospital, Bombay, India
Dr. M.T. Ragab Center 030	Menstrual Regulation at Ain-Shams Medical School
Dr. T.H. Lean Center 070	107 Cases of Laparoscopic Sterilization with Spring-Loaded Clips
Dr. Bolandgray Center 301	Laparoscopic Cautery Sterilization at the Pahlavi University Medical Center
Dr. Luz De La Paz Palaez Center 062	Pregnancy Termination in the Philippines: A Preliminary Investigation of Vacuum Aspiration
Dr. Lonnie S. Burnet Center 903	Abortions Performed at Johns Hopkins Hospital in Baltimore from March 26, 1973 to April 30, 1974
Dr. Yahya Behjatnia Center 034	Incomplete Abortions Treated at Johanshah Hospital in Tehran, Iran from May 14, 1973 to April 30, 1974

- Dr. Mehdi Loghmani
Center 305-6
- Dr. Ajit C. Mehta
Center 500
- Dr. Suporn Koetsawan
Center 075
- Dr. Ruben Apelo
Center 600
- Dr. L. Randic
Center 022
- Dr. Hossein Kashani
Center 032
- Dr. German Riaño Gamboa
Center 806
- Dr. B. Rao
Center 551
- Dr. S. Soroudi Moghadam
Center 311
- Dr. A.C. Mehta
Center 503
- Dr. A.C. Mehta
Center 500
- Dr. Lydia Andolsek
Center 020
- Dr. Agoestine
Center 739
- Dr. Arie Doodoh
Center 074
- Dr. A.C. Mehta
Centers 500, 503, 50
- Dr. E.N. Purandare
Center 501
- Menstrual Regulation by Paramedical Personnel in Isfahan, Iran
- Experience with the Grafenberg Ring at the Hospital for Women in Bombay, India 1963-1974
- Experience with the Copper-7 and Copper-T Intrauterine Devices at Siriraj Hospital in Bangkok, Thailand
- Experience with the Copper-7 Intrauterine Device at the Jose Fabella Memorial Hospital, Manila, Philippines
- Comparison of Plain and Copper-Loaded Spring Coil IUD, Rijeka
- Female Sterilization at Farah Maternity Hospital by Colpotomy and Other Approaches
- Aborto Incompleto en el Hospital Evaristo García, Cali, Colombia (prepared as model for other Colombian Centers)
- An Analysis of 647 Induced Abortion at Government Hospital for Women and Children, Madras, India
- Comparison of Menstrual Regulation and Abortion Cases in a Private Practice
- 168 Pregnancy Termination Cases
- 189 Pregnancy Termination Cases
- Use of the Tecna Intrauterine Device in Ljubljana Yugoslavia
- A Preliminary Report on Menstrual Regulation Procedures performed at Hasan Sadikin Hospital, Bandung, Indonesia
- Comparison of Postpartum Dalkon Shield and Lippe Loop Insertions at the General Hospital, Jakarta, Indonesia
- A Comparison of Socio-Demographic Characteristics of Abortion Patients Requesting Services at Three Facilities in Bombay, India
- Female Sterilisation at the Nowrosjee Wadia Maternity Hospital

IV. DATA PROCESSING DIVISION

Personnel

The Division's authorized staff remained at 17 during 1975. All positions were occupied at the end of the year. Several promotions, resignations and one reclassification affected our efficiency during the early summer months. However, by early fall, forms processing was proceeding more smoothly and rapidly than at any other time since the Division was created.

Hardware

One IBM 029 Key punch was replaced by two IBM 129 Card Data Recorders. Our card data entry devices now include one 029 and three 129s. The two Research Incorporated keyboard displays and the IBM 2741 communicating terminal were replaced by eight Perry Electronics PE9000 Data Terminals. Two of the PE9000s are being used by the Design and Analysis Division. One replaced the HETRA control console. Because of the very low price of the PE9000s, we were able to double our time sharing equipment at almost no increase in net cost.

