

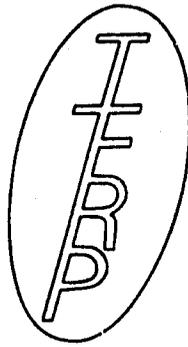
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STATUS
REPORT
April 19 '5



STATUS REPORT

INTERNATIONAL FERTILITY RESEARCH PROGRAM
NCNB Plaza, Suite 400
Chapel Hill, North Carolina 27514 USA

APRIL 1975

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I. INTRODUCTION

Since July, 1971, the International Fertility Research Program (IFRP) has provided a framework through which newer developments in fertility regulation technology can be rapidly evaluated through a series of clinical field trials. The principal objectives of the IFRP have been to:

- Scientifically field test promising developments in fertility regulation.
- Shorten the time between the development of new methods of fertility regulation and their implementation into general clinical practice, by providing a capability for the rapid analysis and reporting of data from clinical field trials.
- Disseminate information on research findings at national and international meetings and conferences, and in national and international journals and research reports.

The extent to which the IFRP can attain these objectives depends on an international network of 169 carefully selected Contributors (clinicians as well as program administrators) in 30 countries who participate in the IFRP's studies. These Contributors represent a variety of clinical and cultural settings on all 5 continents.

The investment of the IFRP and its Contributors is made with the expectation that improved methods of fertility regulation can ultimately make an important contribution to both the contraceptive needs of individuals and to the socioeconomic development of countries by slowing too-rapid population growth. It is also expected that the IFRP's research efforts will further stimulate new developments in fertility regulation which in turn may be field tested and evaluated within the IFRP Contributor network.

II. ORGANIZATION OF STUDIES

The IFRP studies are organized by study area and by the type of study within each study area. Basic to all IFRP studies are standard data collection instruments. These data collection instruments are used to record the following:

- Patient identification. These data are collected for use at the study center and are not transmitted to the IFRP.
- Patient characteristics. A similar set of socio-demographic characteristics is recorded for all patients in all study areas.
- Methods. Specifics of the method of fertility regulation used, and details of all related complications and difficulties are recorded in this section.
- Follow-Up. Depending upon the study area, one or more long-term follow-up visits are required. Pertinent data relating to these follow-up visits are recorded in the follow-up section/form.

Data collection instruments have been developed for the following study areas:

1. Pregnancy Termination
2. Menstrual Regulation
3. Female Sterilization
4. Male Sterilization
5. Intrauterine Devices
6. Systemic Contraceptives
7. Conventional Contraceptives
8. Maternity Survey

Instruction manuals are written for use with each of the standard data collection instruments to assure comparability among studies. These manuals give procedures for handling the forms and detailed instructions for recording and coding each item.

A graphic representation of the IFRP data collection instruments and copies of the actual forms are in Appendix A.

Within each study area, three types of studies are available. These are, in order of increasing complexity and scientific merit: surveillance studies, straight studies, and comparative studies.

Surveillance Studies

For these studies, no specific number of patients is required, no specific criteria for patient selection are given, and limitations are not set for the clinical methods to be reported. The Contributor is asked simply to record data on procedures as they are routinely performed at his center. One reason for initiating surveillance studies is to establish a "records dialogue" between the IFRP and the Contributor in anticipation of future straight and comparative studies (see below). Through this "dialogue" the Contributor gains an understanding and knowledge of the IFRP's standard data collection instruments, the query system, mailing and other procedures. In turn, the IFRP obtains information on the Contributor's standard procedures, volume of cases, ability to accurately complete the standard data collection instruments, and the percentage of patients who are lost-to-follow-up.

At the completion of a surveillance study, a Consultant Report, together with a set of standard computer summary tables on which the report is based, are sent to the Contributor. From this report and tables the Contributor is encouraged to prepare his own scientific publication, and in this way become familiar with the standard IFRP computer feedback.

Data from surveillance studies may sometimes be pooled for the epidemiological evaluation of various methods of fertility regulation when used under a variety of use conditions.

Straight Studies

These studies are differentiated from surveillance studies in that the Contributor will report on a single method of fertility regulation. Straight studies are usually conducted on new methods of fertility regulation when performed in a standard manner. These studies require at least a 90 percent follow-up rate so that the safety and efficacy of the method can be adequately evaluated. Straight studies are undertaken only by Contributors who have demonstrated the ability to

accurately record data on the standard IFRP forms, and who have a high volume of cases in a situation allowing adequate follow-up. For some straight studies, the Contributors are requested to complete additional study forms, i.e., Method Lists, in order to obtain more detailed information on the patients, procedures, and outcomes of the procedures.

Comparative Studies

The purpose of these studies is to compare the relative efficacy of two or more clinical methods rather than to evaluate any one particular method. Comparative studies are conducted by carefully selected Contributors who have demonstrated their ability to accurately complete the IFRP's standard data collection instruments. The comparative studies are conducted according to a protocol which gives specific requirements for the clinical methods used, the criteria for patient selection, the procedure for randomly assigning methods to subjects, the procedures for follow-up of the subjects, and the number of subjects to be studied.

The following elements are common to all comparative studies:

- Methods are randomly assigned to subjects to avoid bias in selection.
- The physician who performs the method is always a physician different from the one who is responsible for follow-up care and evaluation of the patients.
- Method Lists are used to record additional information relating to the methods used and complications and/or difficulties with these methods, either at the time of the procedures or during the follow-up period.
- All subjects are required to sign an appropriate consent form which explains the risks and benefits of the study.
- Surgical supplies and any other critical pieces of equipment are supplied to the Contributor by the IFRP to insure that all methods are conducted in a similar manner.

All IFRP comparative studies must be approved by the IFRP Protection of Human Subjects Committee and the Research Review Committee. These two Committees review and approve the comparative studies on the basis of both patient safety and research design.

Brief summaries of the IFRP comparative protocols are given in Appendix B.

Since in either the surveillance, straight, or comparative studies, socio-demographic data are obtained only for patients undergoing a procedure, i.e., the clinic population, these data cannot be used to make inferences about the population groups within the catchment area of the clinic, i.e., the denominator populations. In order to obtain socio-demographic data for the denominator populations, similar to what is obtained on the standard IFRP patient record forms, the IFRP has developed two additional forms: (1) the Fertility Survey Record which is used to obtain socio-demographic data for women of childbearing age in the catchment area of the clinic/hospital, and (2) the Maternity Record which is used in post partum programs to obtain

socio-demographic data for all delivery cases at an institution, regardless of whether the cases were or were not sterilized at the time of the delivery. Copies of these forms, which are still in the pretest stage of development, are given in Appendix A. Using the Fertility Survey and the Maternity Records the clinic populations can be evaluated and compared to the potential patients in the catchment area of the institution.

III. SCREENING FERTILITY REGULATION METHODS FOR STUDY

Through its extensive contacts with research and development centers, universities, and clinicians, including its network of Contributors, the IFRP receives many suggestions and proposals for future research on methods of fertility regulation. Since limited resources are available with which to conduct these studies, the IFRP maintains several committees and consultants to screen proposals for research and to advise the IFRP on research priorities.

- *Medical Advisory Committee.* This Committee, or its subcommittees, reviews the IFRP's progress within each of the study areas, and recommends priorities for the field testing of new developments in fertility regulation.
- *Protection of Human Subjects Committee.* This Committee reviews and approves all comparative protocols and evaluates the appropriateness of the protocols, their research design, and the potential risks and benefits to the subjects, according to standards developed by the U.S. Department of Health, Education and Welfare.
- *Area Coordinators and Research Review Committees.* The principal function of the Area Coordinators Committee is to monitor the ongoing IFRP studies and to recommend studies for particular Contributors. The Research Review Committee evaluates the scientific merit, study design, and appropriateness of ongoing and proposed studies.
- *Funding agencies.* Before financial commitments are made to the Contributors, the IFRP's funding agencies are asked to review the studies.

Throughout the entire review process for any study, the protection of the interests of human subjects and its scientific merit are of prime importance. Only new methods of fertility regulation, which have the potential of being safer, more efficient and more acceptable than existing methods, are recommended as worth any potential increased risks to human volunteers.

IV. DIVISIONS OF THE IFRP

Field Studies Division

This division through the Area Coordinators and Data Collection Coordinator serves as the main link between the IFRP and its Contributors. The Area Coordinators are responsible for communications with the Contributors, initiating new studies, monitoring the progress of ongoing studies, and representing the interests of the Contributors at the IFRP. Each Area

Coordinator monitors studies in a particular region of the world. There are Area Coordinators for Asia, the Middle East, Iran, Latin America, Africa-Europe and the United States.

The Data Collection Coordinator is responsible for: (1) shipment and receipt of all study forms and supplies, and (2) communications with the Contributors regarding the quality of incoming patient record forms, and problems with the coding of these forms.

Data Processing Division

Through its Data Processing Division, the IFRP can provide its Contributors with rapid feedback of the data they have submitted and reports based on these data. This has been made possible by extensive computerization of the IFRP's data processing system. The keypunching, verifying, and loading of the data into a data file, using a remote, medium-speed input/output terminal connected to an IBM 370/165 computer, are performed at the IFRP. The Data Processing Division has written computer programs which can rapidly provide the IFRP staff or the Contributors with the following information:

- Computer printouts of the status of each IFRP study, including the number of forms received, the loss-to-follow-up rate, and the percentage of forms containing incomplete items or items that must be queried.
- Lists of all unlikely and/or impossible responses recorded on the patient record forms. From these lists, queries are sent to the Contributor, and the IFRP data files are then updated after the Contributor has answered the queries.
- Standard Computer Summary Tables. For each study area these tables, which provide overall summaries of the data, are divided into two parts: demographic tables and clinical tables. Except for the male sterilization study, demographic tables for each study area are essentially identical and include about 35 tables based on patient characteristics. The clinical tables are specific to the method tested. Requests by the Contributors for the standard tables are usually filled and mailed on the day received. The standard tables are printed on the IFRP's input/output terminal, and can be obtained within two hours of request at very nominal expense. The programs for the standard tables have been written so that these tables can be obtained for selected sub-sets of the data, or for pooled data from two or more studies and/or Centers.
- Other Computer Outputs. The IFRP has a staff of experienced programmers who provide support for the IFRP's research staff and Contributors for non-standard data output requests.

Since July 1971, the volume of processed forms (see Figure 1) has steadily increased as well as the amount of computer usage time. These increases reflect both the number of studies being conducted by the IFRP and the number of requests for data analyses and outputs by the Contributors and IFRP staff. In light of these increases and because of a higher cost of computer usage due to IFRP's separation from the University of North Carolina, it has become

cost effective for IFRP to acquire its own computer facility. It is expected that such a facility, configured around an IBM 360/65 or 370/145 CPU, will be installed late in the last quarter of 1975.

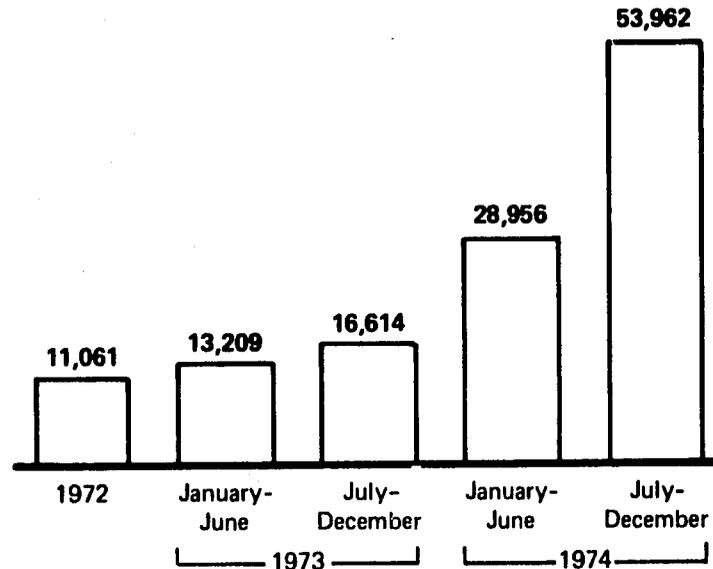


Figure 1. Number of Forms Processed by Time Period, 1972 Through December, 1974.

Design and Analysis Division

The primary responsibilities of this division are to:

- Design data collection instruments, basic data management systems and standard computer tables.
- Design protocols for comparative and straight studies.
- Monitor the overall quality of incoming data.
- Assist and train Contributors in the analysis and interpretation of their study results.
- Prepare brief reports on completed studies for the Contributors.
- Assist Contributors in the preparation of manuscripts for presentation at national or international meetings or conferences.
- Present and/or publish individual methodological papers as well as papers based on pooled data from two or more similar studies.

A brief summary of IFRP study findings appears in Appendix C.

All three divisions of the IFRP participate in reviewing the quality and adequacy of Contributor data. The Heads of each division are members of the IFRP's Research Review Committee which has the responsibility of reviewing and approving all new and ongoing studies. Through the Data Collection Coordinator and Area Coordinators, all divisions participate in the data review process.

The data collection process begins when a study is approved for initiation. At the request of the Area Coordinator, study forms and related materials are sent to the Contributor by the Data Collection Coordinator (DCC). The Contributor returns completed forms each month to the DCC.

After the forms are logged in, the DCC routes them to the Design and Analysis Division for scanning and comments. Scanned forms are returned to the DCC who, when necessary, routes them to the Area Coordinator for review. The DCC then forwards the forms to the Data Processing Division for computer processing.

Queries which result from computer processing are sent to the Contributor through the DCC. The Contributor returns answered queries to the DCC who forwards them to Data Processing.

Feedback concerning the study is available to the Contributor in the form of standard computer tables and Consultant Reports prepared by the Design and Analysis Division.

V. THE CONTRIBUTOR NETWORK

The IFRP is essentially a service organization to its network of Contributors, since it is the Contributors who conduct the IFRP's field studies. The Contributor determines the quality of data collected and thereby the value of each study. Also, the Contributor has primary responsibility for correctly interpreting and reporting study results to colleagues and government officials in his own country and to the international scientific community.

To date the IFRP has been affiliated with 169 centers in 30 countries. At present 91 of these centers in 21 countries are active (forms received within the last 90 days). Table I gives a breakdown of the total contributor network by country and by forms received in each study area from July 1972 to March 1975. The India Fertility Research Programme is now processing forms from centers in India.

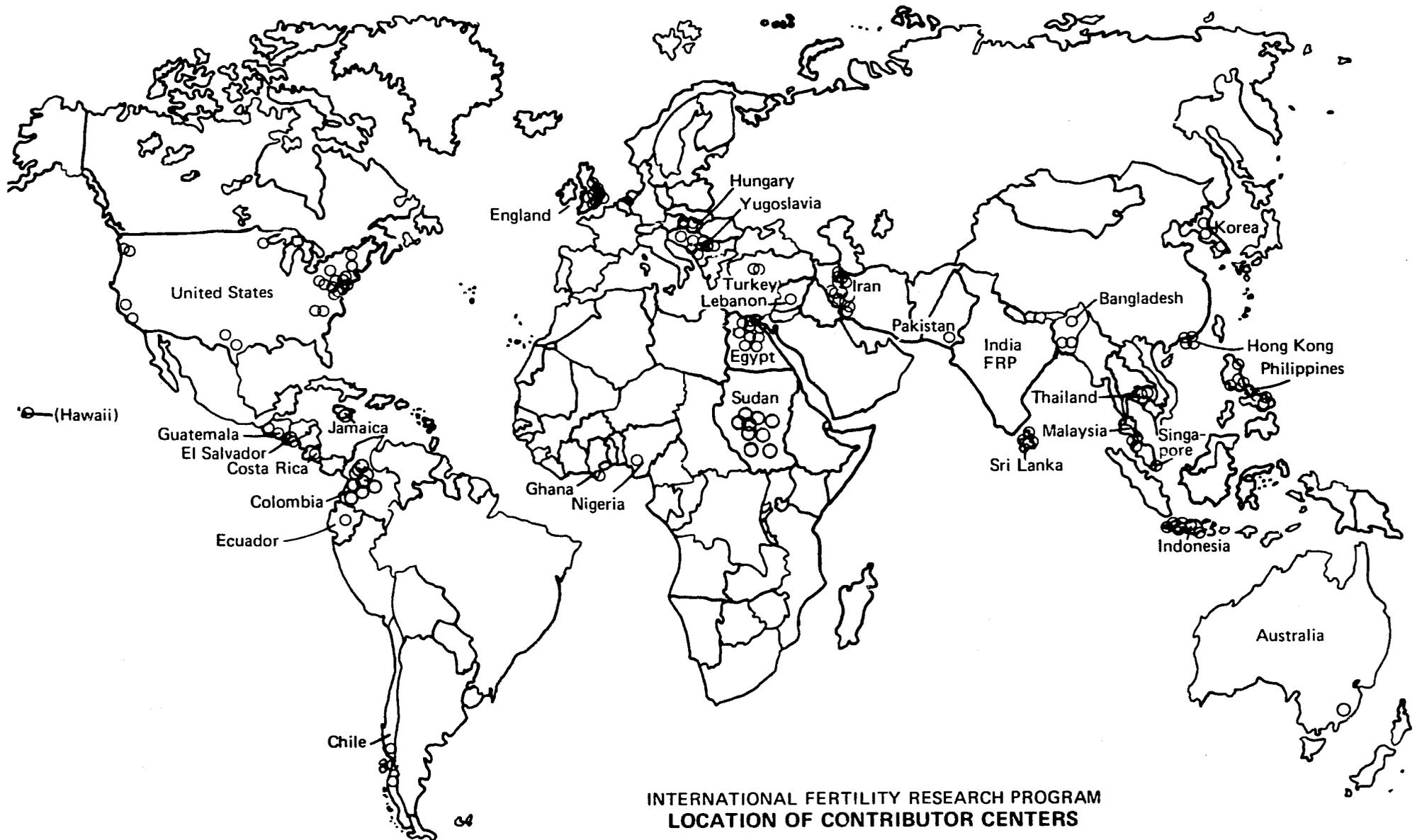
To encourage an exchange of ideas between Contributors and IFRP staff members, Contributor Conferences sponsored by the IFRP have been held in conjunction with the following international meetings:

- Conference on Abortion Techniques and Services, June, 1971, New York, New York.
- VII World Congress on Fertility and Sterility, October, 1971, Tokyo, Japan.

TABLE I
STUDY CENTERS AND FORMS RECEIVED BY COUNTRY
July 1971-March 1975

COUNTRY	PARTICIPATING CENTERS	NUMBER OF STUDIES BY STUDY AREA						TOTAL	
		PREGNANCY TERMINATION	MENSTRUAL REGULATION	INTRAUTERINE DEVICES	FEMALE STERILIZATION	MALE STERILIZATION	SYSTEMIC CONTRACEPTIVES	STUDIES	FORMS
USA	22	10	10	3	11	2	2	38	163,421
England	8	6	4	—	1	—	—	11	3,040
Yugoslavia	8	14	—	15	—	—	—	29	15,558
Hungary	2	—	1	6	—	—	—	7	14,153
Egypt	8	7	1	7	6	—	—	21	6,978
Iran	20	9	5	14	5	—	1	34	7,087
Turkey	2	2	1	1	1	—	—	5	2,228
Lebanon	1	—	—	—	3	—	—	3	489
Sudan	3	3	—	—	—	—	—	3	1,865
Nigeria	1	—	1	—	—	—	—	1	151
Ghana	1	1	1	—	—	—	—	2	1,228
Philippines	7	2	3	3	5	—	—	13	9,838
Pakistan	1	—	1	—	—	—	—	1	20
Singapore	1	4	2	—	3	—	—	9	13,129
Korea	2	2	3	—	1	—	—	6	1,244
Hong Kong	4	1	—	4	—	—	—	5	3,942
Indonesia	6	1	4	2	1	—	—	8	5,209
Malaysia	2	1	—	—	2	—	—	3	331
Thailand	3	1	—	3	4	—	—	8	8,117
Sri Lanka	4	—	—	2	3	1	1	7	1,118
Bangladesh	3	—	1	—	2	—	2	5	154
Australia	1	1	—	—	—	—	—	1	82
Jamaica	1	1	—	—	—	—	—	1	15
Chile	3	1	1	2	1	—	—	5	1,388
Colombia	9	9	—	—	—	—	—	9	2,962
Ecuador	1	—	—	1	—	—	—	1	104
El Salvador	2	1	—	3	3	1	—	8	10,380
Costa Rica	1	—	—	—	2	—	—	2	289
Guatemala	2	2	—	—	—	—	—	2	190
India Fertility Res. Programme	40	45	26	4	21	3	5	104	32,644*
TOTAL	169	124	65	70	75	7	11	352	307,191

* India FRP processing.



- International Planned Parenthood Federation Indian Ocean Regional Conference, December, 1971, Tokyo, Japan.
- International Conference on Voluntary Sterilization, February, 1972, Geneva, Switzerland.
- Twenty-Second Iranian Medical Congress, September, 1973, Ramsar, Iran.
- Menstrual Regulation Conference, December, 1973, Honolulu, Hawaii.
- All India Congress of Obstetrics and Gynaecology, February, 1974, Agra, India (sponsor: India Fertility Research Programme).
- VI Asian Congress of Obstetrics and Gynaecology, July 1974, Kuala Lumpur, Malaysia.
- FIGO Seminar, Bombay, India, March, 1975 (sponsor: India Fertility Research Programme).

VI. CONTRIBUTOR TRAINING

The IFRP provides training to its network of Contributors at the Contributor's Center, in Chapel Hill at the IFRP offices and at various Departments of Obstetrics and Gynecology within the USA where specific training, skills and procedures are available. Two areas of training experience are emphasized:

- Research Management, including methodology, data collection, processing and the interpretation of study results, and
- Specific clinical methods of fertility regulation, such as the use of prostaglandins for pregnancy termination and the spring-loaded clip for sterilization.

Since July, 1971, 46 Contributors, or members of their staffs, from 19 countries have come to Chapel Hill for training. The training period is usually for one month depending on the needs of the individual Contributors. Recently the training emphasis has shifted from clinical methods to research methodology and the interpretation and presentation of study results.

VII. REGIONALIZATION

The objective of regionalization of IFRP research is institutional development in the form of Fertility Research Programs at national and regional levels to coordinate and further develop research efforts already established in defined geographical areas. The regional centers will be based on the present IFRP model: a network of contributing centers; preparation of study designs that utilize IFRP protocols, and data collection instruments; collection of data; computer processing and generation of standard summary tables for analysis; analysis, preparation and presentation of research results.