Software

Major programming systems brought into production for the first time during 1975 include:

- Systemic Contraceptive Loading/Editing (Research)
- Male Sterilization Loading/Editing (Research)
- Female Sterilization Chemical Loading/Editing (Research)
- Pregnancy Termination Loading/Editing (Automatic Correction)
- Menstrual Regulation Loading/Editing (Automatic Correction)
- Maternity Record Loading/Editing (Automatic Correction)
- IUD Clinical Analysis Tables
- Systemic Contraceptive Demographic Tables
- Male Sterilization Demographic Tables
- Female Sterilization Chemical Demographic Tables
- IUD Life Tables for 120 Month Wear Spans
- TUCC Billing Validation System

Existing systems substantially rewritten or enhanced include:

- IUD Loading/Editing (Research)
- Female Sterilization Loading/Editing (Research)
- Female Sterilization Demographic Tables

Programming systems presently under development, being modified, or in final testing include:

- IUD Bleeding Calendar Loading/Editing (Research)
- IUD Loading/Editing (Automatic Correction)
- Female Sterilization Loading/Editing (Automatic Correction)
- Male Sterilization Loading/Editing (Automatic Correction)
- Female Sterilization Master Tables
- Female Sterilization Long Term Follow-up Clinical Tables
- Maternity Record Analysis Tables
- Female Sterilization Chemical Life Table Analysis
- Generalized Forms Accounting Analysis

In addition to the above programming work, we reorganized our procedure library maintenance system by writing a Time Sharing Option procedure library, restructured and rewrote the central driver program used by all analysis systems, and extensively edited and corrected our user documentation.

During 1975 our programming systems were again successfully transferred to the IBM 360/44 at the Delhi University Computer Centre, New Delhi, India.

Forms Flow (See Table)

The trend indicated in the "Six-Month Report, January 1-June 30, 1975" continued in the last half of the year: slightly fewer forms were loaded in machine readable format in 1975 than in 1974, even though forms in two more major study areas, Male sterilization and Systemic Contraceptives, were processed for the first time in the latter part of the year. Although the total number of forms processed appears to be reaching a plateau, the number of different studies initiated continues to grow (Table II). Resources made available by the stabilization of forms flow have been offset by the greater resources needed to handle the increase in the number of studies, particularly comparatives.

Six-Month Projection

Based upon present projections for forms flow and work-load requirements, no additional personnel will be requested by the Data Processing Division during the first six months of 1976. Should work-load requirements change, personnel requirements will be reevaluated.

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

Study Area	1972	1973		1974		1975		TOTAL
	Jan-Dec	Jan-June	July-Dec	Jan-June	July-Dec	Jan-June	July-Dec	
Pregnancy Termination	10 054	8 506	7 440	8 062	12 300	9 004	9 973	65 339
Menstrual Regulation	0	1 075	518	3 847	4 306	2 964	4 804	17 514
Female Sterilization								
Admission								
Pretest	1 007	2 880	98	0	0	0	0	3 985
Final	0	250	2 443	6 092	6 550	4 519	6 259	26 113
Follow-Up/Method List	0	0	0	0	2 905	8 088	8 098	14 091
Intrauterine Device								
Admission	0	0	3 115	4 510	13 324	4 703	4 750	30 402
Follow-Up/Method List	0	0	3 000	6 445	14 577	6 016	10 656	40 694
Male Sterilization								
Admission								
Pretest	0	498	0	0	0	0	0	498
Final	0	0	0	0	0	0	380	380
Follow-Up/Semen Tests								
Pretest	0	496	0	0	0	0	0	496
Final	0	0	0	0	0	0	435	435
Systemic Contraception								
Admission	0	0	0	0	0	0	593	593
Physical/Symptomology	0	0	0	0	0	0	2 822	2 822
Follow-Up	0	0	0	0	0	0	1 016	1 016
Totals	11 061	13 705	16 614	28 956	53 962	30 294	49 786	207 378

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

	June 30, 1974		December 31, 1974		June 30, 1975		December 31, 1975	
	Centers	Studies	Centers	Studies	Centers	Studies	Centers	Studies
All Studies								
Pregnancy Termination	66	7	57	6	57	10	65	13
Menstrual Regulation	34	5	39	6	39	8	46	9
Female Sterilization	34	7	46	8	55	11	83	15
Intrauterine Device	34	16	50	22	58	29	65	36
Male Sterilization	0	0	0	0	0	0	1	1
Systemic Contraception	0	0	0	0	0	0	1	1
Total	168	35	192	42	209	58	261	75
Comparative Studies Only								
Pregnancy Termination	6	2	6	2	13	6	18	6
Menstrual Regulation	0	0	0	0	2	2	3	3
Female Sterilization	1	1	1	1	4	3	12	6
Intrauterine Device	0	0	2	2	6	4	8	6
Male Sterilization	0	0	0	0	0	0	0	0
Systemic Contraception	0	0	0	0	0	0	1	1
Total	7	3	9	5	25	15	42	22