Depending upon the available data processing facilities in a region or country, the Programs may elect to either collect and store their own data on magnetic tape for subsequent editing, querying, and analysis at the IFRP (Chapel Hill), or the IFRP's computer programs may be transferred to the regional center. Development of national and regional centers will follow a pattern of phasing-in the various elements required to fully institutionalize research capabilities. Throughout the process of building centralized national or regional research services, IFRP will assist, train and provide back-up.

The IFRP has already taken preliminary and formative steps to develop autonomous national and regional research programs. The independent India Fertility Research Programme is now operational and has full data collection and processing capabilities. Assistance is presently underway to support the development of the research activities of the Sudan Fertility Research Programme, recently organized in the Sudan. A regional program is being developed with the Intergovernmental Coordinating Committee of Southeast Asia.

VIII. MANAGEMENT INFORMATION SERVICE

To provide program administrators, officials and clinicians with information on the acceptors of various methods of fertility regulation and limited information on the safety and efficacy of these methods, the IFRP has adapted its present data collection system and computer programs. The data from Contributors who participate in these studies are not processed through the usual querying system; instead, all impossible, illegal or missing data are converted into unknown responses. For continuous contraceptive studies (IUDs and orals) with long-term follow ups, only one follow-up record is submitted, either at the time of the event or at the cut-off date for the study.

A frequency distribution of data converted to unknowns is provided to the clinic administrator to enable him to improve the quality of future data submitted. The IFRP's standard computer summary tables are available with notations giving instances of missing data as they apply to specific tables. Computer graphing of several indices by month is being developed for the Management Information Service.

Pretesting of the Management Information Service will be completed by mid-1975. To meet a broader spectrum of administrative needs for program decision making, resource allocation and reporting requirements, the IFRP will explore the development of a more specialized information gathering, processing and reporting system during 1975.

IX. PUBLICATIONS AND CONTRIBUTOR FEEDBACK

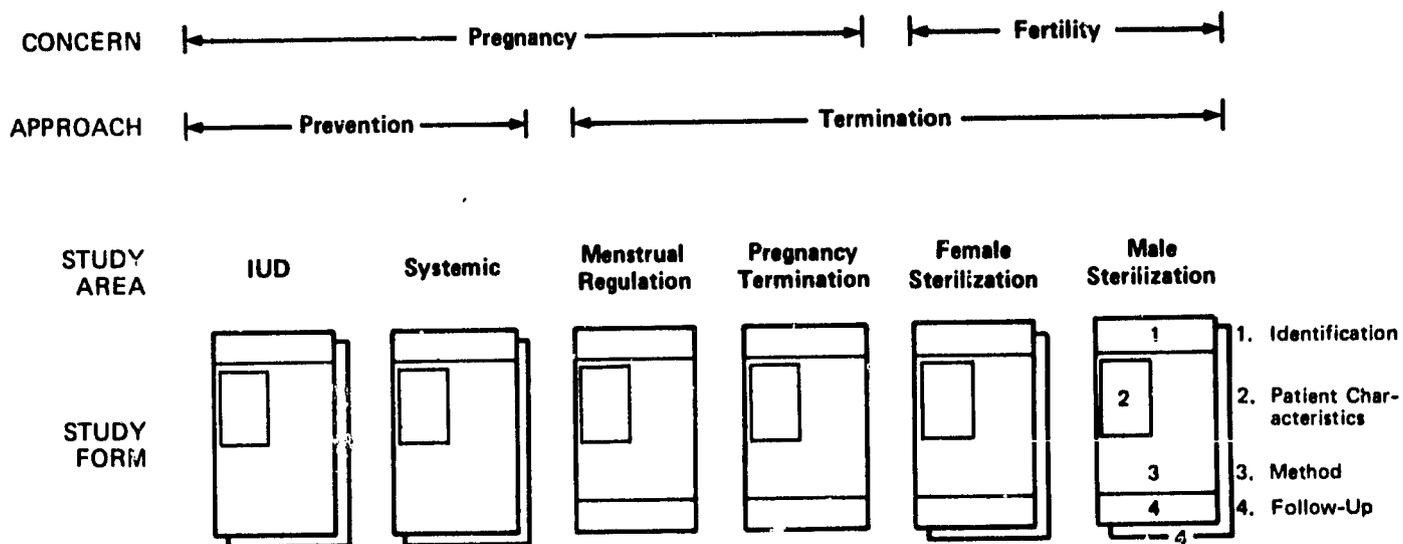
Dissemination of research findings is achieved through the following types of reports which have been summarized in order of increasing complexity:

- Standard Computer Summary Tables. These are readily available to the Contributors upon request for any data set or selected parts of the data set.
- Consultant Reports. These are brief reports for the Contributor based only on the Standard Computer Summary Tables. The reports are prepared by the Design and Analysis Division.

- **Conference Papers.** These are prepared by the Contributor, the IFRP staff or jointly. If the report is prepared by the Contributor, IFRP staff members may assist the Contributor in the analyses of the data. Conference papers are printed by the IFRP for distribution at scientific meetings.
- **Journal Articles.** Contributors and the IFRP staff frequently submit joint or independent articles to journals for publication. The IFRP provides editing services to the Contributors and the IFRP staff so that articles are in appropriate format. A reprint series of journal articles is maintained by the IFRP for wide distribution.
- **Monograph Series.** Monographs summarize some of the broader aspects of the IFRP studies. This monograph series is still in preparation.

A list of the printed outputs of the IFRP is given in Appendix D.

**APPENDIX A
DATA COLLECTION INSTRUMENTS**



**STANDARD DATA COLLECTION INSTRUMENTS
FOR SIX IFRP STUDY AREAS**

**INTERNATIONAL FERTILITY RESEARCH PROGRAM
I.U.D. STUDY-FOLLOW-UP RECORD**

Circle Appropriate Numbers and Fill in Appropriate Boxes and Blanks.

PATIENT IDENTIFICATION:	1. Your Hospital or Clinic No. _____	2. Follow-up Visit Date _____ <small>day month year</small>
3. Patient's Name _____	<small>family first maiden</small>	Telephone _____
4. Address (if changed) _____		

STUDY IDENTIFICATION

5. Center Name _____ and Number

 1-3

6. Study Name _____ and Number

 4-6

7. Patient Order in Study

 7-10

8. IFRP Admission Form Number

 11-16

9. Follow-up Visit Number

 17-18

CONTACT DATA

10. Type of Contact 1) clinic visit 2) home visit
3) moved 4) unable to locate 5) died, cause _____

8) other _____ 19

11. Reason for This Contact 1) routine 20
8) other _____

12. Date (This) Contact:

 21-25

13. Date (Last) Contact:

 27-31
day month year

MENSES

14. Menses Since Last Visit 0) no 1) yes 33

15. Date Last Menses Onset _____
day month year

16. Average Length of Cycle (in days) 88) irregular 34-35

17. Average Duration of Flow (in days, 8 or more = 8) 36

18. Average Amount of Flow 1) scanty 2) normal 3) excessive 37

19. Dysmenorrhea 0) no 1) mild 2) moderate 3) severe 38

20. Intermenstrual Bleeding 0) no 1) staining/spotting 2) moderate 3) severe 39

21. Intermenstrual Pain 0) no 1) mild 2) moderate 3) severe 40

IUD EVENTS SINCE LAST CONTACT

22. Any Self-Examination 0) no 1) yes 42

23. Last Date Device Present _____

24. First Date Device Absent _____
day month year

25. Noticed Displacement Signs 0) no 1) yes 43

26. Date Noticed _____
day month year

27. Noticed Expulsion 0) no 1) yes 44

28. Date Noticed _____
day month year

29. Was Device Removed 0) no 1) yes 45

30. By Whom _____ 46

31. Reason _____ 47

32. Date Removed _____
day month year

33. Pregnancy Since Last Visit 0) no 1) yes 48

34. Date of Conception (Add 14 days to start of last menses.) _____
day month year

35. Pregnancy Outcome 0) currently pregnant 1) live birth 2) still birth 3) induced abortion 12 weeks or less 4) induced abortion over 12 weeks 5) spontaneous abortion 6) septic abortion 8) other 49

36. Date of Termination _____
day month year

37. Have You Recommended This Method to a Friend Since Last Visit 0) no 1) yes 50

Interviewer's Name _____

PELVIC EXAMINATION

38. Thread Visible: 0) no 1) yes 52

39. X-Ray Taken: 0) no 1) yes 53

40. Uterus Probed: 0) no 1) yes 54

41. Device: 1) *in situ* 2) displaced, where _____ 3) absent 4) not determined 55

42. Infection Signs of Uterus and Adnexa (PID): 0) no 1) mild 2) severe 56

43. Pregnancy Signs: 0) no 1) yes 57
specify _____

44. Pregnancy Test: 0) negative 1) uncertain 2) positive 9) not done 58

45. Estimated Date of Conception: _____
day month year

46. Removal of Device Now 0) no 1) for pregnancy 2) for displacement (Item 41) 3) for pain 4) for bleeding 5) for other medical reasons 6) for planned pregnancy 7) for other personal reasons 8) other 59

If no removal or expulsion skip to item 48

47. If Device Removed or Expelled, Other Method of Fertility Control Accepted or Planned by Patient: 0) none 1) IUD, specify by type and size if reinserted today type _____ size _____ 2) orals 3) tubectomy 4) vasectomy 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other 60

48. Date Set for Next Visit

NOTE: If patient had removal, expulsion or confirmed pregnancy, do not code this box.

(It is usual to set a date 1, 3, 6, 12, 24 months after insertion; thus, set visit date NOW.)

DATE:

 /

 /

 62-66
day month year

Examiner's Name _____

I.F.R.P. USE ONLY

49. Termination Type 70

50. Termination Date: _____
day month year 71-75

REMARKS _____

15

**INTERNATIONAL FERTILITY RESEARCH PROGRAM
MENSTRUAL REGULATION STUDY**

Circle Appropriate Numbers and Fill in Appropriate Boxes and Blanks.

No. _____

PATIENT IDENTIFICATION:		1. Your Hospital or Clinic No. _____	2. Admission Date _____ <small>day month year</small>
3. Patient's Name _____ <small>family first maiden</small>		4. Husband's Name _____	
5. Address _____		Telephone _____	
6. Relative/Friend's Name _____		Telephone _____	
7. Address _____		Telephone _____	

STUDY IDENTIFICATION

8. Center Name _____ and Number

 1-3

9. Study Name _____ and Number

 4-6

10. Patient Order in Study _____ 7-10

PATIENT CHARACTERISTICS

11. Residence: 1) urban local 2) urban outside area
3) rural local 4) rural outside area _____ 11

12. Age: (years completed) _____ 12-13

13. Gainfully Employed: 0) no 1) yes _____ 14

14. Race: 1) Caucoid 2) Mongoloid 3) Negroid
8) other _____ 15

15. Religion: 0) none 1) Buddhist 2) Catholic
3) Hindu, caste 4) Jewish 5) Muslim
6) Orthodox 7) Protestant 8) other _____ 16

16. Marital Status: 1) never married 2) currently married
3) formerly married 8) other _____ 17

17. Patient's Education: (school year completed) _____ 18-19

18. Husband's Education: (school year completed) _____ 20-21

19. Total Live Births: _____ 22-23

20. Children Now Living: number of males _____
number of females _____ (8 or more = 8) 24

21. Number of Additional Children Wanted _____ 25

22. Total Number of Abortions: _____ 27-28

23. Number of Spontaneous Abortions (8 or more = 8) _____ 29

24. Total Stillbirths (8 or more = 8) _____ 30

25. Contraceptive Method Mainly Used This Month: 0) none
1) IUD 2) oral 3) tubectomy 4) vasectomy
5) condom 6) withdrawal/rhythm 7) foam/diaphragm/
jelly 8) other _____ 31

ADDITIONAL STUDIES (To Be Filled in Upon Request)

26. _____

 32-33

 34-35

MEDICAL DATA

27. Date Last Menses Onset: _____
day month year 37-41

28. Number of Days Menses Delayed: _____ 42-43

29. Hematocrit: 99) not done _____ 44-45

30. Hemoglobin in Grams: 99) not done _____ 46-47

31. Pre-existing Medical Conditions: 0) none
1) pelvic 2) systemic 3) 1 plus 2 4) psychiatric only
8) other _____ 48

32. Patient Scheduled As: 1) outpatient 2) inpatient _____ 49

33. Admission Temperature _____ °C _____ °F 50

34. Results of Initial Pregnancy Test: 0) negative
1) indefinite 2) positive 9) not performed _____ 51

35. Specimens Collected for Later Analysis: 0) none 1) blood
2) urine 3) uterine tissue 4) combination _____ 52

36. Anesthetic: 0) none 1) analgesia only 2) local
3) regional 4) general 5) 1 plus 2 6) 2 plus 4
8) other _____ 53

REMINDER: Your study requires a follow up visit approximately one month after procedure. Do not record visits less than 14 days after procedure. Confirm post-discharge complications by review of medical records.

FOLLOW UP DATA

69. Follow up Outcome: 1) clinic visit 2) home visit
3) moved 4) unable to locate 5) died, cause _____
8) other _____ 55

70. Fertility Control Accepted or Used: 0) none 1) IUD
2) oral 3) tubectomy 4) vasectomy 5) condom
6) withdrawal/rhythm 7) foam/diaphragm/jelly
8) other _____ 56

71. Results of Microscopic Exam of Uterine Tissue:
0) no evidence of pregnancy
1) presumptive evidence of pregnancy
decidual, etc. _____
2) products of conception identified _____
3) results not known _____
4) exact not done _____ 57

PROCEDURES

37. Vacuum Aspiration: 0) not used 1) single first used
2) single repeated 3) combined first used
4) combined last used _____ 58

38. Curette Check Performed: 0) no 1) yes _____ 59

39. Cannula Type _____ 61-62

40. Cannula Size (in mm) _____ 63

41. Vacuum Source _____ 64-65

42. Dilatation and Curettage (Use item 37 codes) _____ 66

43. Dilatation in Mill. liters: 00) not dilated _____ 67-68

44. Prostaglandin: Complete IFRP (Use item 37 codes) _____ 69
Drug Administration Form (Use item 37 codes) _____ 70

45. Other Drug _____ 71

46. Other Method (Use item 37 codes) _____ 71

47. Concurrent Surgery: 0) none 1) IUD 2) tubectomy
8) other _____ 72

Operator's Name _____

 73-80

COMPLICATIONS

48. Any Complications Related to Procedure:
0) no 1) yes, additional hospitalization not required
2) yes, additional hospitalization required _____ 11

49. Uterine Perforation: 0) no 1) suspect 2) yes _____ 12

50. Cervical Laceration: 0) no 1) yes, without suture
2) yes, with suture _____ 13

51. Blood Loss Over 100 ml: 0) no 1) yes _____ 14

52. Blood Transfusion: 0) no 1) yes, _____ ml. _____ 15

53. Shock Related to Surgery: 0) no 1) yes _____ 16

54. Vomiting: 0) no 1) nausea only 2) mild vomiting
3) moderate vomiting 4) severe vomiting _____ 17

55. Diarrhea: 0) no 1) mild 2) moderate 3) severe _____ 18

56. Fever 38°C / 100.4°F or Over, 24 Hours After Procedure:
0) no 1) yes 2) yes, requiring antibiotics _____ 19

57. Anesthesia Complications: 0) none 1) apnea 2) vomiting
3) convulsions 4) shock 5) aspiration 6) headache
7) combination: _____ 8) other _____ 20

58. Other Complications _____ 21-22

59. Death: 0) no 1) yes, cause _____ 23

60. Prophylactic Antibiotics Given: 0) no 1) yes _____ 24

61. Prophylactic Oxytocics Given: 0) no 1) yes _____ 25

62. Post-Procedure Fertility Control Planned or Used:
0) none 1) IUD 2) oral 3) tubectomy
4) vasectomy 5) condom 6) withdrawal/rhythm
7) foam/diaphragm/jelly 8) other _____ 27

63. Admission Date _____ 28-30

64. Initiation Date _____ 31-33

65. Completion Date _____ 41-43

66. Final Discharge Date _____ 47-51

67. Nights in Hospital _____ 54

68. Time Between Initiation and Completion
(98 hours or over = 98 59) _____ hours _____ minutes 55-59

72. Results of Follow up Pregnancy Test: 0) negative
1) indefinite 2) positive 9) not performed _____ 59

73. Bleeding Requiring Curettage: 0) no 1) yes _____ 60

74. Fever Requiring Antibiotics: 0) no 1) yes _____ 61

75. Other Complications _____ 62-63

76. Readmission Related to Procedure: 00) no
number of nights _____ 64-65

77. Date of Follow up Visit _____
day month year 67-71

Recorded by _____

No. _____

 72-79

IFRP Rev 1/75

PLEASE AIRMAIL TO International Fertility Research Program, NCNB Plaza, Suite 400, Chapel Hill, North Carolina 27514 USA

INTERNATIONAL FERTILITY RESEARCH PROGRAM
PREGNANCY TERMINATION STUDY

No. _____

Circle Appropriate Numbers and Fill in Appropriate Boxes and Blanks.

PATIENT IDENTIFICATION:

1. Your Hospital or Clinic No. _____ 2. Admission Date _____ day month year

3. Patient's Name _____ family first maiden Telephone _____

4. Husband's Name _____ Telephone _____

5. Address _____ Telephone _____

6. Relative/Friend's Name _____ Telephone _____

7. Address _____ Telephone _____

STUDY IDENTIFICATION

8. Center Name _____ and Number

 1-3

9. Study Name _____ and Number

 4-6

10. Patient Order in Study

--	--	--

 7-10

PATIENT CHARACTERISTICS

11. Residence: 1) urban local 2) urban outside area 3) rural local 4) rural outside area

--	--

 11

12. Age: (years completed)

--	--

 12-13

13. Gainfully Employed: 0) no 1) yes

--

 14

14. Race: 1) Caucasian 2) Mongoloid 3) Negroid 8) other

--

 15

15. Religion: 0) none 1) Buddhist 2) Catholic 3) Hindu, caste 4) Jewish 5) Muslim 6) Orthodox 7) Protestant 8) other

--

 16

16. Marital Status: 1) never married 2) currently married 3) formerly married 8) other

--

 17

17. Patient's Education: (school year completed)

--	--

 18-19

18. Husband's Education: (school year completed)

--	--

 20-21

19. Total Live Births:

--	--

 22-23

20. Children Now Living: number of males (8 or more = 8)

--

 24
number of females

--

 25

21. Number of Additional Children Wanted:

--

 26

22. Total Number of Previous Abortions:

--	--

 27-28

23. Number of Spontaneous Abortions: (8 or more = 8)

--

 29

24. Total Stillbirths: (8 or more = 8)

--

 30

25. Contraceptive Method Mainly Used in Month of This Conception: 0) none 1) IUD 2) oral 3) tubectomy 4) vasectomy 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other

--

 31

ADDITIONAL STUDIES (To be filled in upon request)

26.

 32-33

27.

 34-35

28.

 36-37

--	--

 38-39

MEDICAL DATA

29. Estimated Duration of Pregnancy: (menstrual age in weeks)

--	--

 41-42

30. Hematocrit: 99) not done

--	--

 43-44

31. Hemoglobin in Grams: 99) not done

--	--

 45-46

32. Pre-existing Medical Conditions: 0) none 1) septic abortion 2) incomplete/inevitable abortion 3) threatened abortion 4) systemic 5) systemic with 1, 2 or 3 6) psychiatric only 7) pelvic only, specify _____ 8) other

--

 47

33. Patient Scheduled as: 1) outpatient 2) inpatient

--

 48

34. Admission Temperature: _____ °C _____ °F.

--

 49

35. Anesthetic: 0) none 1) analgesia only 2) local 3) regional 4) general 5) 1 plus 2 6) 2 plus 4 8) other

--

 50

REMINDER: Your study requires a follow-up visit approximately one month after termination. Do not record visits less than 14 days after termination. Confirm post-discharge complications by review of medical records.

FOLLOW-UP DATA

67. Follow-up Outcome: 1) clinic visit 2) home visit 3) moved 4) unable to locate 5) died, cause _____ 8) other

--

 51

68. Fertility Control Accepted or Used: 0) none 1) IUD 2) oral 3) tubectomy 4) vasectomy 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other

--

 52

TERMINATION PROCEDURES

36. Dilatation and Curettage: 0 1 2 3 4

--

 63

37. Vacuum Aspiration: 0 1 2 3 4

--

 64
Was Curette Check Performed: (Circle) no yes

--

 65

38. Intra-amniotic Injection: Coding 0 1 2 3 4

--

 66
0) not used
1) single used
2) single repeated
3) combined IUD used
4) combined IUD used

39. Hysterectomy: 0 1 2 3 4

--

 67

40. Hysterotomy: 0 1 2 3 4

--

 68

41. Prostaglandin: type _____ route _____ dose _____ 0 1 2 3 4

--

 69

42. Other _____ 0 1 2 3 4

--

 70

43. Dilatation in Millimeters: 00) not dilated

--

 71-72

44. Laminaria Used: 0) no 1) yes, type _____

--

 73

45. Retained Products of Conception After First Procedure: 0) no 1) yes 2) yes, patient discontinued treatment

--

 74

46. Re-evaluation of Estimated Duration of Pregnancy (see Item 29): 0) no change 1) estimate increased 2) estimate decreased 3) no pregnancy 4) doubtful pregnancy 5) vesicular mole 8) other

--

 75

47. Concurrent Surgery: 0) none 1) IUD 2) tubectomy 8) other

--

 76

Operator's Name _____

COMPLICATIONS

48. Uterine Perforation: 0) no 1) suspect 2) yes

--

 11

49. Cervical Laceration: 0) no 1) yes, without suture 2) yes, with suture

--

 12

50. Excessive Blood Loss: 0) no 1) yes

--

 13

51. Transfusion Given: 0) no 1) yes, _____ ml.

--

 14

52. Shock Related to Surgery: 0) no 1) yes

--

 15

53. Fever 38°C/100.4°F. or Over, 24 Hours After Termination: 0) no 1) yes 2) yes, requiring antibiotics

--

 16

54. Anesthesia Complications: 0) none 1) apnea 2) vomiting 3) convulsions 4) shock 5) combination 8) other

--

 17

55. Any Complication Requiring Additional Hospitalization: 0) no 1) observation 2) medical treatment 3) laparotomy 8) other

--

 18

56. Other Complications _____

--	--

 19-20

57. Death: 0) no 1) yes, cause _____

--

 21

58. Prophylactic Antibiotics Given: 0) no 1) yes

--

 22

59. Prophylactic Oxytocics Given: 0) no 1) yes

--

 23

60. Post-termination Fertility Control Planned or Used: 0) none 1) IUD 2) oral 3) tubectomy 4) vasectomy 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other

--

 24

61. Admission Date:

--	--	--

 25-26

62. Initiation Date:

--	--	--

 27-28

63. Completion Date:

--	--	--

 29-30

64. Final Discharge Date:

--	--	--

 day month year 31-32

65. Nights in Hospital:

--	--

 33-34

66. Time Between Initiation and Completion: (99 hours or over = 98:59)

--	--

 hours

--	--

 minutes 35-36

69. Bleeding Requiring Curettage: 0) no 1) yes

--

 37

70. Fever Requiring Antibiotics: 0) no 1) yes

--

 38

71. Other Complications _____

--

 39-40

72. Readmission Related to Termination: 00) no number of nights

--	--

 41-42

73. Date of Follow-up Visit:

--	--	--

 day month year 43-44

74. Completed Weeks From Discharge to Follow-up:

--	--

 45-46

Recorded By _____

IFRP Rev 1/75

NO _____ 54-61

PLEASE AIRMAIL TO: International Fertility Research Program, NCNB Plaza, Suite 400, Chapel Hill, North Carolina 27514 USA

**INTERNATIONAL FERTILITY RESEARCH PROGRAM
FEMALE STERILIZATION STUDY - ADMISSION RECORD**

Please Circle Appropriate Numbers and Hexagons and Fill In Appropriate Boxes and Blanks.

No. _____

PATIENT IDENTIFICATION:

1. Your Hospital or Clinic No. _____ 2. Admission Date _____
day month year

3. Patient's Name _____ 4. Husband's Name _____
family first maiden

5. Address _____ Telephone _____

6. Relative/Friend's Name _____ 7. Address _____

STUDY IDENTIFICATION

8. Center Name _____ and Number _____
 9. Study Name _____ and Number _____
 10. Patient Order in Study _____

PATIENT CHARACTERISTICS

11. Residence: 1) urban local 2) urban outside area
 3) rural local 4) rural outside area

12. Age: (years completed) _____

13. Gainfully Employed: 0) no 1) yes

14. Race: 1) Caucasian 2) Mongoloid 3) Negroid
 8) other

15. Religion: 0) none 1) Buddhist 2) Catholic 3) Hindu,
 caste 4) Jewish 5) Muslim 6) Orthodox
 7) Protestant 8) other

16. Marital Status: 1) never married 2) currently married
 3) formerly married 8) other

17. Patient's Education: (school year completed) _____

18. Husband's Education: (school year completed) _____

19. Total Live Births: _____

20. Children Now Living: number of males (8 or more = 8)
 number of females

21. Age of Youngest Child: (8 or more years = 8)

22. Total Number of Abortions: _____

23. Number of Spontaneous Abortions: (8 or more = 8)

24. Total Stillbirths: (8 or more = 8)

25. Contraceptive Method Mainly Used Before this Operation:
 0) none 1) IUD 2) oral 3) tubectomy
 4) vasectomy 5) condom 6) withdrawal/rhythm
 7) foam/diaphragm/jelly 8) other

26. Patient Status: 1) private 2) nonprivate

27. Patient Scheduled as: 1) outpatient 2) inpatient

PREGNANCY AND MENSES

28. Last Pregnancy's Outcome: 0) not previously pregnant
 1) live birth 2) stillbirth 3) induced abortion 12 weeks
 or less 4) induced abortion over 12 weeks
 5) spontaneous abortion 6) septic abortion 7) ectopic
 8) other

29. Date Last Pregnancy Ended: _____

30. Date Last Menses' Onset: _____
day month year

31. Currently Pregnant: 00) no number of weeks _____

32. Average Length of Cycle: (in days) 88) irregular

33. Average Duration of Flow: (in days; 8 or more = 8)

34. Average Amount of Flow: 1) scanty 2) normal 3) excessive

36. Dysmenorrhea: 0) no 1) mild 2) moderate 3) severe

Interviewer's Name (print) _____

MEDICAL DATA

36. Weight in kg: (98 and over = 98)

37. Height in cm: _____

38. Hematocrit: (or Hb. x 3) 99) not done

REMINDER: Retain this form and complete it at the first follow-up visit 7 - 21 days after sterilization.

FOLLOW-UP DATA

67. Patient Discharged: 0) no → SKIP TO ITEM 75
 1) yes

68. Follow-up Outcome: 1) clinic visit 2) home visit
 3) moved 4) unable to locate 5) confirmed wrong address
 6) died, cause _____ 8) other

69. Reason For This Contact: 1) scheduled follow-up
 2) emergency 8) other

70. Number of Additional Contacts Related to Sterilization
 (8 or more = 8)

71. Readmission Related to Sterilization 00) no
 number of nights _____

MEDICAL HISTORY

39. Abdominal Surgery: 0) no 1) yes: specify _____

40. Pelvic Surgery: 0) no 1) yes: specify _____

41. Systemic Disease: 0) no 1) yes: specify _____

42. Other Complaints _____

EXAMINATION AND SURGERY

43. Pelvic and Operative Examination: 1) normal 2) adhesions
 3) prolapse 4) fibroid 5) cyst 6) combination
 8) other

44. Pelvic Infection: 0) none 1) yes, acute 2) yes, chronic

45. Anesthesia: 0) none 1) analgesia only 2) local
 3) regional 4) general 5) 1+2 6) 2+4 8) other

46. Planned Procedure: 1) culdoscopy 2) vaginal ligation
 3) vaginal hysterectomy 4) laparoscopy 5) abdominal
 ligation 6) abdominal hysterectomy 7) transcervical
 8) other

47. Performed Procedure: (Use Item 46 Codes)

48. Technique Used _____

49. Difficulties at Surgery _____

50. Pregnancy Termination This Admission:
 0) no 1) concurrent with sterilization
 2) preceding sterilization 3) after sterilization

51. Pregnancy Termination Procedure: 1) D&C 2) vacuum
 aspiration 3) intra-amniotic
 4) hysterotomy 5) cesarean 6) vaginal delivery
 8) other

52. Pregnancy Termination Outcome: (Use Item 28 Codes)

53. Other Surgery This Admission (Use Item 50 Codes)
 specify procedure _____

54. Surgical Time (From incision through closure)
 (in minutes, 98 minutes and over = 98)

55. Prophylactic Antibiotics Given: 0) no 1) yes

COMPLICATIONS: STERILIZATION TO DISCHARGE

56. Any Complications Related to Sterilization Procedure:
 0) no 1) yes, no additional hospitalization required
 2) yes, additional hospitalization required

57. Excessive Blood Loss: 0) no 1) yes

58. Blood Transfusion Given: 0) no 1) yes _____ ml.

59. Surgical Complications: 0) none 1) shock 2) bowel-
 bladder injury 3) laparotomy required 4) 1+2
 5) 1+3 6) 2+3 7) 1+2+3 8) other

60. Fever 38°C./100.4°F. or Over, 24 Hours After Surgery:
 0) no 1) yes 2) yes, requiring antibiotics

61. Anesthesia Complications: 0) none 1) apnea 2) vomiting
 3) convulsions 4) shock 5) aspiration 6) headache
 7) combination 8) other

62. Other Complications _____

63. Death: 0) no 1) yes, cause _____

64. Admission Date: _____

65. Surgery Date: _____

66. Discharge Date: _____
day month year

Surgeon's Name (print) _____

72. Fever Requiring Antibiotics: 0) no 1) yes

73. Other Complications _____

74. Resumption of Full Work or Household Activities: 0) no 1) yes

75. Have You Recommended Sterilization To Anyone Since
 Your Operation? 0) no 1) yes

76. Date of This Follow-up Visit: _____

77. Date Set For Next Follow-up Visit: _____
day month year

IFRPF (Rev 12/74) No. _____

PLEASE AIRMAIL TO: International Fertility Research Program, NCNB Plaza, Suite 400, Chapel Hill, North Carolina 27514 USA

18

**INTERNATIONAL FERTILITY RESEARCH PROGRAM
FEMALE STERILIZATION STUDY - FOLLOW-UP RECORD**

Circle Appropriate Numbers and Fill In Appropriate Boxes and Blanks

PATIENT IDENTIFICATION	1. Your Hospital or Clinic No. _____	2. Follow-Up Date _____ <small>day month year</small>
3. Patient's Name _____	Telephone _____	
4. Address (if changed) _____		

STUDY IDENTIFICATION

5. Center Name _____ and Number _____ 1-3

6. Study Name _____ and Number _____ 4-6

7. Patient Order in Study _____ 7-10

8. IFRP Admission Form Number _____ 11-16

ADMISSION INFORMATION (Complete at Time of Admission Only)

9. At What Age Did You (First) Get Married: _____ 17-18

10. Who Was Most Important in Your Decision to Request Sterilization: 1) self 2) husband 3) friend/relative 4) doctor 5) family planning clinic staff 8) other _____ 19

11. Primary Reason for Preferring Sterilization to Other Methods: 1) other methods not easily available 2) other methods unreliable 3) undesirable side-effects of other methods 4) inconvenience of other methods 8) other _____ 20

12. Referral Source: 1) self 2) husband 3) family planning/health staff 4) private physician 5) other agency 6) operated person 7) unoperated person 8) other _____ 21

13. Where Operated: 1) hospital/clinic - static team 2) hospital/clinic - mobile team 3) mobile clinic 4) temporary facility 5) doctor's office 8) other _____ 22

14. Intermenstrual Bleeding: 0) no 1) staining/spotting 2) moderate 3) severe _____ 23

15. Breasts: 0) normal 1) masses 2) galactorrhea 3) bleeding 4) combination 8) other _____ 24

16. Pap Smear: 0) normal 1) atypia 2) dysplasia 3) carcinoma *in situ* 4) invasive carcinoma 8) other _____ 9) not done _____ 25

7-21 DAY FOLLOW-UP

17. Resumption of Intercourse: 98) not resumed number of days after sterilization _____ 27-28

18. Dyspareunia: 0) no 1) yes _____ 29

SPECIAL STUDIES

19. _____ 31-32

20. _____ 33-34

21. _____ 35-36

_____ 80

22. Follow-Up Visit: 1) 5 month 2) 12 month 3) 18 month 4) 24 month _____ 17

23. Follow-Up Outcome: 1) clinic visit 2) home visit 3) moved 4) unable to locate 5) confirmed wrong address 6) died, cause _____ 8) other _____ 18

24. Reason for This Contact: 1) scheduled follow-up 2) emergency 8) other _____ 19

25. Number of Additional Contacts Related to Sterilization (8 or more = 8) _____ 20

26. Date (This) Contact _____ 21-25

27. Date (Last) Contact _____ 26-30

Complete at 6-Month Follow-Up Visit Only

28. Resumption of Full Work or Household Activities: 0) no 1) yes _____ 31

29. Lactating at Time of or Since Sterilization: 0) no 1) no, but desired to start - **SKIP TO ITEM 32** 2) yes _____ 32

30. Has Lactation Stopped: 0) no - **SKIP TO ITEM 32** 1) yes, but desired to continue 2) yes _____ 33

31. Number of Months After Sterilization Lactation Stopped (8 or more = 8) _____ 34

PREGNANCY AND MENSES SINCE LAST FOLLOW-UP VISIT (If uterus removed SKIP TO ITEM 40)

32. Pregnancy Since Last Follow-Up: 0) no 1) yes - **Complete Pregnancy Confirmation Form** _____ 35

33. Number of Menses Since Last Follow-Up: 0) none - **SKIP TO ITEM 40 (8 or more = 8)** _____ 36

34. Average Length of Cycle (in days) 88) irregular _____ 37-38

35. Average Duration of Flow (in days: 8 or more = 8) _____ 39

36. Average Amount of Flow: 1) scanty 2) normal 3) excessive _____ 40

37. Dysmenorrhea: 0) no 1) mild 2) moderate 3) severe _____ 41

38. Intermenstrual Bleeding: 0) no 1) staining/spotting 2) moderate 3) severe _____ 42

39. Date Last Menses Onset: _____ day _____ month _____ year _____ 43-47

40. Overall Attitude Towards Sterilization: 1) satisfied 2) dissatisfied 3) undecided _____ 48

Interviewer's Name _____

MEDICAL DATA

41. Weight in kg. (98 and over = 98) _____ 50-51

42. Hematocrit: (for Hb. x 3) 99) not done _____ 52-53

COMPLICATIONS OR INCIDENTS SINCE LAST FOLLOW-UP

43. Pelvic Surgery: 0) no 1) yes _____ 54

44. Systemic Disease: 0) no 1) yes _____ 55

45. Wound Complications: 0) no 1) yes _____ 56

46. Pain: 0) no 1) mild 2) moderate 3) severe _____ 57

47. Drainage: 0) no 1) yes _____ 58

48. Suture Problems: 0) no 1) yes _____ 59

49. Keloid: 0) no 1) yes _____ 60

50. Separation: 0) no 1) yes _____ 61

51. Other, specify _____ 62

52. Other Complications: 0) no 1) yes, specify _____ 63-64

53. Pelvic or Back Pain at Time of This Visit: 0) no 1) mild 2) moderate 3) severe _____ 65

54. Etiology of Pain: 0) unknown 1) unrelated to surgery, specify _____ 2) related to surgery, specify _____ 66

55. Readmission Related to Sterilization Since Last Follow-Up Visit: 00) no number of nights _____ 67-68

PHYSICAL EXAMINATION

56. Breasts: 0) normal 1) masses 2) galactorrhea 3) bleeding 4) combination 8) other _____ 69

57. Adnexa: 1) normal 2) abnormal, specify _____ 70

58. Uterus: 1) normal 2) abnormal, specify _____ 71

59. Cervix: 1) normal 2) abnormal, specify _____ 72

60. Pelvic Infection: 0) no 1) yes acute 2) yes chronic _____ 73

61. Pap Smear: 0) normal 1) atypia 2) dysplasia 3) carcinoma *in situ* 4) invasive carcinoma 8) other _____ 9) not done _____ 74

62. Pregnancy Signs: 0) no 1) yes - **Complete Pregnancy Confirmation Form** _____ 75

63. Other Abnormalities: 0) no 1) yes, specify _____ 76-77

IFRP 5150 4-75 _____ 78-80

PLEASE AIRMAIL TO International Fertility Research Program, NCNB Plaza, Suite 400, Chapel Hill, North Carolina 27514 USA

**INTERNATIONAL FERTILITY RESEARCH PROGRAM
SYSTEMIC CONTRACEPTIVE STUDY - ADMISSION RECORD**

Please Circle Appropriate Numbers and Fill In Appropriate Boxes and Blanks

No. _____

PATIENT IDENTIFICATION:	1. Your Hospital or Clinic No. _____	2. Admission Date _____ <small>Day Month Year</small>
3. Patient's Name _____	4. Husband's Name _____	
5. Address _____ <small>Family First Maiden</small>	Telephone _____	
6. Relative/Friend's Name _____		
7. Address _____	Telephone _____	

STUDY IDENTIFICATION

8. Center Name _____ and Number

 1-3

9. Study Name _____ and Number

 4-6

10. Patient Order in Study

 7-10

PATIENT CHARACTERISTICS

11. Residence: 1) urban 2) rural

--	--

 11

12. Age (years completed)

--	--	--

 12-13

13. Gainfully Employed 0) no 1) yes

--

 14

14. Race: 1) Caucasian 2) Mongoloid 3) Negroid 8) other _____

--

 15

15. Religion: 0) none 1) Buddhist 2) Catholic 3) Hindu, caste _____ 4) Jewish 5) Muslim 6) Orthodox 7) Protestant 8) other _____

--

 16

16. Marital Status: 1) never married 2) currently married 3) formerly married 8) other _____

--

 17

17. Patient's Education (school year completed)

 18-19

18. Husband's Education (school year completed)

 20-21

19. Total Live Births

 22-23

20. Children Now Living number of males (if no living children SKIP TO ITEM 22) _____ number of females _____

 24-25

21. Age of Youngest Child (completed years, 8 or more = 8) _____

--

 26

22. Number of Additional Children Wanted

--

 27

23. Total Number of Abortions

 28-29

24. Number of Spontaneous Abortions (8 or more = 8) _____

--

 30

25. Total Stillbirths (8 or more = 8) _____

--

 31

26. Contraceptive Method Mainly Used Before This Prescription 0) none 1) IUD 2) orals 3) tubectomy 4) vasectomy 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other _____

--

 32

ADDITIONAL ITEMS (To Be Filled in Upon Request)

27. _____

 33-34

28. _____

 35-36

29. _____

 37-38

30. _____

 39-40

 41-42

PREGNANCY AND MENSES

31. Ever Pregnant no yes

--	--

 43

32. Date Last Pregnancy Ended

--	--	--

Day Month Year 45-50

33. Last Pregnancy's Outcome 1) live birth 2) stillbirth 3) induced abortion 12 weeks or less 4) induced abortion over 12 weeks 5) spontaneous abortion 6) septic abortion 8) other _____

--

 52

34. Breastfeeding Now 0) no 1) yes

--

 53

35. Menses Since Last Pregnancy no → SKIP TO ITEM 37 yes

--	--

 54

36. Date Last Menses' Onset

--	--	--

Day Month Year 55-60

OVER LAST THREE PERIODS

37. Average Length of Cycle: (in days) 88) irregular

--	--

 62-63

38. Average Duration of Flow: (in days; 8 or more = 8)

--	--

 64

39. Average Amount of Flow: 1) scanty 2) less than normal 3) normal 4) more than normal 5) excessive

--	--

 65

40. Dysmenorrhea: 0) none 1) mild 2) moderate 3) severe

--	--

 66

41. Intermenstrual Bleeding: 0) none 1) staining/spotting 2) moderate 3) severe

--	--

 67

42. Intermenstrual Pain: 0) none 1) mild 2) moderate 3) severe

--	--

 68

Interviewer's Name _____

--	--

 79

MEDICAL DATA

43. Hematocrit: 99) not done

--	--

 11-12

44. Hemoglobin in Grams: 99) not done

--	--

 13-14

45. Blood Pressure: Systolic _____ Diastolic _____ 999) not done

 15-17

46. Weight in kg.: (98 and over = 98) _____

 21-22

47. Height in cm.: _____

 23-25

48. Primary Pre-Existing Medical Condition: _____

--	--

 26-27

--	--

 28

PRESCRIPTION

49. Contraceptive Prescribed Today: 1) daily combined orals 2) daily sequential orals 3) daily minipill 4) monthly orals 5) injectibles 6) vaginal ring 7) implants 8) other _____

--

 29

50. Identification by Name or Code _____

--	--	--

 30-33

51. Number of Cycles Given This Visit: _____

--	--

 34-35

52. How Will Patient Receive Next Supply: 1) at follow-up visit 2) clinic depot 3) community depot 4) pharmacy 5) mobile unit 6) home delivery 7) mail 8) other _____

--	--

 36

53. Today's Date

--	--	--

Day Month Year 38-43

54. Date of Starting Contraceptive

--	--	--

Day Month Year 44-49

55. Who Prescribed the Contraceptive: 1) doctor 2) nurse 3) midwife 8) other _____

--

 50

56. Date Set for First Follow-Up Visit:

--	--	--

Day Month Year 51-56

Prescriber's Name _____

Note: FOR SELF-STARTING CONTRACEPTORS: Retain this form until the first Follow-Up Contact - confirming the initiation of contraception - but not longer than 90 days. (See Manual for instructions.)