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

All currently unfinished programming tasks (see: Software) will be completed by the end of this fiscal year. It is unlikely that any major system development requirements submitted after January 1, 1976, will be completed this fiscal year. This is a conservative estimate. The Burroughs 6746 computer installation is scheduled for April 1, 1976. Data processing should be disrupted for no more than two weeks in early April.

After extensive study we believe this temporary interruption in processing and program development will be more than offset by future cost savings and increased productivity. We projected cost increases in computer use beginning July 1, 1976, of 2.5 to 3.1 times the rate we were previously charged as an educational institution. Figure 1 bears out this projection. The B-6746 charges will, by agreement, never exceed 80 percent of what we would have been charged by the Triangle Universities Computation Center for equivalent work. A more important point is that since we need not share a computer with several hundred other users, turnaround time for jobs run will be much quicker.

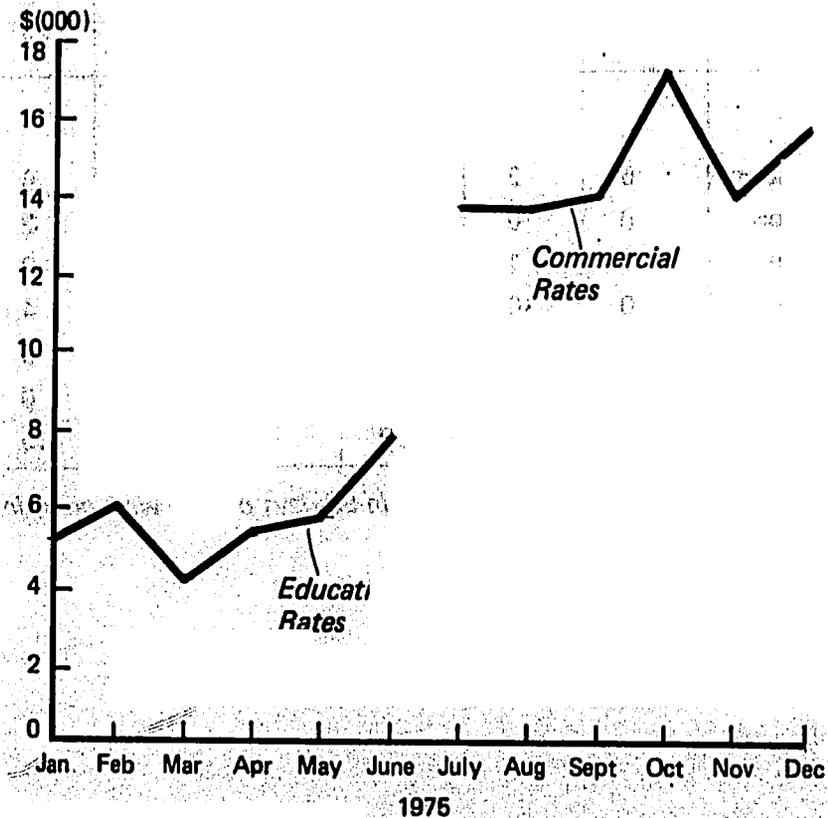


Figure 1. Monthly Cost of Computer Use at TUCC.

The second quarter of 1976 will be a very difficult time for the Data Processing Division, and this will have a definite impact upon those for whom we provide service. However, once we have accomplished this transfer our capacity to serve will be radically improved.

V. FIELD DEVELOPMENT DIVISION

A newly created position, Associate Director for Field Development, was assumed in February of this year by George Stathes. His primary duties are to plan, coordinate, and carry forward strategy and activities to institutionalize Fertility Research Programs at national and regional levels overseas. The division is presently staffed with the associate director, assistant, and section secretary.