No. _____ 58-65

IFRP SYST 1/75

--

 80

COMMENTS: _____

20

**INTERNATIONAL FERTILITY RESEARCH PROGRAM
SYSTEMIC CONTRACEPTIVE STUDY – FOLLOW-UP RECORD**

Please Circle Appropriate Numbers and Fill In Appropriate Boxes and Blanks

PATIENT IDENTIFICATION: 1. Your Hospital or Clinic No. _____ 2. Follow-Up Date _____
Day Month Year

3. Patient's Name _____ Telephone _____
Family First Maiden

4. Address (if changed) _____

STUDY IDENTIFICATION

5. Center Name _____ and Number _____ 1-3
6. Study Name _____ and Number _____ 4-6
7. Patient Order in Study _____ 7-10
8. IFRP Admission Form Number _____ 11-16
9. Follow-Up Visit Number _____ 17-18
10. Number of Contraceptive Cycles Completed _____ 19-20

CONTACT DATA

11. Type of Contact: 1) clinic visit 2) home visit 3) moved
 4) unable to locate 5) died, cause _____
 8) other _____ 21
12. Reason for This Contact: 1) scheduled
 8) other _____ 22
13. Date This Contact: _____ 23-28
Day Month Year
14. Date Last Contact: _____ 29-34
Day Month Year

LAST COMPLETED MENSTRUAL CYCLE

15. Menses Since Last Visit: no 1) yes _____ 36
16. Date Last Menses' Onset: _____ 37-38
Day Month Year
17. Length of Cycle: (in days) _____ 37-38
18. Duration of Flow: (in days: 8 or more = 8) _____ 39
19. Amount of Flow: 1) scanty 2) less than normal
 3) normal 4) more than normal 5) excessive _____ 40
20. Dysmenorrhea: 0) none 1) mild 2) moderate 3) severe _____ 41

MENSTRUAL COMPLAINTS SINCE LAST FOLLOW-UP VISIT

21. Intermenstrual Bleeding: 0) none 1) staining/spotting
 2) moderate 3) severe _____ 42
22. Intermenstrual Pain: 0) none 1) mild 2) moderate
 3) severe _____ 43
23. Number of Amenorrheic Contraceptive Cycles: _____ 44

PREGNANCY

24. Breastfeeding Now: 0) no 1) yes _____ 45
25. Pregnancy Since Last Visit: 0) no → SKIP TO ITEM 29
 1) yes → COMPLETE PREGNANCY CONFIRMATION FORM _____ 46
26. Pregnancy Diagnosed By: 1) pregnancy test 2) physical
 examination 3) history only 4) combination
 8) other _____ 47
27. Estimated Date of Conception: _____ 48
Day Month Year
28. Pregnancy Outcome: 1) currently pregnant 2) live birth
 3) stillbirth 4) induced abortion 12 weeks or less
 5) induced abortion over 12 weeks 6) spontaneous abortion
 7) septic abortion 8) other _____ 48

MEDICAL DATA

29. Hematocrit: 99) not done _____ 49-50
30. Hemoglobin in Grams: 99) not done _____ 51-52
31. Blood Pressure Systolic _____ 53-55
 Diastolic _____ 56-58
999) not done
32. Weight in kg: (98 and over = 98) _____ 59-60

ADDITIONAL ITEMS (To Be Filled In Upon Request)

33. _____ 63-64
34. _____ 65-66

CONTINUATION DATA

35. Contraceptive Identification by Name or Code: _____ 68-71
36. Contraceptive Type: 1) daily → SKIP TO BOX A
 2) nondaily → SKIP TO BOX B _____ 72

BOX A – Daily Contraceptive. Record for Last 28 Days or Since Last Visit, Whichever is Less

37. Maximum Number of Consecutive Days Missed (8 or more = 8) _____ 73
38. Total Number of Days Missed: _____ 74-75
39. Total Number of Days Dose Doubled: (8 or more = 9) _____ 76
 SKIP TO ITEM 43 _____ 79

BOX B – Nondaily Contraceptive

40. Duration of Protection of Last Administration: (in days) _____ 21-23
41. Number of Days Elapsed Since Last Administration: _____ 24-26
42. Administration This Visit: 0) no 1) yes _____ 27

43. Patient Discontinued Use: no 1) yes _____ 28

44. Date of Last Use _____ 30-35
Day Month Year

45. Decision to Discontinue Made By: 1) patient
 2) doctor 8) other _____ 36

46. Primary Medical Reason for Discontinuing: _____ 37-38

47. Primary Nonmedical Reason for Discontinuing:
 1) desires to become pregnant 2) will move away
 3) adverse publicity 4) no further need
 5) husband objects 6) cannot visit clinic,
 reason _____
 7) no supply, reason _____
 8) other _____ 39

48. Other Method of Fertility Control Accepted or Planned
 by Patient: 0) none 1) IUD 2) systemic, type _____
 3) tubectomy 4) vasectomy _____ 40
 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/
 jelly 8) other _____ 41

49. Primary Reason for Irregular Use: 0) not irregular
 1) discontinued 2) forgetfulness 3) side effects
 4) clinic supply not available 5) temporarily not
 needed 6) supply misplaced 8) other _____ 42

50. How Did Patient Receive Last Supply: 1) at follow-up
 visit 2) clinic depot 3) community depot 4) pharmacy
 5) mobile unit 6) home delivery 7) mail
 8) other _____ 43

51. Has Patient Recommended This Systemic Contraceptive
 to Anyone Since Last Visit: 0) no 1) yes _____ 44

52. Date Set for Next Follow-Up Visit: _____ 46-51
Day Month Year

Interviewer's Name _____

Comments _____

IFR SYST 1/75 4 80

21

**INTERNATIONAL FERTILITY RESEARCH PROGRAM
MALE STERILIZATION STUDY - ADMISSION RECORD**

Please circle appropriate numbers and fill in appropriate boxes and blanks

No. _____

PATIENT IDENTIFICATION:

1. Your Hospital or Clinic No. _____ 2. Admission Date _____
day month year

3. Patient's Name _____ 4. Wife's Name _____
last first middle

5. Address _____ Telephone _____

6. Relative/Friend's Name and Address _____

STUDY IDENTIFICATION

7. Center Name _____ and Number _____ 1-3

8. Study Name _____ and Number _____ 4-6

9. Patient Order Number _____ 7-10

PATIENT CHARACTERISTICS

10. Residence: 1) urban 2) rural 12

11. Patient's Age: (years completed) 13-14

12. Patient's Education: (school year completed) 15-16

13. Patient's Current Occupation: 0) unemployed 1) retired/student/housewife 2) professional 3) manager/proprietor/farm owner 4) clerical 5) craftsman 6) operative 7) laborer/farm worker 8) other _____ 17

14. Marital Status: 0) never married 1) formerly married 2) currently married, one wife 3) currently married, more than one wife
 If coded 0, 1 or 3 → SKIP TO ITEM 18 18

15. Wife's Age: (years completed) 19-20

16. Wife's Education: (school year completed) 21-22

17. Wife's Current Occupation: Use Item 13 Codes 23

18. Religion: 0) none 1) Buddhist 2) Catholic 3) Hindu 4) Jewish 5) Muslim 6) Orthodox 7) Protestant 8) other _____ 24

19. Race: 1) Caucasoid 2) Mongoloid 3) Negroid 8) other _____ 25

PATERNITY HISTORY

20. Total Live Births: 28-29

21. Children Now Living: number of males (8 or more = 8) 30
 number of females 31

22. Age of Youngest Living Child: (8 or more years = 8) 32

FERTILITY CONTROL HISTORY

23. Contraceptive Method Mainly Used During Past 3 Months: 0) none 1) IUD 2) oral 3) tubectomy 4) vasectomy 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other _____ 35

24. Primary Reason for Preferring Sterilization to Other Methods: 1) other methods not easily available 2) other methods unreliable 3) undesirable side-effects of other methods 4) inconvenience of other methods 8) other _____ 36

25. Primary Referral Source: 1) self 2) wife 3) family planning/health staff 4) private physician 5) other agency 6) operated person 7) unoperated person 8) other _____ 37

Interviewer's Name _____

MEDICAL HISTORY

26. Injury or Operation of Scrotum/Testis: 0) no 1) yes 40

27. Excessive Pain in Scrotum/Testis: 0) no 1) yes 41

28. Swelling of Scrotum/Testis: 0) no 1) yes 42

29. Inguinal Hernia Operation: 0) no 1) yes 43

30. Other Related History: 0) none 1) yes, specify _____ 44-45

SPECIAL STUDIES (To Be Filled In Upon Request)

31. _____ 57-58

32. _____ 59-60

_____ 61-62

EXAMINATION

33. Height in cm: 65-67

34. Weight in kg: 68-70

35. Urogenital Abnormalities: 0) none 1) yes, specify _____ 71-72

36. Other Existing Medical Conditions: 0) none 1) yes, specify _____ 73-74

STERILIZATION PROCEDURE

37. Anesthetic: 0) none 1) analgesia only 2) local 3) regional 4) general 5) 1 + 2 8) other _____ 12

38. Type of Incision: 1) single-vertical 2) single-horizontal 3) double-vertical 4) double-horizontal 5) percutaneous 8) other _____ 13

39. Sterilization Technique _____ 14-16

STERILIZATION PROCEDURE

40. Length of Vas Resected: (in mm) 00) not resected (record average of two segments) 17-18

41. Method of Vas Occlusion: 0) none 1) silk 2) linen 3) nylon 4) chromic catgut 5) clip 6) cautery 8) other _____ 19

42. Abnormal Findings/Difficulties at Surgery _____ 20-21

43. Surgical Time in Minutes: (98 or over = 98) 22-23

44. Prophylactic Antibiotics Given: 0) none 1) local 2) systemic 3) both _____ 24

IMMEDIATE COMPLICATIONS/COMPLAINTS

45. Any Complications/Complaints Related to Sterilization Procedure: 0) no 1) yes, hospitalization not required 2) yes, hospitalization required 28

46. Injury to Testicular Artery/Pampiniform Plexus: 0) no 1) yes 29

47. Hematoma of Scrotum: 0) no 1) yes 30

48. Anesthesia Complications: 0) none 1) apnea 2) vomiting 3) convulsions 4) shock 5) aspiration 6) headache 7) combination, specify _____ 8) other _____ 31

49. Other Complications/Complaints _____ 32-33

50. Pain During Procedure: 0) none 1) mild 2) moderate 3) severe 34

51. Surgery Date _____ 36-41
day month year

Surgeon's Name _____

REMINDER: Retain this form and complete it at the first follow-up visit from three to thirty days after sterilization.

FOLLOW-UP

52. Follow-Up Outcome: 0) not yet discharged 1) clinic visit 2) home visit 3) moved out of area 4) unable to locate 5) confirmed wrong address 6) died, cause _____ 8) other _____ 48

53. Wound Healed: 0) no 1) yes 49

54. Any Complications/Complaints Related to Sterilization Procedure: 0) no → SKIP TO ITEM 52 1) yes, hospitalization not required 2) yes, hospitalization required 50

55. Fever 38° C/100.4° F. or Over, 24 Hours After Surgery: 0) no 1) yes 2) yes, requiring antibiotics 51

56. Wound Septic: 0) no 1) yes 52

57. Excessive Swelling of Scrotum: 0) no 1) yes 53

58. Hematoma of Scrotum: 0) no 1) yes 54

59. Abscess of Scrotum: 0) no 1) yes 44

60. Pain of Scrotum: 0) none 1) mild 2) moderate 3) severe 45

61. Other Complications/Complaints _____ 46-47

62. Number of Days Analgesics Taken: 0) none (8 or more = 8) 46

63. Resumption of Intercourse: (number of days after sterilization) 98) not resumed 49-50

64. Date of This Follow-Up Visit: _____ 52-57
day month year

Recorded By _____ 71-78

IFRPM 1/75 No. _____

PLEASE AIRMAIL TO: International Fertility Research Program, NCNB Plaza, Suite 400, Chapel Hill, North Carolina 27514 USA

80

**INTERNATIONAL FERTILITY RESEARCH PROGRAM
MALE STERILIZATION STUDY - FOLLOW-UP RECORD**

Please circle appropriate numbers and fill in appropriate boxes and blanks

PATIENT IDENTIFICATION: 1. Your Hospital or Clinic No. _____ 2. Follow-Up Date _____
day month year

3. Patient's Name _____ Telephone _____
last first middle

4. Address (if changed) _____

STUDY IDENTIFICATION

5. Center Name _____ and Number

--	--	--	--

 1-3
6. Study Name _____ and Number

--	--	--	--	--

 4-6
7. Patient Order Number

--	--	--	--	--	--

 7-10
8. IFRP Admission Form Number

--	--	--	--	--	--	--	--

 11-16

CONTACT DATA

9. Follow-Up Outcome: 1) clinic visit 2) home visit
 3) moved out of area 4) unable to locate
 5) confirmed wrong address 6) died,
 cause _____ 7) mailed specimen
 8) other _____ 19
10. Reason for This Contact: 1) routine semen test
 2) long-term follow-up visit 8) other 20
11. Date This Contact:

--	--

day

--	--

month

--	--	--

year 22-27

SEMEN TEST DATA

12. Test Number: 0 test not done → **SKIP TO ITEM 17**
 1) first 2) second 3) third 4) fourth 5) fifth 6) sixth
 7) seventh 8) eighth or more 30
13. Estimated Number of Ejaculations Since Last
 Semen Test (or since operation, if first semen
 test): (98 or over = 98)

--	--

 31-32
14. Result of Test: (sperm per high power field)
 (98 or over = 98)

--	--

 33-34
15. Any Motile Sperm: 0) no 1) yes 35
16. Patient Declared Sterile: 0) no 1) yes
 (If yes and any sperm are seen, please explain
 basis for decision) _____

 _____ 37

COMPLICATIONS/COMPLAINTS

17. Complications/Complaints Related to
 Sterilization Since Last Contact: 0) no
 1) yes, specify _____ 40-41

SPECIAL STUDIES (To Be Filled In Upon Request)

18. _____

--	--

 44-45
19. _____

--	--

 46-47
- Recorded By _____ 3 79-80

INSTRUCTIONS

Please complete this form for every semen test.

Examine the semen under the high power field (magnification of 450x) of a microscope. Look at ten high power fields and total the number of sperm, both motile and immotile, that are seen. Divide this total by 10, calculating average number of sperm per high power field. Write this figure in the boxes for Item 14.

Semen tests should be repeated until the patient is declared sterile.

Please attach a copy of your semen test report form.

MSfu 1/75

PLEASE AIRMAIL TO: International Fertility Research Program, NCNB Plaza, Suite 400, Chapel Hill, North Carolina 27514 USA

23

**INTERNATIONAL FERTILITY RESEARCH PROGRAM
MATERNITY RECORD**

Please circle appropriate numbers and fill in appropriate boxes and blanks

PATIENT IDENTIFICATION:		1. Hospital or Clinic No. _____	2. Admission Date _____ <small>day month year</small>
3. Patient's Name _____ <small>family first maiden</small>		Father's Name _____	
4. Address _____		Grandfather's Name _____	

STUDY IDENTIFICATION

5. Centre Name _____ and Number

--	--	--	--

 1-3

6. Patient Order Number

--	--	--	--	--	--

 4-8

7. Delivery Date

<small>day</small>	<small>month</small>	<small>year</small>			

 9-14

8. Number of Days Hospitalised After Delivery

--	--

 15-16

9. Total Number of Days Hospitalised

--	--

 17-18

PATIENT CHARACTERISTICS

10. Residence: 1) urban 2) rural 3) slum 19

11. Ethnicity: 1) Northern (Nubian) 2) Eastern (Bial) 3) Central (Arab) 4) Western (Tribes) 5) Southern (Negroid) 6) European 8) other 20

12. Religion: 0) none 1) Buddhist 2) Catholic 3) Hindu 4) Jewish 5) Muslim 6) Orthodox 7) Protestant 8) other 21

13. Marital Status: 1) never married 2) currently married 3) formerly married 8) other 22

14. Wife's Age: (years completed)

--	--

 23-24

15. Wife's Education: (school year completed)

--	--

 25-26

16. Wife's Occupation: 0) unemployed 1) retired/student/housewife 2) professional 3) manager/farm owner 4) clerical 5) craftsman 6) operative 7) labourer (including farm) 8) other 27

17. Husband's Age: (years completed)

--	--

 28-29

18. Husband's Education: (school year completed)

--	--

 30-31

19. Husband's Occupation: (Use Item 16 Codes) 32

20. Completed Years of Current Marriage (Union):

--	--

 33-34

21. Total Live Births:

--	--

 35-36

22. Children Now Living:

--	--

 number of males (8 or more = 8) 37
number of females 38

23. Number of Infant Deaths: (12 completed months or less)

--	--

 number of males (8 or more = 8) 39
number of females 40

24. Number of Early Childhood Deaths: (over 12 completed months through 60 completed months)

--	--

 number of males (8 or more = 8) 41
number of females 42

25. Age of Youngest Child: (8 or more = 8) 43

26. Number of Spontaneous Abortions: (8 or more = 8) 44

27. Number of Induced Abortions: (8 or more = 8) 45

28. Total Stillbirths: (8 or more = 8) 46

29. Contraceptive Method Mainly Used in Three Months Before Conception: 0) none 1) IUD 2) orals 3) female sterilisation 4) male sterilisation 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other 47

MEDICAL DATA

30. Number of Prenatal Visits: (8 or more = 8) 48

31. Primary Maternal Prenatal Condition NOT Requiring Hospitalisation: 0) none 1) anaemia 2) hypertension 3) toxemia 4) haemorrhage 5) hyperemesis 6) disease of genital tract 7) systemic disease 8) other 49
Specify details of above condition _____

32. Primary Maternal Prenatal Condition Requiring Hospitalisation: (Use Item 31 Codes) 8) other 50
Specify details of above condition _____

33. Type of Presentation During Labour: 0) vertex (occiput anterior or transverse) 1) vertex (occiput posterior) 2) breech 3) face 4) brow 5) transverse 6) compound 7) cord prolapse 8) other, specify _____ 51

34. Type of Labour and Delivery: Spontaneous Labour: 1) spontaneous delivery 2) forceps/vacuum delivery 3) caesarean section Induced Labour: 4) spontaneous delivery 5) forceps/vacuum delivery 6) caesarean section No Labour: 7) caesarean section Other Delivery: 8) specify _____ 52

35. Primary Complication of Delivery: 0) none 1) premature rupture of membranes 2) prolonged labour 3) cephalo-pelvic disproportion 4) abnormal uterine contractions 5) postpartum haemorrhage/retained placenta 6) maternal injuries 8) other 53
Specify etiology _____

36. Estimated Duration of Pregnancy: (menstrual age in weeks)

--	--

 54-55

37. Haemoglobin at Admission for Delivery: 99) not done 56-57

PREGNANCY OUTCOME AND MANAGEMENT

38. Birthweight: (grams) (multiple births -- give combined weight) (9998 and over = 9998)

--	--	--	--

 58-61

39. Sex of Infant(s) Born at This Delivery: (write number of each) male 62
female 63

40. Live Birth(s) that Died Before Discharge: 0) none (code number of deaths) 64

41. Stillbirth(s): 0) none 1) fresh 2) more than one, fresh 3) one, macerated 4) more than one, macerated 5) combination 65

42. Postpartum Maternal Status: 0) normal 1) complication not requiring treatment, specify _____ 2) complication requiring treatment, specify _____ 3) death, specify cause _____ 66

43. Maternal Blood Transfusion During Hospitalisation: 0) none 1) yes, before delivery 2) yes, during delivery 3) yes, after delivery 4) any combination of 1), 2), and 3) 67

44. Primary Foetal/Neonatal Complication: 0) none 1) yes, before labour 2) yes, during labour 3) yes, after delivery 4) congenital malformation, specify condition _____ 68

SPECIAL STUDIES (To Be Filled In Upon Request)

45. Registration Status: 0) not booked 1) booked patient's choice 2) referred by physician 3) emergency admission 69

46. Artificial Rupture of Membrane: 0) no 1) yes 70

47. Oxytocin Administered: 0) no 1) yes 71

48. _____ 72-73

49. _____ 74-75

50. Female Sterilisation at This Hospitalisation: 0) none 1) immediately after delivery 2) same day 3) 1-2 days later 4) 3-4 days later 5) 5-6 days later 6) 7-8 days later 7) 9 or more days later 8) other 76

51. Other Surgery This Hospitalisation: 0) none 1) immediately after delivery 2) same day 3) 1-2 days later 4) 3-4 days later 5) 5-6 days later 6) 7-8 days later 7) 9 or more days later 8) other 77

Complete These Two Items At Time Of Discharge

52. Number of Additional Children Wanted After This Delivery 78

53. Post-Partum Fertility Control Planned or Used: 0) none 1) IUD 2) orals 3) female sterilisation 4) male sterilisation 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other 79

Recorder's Name _____ MAT 4775

24

APPENDIX B

SUMMARIES OF IFRP COMPARATIVE STUDIES AND PROTOCOLS

		FERTILITY EVENTS		IFRP COMPARATIVE STUDIES APPLICABLE AT EACH PERIOD IN THE FERTILITY CONTINUUM	
NOT RECENTLY PREGNANT				Male Sterilization Study	CONTRACEPTIVE METHODS
		Menstrual Period	<i>Normal Menstrual Cycle</i>	<ul style="list-style-type: none"> - Blind IUD Study (Not Recently Pregnant Patients) - IUD Insertion After Endometrial Aspiration - Studies of Oral Contraceptives - Female Sterilization Studies (Not Recently Pregnant Patients) 	
		Ovulation			
		Last Menstrual Period			
	Ovulation (fertilization)	<i>Weeks' Gestation</i>			
PREGNANT		First Missed Menstrual Period	4	Menstrual Regulation Studies - Induction of Uterine Bleeding with Suction Curettage - Medical Versus Surgical Induction of Uterine Bleeding	POST-CONCEPTIVE METHODS
		Positive Pregnancy Test	5		
			6		
		Second Missed Period	7	First-Trimester Abortion Studies - Study of D&C and VA for First Trimester Abortion - Cannulae Studies - Study of D&C and VA for Treating Septic or Aseptic Inevitable Incomplete Abortions - Blind IUD Study (Post First Trimester Abortion Insertion) - Female Sterilization Study (Concurrent to First Trimester Abortion) - Post Abortion Systemic Studies	
			8		
			9		
			10		
			11		
			12		
			13	Mid-Trimester Abortion Studies - Study of Intra-Amniotic Saline, Intra-Amniotic Prostaglandin F _{2α} , and Urea for Inducing Mid-Trimester Abortion - Blind IUD Study (Post Second Trimester Abortion Insertion) - Female Sterilization Study (Concurrent with Second Trimester Abortion) - Post Abortion Systemic Studies	
			14		
			15		
			16		
		17			
		18			
		19			
		20			
		36			
POST-PARTUM	Term Delivery	40	<ul style="list-style-type: none"> - Blind IUD Study (Post Term Delivery Insertion) - Female Sterilization Study (in the Immediate Post Partum Period) - Post Partum Systemic Contraceptive Studies on Post Partum Lactation 	CONTRACEPTIVE METHODS	

AN OUTLINE OF THE PROTOCOLS

For all study areas (pregnancy termination, menstrual regulation, female and male sterilization, IUDs, and systemic contraceptives), the format of the protocols is basically the same. A brief outline of the format is given below.

A. Methods, Techniques, Devices, Drugs to be Studied

Each protocol specifies the "methods" to be studied. For some protocols the principal investigator will specify, prior to initiating a study, the particular "method" he will study. For example, in the comparative IUD Study the principal investigator selects two or more IUDs from a list of 12 IUDs.

B. Subject Selection

All protocols specify the number of subjects to be studied as well as specifying certain criteria for subject selection. For the female sterilization, IUD, and systemic contraceptive studies, the principal investigator will specify the category of subjects he desires to study: not recently pregnant, immediately post abortion, immediately post delivery.

C. System of Randomly Assigning Methods, Techniques, Devices, Drugs to Subjects

In all comparative protocols "methods" are randomly assigned to subjects as follows. The principal investigator receives from the IFRP a set of envelopes, each containing a Method Indicator Card. The number of envelopes corresponds to the number of subjects in the study. Prior to performing the study procedure (abortion, menstrual regulation, sterilization, IUD insertion, or dispensing oral contraceptives) the physician opens the envelope corresponding to the subject's patient order number. The Method Indicator Card inside of the envelope designates the particular method to be used in the procedure.

D. Study Forms

In addition to the IFRP forms which are completed for surveillance studies, comparative protocols require at least three additional forms: the Method List, Consent Form and Pregnancy Confirmation Form. The principal purpose of the Method List is to obtain pertinent information on the study procedures that cannot be coded on the standard IFRP forms. All subjects in all comparative IFRP studies are required to sign the consent form regardless of whether the hospital/clinic where the study is being conducted has its own consent form. This is a requirement of the IFRP's Committee for the Protection of the Rights of Human Subjects which must approve all of the IFRP's comparative protocols before they can be initiated in the field.

E. Study Personnel

All comparative protocols require that the physicians who admit subjects into the study and who perform the study procedures be different from the physicians who are responsible for post-procedure care and follow-up evaluation of the subjects. To minimize bias whenever feasible, the physicians responsible for follow-up care and evaluation of the subjects are kept unaware of the specific procedure used for any subject.

Operator	Enter OR	Immediate Complications/ Complaints
	Premedication	
Anesthesia		
Incision*		
Evaluator	Closure*	Early Postoperative Complications/Complaints
	Discharge OR	
	Discharge Clinic	
	7-21 day Follow-Up	
	6-Month Follow-Up	Late Postoperative Complications/Complaints
	12-Month Follow-Up	

- * *Operative time report:*
- *Pain during procedure*
 - *Technical failure*
 - *Technical difficulties*
 - *Surgical difficulties*

DATA RECORDING SYSTEMS FOR COMPARATIVE STUDIES

F. Supplies

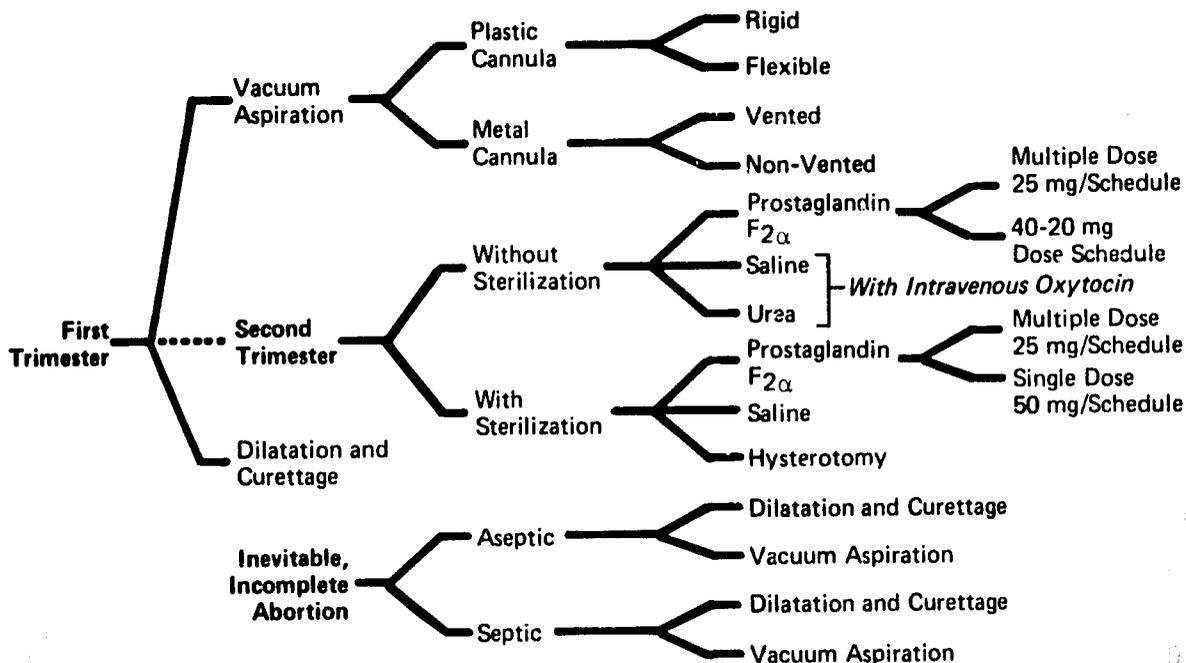
Prior to the start of a comparative study the principal investigator will receive from the IFRP all necessary supplies (forms and medical supplies) for the study.

Before a comparative study can be initiated in the field it must be approved by the following review:

- Medical Advisory Committee
- Committee on the Protection of the Rights of Human Subjects
- Research Review Committee

The following are brief summaries of the comparative protocols that have been approved by the above committees.

I. PREGNANCY TERMINATION STUDIES



A. First Trimester Abortion Studies

Comparative Study of the Jet-Ejector Cannula. The objectives of this study are to compare the Jet-Ejector cannula with and without the jet stream at the uterine opening for effectiveness, technical ease, and safety for performing induced abortions by vacuum aspiration in women from 6-12 menstrual weeks' gestation. One hundred and fifty subjects will be aborted by each method. All subjects are required to return for a follow-up physical examination 2-4 weeks after the abortion.

Comparative Metal versus Plastic Cannula Study. The objective of the study is to compare the performance of the 8 mm metal and 8 mm plastic cannulae for performing abortions by vacuum aspiration in women from 7-10 menstrual weeks' gestation. The different cannulae are each randomly assigned to 150 subjects. Only healthy women requesting artificial abortion are studied. Standard procedures for performing the vacuum aspiration will be followed. All subjects are required to return for a follow-up physical examination 2-4 weeks after the abortion.

Comparative Flexible versus Non-Flexible Plastic Cannula Study. The objectives of the study are to compare two types of plastic cannulae – flexible and non-flexible – for effectiveness, technical ease and safety in performing artificial abortions by suction curettage in women from 6-12 weeks' gestation. Healthy women requesting a therapeutic termination of pregnancy are included in the study. Each type of cannula will be used in aborting 550 subjects. Standard procedures for performing abortions by suction curettage will be followed. All abortions will be performed using sterile procedures with paracervical block anesthesia, and using a cannula size appropriate to the subject's gestational age. All subjects are required to return for a physical examination 2-4 weeks after the abortion.

Comparative Study of Dilatation and Curettage and Vacuum Aspiration. The objectives of this study are to compare the effectiveness and complications of dilatation and curettage (D&C) and vacuum aspiration (VA) for performing artificial abortions in women at 6-12 weeks' gestation. A total of 420 subjects will be studied. 210 will be aborted by D&C and 210 will be aborted by VA. Of the 210 subjects aborted by each procedure, 105 will be of 6-10 weeks' gestation and 105 will be of 11-12 weeks' gestation. Standard procedures for performing D&C and VA are followed. All subjects are required to return for a follow-up visit and physical examination 2-4 weeks after the abortion.

Comparative Study of Dilatation and Curettage and Vacuum Aspiration for Treating Septic or Aseptic Inevitable Incomplete Abortions. The objectives of this study are to compare dilatation and curettage (D&C) and vacuum aspiration (VA) for effectiveness and safety in the treatment of septic or aseptic incomplete or inevitable abortions in women from 6-12 weeks' gestation. Healthy women from 6-12 weeks' gestation requesting treatment of an inevitable or incomplete abortion and consenting to participate in the study will be selected as subjects. Excluded from the study are subjects with any significant pre-existing systemic medical conditions, subjects admitted to the hospital in shock (all types), and subjects not treated within 48 hours after being admitted to the hospital. A total of 420 subjects will be studied; 210 will be aborted by D&C and 210 will be aborted by VA. For all subjects an intravenous drip of 1000 cc of 5% dextrose in normal saline with 10 IU oxytocin (10mu/cc) at a rate of 200 cc/hr will be continued throughout the surgery. Standard procedures for performing D&C and VA will be followed. Septic abortions will be treated using the typical doses of antibiotics ordinarily used at the institutions. All abortions are performed using sterile procedures, with paracervical block anesthesia administered when necessary. All subjects are required to return for a physical examination 2-4 weeks after the surgery.

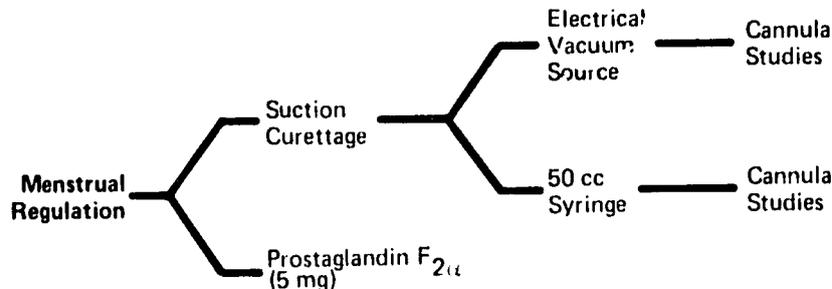
B. Second Trimester Abortion Studies

Comparative Mid-Trimester Abortion Study. The objectives of this study are to compare the effectiveness and complications of the intra-amniotic saline, intra-amniotic Prostaglandin $F_{2\alpha}$ ($PGF_{2\alpha}$) and hysterotomy methods for aborting women at 16-20 weeks' gestation. The saline and $PGF_{2\alpha}$ methods will be studied with and without concurrent sterilization and the hysterotomy method with concurrent sterilization only. Two dose schedules of intra-amniotic $PGF_{2\alpha}$ administration will be evaluated: (1) a single dose of 50 mg $PGF_{2\alpha}$, and (2) an initial dose of 25 mg $PGF_{2\alpha}$ repeated at 6, 24, and 30 hours if the patient does not abort. With either the saline or $PGF_{2\alpha}$ methods the trial is declared a failure if the patient fails to abort within 72 hours, in which case a second method will be used to complete the abortion. All sterilizations will be performed using the Pomeroy technique. Abortion methods will be randomly allocated to subjects. Fifty subjects will be aborted by each method in both the abortion with sterilization and abortion without sterilization groups. All subjects are required to return for a follow-up visit and physical examination 2-4 weeks after the abortion.

Comparative Study of Intra-Amniotic Saline, Intra-Amniotic Prostaglandin $F_{2\alpha}$, and Urea for Inducing Mid-Trimester Abortion. The objectives of the study are to compare the effectiveness and complications of the following four methods of abortion: (1) intra-amniotic hypertonic saline with intravenous oxytocin (200 mu/min), (2) 40 mg dose of $PGF_{2\alpha}$ intra-amniotically administered with a repeat dose of 20 mg 24 hours later if the patient has not yet aborted, (3) a 25 mg dose of $PGF_{2\alpha}$ intra-amniotically administered after intra-cervical placement of laminaria tents, with a repeat dose of 25 mg of $PGF_{2\alpha}$ 6, 24, and 30 hours later if the patient has not yet aborted, and (4) an 80 gm dose of urea intra-amniotically administered, and intravenous oxytocin (200 mu/min). The study will also evaluate whether with each of the above abortion methods the administration of intravenous oxytocin after delivery of the

fetus results in increased rates of placental expulsion and/or changes in maternal morbidity. One hundred subjects will be aborted by each method in a study design where methods are randomly assigned to subjects. If a subject does not abort within 48 hours of amniocentesis, the trial is declared a failure and the subject will be aborted by the conventional means of the institution. Following abortion of the fetus, intravenous oxytocin (200 mu/min) will be continued or initiated for one half of the subjects aborted by each method. If the subject does not spontaneously expel the placenta within 4 hours of abortion of the fetus she will be treated by the appropriate conventional therapy. All subjects are required to return for a follow-up examination 2-4 weeks after the abortion.

II. MENSTRUAL REGULATION



Comparative Menstrual Regulation Study - The Induction of Uterine Bleeding with Suction Curettage. The objectives of the study are to compare the relative effectiveness, safety, and technical ease of performing menstrual regulation (MR) with different vacuum sources (Berkeley pump or 50 cc Karman Syringe), and different types (flexible or non-flexible) and sizes (4, 5, 6 mm) of cannulae. In this study MR is defined as suction curettage performed in women with a delayed menstrual period of 1-14 days to insure the woman is not pregnant or does not continue to be pregnant. For each vacuum source, type and size of cannula, 200 subjects will be studied. Standard surgical procedures for performing abortions by suction curettage will be followed. All subjects are required to return for a physical examination 2-4 weeks after the MR, at which time a pregnancy test will be administered to each subject. All subjects consenting to participate in the study will consent to have a therapeutic abortion by the usual methods of the institution if they continue to be pregnant.

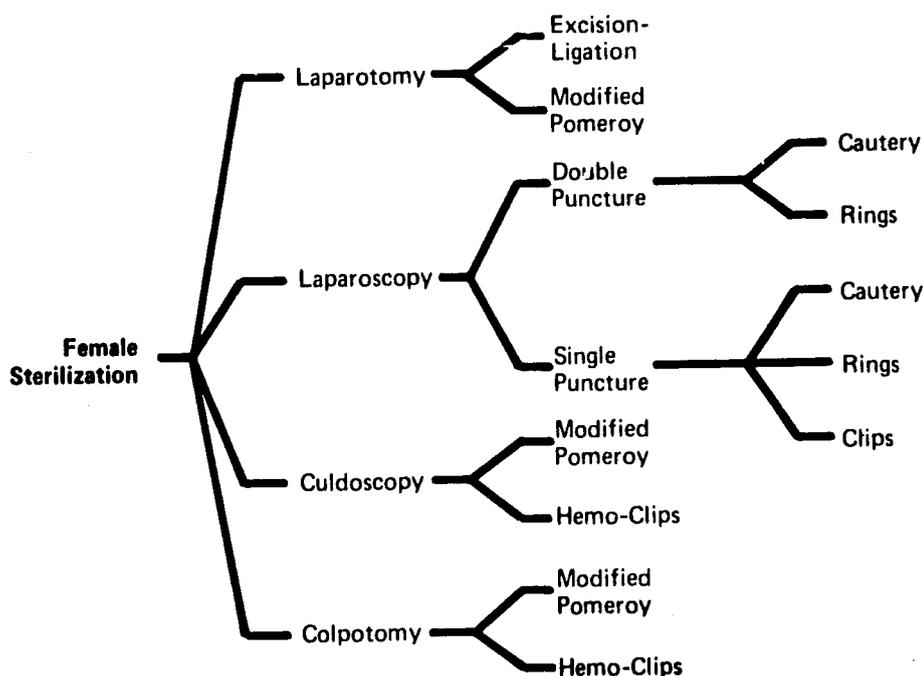
Comparative Menstrual Regulation Study - Medical versus Surgical Induction of Uterine Bleeding. The objectives of the study are to compare the continuation of pregnancy, complication, and side effect rates of the intrauterine administration of $PGF_{2\alpha}$ and the suction curettage methods of menstrual regulation (MR), i.e., the induction of uterine bleeding in women with a delayed menstrual period of up to 14 days. For each MR procedure 100 subjects will be studied. Only healthy women with a delayed menstrual period of at most 14 days, and who have a positive pregnancy test prior to the MR will be selected as subjects. Prior to $PGF_{2\alpha}$ administration all subjects will be sedated intravenously with 100 mg meperidine hydrochloride, 0.4 mg atropine, and 20 mg diazepam (valium). Five milligrams of $PGF_{2\alpha}$ dissolved in 2 ml of 0.9% normal saline are administered over a 20 minute period, transcervically through a 1.5 mm (OD) polyethylene catheter through the undilated cervix into the uterine cavity to the fundus. All subjects undergoing MR with suction curettage will first be administered a paracervical block. Standard surgical procedures for performing abortions by suction curettage will be followed. The suction curettage will be performed with a 6 mm flexible plastic cannula and a

50 cc syringe. All subjects are required to return for a follow-up history and physical examination two weeks after the MR, and again at 8 weeks after the MR. At the time of the first follow-up visit a pregnancy test will be administered to each subject. All subjects consenting to participate in the study will consent to have a therapeutic abortion by the usual methods of the institution if they continue to be pregnant.

III. STERILIZATION

A. Female

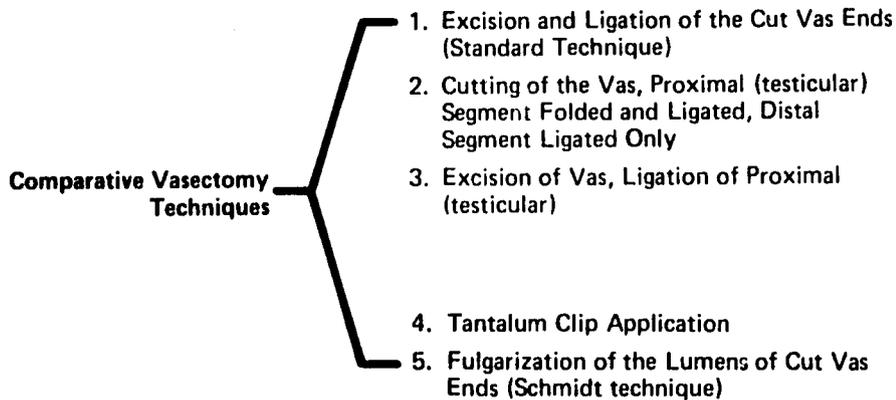
Comparative Female Sterilization Study. Each investigator participating in the comparative female sterilization studies will select for study two or more methods of sterilization, with the appropriate surgical approach, in the appropriate category of patients. The techniques of tubal occlusion are: Modified Pomeroy, hemo-clip, spring-loaded clip, tubal ring, and cautery. The



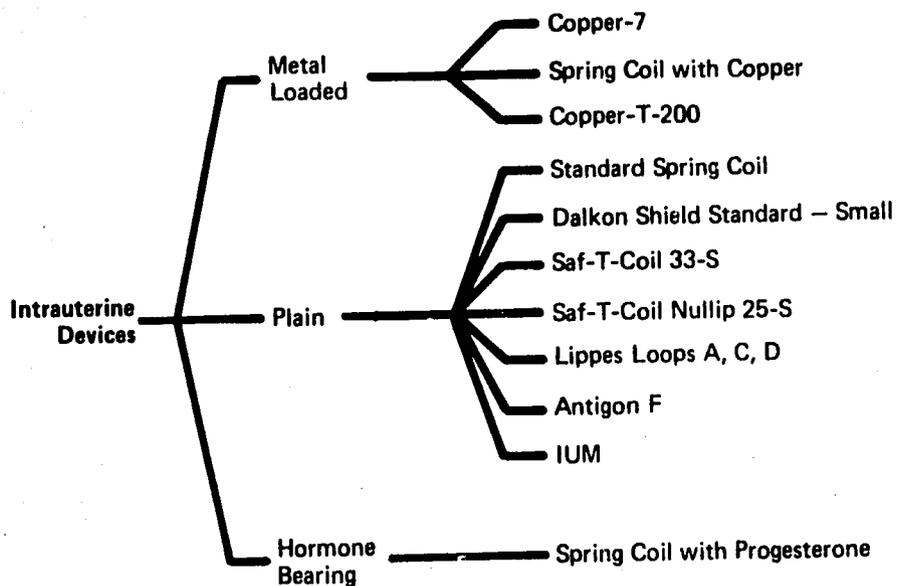
surgical approaches are laparotomy, colpotomy, culdoscopy and laparoscopy. The categories of patients are: not recently pregnant, immediately post abortion, and post term delivery. The objectives of the studies are to compare the complications, cost, and technical ease of performance of different methods of sterilization. A total of 150 subjects will be sterilized by each method. Only healthy subjects over 21 years of age, legally capable of consenting to the sterilization, and consenting to participate in the study will be selected as subjects. All subjects will have easy accessibility to the hospital for 24-hour emergency care and will be requested to return for follow-up examinations at 7-21 days, 6 months and 1 year after the surgery.

B. Male

Comparative Male Sterilization Study. The objectives of the study are to compare the complications and failure rates of the sterilization techniques noted below. Each investigator will select two of the techniques for study in a study design where the techniques are randomly assigned to subjects. Two hundred subjects, over 21 years of age, legally capable of consenting to the sterilization, and consenting to participate in the study will be selected as subjects. All subjects will return for follow-up examination 7-15 days after the sterilization, and after at least fifteen ejaculations after the sterilization to present a semen specimen for analysis. The absence of sperm in the semen will document sterility. If this test indicates the presence of sperm in the semen the subject will submit another semen specimen after at least 5 ejaculations. All subjects are required to return for a physical examination and semen test six months post sterilization.



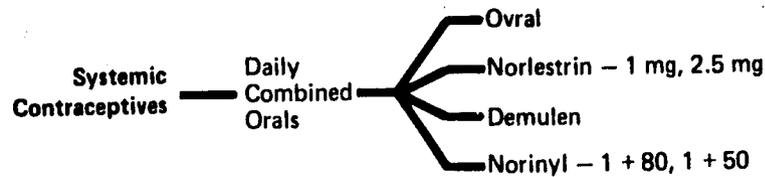
IV. INTRAUTERINE CONTRACEPTIVE DEVICES



Comparative "Blind" IUD Study. The objectives of the study are to compare the continuation rates and the specific complications associated with two or more IUDs over a two-year period. Only women with no gynecologic abnormalities who have not previously used an IUD will be studied. The principal investigator will select two or more IUDs for study using one patient category. The study IUDs include: Spring Coil with or without copper, Spring Coil with progesterone (60 mg), standard Dalkon Shield, small Dalkon Shield, Copper 7, Lippes Loops A, C, and D, Saf-T-Coil-33-S, Saf-T-Coil Nullip 25-S, Copper T-200, Antigon F and IUM. Other IUDs will be included as they are developed. The patient categories are: immediate post abortion, immediate post delivery, not recently pregnant (multigravida), and nulligravida. All IUDs are inserted within 1 week of the first day of the subject's last normal menstrual period, abortion, or delivery. Each studied IUD is assigned to 450 subjects. IUDs will be compared in a program of regularly scheduled follow-up clinic visits at one, three, six, twelve, eighteen, and twenty-four months post insertion.

Comparative Study of IUD Insertion Techniques - Evaluation of Endometrial Aspiration Prior to IUD Insertion. The objective of the study is to determine if aspiration of the endometrial tissue immediately prior to IUD insertion will result in significantly lower rates of specific complications, IUD expulsion, and IUD removal for bleeding or pain over a six-month period of time. A total of 540 subjects will be evaluated; 270 subjects will undergo an endometrial aspiration prior to IUD insertion and 270 subjects will have the IUD inserted without performing an endometrial aspiration. The principal investigator will select one IUD for study from a list of IUDs, and will specify the category of subjects to be studied - nulligravida or multigravida. All subjects will be followed up at one, three, and six months post IUD insertion.