The basic strategy being used to establish regional and national institutions consists of assisting Contributors to build upon their current IFRP research activity toward a self-sustaining institution. This is achieved, at first, by continuing to support IFRP data collection activities, training local staff in required data collection and management procedures, and assisting with those research activity elements not yet incorporated by the country research organization. To further this goal the IFRP has undertaken to: (1) encourage and assist the establishment of local research organizations and associations of Contributors, (2) centralize country data collection, forms flow, and liaison with the IFRP, and (3) phase in subsequent elements of a full research system.

Based on the activities of the local institution and network of contributors, the IFRP assists the institution in planning for and procuring program development funds as required. It is expected that major basic support for the staff, administration, and activities of the local institution will be provided from national and ministerial budgets; local, regional and international organizations; foundation grants; and the UNFPA.

REGIONALIZATION ACTIVITIES

1. INDIA. During the year, IFRP staff from Chapel Hill updated the computer programs that had been transferred earlier to facilities at Delhi University which service the data processing requirements of the India Fertility Research Programme. Loading systems were transferred for pregnancy termination, menstrual regulation and female sterilization studies, and computer staff at Delhi University were trained to run all systems. Full operating programs are now installed in India for data loading and for producing master, clinical and demographic tables.

Early in the year, delays were experienced by the Executive Committee of the India Fertility Research Programme in seeing their proposal for UNEPA funding move through government channels. Alternatively, the Administrative Staff College of India (ASCI) at Hyderabad, with new computer facilities and trained staff expressed interest in managing the data processing requirements of the India FRP. In consultation with the India FRP the ASCI has moved forward a funding proposal to DANIDA through the Ministry of Education.

This proposal has government approval and is scheduled in January 1976 for presentation to DANIDA at their meeting with the Ministry of Finance which coordinates all proposals. Additionally, the Christian Medical Association of India (CMAI) has expressed interest in adopting the IFRP research system for their network of hospitals and clinics. They plan to establish a linkage with the India FRP for processing and analyzing their data. CMAI is discussing a funding proposal with the Church World Service to implement research and reporting activities in 1976.

Dr. Saroj Pachauri, formerly Head of the IFRP Design and Analysis Division returned to India during the year and is now Consultant to the India Fertility Research Programme. Her duties include coordinating and assisting with research, organizational, and funding activities.

The India Fertility Research Programme has consolidated its association of Contributors during this year and has continued its series of research projects. In December, it held its 3rd Contributor's Conference, at which several contributors presented scientific papers on their research activities.

2. BANGLADESH. During the year IFRP study activities and discussions with Contributors and private and governmental individuals have led to the first steps in establishing and registering a Bangladesh Fertility Research Programme (BFRP). A preliminary proposal for funding by the UNFPA has been prepared for governmental approval. At the end of December full discussions were held by Dr. Kessel, in Dacca, to outline the plans and strategy with those involved: Contributors, Ministerial representatives, AID Population Officer, UNFPA Coordinator and other organizations interested in associating with the research system. Meetings with UNFPA staff in New York to discuss funding of a BFRP and the scope of work and level of effort are planned for January 1976. Arrangements have been made for the preliminary training of a BFRP Data Collection Coordinator at the India FRP offices in Calcutta.

3. ASIA/IGCC Countries. At the end of January, Dr. L. S. Sodhy, Secretary General of the Inter-Governmental Coordinating Committee (IGCC) at Kuala Lumpur, met with IFRP staff to discuss further steps in establishing a regional Asia Fertility Research Programme (AFRP) as a program of the IGCC which presently includes IFRP research activities in six countries in Southeast Asia (Indonesia, Malaysia, Nepal, the Philippines, Singapore, and Thailand). Discussions were held at the UNFPA with Dr. R. Salas and Dr. S. Tomita, Chief, UNFPA Regional Programs, concerning funding for the AFRP. Based on these discussions, the draft summary proposal approved by members of the IGCC was later refined and rebudgeted as a series of country proposals to emphasize the individual country program aspects of the proposal. These proposals have been reviewed by the Secretariat of the IGCC and are scheduled for circulation to IGCC member countries following their next Expert Meeting in January, 1976.

In the interim, a proposal to fund a central office of the Asia Fertility Research Programme has been prepared for submission to NORAD (Norwegian Aid Agency). It is expected that this will be approved at the IGCC Expert Meeting in January and forwarded to NORAD soon after. Such funding will initiate and support selected centralized research and training activities in the six member countries.