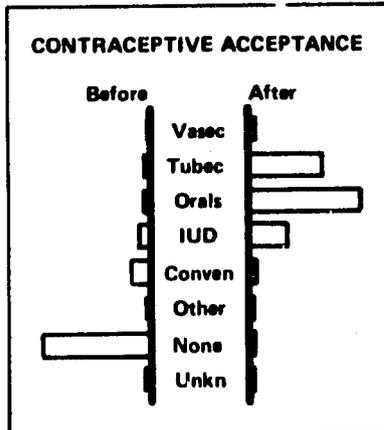
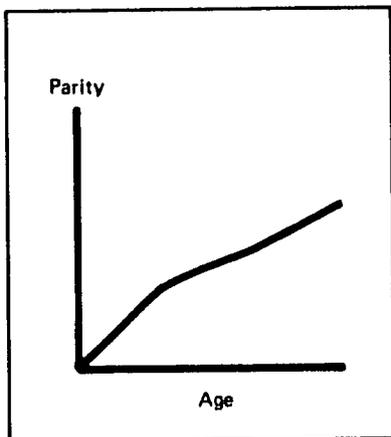
V. SYSTEMIC CONTRACEPTIVES



Comparative Studies of Oral Contraceptives. The objectives of the studies are to compare continuation rates and the incidence of specific side-effects for two or more oral contraceptives. Healthy women from 15 to 44 years of age desiring oral contraceptives will be studied. Not included in the studies are: (1) women using oral contraceptives for therapeutic reasons, (2) women who have used any systemic contraceptives during the past six months, and (3) women whose medical histories indicate that oral contraceptives are an unsuitable method of contraception. The principal investigator will select two or more study drugs for study in one of two different comparative studies using one patient category. The study drugs include Ovral, Norlestrin 1 mg, Norlestrin 2.5 mg, Demulen, Norinyl 1 + 80, and Norinyl 1 + 50, which are routinely prescribed in the United States. Other drugs will be added as they are developed and approved for human use. The two comparative studies are: inter-comparison of daily oral contraceptives, and cross-over study of daily oral contraceptives. The patient categories are: not recently pregnant, immediate post abortion and immediate post delivery. The oral contraceptives will be compared in a program of regularly scheduled follow-up visits, which are more frequent than those routinely required for women in the United States using the study drugs. All women will be followed for one year. At the beginning and completion of the study all subjects will undergo a complete physical examination. Each study drug is assigned to 305 subjects.

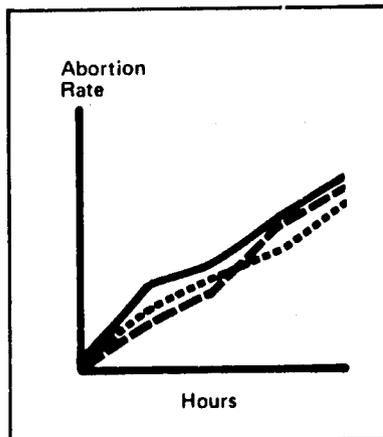
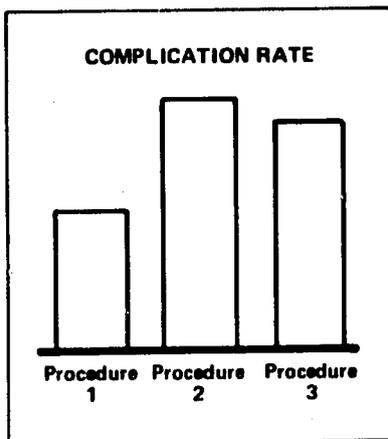
**APPENDIX C
STUDY STATUS REPORTS**

DEMOGRAPHIC ANALYSES



Pregnancy Outcome	Age			
	18	20	22	24
Abortion Induced				
Spontaneous				
Now Living Children Male				
Female				

CLINICAL ANALYSES



By Procedure	Surgical Time (Hrs)	
	With Comp.	Without Comp.
Procedure 1	0.10	0.25
Procedure 2	0.15	0.18
Procedure 3	0.15	0.17

I. STATUS OF PREGNANCY TERMINATION STUDIES

Summary of Results

- VA compared to D&C when performed in gravidas at 13-15 weeks' gestation is associated with significantly higher rates of complications.
- Performing D&C at 13-15 weeks' gestation appears to be safer than waiting until after 15 weeks' gestation and administering intra-amniotic hypertonic saline.
- The incidence of complications for saline abortion increases with the duration of placental retention, while the hourly rates of spontaneous expulsion of the placenta decrease. Surgical removal of the placenta appears indicated if it is not spontaneously expelled within two hours of delivery of the fetus.
- Intra-amniotic hypertonic saline augmented with intravenous oxytocin is associated with shortened instillation-to-abortion times (median, 25.5 hours) compared to intra-amniotic hypertonic saline without supplemental oxytocin (median, 33.3 hours). The instillation-to-abortion time does not depend on the rate of oxytocin administration (17-64 miu/min), but does depend on the time of administration. Oxytocin initiated within 8 hours after saline instillation decreases the instillation-to-abortion time.
- Removal of 100 or 150 ml of amniotic fluid prior to the 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.
- Instillation-to-abortion times for intra-amniotic saline are not dependent on the patient's gestational age (16-24 weeks'), age, race, or parity.
- Controllable risk factors associated with infection after saline abortion are: prolonged instillation-to-abortion time, repeat instillations, and the techniques used by the physician performing the instillation. The only controllable risk factor associated with hemorrhage is placental retention beyond one hour's duration.
- Compared to the single 50 mg $\text{PGF}_{2\alpha}$ dose schedule, the 25 mg multiple dose schedule (additional 25 mg $\text{PGF}_{2\alpha}$ injected at 6, 24, and 30 hours if abortion has not yet occurred) results in shortened median instillation-to-abortion times (17.4 vs. 20.8 hours), and similar rates of complications and side effects except for vomiting.
- Both the 50 mg and repeated 25 mg $\text{PGF}_{2\alpha}$ 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.
- Sterilization via laparotomy with a Pomeroy ligation of the tubes does not significantly increase the complication rates after terminating pregnancies at 15-20 weeks' gestation with either intra-amniotic $\text{PGF}_{2\alpha}$ (single or multiple dose schedule) or intra-amniotic hypertonic saline.

- In some studies complication rates are significantly higher for women who probably had an illegally induced abortion compared to women who probably had a spontaneous abortion. Rates of serious complications and death from spontaneous (including illegally induced) abortions are significantly higher than for legally induced abortions.
- Vacuum aspiration has become the most frequently used procedure for performing induced first trimester abortions. Many institutions now perform the procedure on an outpatient basis without the use of general anesthetics. The complication rate of the procedure is low.
- With respect to all criteria of performance (rates of specific complications, blood loss, frequency of cannula reinsertion, amount of retained tissue) there are no significant differences between the metal and flexible plastic (Karman type) cannulae for terminating pregnancies of 7-10 weeks' gestation by vacuum aspiration.
- The vented and nonvented cannulae result in similar rates of effectiveness and complications when used for terminating pregnancies at 7-12 weeks' gestation.

Active Straight and Surveillance Studies

STUDY	NUMBER OF CENTERS	NUMBER OF CASES LOADED
Induced Abortion		
- First trimester procedures only	5	1,393
- First and second trimester procedures	<u>15</u>	<u>11,076</u>
	20	12,469
Threatened, Inevitable, Incomplete Abortion	19	10,858

Completed Straight and Surveillance Studies

STUDY	NUMBER OF CENTERS	NUMBER OF CASES
Induced Abortion		
- First trimester procedures only	18	1,475
- First and second trimester procedures	<u>16</u>	<u>12,854</u>
	34	23,310
Threatened, Inevitable, Incomplete Abortions	13	4,195

Active Comparative Studies

STUDY	GESTATIONAL AGE (WEEKS)	NUMBER OF STUDIES	NUMBER OF CASES PLANNED
Vented vs. Nonvented Cannulae	6-12	2	600
Metal vs. Plastic Cannulae	7-10	3	900
Flexible vs. Rigid Plastic Cannulae	6-12	2	2,200
D&C vs. Vacuum Aspiration (induced abortions)	6-12	2	840
Mid-Trimester Study: Saline; 50 mg dose PGF _{2α} ; multiple 25 mg dose PGF _{2α} (one-half of the cases sterilized after the abortion)	16-20	4	1,300

Completed Comparative Studies

STUDY	GESTATIONAL AGE (WEEKS)	NUMBER OF STUDIES	NUMBER OF CASES
Vented vs. Nonvented Cannulae	6-12	2	600
Metal vs. Plastic Cannulae	7-10	4	1,200
Mid-Trimester Study: Saline; 50 mg dose PGF _{2α} ; multiple 25 mg dose PGF _{2α} (one-half of the cases sterilized after the abortion)	16-20	1	300

Planned Comparative Studies

STUDY	GESTATIONAL AGE (WEEKS)	NUMBER OF STUDIES
Vacuum Pressures: 40 vs. 60 mg HG	6-12	1
Metal vs. Plastic Cannulae	6-12	2
D&C vs. Vacuum Aspiration (induced abortions)	6-12	12
D&C vs. Vacuum Aspiration (inevitable, incomplete abortions)		4
Mid-Trimester Study: Saline; 50 mg dose PGF _{2α} ; multiple 25 mg dose PGF _{2α}	16-20	1
Mid-Trimester Study: with I.V. oxytocin PGF _{2α} 40-20 mg dose schedule; PGF _{2α} repeated 25 mg dose schedule augmented with laminaria tents; 80 gm urea with I.V. oxytocin; 80 gm urea with 10-20 mg PGF _{2α}	16-20	5
Mid-Trimester Study: Saline – I.V. oxytocin vs. intra-amniotic oxytocin	16-20	1
Mid-Trimester Study: Extra-amniotic saline, 20 cc at 3-hour intervals – oral methergin vs. no methergin	16-20	1

II. STATUS OF MENSTRUAL REGULATION STUDIES

Summary of Results

- The Pregnosticon Dri-Dot pregnancy test is not an adequate test for discriminating between subjects who are pregnant and who are not pregnant prior to the MR.
- The proportion of patients documented (products of conception in aspirated uterine contents) to be pregnant increases from about 30 percent for patients at less than 32 days of amenorrhea to over 80 percent for patients at 46-49 days of amenorrhea.
- Regardless of the size of cannula (4, 5, or 6 mm), vacuum source (50 cc syringe, electric pump), or length of amenorrhea, rates of significant complications are low — less than 3 percent in most of the studies reported by the IFRP. In fact, the variations in complication rates among centers does not appear to be related to the equipment used but does appear to be related to the training and experience of the physicians performing the procedures.
- Complication rates are higher for patients documented to be pregnant than for patients who are not pregnant at the time of MR.
- Higher rates of complications have been reported for MRs performed in countries where artificial abortion is illegal than in countries where it is legal.
- The overall failure rate of MR to terminate pregnancy is about 2 percent.
- While the type of vacuum source, cannula size, and length of amenorrhea may be factors which are related to the failure rate of MR, these factors cannot be adequately evaluated since the failure rates vary from center to center in which the same vacuum sources and type of cannula are used, and the subjects were similar with respect to the lengths of amenorrhea. The inter-center variation in the failure rate of MR may reflect the experience and training of the physicians who perform the MR procedures.
- One study has demonstrated that nurse-midwives can be trained to perform MRs, that their complication and failure rates are no different than those of physicians who performed the procedure. However, in one study where nurse-midwives had been inadequately trained high rates of complications and failure were obtained.

Active Studies

STUDY NAME	STUDY NUMBER	NUMBER OF CASES LOADED
14 Days Delayed, Days Amenorrhea 21-45	302	4,436
Negative First Test, \leq 14 Days Delayed Amenorrhea 21-45	301	49
Czapo Protocol, Prostaglandin	304	5
Days Amenorrhea \geq 21	305	1,823
Vacuum Source, Syringe or Flask	310	200*
Surveillance	399	

* Received but not loaded.

Completed Studies

STUDY NAME	STUDY NUMBER	NUMBER OF CASES LOADED
Negative First Test, \leq 14 Days Delayed Amenorrhea 21-45	301	670
14 Days Delayed, Days Amenorrhea 21-45	302	2,834
Laufe Protocol	303	306
Estrogen to Induce Bleeding in Non-Pregnant Women, MR One Week Later for Non-Bleeding, Pregnant Women	306	300
Total All Completed Studies = 4,110		

Planned Studies

STUDY NAME	STUDY NUMBER	NUMBER OF STUDIES
14 Days Delayed, Days Amenorrhea 21-45	302	8
Days Amenorrhea \geq 21	305	2
Surgical vs. Medical	309	3
6 mm Metal vs. Plastic Cannula	311	1
Vacuum: Berkeley vs. Syringe	312	1

III. STATUS OF IUD STUDIES

Summary of Results

- Results from the small (119 first insertions) multiclinic trial of the Pleated Membrane (IUM) indicate that pregnancy with the device in situ and expulsion will not be a major problem. However, complaints of intermenstrual bleeding and removals for bleeding were frequent among the IUM users. From these initial trials, design modifications have been made with the intention of reducing the bleeding problems associated with the IUM. These trials have only recently been initiated and results are not yet available. The IUM may be better suited for post-abortion rather than inter- or intra-menstrual insertions based on the preliminary results reported from one center.
- The results from two independent studies of the Spring Coil IUD have confirmed the finding of a very low pregnancy rate, but high rates of expulsion and removal for pain and/or bleeding. However, in these two independent studies the Spring Coil was inserted immediately after an induced abortion, whereas in the initial study of this device all insertions were either inter- or intra-menstrual.
- In a five-year follow-up study of two variants of the M-device (M-211 and M-213), high retention rates were reported for both devices. Although the removal rates of the two devices were similar at the end of 5 years, the M-211 device was associated with lower pregnancy rates. Removal rates for pain and/or bleeding for either M device were similar to those reported for the Lippes Loop D. However, as with most stainless steel devices with a thin edge, embedding of the M device in the endometrium complicated its removal.
- A small (354 first insertions) multiclinic trial of the Anderson latex leaf IUD when inserted in the interval and immediate post-partum periods, gave one-year pregnancy, expulsion and removal rates similar to 625 interval insertions of the Lippes Loop D at the same clinic.
- Although the one-year bleeding/pain removal rate of the Lem IUD is low for immediate post-partum insertions, the one-year pregnancy and expulsion rates of this device appear to be less than optimal. While no uterine perforations with the Lem IUD have been reported, there is thought to be an increased risk of uterine (cervical) perforation with the "arms" of this device in puerperal insertions.
- 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 3 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 become 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.
- The Dalkon Shield can be safely inserted immediately after an inevitable or incomplete abortion with satisfactory performance of the device. However, compared to interval insertions of this device, higher 6-month rates of pregnancy and expulsion were obtained.

- In a study of 408 post-partum insertions of the Dalkon Shield the one-year pregnancy and expulsion rates were higher than those reported from centers performing inter- and intra-menstrual insertions. The one-year removal rates for pain, bleeding or medical reasons were similar for post-partum and interval insertions of the device.
- 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 prior 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.
- Two studies with the Weiss device were terminated after 45 insertions because of a high number of expulsions and the incidence of heavy and prolonged bleeding. While the device took the shape of the Lippes Loop on insertion in a few cases, more often it assumed an irregular, three-dimensional shape.
- The Tecna IUD study is ongoing but at the end of one year, displacement and subsequent expulsion and/or pregnancy is a major problem. Nearly 10% of the devices were spoiled because of difficulties related to inflation of the bag at the time of insertion. The fact that these difficulties were encountered in the hands of a skilled investigator suggests that technical difficulties such as the loading of the saline and possible leakage are currently a major barrier to the use of this IUD.

Active and Completed Straight Studies

IUD	NUMBER OF STUDIES	PATIENT CATEGORY	NUMBER OF CASES
Spring Coil – Progesterone	1	Post Menses	100
Spring Coil – Mestranol	1	Post Menses	100
Spring Coil – 500 mg Cu	1	Post Menses Post Abortion	100 261
Spring Coil – Plain	5	Post Menses Post Abortion	228 1,438
Quadracoil – 85 mm ² Cu	1	Post Menses	250
U-Coil – Cu	1	Post Menses	250
Lippes C	4	Post Menses	1,479
Lippes C – 150 mm ² Cu	1	Post Menses	250
Lippes D	4	Post Menses	1,248
Dalkon Shield	7	Post Menses Post Abortion	5,502 500
Cu-7	3	Post Menses	698
Cu-T-200	3	Post Menses Post Abortion	1,682 158
Weiss	1	Post Menses	45
Szontagh	2	Post Menses	4,847
Tecna	1	Post Menses	278
Grafenberg Ring	1	Post Menses	100
Anderson Leaf	1	Post Partum	371
LEM	1	Post Partum	1,495

Completed Comparative Study

IUD	PATIENT CATEGORY	NUMBER OF CASES
M-211 vs. M-213	Post Menses	841

Planned Straight Studies

IUD	NUMBER OF STUDIES	PATIENT CATEGORY
U-Coil	2	Post Menses
Cu-F-200	1	Post Menses Post Abortion
Szontagh with Copper	1	Post Menses
IUM small	1	Post Abortion
Lippes C with Copper	1	Post Menses
Cu-T-200	1	Post Menses
Textured IUD (Battelle)	1	Post Menses

Planned Comparative Studies

IUD	PATIENT CATEGORY	NUMBER OF CASES
IUM:		
– Standard, modified wishbone	Post Menses	200
– Standard, hydrophilic coated	Post Menses	200
– Standard, medium, modified wishbone	Post Menses	300
– Standard, hydron EVA	Post Menses	300
– Standard, medium	Post Menses	200
– Standard, modified wishbone	Post Menses	500
– Standard, EVA, modified wishbone	Post Menses	300
– Standard, EVA	Post Abortion	200
– Standard, modified wishbone, Lippes D	Post Abortion	300
Cu-7, Lippes D	Post Menses	450
Quadracoil: Plain, 85 mm ² Cu	Post Menses	450
Lippes C, Lippes C with 150 mm ² Cu	Post Menses	450
Lippes D: Plain, 200 mm ² Cu	Post Menses	300
Anderson Leaf:		
– Plain vs. Cu	Post Menses	200
– Plain vs. Cu-Zn	Post Menses	200
– Cu vs. Cu-Zn	Post Menses	200

IV. STATUS OF FEMALE STERILIZATION STUDIES

Summary of Results

- When offered in service programs, colpotomy, culdoscopy, laparotomy and laparoscopy all have clinically acceptable rates of safety. However, the vaginal techniques are associated with higher overall rates of complications (mostly pelvic infections) when compared to the abdominal techniques. While wound complications were rarely noted after sterilization via the vaginal route, they were relatively frequent after sterilization via the abdominal route.
- A study of interval, post-abortal, and puerperal sterilizations via laparotomy with the modified Pomeroy technique indicated:
 - The rates of complications were similar for the interval, post-abortion (by D&C or vacuum aspiration), and puerperal cases (by vaginal delivery).
 - The complication rates and rates of readmission for treatment of complications were higher for hysterotomy and sterilization than for sterilization after an abortion by D&C or vacuum aspiration.
 - Cesarean section with sterilization has a higher morbidity than vaginal delivery with sterilization. The higher rates were more likely attributable to the cesarean section than to the sterilization procedure.
- Sterilization via laparotomy with a Pomeroy ligation of the tubes does not result in significantly increased complication rates after abortion at 15-20 weeks' gestation with either Prostaglandin F_{2α} (single 50 mg or multiple 25 mg dose schedule) or hypertonic saline.
- Costs to the patients in terms of surgical and hospitalization time and time required for patients to resume their normal activities are lower for the endoscopic procedures compared to either colpotomy or laparotomy.
- When performed in a single clinic, laparoscopy and culdoscopy resulted in similar rates of operative and early post-operative complications. Both procedures were acceptable to the patients.
- Laparoscopic and culdoscopic sterilizations can be safely performed on an outpatient basis using local anesthetics.
- Laparoscopic sterilization performed within 84 hours of a normal term delivery appears to be a practical procedure which does not significantly increase the duration of post-partum hospitalization.
- Outpatient laparoscopic sterilization combined with first trimester abortion by vacuum aspiration (VA) does not result in significantly increased rates of complications or hospitalization when compared to outpatient first trimester abortion performed by VA as a single procedure.
- 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:

- Rates of operative and early post-operative complications were similar for the three techniques of tubal occlusion – operative, 1.2%, early post-operative, 1.9%.
 - Rates of technical failure, i.e., failure to perform the elected technique of occlusion, were significantly higher with the spring-loaded clip technique (1.5%) than for electrocoagulation (0.4%), or tubal rings (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%) compared to electrocoagulation (3.5%) or tubal ring (2.9%) techniques. Mechanical and/or optical difficulties with the prototype spring-clip applicator were the major sources of technical failures and difficulties.
- 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.
 - Rates of surgical and early post-operative complications were similar for the two techniques.
 - Post-operative pain was more frequent after the application of spring-loaded clips. However, rates of post-operative complaints including pain were similar for the two techniques.
- 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:
- The failure rate (pregnancy rate) of the procedure was 0.7 percent.
 - 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 in 1.4 percent of the cases within 22 to 31 months of sterilization.
 - Some changes in menstrual function occurred. There was an increase over time in the proportion of patients who developed irregular menstrual cycles and dysmenorrhea.
- Sterilization camps offer a convenient method of providing sterilization services to women in areas where such services are not generally available. The overall complication rate for camp sterilizations performed by the physicians from one hospital was not higher than for inpatient sterilizations performed at this hospital.

Active and Completed Surveillance and Straight Female Sterilization Studies by Procedure, Technique, and Long-Term Follow-Up Category

STERILIZATION PROCEDURE	TECHNIQUES OF TUBAL OCCLUSION	CASES WITH FOLLOW-UP		CASES WITH NO FOLLOW-UP	
		NUMBER STUDIES	NUMBER PATIENTS*	NUMBER STUDIES	NUMBER PATIENTS*
Culdoscopy	Tantalum Clips	3	268		
	Pomeroy, Modified Pomeroy	4	494		
	Cautery			1	37
	Fimbriectomy	2	26		
			<u>788</u>		<u>37</u>
Colpotomy	Fimbriectomy	2	51	2	170
	Pomeroy, Modified Pomeroy	3	54	8	972
	Madlener			1	23
	Purandare Technique	2	266	2	261
			<u>371</u>		<u>1,426</u>
Laparoscopy	Cautery	15	2,303	5	199
	Spring-Loaded Clips	10	1,217		
	Tubal Ring	1	399		
	Pomeroy, Modified Pomeroy	1	28		
			<u>3,947</u>		<u>199</u>
Laparotomy	Fimbriectomy	2	336	3	40
	Pomeroy, Modified Pomeroy	9	2,663	13	4,161
	Supra-Pubic Uterine Elevation-Pomeroy			1	39
	Supra-Pubic Proctoscopy-Pomeroy			1	13
	Madlener			1	116
	Purandare Technique	3	904	2	202
	Uchida			2	44
	Irving	1	42		
			<u>3,945</u>		<u>4,615</u>

* Number of cases processed as of March 1, 1975.