Supporting the activities and the objectives of the AFRP, agreements have been reached amongst Contributors in Thailand to centralize the management of

data collection and forms flow with Dr. Suporn Koetsawang. Computer processing of data in Thailand is being explored. In Indonesia, Contributors will centralize data collection through Dr. T. Agoestina. She was trained at IFRP during the year and will establish the office and function of Data Collection Coordinator. Both countries are expected to establish national Fertility Research Programmes during 1976.

4. IRAN. During the latter part of the year, discussions were initiated with Ministerial representatives and Contributors concerning the institutionalization and funding of a Fertility Research Program in Iran. Further planning to initiate centralized activities at a study site and to train a Data Collection Coordinator will take place in Iran in February, 1976.

5. EGYPT. The Egyptian Fertility Control Society (EFCS) has established a National Sterilization Registry which includes IFRP studies and its data collection system. The Executive Board of the EFCS considers this a first step towards the establishment of a more comprehensive national Fertility Research Program. A preliminary proposal for funding a full range of research activities in an Egyptian Fertility Research Program was prepared for IFRP/EFCS discussions to take place at Tunis in February, 1976. Arrangements for IFRP training of a Data Collection Coordinator to centralize data collection in Egypt will be implemented in 1976.

6. SUDAN. A group of physicians contributing to IFRP research established and officially registered the Sudan Fertility Control Association (SFCA). Membership includes Contributors, potential Contributors throughout the Sudan, governmental representatives, and representatives of societies and councils interested in supporting the Association's activities.

The SFCA presented its first scientific paper, a preliminary report including 1000 cases of the treatment of incomplete abortion, at the IV Sudanese Congress of Obstetrics and Gynaecology in February. It is now analyzing study data on 3000 cases to be reported in 1976.

After training at the IFRP, Ms. Nadia Bushra, SFCA Data Collection Coordinator, began centralized collection of data for the Association in Khartoum.

She coordinates the flow of forms and queries between the SFCA Contributors and IFRP. This has proved a success. Coding of open-ended questions at Khartoum will begin in 1976.

Dr. Hamid Rushwan, Director of the SFCA, met with IFRP staff during an ATMF training trip to the States to discuss strategy for procuring funds to increase the SFCA level of effort and scope of research. He met with Mr. R. El Heneidi, Chief of the Mediterranean and Middle East Section of the UNFPA, to outline SFCA program activities, its potential for the Sudan and related areas, and to determine steps to be taken to procure UNFPA support and funding. In October, Dr. Ali Fadl, Deputy Vice Chancellor of the University of Khartoum and member of the SFCA, presented to Mr. R. El Heneidi an outline summary proposal for funding. It is expected that the formal proposal will be prepared early in 1976 for government approval in the Sudan and forwarding to the UNFPA.

7. NIGERIA. Development of a Nigeria Fertility Research Programme, based at the University of Ibadan, has not matured since mid-year.

8. BRAZIL. In November, Dr. Helio Aguinaga, Director of the Programa de Assistência Integrada à Mulher et à Criança (PAIMCO), based at the Hospital-Escola S. Francisco de Assis, Rio de Janeiro, discussed a possible linkage with IFRP to develop a research and reporting system for their projected integrated health program. The program has been approved by the Brazilian government and will be submitted to the UNDP for funding in 1976. Such an association during the early stages of the establishment of the PAIMCO program is expected to lead to a national Fertility Research Program.

9. CHILE. The progress of IFRP studies and the volume of forms associated with the studies at Instituto de Fisiología at the Medical School, University of Chile, Santiago (Drs. Zipper and Medel) led to discussion of training a Data Collection Coordinator to manage forms flow and scanning procedures. It is expected that a Data Collection Coordinator will be designated during 1976 and trained by IFRP staff. This will effectively establish an experienced DCC for possible future centralization of activities in Chile.

10. COLOMBIA. Discussion, during the latter part of 1975, with Dr. G. Lopez Escobar, President of the Corporacion Centro Regional de Poblacion at Bogota, led to a shift in the approach to establishing a Colombia Fertility Research Program, to be funded by the UNFPA. It was decided to first establish a limited country office under the direction of Dr. Riaño, affiliated with Dr. Lopez Escobar's Regional office. This will be the core upon which to build and coordinate activities before formally requesting UNFPA support. Dr. Riaño is expected to visit the U. S. early in 1976 to finalize arrangements for training and logistics requirements.