**Active Comparative Female Sterilization Studies
by Procedure, Technique, and Category of Patients**

STERILIZATION PROCEDURE	TECHNIQUES OF TUBAL OCCLUSION	CATEGORY OF PATIENTS	NUMBER OF STUDIES
Laparoscopy	Cautery, Spring-Loaded Clip	Interval	2
	Culdoscopy, Tantalum Clips, Laparoscopy, Cautery	Interval	1

**Planned Straight Female Sterilization Studies by
Procedure, Technique, and Category of Patients**

STERILIZATION PROCEDURE	TECHNIQUES OF TUBAL OCCLUSION	CATEGORY OF PATIENTS	NUMBER OF STUDIES
Culdoscopy	Tantalum Clips	Interval	2
	Pomeroy, Modified Pomeroy	Interval	2
	Cautery	Interval	1
		Post Abortion	1
		Post Partum	1
Colpotomy	Fimbriectomy	Interval	1
	Pomeroy, Modified Pomeroy	Interval	4
		Post Abortion	3
		Post Partum	3
Laparoscopy	Cautery	Interval	8
		Post Abortion	2
		Post Partum	1
	Spring-Loaded Clips	Interval	2
		Post Abortion	1
	Tubal Ring	Interval	13
		Post Abortion	5
Laparotomy	Fimbriectomy	Interval	1
		Post Abortion	1
		Post Partum	1
	Pomeroy, Modified Pomeroy	Interval	5
		Post Abortion	4
		Post Partum	3
	Tubal Ring	Post Abortion	1
	Supra-Pubic Uterine Elevation-Pomeroy	Interval	5
		Post Partum	2
	Supra-Pubic Uterine Elevation-Tubal Ring	Interval	1
Supra-Pubic Proctoscopy-Pomeroy	Interval	1	
Hysteroscopy	Cautery	Interval	1
	Corrosive Dyes	Interval	1
Transcervical Quinacrine	Transcervical Quinacrine	Interval	1

**Planned Comparative Female Sterilization Studies
by Procedure, Technique, and Category of Patients**

STERILIZATION PROCEDURE	TECHNIQUES OF TUBAL OCCLUSION	CATEGORY OF PATIENTS	NUMBER OF STUDIES
Culdoscopy	—	—	—
Colpotomy	Hemoclips, Tubal Ring, Spring-Loaded Clips	Post Abortion	1
Laparoscopy	Tubal Ring, Spring-Loaded Clips	Interval	5
	Tubal Ring, Spring-Loaded Clips	Post Abortion	1
	Tubal Ring, Cautery	Interval	7
	Tubal Ring, Tantalum Clip	Interval	1
Laparotomy	Tubal Ring, Purandare Technique	Post Partum	1
	Supra-Pubic Uterine Elevation-Tubal Ring, Modified Pomeroy	Interval	1
	Supra-Pubic Uterine Elevation-Pomeroy, Dassenaiké Technique	Interval	1

V. STATUS OF MALE STERILIZATION STUDIES

- To date only one prospective study has been initiated and is not yet completed. This study will involve 250 subjects. A retrospective study of 250 subjects is planned for initiation.
- Study forms have been finalized and printed and the data management system completed; the IFRP is now in a position to initiate new straight and comparative studies.

VI. STATUS OF SYSTEMIC CONTRACEPTIVE STUDIES

- No results are presently available. One study — a surveillance study of the side effects associated with daily oral contraceptives — has been completed, but has not yet been analyzed. Another study — a comparative cross-over study of three daily oral contraceptives — is in progress. This study will evaluate the side effects associated with Norinyl 1/50, Norlestrin 1, and Ovralkin and the effects of switching from one oral to another.

APPENDIX D
IFRP REPORTS AND PUBLICATIONS

MEMORANDUM

To: All Contributors
From: IFRP Publications Unit
Date: July 1974 to April 1975
Subject: Dissemination of Research Findings

During the period from July 1974 to April 1975, 68 research papers were prepared by the IFRP Publications Unit for conference presentation or journal publication. Of these, 48 were prepared wholly or in part by contributors and 20 were prepared from pooled data by the IFRP staff. Many of the conference papers will be published in proceedings or are pending publication in journals. Papers were written in all six study areas: Pregnancy Termination, 21; Menstrual Regulation, 9; Female Sterilization, 22; Intrauterine Devices, 11; and 1 each on Male Sterilization and Systemic Contraceptives. Three were research methodology papers. These papers were accepted by a wide variety of journals and conferences including:

Journals

- American Journal of Obstetrics and Gynecology
- New England Journal of Medicine
- IPPF Medical Bulletin
- Journal of Obstetrics and Gynaecology of the British Commonwealth
- Fertility and Sterility
- Surgery Gynecology and Obstetrics
- Journal of Reproductive Medicine
- Journal of the Asian Federation of Obstetrics and Gynecology

Conferences

- VIII World Congress on Fertility and Sterility
- VI Asian Congress on Obstetrics and Gynecology
- American Fertility Society
- American Association of Planned Parenthood Physicians
- American Public Health Association
- International Federation of Gynecology and Obstetrics
- Symposium of Gynecological Endoscopy
- International Family Planning Research Association

In addition to the papers listed in this appendix, the Publications Unit has provided editorial and graphic arts assistance to Contributors on a number of individual publications. The wide acceptance of your research papers confirms the value of the research you are performing. This unit looks forward to serving you in the same way during the coming year.

INTERNATIONAL FERTILITY RESEARCH PROGRAM
PUBLICATIONS AND PRESENTATIONS

PREGNANCY TERMINATION SERIES

- PT-1** Hendricks, C.H., Brenner, W.E., Ekbladh, L., Brotanek, V., and Fishburne, J.I., Jr. Efficacy and Tolerance of Intravenous Prostaglandins F_{2α} and E₂. Presented: Ninety-Fourth Annual Meeting of the American Gynecological Society, Phoenix, Arizona, April 14-17, 1971. Published: Amer. J. Obstet. Gynec., 111:564-579, 1971.
- PT-2** Brenner, W.E., Hendricks, C.H., Braaksma, J.T., and Fishburne, J.I., Jr. Intravenous Prostaglandin F_{2α} for Abortion – A. The Efficacy and Tolerance of Three Dosage Schedules. Presented: World Health Organization Conference on Prostaglandins, Stockholm, Sweden, August, 1971. Published: Amer. J. Obstet. Gynec., 113: 1037-1045, 1972.
- PT-3** Ragab, M.I. Jet Ejector Vacuum Cannula for Abortion: A New Engineering Principle. Presented: Fifth Asian Congress of Obstetrics and Gynecology, Jakarta, October, 1971. Published: Contraception, 4:199-206, 1972.
- PT-4** Rao, K.B. Management of Induced Abortions. VII World Congress on Fertility and Sterility, Tokyo and Kyoto, October 17-25, 1971.
- PT-5** Brenner, W.E., Hendricks, C.H., Braaksma, J.T., and Fishburne, J.I., Jr. Intravenous Prostaglandin F_{2α} Administered Vaginally for Inducing Therapeutic Abortion. Presented: World Health Organization Conference, Stockholm, Sweden, January 15-22, 1972. Published: Prostaglandins in Fertility Control, pp. 170-174, January 1972.
- PT-6** Brenner, W.E., Hendricks, C.H., Braaksma, J.T., and Fishburne, J.I., Jr. Intravenous Prostaglandin F_{2α} for Therapeutic Abortion – B. Cardiovascular and Respiratory Effects. Presented: World Health Organization Conference, Stockholm, Sweden, January 15-22, 1972. Published: Prostaglandins in Fertility Control, pp. 156-163, January, 1972.
- PT-7** Brenner, W.E., Hendricks, C.H., Braaksma, J.T., and Fishburne, J.I., Jr. The Abortifacient Efficacy by the Intra-Amniotic and Intra-Uterine Routes. Presented: World Health Organization Conference, Stockholm, Sweden, January 15-22, 1972. Published: Prostaglandins in Fertility Control, pp. 139-155, January, 1972.
- PT-8** Fishburne, J.I., Jr., Brenner, W.E., Braaksma, J.T., Staurovsky, L.G., Mueller, R.A., Hoffer, J.L., and Hendricks, C.H. Cardiovascular and Respiratory Response to Intravenous Infusion of Prostaglandin F_{2α} in the Pregnant Human Female. Presented: Meeting of the Society for Gynecologic Investigation, San Francisco, California, March 23, 1972. Published: Amer. J. Obstet. Gynec., 114:765-772, 1972.
- PT-9** Mehta, A.C. and Bernard, R.P. Early Findings of a Cooperative Study of Abortions in India. 10th Annual Meeting of the American Association of Planned Parenthood Physicians, Detroit, Michigan, April 6-7, 1972.
- PT-10** Brenner, W.E., Hendricks, C.H., Braaksma, J.T., Fishburne, J.I., Jr., Kroncke, F.G., and Staurovsky, L.G. Intra-Amniotic Administration of Prostaglandin F_{2α} to Induce Therapeutic Abortion – A. Efficacy and Tolerance of Two Dosage Schedules. Presented: ACOG 20th Annual Meeting, Chicago, Illinois, May 1-4, 1972. Published: Amer. J. Obstet. Gynec., 114:781-787, 1972.

- PT-11** Brenner, W.E., Hendricks, C.H., Braaksma, J.T., Fishburne, J.I., Jr., and Staurovsky, L.G. Intraamniotic Administration of Prostaglandin F_{2α} for Induction of Therapeutic Abortion – B. A Comparison of Four Dosage Schedules. Presented: Brook Lodge Symposium on Prostaglandins, Augusta, Michigan, June 12-14, 1972. Published: Brook Lodge Symposium – The Prostaglandins, pp. 457-470, 1972; and J. Reprod. Med., 9:456-463, 1972.
- PT-12** Brenner, W.E., Hendricks, C.H., Braaksma, J.T., Fishburne, J.I., Jr., and Staurovsky, L.G. Vaginal Administration of Prostaglandin F_{2α} for Inducing Therapeutic Abortion. Presented: District IV ACOG Meeting, Atlanta, Georgia, October 24, 1972. Published: Prostaglandins, 1:455-467, 1972.
- PT-13** Bernard, R.P. and Mehta, A.C. Clinical Abortions and Abortees in 1971 in India, the U.S.A., and Yugoslavia.
- PT-14** Braaksma, J.T., Brenner, W.E., Fishburne, J.I., Jr., and Staurovsky, L.G. Intra-uterine Extraamniotic Administration of Prostaglandin F_{2α} for Therapeutic Abortion – A. Early Myometrial Effects. Amer. J. Obstet. Gynec., 114:511-515, 1972.
- PT-15** Fishburne, J.I., Jr., Brenner, W.E., Braaksma, J.T., and Hendricks, C.H. Bronchospasm Complicating Intravenous Prostaglandin F_{2α} for Therapeutic Abortion. Obstet. Gynec. 39:892-896, 1972.
- PT-16a** Brenner, W.E., Dingfelder, J.R., Staurovsky, L.G., and Hendricks, C.H. Vaginally Administered PGF_{2α} for Cervical Dilatation in Nulliparas Prior to Suction Curettage. Prostaglandins, 4:819-836, 1973.
- PT-16b** Brenner, W.E., Hendricks, C.H., Fishburne, J.I., Braaksma, J.T., Staurovsky, L.G., and Harrell, L.C. Induction of Therapeutic Abortion with Intra-Amniotically Administered Prostaglandin F_{2α} – A Comparison of Three Repeated-Injection Dose Schedules. Amer. J. Obstet. Gynec., 116:923-930, 1973.
- PT-17** Brenner, W.E. and Bygdeman, M. Intrauterine Administration of Prostaglandin F_{2α} for Induction of Abortion. Intra-Amniotic Method. Presented: Prostaglandin Task Force Meeting, Stockholm, Sweden, October 2-3, 1972. Published: Prostaglandins in Fertility Control, WHO Prostaglandin Task Force, 1972-1973, p. 27.
- PT-18** Brenner, W.E. and Bygdeman, M. Results with Intra-Amniotic Administration. Presented: Prostaglandin Task Force Meeting, Geneva, Switzerland, February 26-28, 1973. Published: Prostaglandins in Fertility Control, WHO Prostaglandin Task Force, 1972-1973, p. 33.
- PT-19a** Brenner, W.E., Hendricks, C.H., Fishburne, J.I., Jr., Dingfelder, J.R., and Staurovsky, L.G. Phase II Clinical Trials of Prostaglandin F_{2α}. Symposium on Methods of Evaluating New Drugs in Man, New Orleans, Louisiana, March 24, 1973.
- PT-19b** Brenner, W.E., Hendricks, C.H., Fishburne, J.I., Jr., Staurovsky, L., Braaksma, J., and Taft, R. Intra-Amniotic Prostaglandin F_{2α} Dose-Twenty-Four-Hour Abortifacient Response. J. Phar. Sci., 62:1278-1282, 1973.
- PT-20a** Brenner, W.E., Speroff, L., Spellacy, W., Anderson, G., and Csapo, A. Symposium. A Report on Prostaglandins for Abortion. ACOG Meeting, Bal Harbor, Florida, May 19-25, 1973. Reported in: Contemporary Ob/Gyn, December, 1973, p. 83.
- PT-20b** Brenner, W.E., Fishburne, J.I., McMillan, C.W., Johnson, A.M., Hendricks, C.H. Coagulation Changes During Abortion by Prostaglandin F_{2α}. Amer. J. Obstet. Gynec., 117:1080-1087, 1973.

53

- PT-21** Mullick, B., Brenner, W.E., and Berger, G. Termination of Pregnancy with Intra-uterine Devices. A Comparative Study of Coils, Coils and Balsa, and Catheters. *Amer. J. Obstet. Gynec.*, 116:305-308, 1973.
- PT-22** Brenner, W.E., Chi I-cheng, Bernard, R.P., and Brinton, L. Abortion in Four Asian Countries – Patient Characteristics, Morbidity, and Contraceptive Acceptance. Presented: Second Indonesian Congress of Obstetrics and Gynecology, Surabaya, Indonesia, July 29-August 3, 1973. Published: *J. Asian Fed. Obstet. Gynaec.*, 4:53-70, 1973.
- PT-23** Brenner, W.E., Hendricks, C.H., Braaksma, J.T., Fishburne, J.I., Jr., Dingfelder, J.R., and Staurovsky, L.G. Prostaglandin F_{2α} for Induction of Therapeutic Abortion. VII World Congress of Obstetrics and Gynecology, Moscow, August 13, 1973; and VIII International Seminar of Obstetrics and Gynecology, Ankara, Turkey, September 30, 1973. Abstracted: *Excerpta Medica*, VII World Congress of Obstetrics and Gynecology, #279, p. 26, August, 1973.
- PT-24** Hendricks, C.H., Brenner, W.E., Fishburne, J.I., Jr., and Braadsma, J.T. Second Trimester Abortions Induced by Prostaglandin F_{2α}. VII World Congress of Obstetrics and Gynecology, Moscow, August 13, 1973.
- PT-25** Brenner, W.E. Second Trimester Interruption of Pregnancy. Chapter in Textbook: *Progress in Gynecology*, Melvin Taymer and Thomas Green, Jr., eds.
- PT-26** Vakilzadeh, J., Bernard, R.P., Brinton, L., Brenner, W.E., Harkins, P., and Kessel, E. Studies of Abortion Health Services in the United States, England, and Singapore. Presented: 22nd Iranian Medical Congress, Ramsar, Iran, September 15-20, 1973. Abstracted: *J. Iranian Assoc. Obstet. Gynec.*, September, 1973, p. 52.
- PT-27** Brenner, W.E., Dingfelder, J.R., Hendricks, C.H., and Staurovsky, L.G. Induction of Therapeutic Abortion with a Single Dose of Intra-Amniotically Administered Prostaglandin F_{2α}. Presented: District IV American College of Obstetricians and Gynecologists, San Juan, Puerto Rico, October 23, 1973. Published: *Prostaglandins*, 4:485-498, 1973.
- PT-28** Edelman, D.A., Brenner, W.E., and Harkins, P. Initial Experiences with Suction Curettage Versus Long-Term Experience with Sharp Curettage for Artificial Abortion. District IV ACOG Meeting, October 23, 1973.
- PT-29** Berger, G.S. Factors Associated with Complications of Saline Abortion. 101st Annual Meeting of the American Public Health Association, San Francisco, California, November 4-8, 1973.
- PT-30** Edelman, D.A., Brenner, W.E., and Berger, G.S. The Effectiveness and Complications of Abortion by Dilatation and Vacuum Aspiration Versus Dilatation and Rigid Metal Curettage. Presented: 101st Annual Meeting of the American Public Health Association, San Francisco, California, November 4-8, 1973. Published: *Amer. J. Obstet. Gynec.*, 119:473, 1974.
- PT-31** Edelman, D.A., Brenner, W.E., and Berger, G.S. The Relative Risks of Abortion by Suction Curettage and Dilatation and Curettage. 101st Annual Meeting of the American Public Health Association, San Francisco, California, November 4-8, 1973.

54

- PT-32** Ragab, M.I., Vakilzadeh, J., Brenner, W.E., Harkins, P., Kessel, E. and Bernard, R.P. Elective Versus Emergency Abortion. 101st Annual Meeting of the American Public Health Association, San Francisco, California, November 4-8, 1973.
- PT-33** Vakilzadeh, J., Brenner, W.E., Chi I-cheng, Brinton, L., Lean, T.H., Hendricks, C.H., and Porter, C. Comparison of Induced Abortion in Singapore and North Carolina: A Clinical Epidemiologic Study. 101st Annual Meeting of the American Public Health Association, San Francisco, California, November 4-8, 1973.
- PT-34** Chi I-cheng, Bernard, R.P., Ampofo, D.A., Suporn, K. Incomplete Abortions in Accra and Bangkok University Hospitals 1972-1973. Conference on the Medical and Social Aspects of Abortion, The International Planned Parenthood Federation Africa Regional Conference, Accra, Ghana, December 12-15, 1973.
- PT-35** Brenner, W.E. The Use of the Karman Cannula with Vacuum Aspiration. International Correspondence Society of Obstetricians and Gynecologists, OB/GYN Collected Letters, Series XV, p. 115, 1974.
- PT-36** Brenner, W.E., Hendricks, C.H., Dingfelder, J.R., and Staurovsky, L.G. Laminaria Augmentation of Intra-Amniotic Prostaglandin $F_{2\alpha}$ for the Induction of Mid-Trimester Abortion. Prostaglandins, 3:879-894, 1973.
- PT-37** Antonovski, L., Sukarov, L., Brenner, W.E., Edelman, D.A., and Bernard, R.P. A Comparative Study of Metal and Plastic (Karman) Cannulae for First Trimester Abortion by Suction Curettage. Int. J. Obstet. Gynaec. (In Press).
- PT-38** Edelman, D.A., Brenner, W.E., Davis, G.L.R., and Childs, P. An Evaluation of the Pregnosticon Dri-Dot Test in Early Pregnancy. Amer. J. Obstet. Gynec., 119:521-524, 1974.
- PT-39** Hendricks, C.H., Brenner, W.E., Dingfelder, J.R., and Staurovsky, L.G. Single Intra-Amniotic Injections of Prostaglandin $F_{2\alpha}$ as an Abortifacient Agent: Size of Effective Dose and Effect of Parity. Published: Prostaglandins, 6:55-64, 1974. Abstracted: Proceedings of VII FIGO Congress.
- PT-40** Kumarasamy, T. Prostaglandins and Therapeutic Abortion. Presented: The First Scientific Congress in Family Planning, The Family Planning Association of Sri Lanka, January, 1974. To be published in the Proceedings.
- PT-41** Suporn, K., Gordon, J., and Pachauri, S. Spontaneous and Illegally Induced Abortions at Siriraj Hospital, Bangkok. First Scientific Congress in Family Planning, Sri Lanka, January 1974. To be published in the Proceedings.
- PT-42** Goldsmith, A. and Lavergne, A. Attitudes Regarding Abortion Laws. Central American Obstetrics and Gynecology Meeting, Panama, January, 1974.
- PT-43** Brenner, W.E. Are Second Trimester Abortions Safer than Letting the Patient Continue to Term? Accepted for Publication in J. of Reprod. Med.
- PT-44** Berger, G.S. and Kerenyi, T.D. Analysis of Retained Placenta Associated with Saline Abortion: Methodological Considerations. Amer. J. Obstet. Gynec., 120: 479-484, 1974.
- PT-45** Berger, G.S. and Kerenyi, T.D. Analysis of Retained Placenta Associated with Saline Abortion: Clinical Considerations. Amer. J. Obstet. Gynec., 120:484-488, 1974.