VI. ADMINISTRATION

An agreement between the University of North Carolina (UNC) and the Agency for International Development (AID) that IFRP should establish itself as a separate non-profit corporation capable of conducting the work of Contract AID/csd-2979 was reached in October, 1974. This prompted a site visit by an AID evaluation team in early January 1975 to review preparations for transferring the contract. The proposed policies and procedures, financial management system, and organizational composition of the new corporation were approved by the team.

Effective February 14, 1976, IFRP assumed all assets, liabilities, and the responsibility for conducting the work of the contract by execution of a novation agreement between UNC, AID, and the new corporation. A review of the year ended December 31, 1975, reveals that an orderly separation and effective continuation of program activities resulted.

Financial Information

The financial statement included as Appendix G provides expenditures and encumbrances incurred by both UNC and IFRP during fiscal year ended December 31, 1975. As approved by the Contracting Officer, UNC calculated all outstanding firm encumbrances as of the date the contract was transferred and included these in their final billing to AID. Records were maintained by UNC of actual payments made for a period of ten months after the transfer. Final settlement with IFRP took place December 19, 1975, which resulted in a refund to IFRP of \$16,665.25 in unexpended funds. In order to coincide with the new fiscal year

of AID and other US government organizations, the Board of Directors approved changing the fiscal year of IFRP to the year ending September 30.

The transfer of AID/csd-2979 to the new IFRP corporation effectively reduces the total cost to AID by approximately \$400,000 annually when compared to the same program activity level at UNC. This is a result of the use of overhead funds to provide for what were previously direct expenses. All administrative personnel which were paid from direct costs while within UNC are now charged to overhead. To compound the difference, overhead at the rate of 48 percent was charged based on these salary expenses when the contract was with UNC.

Personnel

Only three additional positions were required as a direct result of assuming the independent responsibility for the contract. These positions related directly to the functions of accounting and personnel management and were charged to overhead.

Placement efforts during the past year have been directed primarily toward recruiting personnel to fill vacant positions in the Design and Analysis Division and the position of Director of Research and Training. A complete listing of all employees and consultants charged directly to the contract as of December 31, 1975 is included as Appendix F.

Publications Unit

The number of papers for publication and/or presentation and the number of data collection instruments being prepared for printing continued to increase in 1975. In addition, the IFRP began negotiations with FIGO to make the INTERNATIONAL JOURNAL OF GYNAECOLOGY AND OBSTETRICS an official publication of the IFRP as well as of FIGO. The contract calls for the IFRP to prepare 48 journal pages per issue; the journal is published six times a year. The contract also calls for the preparation of one or more supplements to the journal per year, with the stipulation that these may be supplied to the publisher in camera-ready form. To meet this increased demand for in-house typesetting capabilities, the Publications Unit investigated automated typesetting equipment. In December, IFRP acquired an IBM Magnetic Tape Typewriter/ Composer (MT/SC) System.

Adjustments in personnel were also made to meet the increased work load. In the first half of 1975, an assistant editor was added to the staff. In December, with the addition of the MT/SC, a new position, graphics assistant, was created and the composer operator position was changed to MT/SC operator. No personnel changes are anticipated through the first half of 1976.

With a staff of six, the Publications Unit now offers the following services:

1. Coordinating the preparation of manuscripts from first draft through printing, presentation, and/or journal publication
2. Editing and copy proofing
3. Typesetting
4. Complete graphic services, including forms design, illustrations, layout, and slide and poster presentations
5. Handling all requests for printing, major copying jobs, and photographic services
6. Maintaining complete files on all IFRP publications, including illustrations, charts, and photographs, and slide presentations
7. Gathering information, including maintaining an in-house library, conducting literature searches, and providing a current awareness service on the literature of human fertility control for the research staff
8. Disseminating information, including maintaining a mailing list, coordinating mass mailings, and responding to individual requests

To help writers, editors, and typists work together more efficiently, the Publications Unit has prepared a manual outlining IFRP editorial policies (Appendix C).

Appendix D is a progress report on the status of the library and information gathering and dissemination systems. It outlines the progress made in the first year by the information coordinator.

Significant Problems

Organizing and establishing a completely separate, independent corporation involved considerable expenditures which could not be covered by contract

funds. This expense was therefore taken from flexible, non-contract funds available to IFRP, reducing the amount of non-contract funds at a time when the need for financial flexibility was at its peak.

Effective June 30, 1975, UNC withdrew its permission to allow the program to purchase computer time at educational rates. This forced data processing costs up approximately 2.5 times the previous rate. As soon as this was made known to IFRP, the head of data processing began working with administration to find alternatives that would reduce this cost, which is a significant part of our budget.

Lack of space for personnel and storage has been a problem during the full calendar year. Temporary relief was gained by negotiating short-term leases for office space on another floor of the building and storage space in a location several blocks away. Although a concerted effort to locate office space in the Chapel Hill area was made, it was not successful. IFRP then began the difficult task of locating a firm which would build office space for a very young organization largely dependent upon government contracts.

The requested budget for the 15-month period ending September 30, 1975 was reduced by approximately \$840,000, effectively precluding many programmatic activities during the following 15-month fiscal year. The situation was made worse by the underrealization of projected carryover by \$129,000 as of June 30, 1975.

Significant Accomplishments

In July 1975 a lease/purchase agreement was executed for a building in the Research Triangle Park (RTP), located between Raleigh, Durham, and Chapel Hill. RTP has become a nationally known center for research organizations. The building, designed specifically for IFRP's needs, will provide 21,600 square feet of space which will include housing for a new computer which is being purchased by IFRP.

After investigating a number of alternatives designed to reduce data processing costs, IFRP decided to purchase its own computer. Made possible by a grant from the Cordelia S. May Family Trust, the purchase of the computer is

calculated to reduce data processing costs to the contract by approximately 20 percent.

In December 1975 an agreement was reached between the International Federation of Gynaecology and Obstetrics (FIGO), Almqvist and Wiksell, Publishers, and IFRP to expand the INTERNATIONAL JOURNAL OF GYNAECOLOGY AND OBSTETRICS and have it become the official organ of IFRP as well as of FIGO. IFRP has exclusive distribution rights in all LDC's and exclusive rights to sell advertising in the Journal. It is hoped that revenue from advertising will help off-set costs incurred. Through an arrangement by which issues would be shipped to central points in bulk and then distributed within the country, IFRP has already increased circulation by 1,400 subscriptions.

As a result of discussions with Professor Hubert de Watteville, Secretary General of FIGO, a research relationship with FIGO is expected to be finalized in early 1976. It is proposed that IFRP become the central data gathering and processing organization for FIGO.

During the reporting period, IFRP administrative staff has continued to comply with legal requirements and functions which are mandated by good business practice. Significant among these are:

1. A pension plan trust document which complies with all ERISA regulations has been prepared and forwarded to the Internal Revenue Service for a ruling that it is in compliance with IRS and Department of Labor regulations.
2. A 48-page Affirmative Action Plan has been compiled to indicate goals for maintaining fair employment practices. After a period of five months, no changes have been suggested by the Office of Civil Rights, General Services Administration.

A comprehensive IFRP Employees Handbook has been prepared and distributed to all staff members as required by law. The objective in preparing such a handbook is to fully explain all employee benefits in terms which can be understood by all personnel. A copy of this handbook is included in Appendix E.

The IFRP Protection of Human Subjects Committee composition and procedures were established and the first meeting held on November 6 and 7. Research

activities which had been previously approved by the UNC Human Subjects Committee were reviewed and approved with the exception of three which could not be reviewed because of time constraints. New proposals for anticipated research activities were also reviewed and approved. It is anticipated that future meetings must be scheduled on a quarterly basis.

Future Plans

Establishing IFRP in its new offices in the Research Triangle Park involving little or no delay in program activities will require a major effort within administration. The move to RTP is anticipated to take place in late March or early April.

Continued efforts will be directed toward improving the administrative support provided to IFRP. Internal audits of financial and administrative policies and procedures are being initiated to reveal areas in which improvement can be implemented.

Considerable effort will be made to sell advertising to reduce the cost of expanding the International Journal of Gynaecology and Obstetrics. In order to increase information dissemination in LDC's IFRP will offer subscriptions at or near cost. Each FIGO country society will be offered bulk subscriptions for a rate of \$5-6. The individual societies will assume the responsibility for distribution within their country.