55

- PT-46** Berger, G.S., Edelman, D.A., and Kerenyi, T.D. Fetal Crown-Rump Length and Biparietal Diameter in the Second Trimester of Pregnancy. *Amer. J. Obstet. Gynec.* (In Press).
- PT-47** Berger, G.S., Edelman, D.A., and Kerenyi, T.D. Oxytocin Administration Instillation-to-Abortion Time, and Morbidity Associated with Saline Instillation. *Amer. J. Obstet. Gynec.*, 121:941-946, 1975.
- PT-48** Brenner, W.E., Dingfelder, J.R. and Staurovsky, L.G. The Efficacy and Safety of Intramuscularly Administered 15(S) 15 Methyl Prostaglandin E₂ Methyl Ester for Induction of Artificial Abortion. South Atlantic Association of Obstetricians and Gynecologists, Hot Springs, Virginia, February 2, 1975.
- PT-49** Brenner, W. E. Termination of Second Trimester Pregnancy Using Prostaglandin F_{2α}. *ACOG Technical Bulletin*, #27, April, 1974.
- PT-50** Brenner, W.E. and Edelman, D.A. Dilatation and Evacuation at 13 to 15 Weeks' Gestation. *Contraception*, 10:171-180, 1974.
- PT-51** Berger, G.S. and Kerenyi, T.D. Control of Morbidity Associated with Saline Abortion. Presented: Association of Planned Parenthood Physicians, Memphis, Tennessee, April 16-17, 1974. Published: *Advances in Planned Parenthood*, Volume IX, Nos. 3 & 4 (Amsterdam: Excerpta Medica, 1975), pp. 31-37.
- PT-52** Brenner, W.E., Dingfelder, J.R., Staurovsky, L.G., Kumarasamy, T., and Grimes, D.A. Intramuscular Administration of 15 (S) 15 Methyl Prostaglandin E₂ Methyl Ester for Induction of Abortion. Presented: North Carolina Obstetrics and Gynecology Society, Pinehurst, May 10, 1974. Published: *Amer. J. Obstet. Gynec.*, 120:833-835, 1974.
- PT-53** Arya, K.D., and Pai, D.N. Vented Versus Non-Vented Suction Cannulae for First Trimester Abortion. VI Asian Congress in Obstetrics and Gynecology, Kuala Lumpur, Malaysia, July 20-24, 1974.
- PT-54** Dingfelder, J.R., Brenner, W.E., and Hendricks, C.H. Reduction of Cervical Resistance Induced by Prostaglandin Suppositories Prior to Dilatation for Induced Abortion. Presented: VI Asian Congress in Obstetrics and Gynecology, Kuala Lumpur, Malaysia, July 20-27, 1974 and VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974. Published: *Amer. J. Obstet. Gynec.* (In Press).
- PT-55** Hanifa, W., Doodoh, A., Azia, M.F., and Affandi, B. Socio-Demographic Aspects and Medical Implications of Spontaneous Abortions Treated at the Dr. T.M.G. Hospital, Jakarta, Indonesia. VI Asian Congress in Obstetrics and Gynecology, Kuala Lumpur, Malaysia, July 20-27, 1974.
- PT-56** Hanifa, W., Affandi, B., Azia, M.F., Doodoh, A., Santo, R.M., and Bernard, R.P. Illegally Induced Abortions Among Incomplete Abortion Patients Treated at the Dr. T.M.G. Hospital, Jakarta. VI Asian Congress in Obstetrics and Gynecology, Kuala Lumpur, Malaysia, July 20-27, 1974.
- PT-57** Mehta, A., Talati, R., Mirchandani, S., and Katrak, J. Mid-Trimester Pregnancy Terminations: A Comparison of Methods. VI Asian Congress in Obstetrics and Gynecology, Kuala Lumpur, Malaysia, July 20-27, 1974.

- PT-58** Rao, S.R., Kanitkar, S.D., and Brinton, L.A. Post Abortal Fertility Control Acceptance. VI Asian Congress in Obstetrics and Gynecology, Kuala Lumpur, Malaysia, July 20-27, 1974.
- PT-59** Borko, E., Breznik, R., Kokos, Z., Edelman, D.A., and Brenner, W.E. Comparison of Metal and Plastic Cannulae for Performing First Trimester Abortions by Vacuum Aspiration. Submitted for publication.
- PT-60** Hogue, C.J., Kleinbaum, D.G., Omran, A.R., Gruber, F.J., and Freeman, D.H. The Impact of Personal Characteristics on Post-Abortion Contraceptive Acceptance. 102nd Annual Meeting of the American Public Health Association, New Orleans, Louisiana, October 20-24, 1974.
- PT-61** Mehta, A., Katrak, J., and Mirchandani, S. Comparison of Methods of Mid-Trimester Pregnancy Termination. VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974.
- PT-62** Staurovsky, L.G., Brenner, W.E., Dingfelder, J.R., Kumarasamy, T., Grimes, D., and Ogburn, P. The Effect of Meperidine Analgesia in PGF_{2α} Induced Mid-Trimester Abortions. VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974.
- PT-63** Staurovsky, L.G., Brenner, W.E., Dingfelder, J.R., and Kumarasamy, T. Induction of Therapeutic Abortion with Intra-Amniotically Administered Prostaglandin F_{2α}: A Comparative Study of Two Dose Schedules. VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974.
- PT-64** Shams Ardekani, M., Zolfagharie, M., Nazemian, M., Wallman, J.A., and Vakilzadeh, J. A Clinic Based Study of Emergency Abortions in Iran. International Fertility Research Program Contributors' Conference, Ramsar, Iran, September 15-20, 1973.
- PT-65** Edelman, D.A., Sakoda, J.M., and Brenner, W.E. The Scoring of the Severity of Complications in an Abortion Study. Submitted for publication.
- PT-66** Bernard, R.P., Chi, I.C., Miller, E.R. Abortions Requiring Hospital Treatment in Four Countries in Asia and Africa. IV Sudanese Congress of Obstetrics and Gynaecology, Khartoum, Democratic Republic of Sudan, Africa, February 10-13, 1975.
- PT-67** Rushwan, H., Ferguson, J., Nayal, Z., Nahas, E. and Bernard, R.P. Three Center Study of Incomplete Abortions in Khartoum, Sudan — A Preliminary Report. IV Sudanese Congress of Obstetrics and Gynaecology, Khartoum, Democratic Republic of Sudan, Africa, February 10-13, 1975.
- PT-68** Raji, M., Ferguson, J.G., and Vakilzadeh, J. Incomplete Abortion at Jahansha Saleh Hospital, Teheran, Iran: A Comparison of Inpatient and Outpatient Cases. Pahlavi University Medical Forum, Shiraz, Iran, April, 1975.
- PT-69** Berger, G.S. Recent Facts About Abortion: An Appraisal of Its Health Impact. The Continuing Medical Education Program of Sexuality and Contraception, State University of New York at Buffalo, April 23-24, 1975.

MENSTRUAL REGULATION SERIES

- MR-1** Kessel, E., Laufe, L.E., Husman, C., Brinton, L.A. Menstrual Regulation: A New Family Planning Service. 22nd Iranian Medical Congress, Ramsar, Iran, September 15-20, 1973.
- MR-2** Kessel, E., Brenner, W.E. and Stathes, G.H. Menstrual Regulation in Family Planning Services. Presented: 101st Annual Meeting of the American Public Health Association, San Francisco, California, November 4-8, 1973. Published: Amer. J. Pub. Hlth., 65:4, 1975.
- MR-3** Brenner, W.E. Report of the Workshop on Complications of Menstrual Regulation. Conference on Menstrual Regulation, Honolulu, Hawaii, December 17-19, 1973. Reported in: Proceedings of the Conference on Menstrual Regulation.
- MR-4** Kanitkar, S.D., Parikh, I., Taskar, V., Walnekar, V., Bernard, R.P. Early Experiences with Menstrual Regulation Services at a Teaching Hospital and in a Community Health Clinic in Bombay. Conference on Menstrual Regulation, Honolulu, Hawaii, December 17-19, 1973.
- MR-5** Lean, T.H., Vengadasalam, D., and Edelman, D. Initial Experience with Menstrual Regulation at Kandang-Kerbau Hospital, Singapore. Conference on Menstrual Regulation, Honolulu, Hawaii, December 17-19, 1973.
- MR-6** Mullick, B., Dawn, C.S., Pachauri, S., Bernard, R.F., and Kessel, E. Menstrual Regulation – A Community Service in Howrah District, India. Conference on Menstrual Regulation, Honolulu, Hawaii, December 17-19, 1973.
- MR-7** Pachauri, S. Menstrual Regulation Study of the International Fertility Research Program. Workshop on Study Monitoring and Evaluation, Conference on Menstrual Regulation, Honolulu, Hawaii, December 18, 1973.
- MR-8** Brenner, W.E., and Edelman, D.A. Current Status of Menstrual Regulation. Seminar on Voluntary Sterilization and Post-Conceptive Regulation, Bangkok, Thailand, January 31, 1974. In: Seminar on Voluntary Sterilization and Post-Conceptive Regulation (Bangkok: The Planned Parenthood Association of Thailand, 1974), pp. 32-37.
- MR-9** Kessel, E. Menstrual Regulation in Fertility Control. Presented: The First Scientific Congress in Family Planning, The Family Planning Association of Sri Lanka, January 21-26, 1974. To be published in the proceedings.
- MR-10** Pachauri, S., Kessel, E., and Gordon, J. Menstrual Regulation – Results of Early Studies. First Scientific Congress in Family Planning, The Family Planning Association of Sri Lanka. Colombo, Sri Lanka, January 21-26, 1974. To be published in the proceedings.
- MR-11** Brenner, W.E., Edelman, D.A., and Kessel, E. Menstrual Regulation in the United States: A Preliminary Report. Presented: Annual Meeting of the American Fertility Society, Miami, Florida, April 6, 1974. Published: Fertil. Steril., 26:289-295, 1975.
- MR-12** Brenner, W.E., Edelman, D.A., Davis, G.L.R., Kessel, E. Suction Curettage for Menstrual Regulation. Presented: American Association of Planned Parenthood Physicians, Houston, Texas, April 11-13, 1973. Published: Advances in Planned Parenthood, Volume IX, S. Lewit, ed. (Amsterdam: Excerpta Medica, 1974), pp. 15-25.

- MR-13** Kessel, E. Estimated Incidence of Pregnancy by Duration of Amenorrhea. Presented: Association of Planned Parenthood Physicians, Memphis, Tennessee, April, 1974. Published: *Advances in Planned Parenthood*, Volume IX, Nos. 3 & 4 (Amsterdam: Excerpta Medica, 1975) pp. 16-22.
- MR-14** Mullick, B.C. and Pachauri, S. Menstrual Regulation Studies in Urban, Slum and Rural Communities in Howrah, India. VI Asian Congress in Obstetrics and Gynecology, Kuala Lumpur, Malaysia, July 20-27, 1974.
- MR-15** Santo, R.M., Reksoprodjo, M., Husodo, L., Doodoh, A., Pachauri, S., and Chi I-cheng. Menstrual Regulation -- A Pilot Study in Jakarta. VI Asian Congress in Obstetrics and Gynecology, Kuala Lumpur, Malaysia, July 20-27, 1974.
- MR-16** Vengadasalam, D., Lean, T.H., and Edelman, D.A. Menstrual Regulation: A Review of 496 Cases at Kandang Kerbau Hospital in Singapore. VI Asian Congress in Obstetrics and Gynecology, Kuala Lumpur, Malaysia, July 20-27, 1974.
- MR-17** Vengadasalam, D., Lean, T.H., and Edelman, D.A. Fourteen Months Experience with Menstrual Regulation at Kandang Kerbau Hospital, Singapore. Ninth Malaysia-Singapore Congress of Medicine, Kuala Lumpur, August 23-25, 1974.
- MR-18** Edelman, D.A. and Brenner, W.E. International Experiences with Menstrual Regulation. VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974. To be published in the proceedings.
- MR-19** Vengadasalam, D., Lean, T.H., and Edelman, D.A. Menstrual Regulation as a Method of Fertility Control. VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974. To be published in the proceedings.
- MR-20** Berger, G.S., Edelman, D.A., Kessel, E., and Brenner, W.E. "Menstrual Regulation" to Terminate Pregnancy. Letter to the Editor. *New Eng. J. Med.*, May, 1974.
- MR-21** Edelman, D.A., Brenner, W.E., and Goldsmith, A. Menstrual Regulation in Four Countries. *IPPF Med. Bull.*, 8(6):1-2, 1974.
- MR-22** Pachauri, S. and Fortney, J. Menstrual Regulation -- An International Overview. Second International Seminar on Maternal and Perinatal Mortality, Pregnancy Termination and Sterilization, International Federation of Gynaecology and Obstetrics, Bombay, India, March 3-5, 1975.

FEMALE STERILIZATION SERIES

- FS-1** Hulka, J.F., Fishburne, J.I., Mercer, J.P., Omran, K.F. Laparoscopic Sterilization with a Spring Clip: A Report of the First Fifty Cases. *Amer. J. Obstet. Gynec.*, 116:715-718, 1973.
- FS-2a** Kumarasamy, T., Hulka, J.F., Mercer, J.P., Fishburne, J.I., and Omran, K.F. Laparoscopic Sterilization with a Spring-Loaded Clip. Presented: The First Scientific Congress in Family Planning, The Family Planning Association of Sri Lanka, January, 1974. Published: *J. Obstet. Gynaec. Brith. Cmmwlth.*, 81:913-920, 1974.
- FS-2b** Kumarasamy, T., Brenner, W.E., Hulka, J.F., Fishburne, J.I., Mercer, J.P., Omran, K.F., Dingfelder, J.R., Staurovsky, L.G., Grimes, D.A., and Hendricks, C.H. Research Programs in Sterilization and Post-Conceptive Regulation. Presented: Seminar on Voluntary Sterilization and Post-Conceptive Regulation, January, 1974, Bangkok, Thailand. In: *Seminar on Voluntary Sterilization and Post-Conceptive Regulation* (Bangkok: The Planned Parenthood Association of Thailand, 1974), pp. 79-85.

59

- FS-3** Madrigal, V., Wallman, J., and Goldsmith, A. Laparoscopic Sterilization in a Free-Standing Family Planning Clinic: Six Month Follow-Up. Presented: Association of Planned Parenthood Physicians, Memphis, Tennessee, April, 1974. Published: Advances in Planned Parenthood, Volume IX, Nos. 3 & 4 (Amsterdam: Excerpta Medica, 1975) pp. 23-30.
- FS-4** Suporn, K., Omran, K., and Wallman, J. Laparoscopic Sterilization Using Spring-Loaded Clips: Early Experience in Bangkok, Thailand. Association of Planned Parenthood Physicians, Memphis, Tennessee, April, 1974. To be published in Advances in Family Planning.
- FS-5** Bhatt, R.V., Patel, N.F., and Pachauri, S. Scope and Limitation of Camp Approach to Female Sterilization: Our Experience. VI Asian Congress in Obstetrics and Gynecology, Kuala Lumpur, Malaysia, July 20-27, 1974.
- FS-6** Doodoh, A., Hanifa, W., Sumapradja, S., and Harahap, H. Early Experience with Female Sterilization at the Dr. T.M.G. Hospital, 1973. VI Asian Congress in Obstetrics and Gynecology, Kuala Lumpur, Malaysia, July 20-27, 1974.
- FS-7** Khandwala, S.D. and Pai, D.N. Laparoscopic Sterilization Using Spring-Loaded Clips: Early Experience in Bombay. VI Asian Congress in Obstetrics and Gynecology, Kuala Lumpur, Malaysia, July 20-27, 1974.
- FS-8** Suporn, K., Wallman, J., and Pachauri, S. A Comparison of Culdoscopy and Laparoscopy for Interval Sterilization. VI Asian Congress in Obstetrics and Gynecology, Kuala Lumpur, Malaysia, July 20-27, 1974.
- FS-9** Lean, T.H., Chi I-cheng, Wallman, J.A., Harkins, P.B. and Brenner, W.E. A Comparative Study of Interval, Post-Abortion and Post-Partum Sterilization Cases in Singapore. 102nd Annual Meeting of the American Public Health Association, New Orleans, October 20-24, 1974.
- FS-10** Brenner, W.E. and Edelman, D.A. Early Complications of Sterilization in Women Who Have Not Recently Been Pregnant. Presented: VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974. Published: Surg. Gynec. Obstet., 140:69-74, 1975.
- FS-11** Dingfelder, J.R. and Hulka, J.F. Report of the Workshop on Recent Advances in Female Sterilization. To be published in the Proceedings of the VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974.
- FS-12** Hulka, J.F. Sterilization by Clip in the Female. VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974.
- FS-13** Hulka, J.F. and Omran, K.F. Laparoscopic Sterilization With a Spring Clip: A Report of 1,000 Cases. VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974.
- FS-14** Madrigal, V., Henriques, E., Edelman, D.A., Goldsmith, A., and Brenner, W.E. Spring-Loaded Clip or Electrocoagulation for Female Sterilization: A Comparative Study. VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974. To be published in the proceedings.

- FS-15** Suporn, K., Pachauri, S., and Wallman, J.A. A Comparison of Laparoscopic Cauterization and Laparoscopic Application of Spring-Loaded Clips. VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974. To be published in the proceedings.
- FS-16** Aranda, C., Prada, C., Broutin, A., Mangel, T., Edelman, D.A., and Goldsmith, A. Laparoscopic Sterilization Immediately After Term Delivery: A Preliminary Report. Presented: Annual Meeting of the American Association of Gynecological Laparoscopists, Anaheim, California, November 20-23, 1974. Published: J. Reprod. Med. (In Press).
- FS-17** Hulka, J.F., Omran, K., Fishburne, J.I., Mercer, J.P., Kumarasamy, T., Phillips, J.M., Lefler, H.T., Beard, R., Suporn, K., Pai, D., and Lean, T.H. Sterilization by Spring-Clip: A Report of 1,000 Cases with 6 Month Follow-Up. 1974 Symposium of Gynecologic Endoscopy, Anaheim, California, November 21-25, 1974.
- FS-18** Fishburne, J.I., Jr., Omran, K.F., Hulka, J.F., Mercer, J.P., and Edelman, D.A. Laparoscopic Tubal Clip Sterilization Under Local Anesthesia. Fertil. Steril., 25: 762-766, 1974.
- FS-19** Fishburne, J.I., Jr., Edelman, D.A., Hulka, J.F., and Mercer, J.P. Outpatient Laparoscopic Sterilization with Therapeutic Abortion vs. Abortion Alone. Obstet. Gynec. (In Press).
- FS-20** Edelman, D.A., Goldsmith, A., and Brenner, W.E. The Safety of Interval, Post-Abortal, and Puerperal Female Sterilization Via Laparoscopy. Second International Seminar on Maternal and Perinatal Mortality, Pregnancy Termination and Sterilization, International Federation of Gynaecology and Obstetrics, Bombay, India, March 3-5, 1975.
- FS-21** Pachauri, S., Saha, A., and Omran, K.F. Experience with the Spring-Loaded Clip in Asia and the USA. 13th Annual Scientific Meeting of the Association of Planned Parenthood Physicians, Los Angeles, April 17-18, 1975.
- FS-22** Kwak, H., Saha, A., and Pachauri, S. Laparoscopic Sterilization With Tubal Ring. Second International Seminar on Maternal and Perinatal Mortality, Pregnancy Termination and Sterilization, International Federation of Gynaecology and Obstetrics, Bombay, India, March 3-5, 1975.
- FS-23** Madrigal, V., Edelman, D.A., Goldsmith, A., and Brenner, W.E. Female Sterilization via Laparoscopy: A Long-Term Follow-Up Study. Second International Seminar on Maternal and Perinatal Mortality, Pregnancy Termination and Sterilization, International Federation of Gynaecology and Obstetrics, Bombay, India, March 3-5, 1975.
- FS-24** Suporn, K., Pachauri, S., and Saha, A. A Comparative Study of Laparoscopic Sterilization Using Cautery and Spring-Loaded Clips. Second International Seminar on Maternal and Perinatal Mortality, Pregnancy Termination and Sterilization, International Federation of Gynaecology and Obstetrics, Bombay, India, March 3-5 1975.
- FS-25** Omran, K.F., Badawy, A., El-Kadi, A., Fathalla, M., Hefnawi, F., and Talaat, M. Current Advances in Female Sterilization with a Review of Egyptian Experience. Population Control: Current Concepts and Application, Cairo, December, 1974.

61

MALE STERILIZATION SERIES

- MS-1** Madrigal, V., Edelman, D.A., and Goldsmith, A. Male Sterilization in El Salvador: A Preliminary Report. Presented: VI Annual Meeting of the International Family Planning Research Association, Palm Springs, California, October 20-23, 1974. Published: J. Reprod. Med. (In Press).

INTRAUTERINE DEVICE SERIES

- IUD-1** Bernard, R.P. The M-IUD: An International Clinical Trial. 99th Annual Meeting of the American Public Health Association, Minneapolis, Minnesota, October 10-15, 1971.
- IUD-2** Bernard, R.P., Kessel, E., and Ravenholt, R. Fertility and Fertility Desire Among Primary IUD Acceptors on Four Continents. VII World Congress on Fertility and Sterility Tokyo and Kyoto, October 17-25, 1971.
- IUD-3** Ragab, M.I. IUDs on Trial. VII World Congress on Fertility and Sterility, Tokyo and Kyoto, October 17-25, 1971.
- IUD-4a** Andolsek, L., Ogrinc-Oven, M., Thomas, M., and Bernard, R.P. The M-IUD: A Four Year Follow-Up Study in Ljubljana. 101st Annual Meeting of the American Public Health Association, San Francisco, California, November 4-8, 1973.
- IUD-4b** Kessel, E. Fielding of New IUDs in Developing Countries. Presented: Workshop on Advances in IUD Contraception for Developing Countries, Battelle Seattle Research Center, October 18-20, 1973. Published: Intrauterine Devices: Development, Evaluation and Program Implementation, 1974, pp. 49-59.
- IUD-5** Bernard, R.P. and Kessel, E. IUD Performance Patterns: Lippes Loop D, Copper-T, and M-Device. First Scientific Congress in Family Planning, The Family Planning Association of Sri Lanka, January 21-26, 1974. To be published in the proceedings.
- IUD-6** Andolsek, L., Bernard, R.P., Ogrinc-Oven, M., Thomas, M.N. The M-IUD: A Five Year Follow-Up Study in Ljubljana. Association of Planned Parenthood Physicians, Memphis, Tennessee, April 16-17, 1974. To be published in Advances in Planned Parenthood.
- IUD-7** Goldsmith, A., Edelman, D.A., and Brenner, W.E. Contraception Immediately After Abortion. American Association of Planned Parenthood Physicians, Memphis, Tennessee, April 16-17, 1974. Published: Advances in Planned Parenthood, Volume IX, Nos. 3 & 4 (Amsterdam: Excerpta Medica, 1975), pp. 38-44.
- IUD-8** Randic, L., Ragab, M.I., Thomas, M.N., Bernard, R.P., and Kessel, E. One Year Evaluation of the Spring Coil IUD in Rijeka, Yugoslavia and Cairo, Egypt. Association of Planned Parenthood Physicians, Memphis, Tennessee, April 16-17, 1974. To be published in Advances in Planned Parenthood.
- IUD-9** Agoestina, Anderson, I., and Thomas, M.N. The Anderson Leaf IUD: A Multi-Clinic Study in Bandung, Indonesia. VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974. To be published in the proceedings.

- IUD-10** Goldsmith, A., Brenner, W.E., and Edelman, D.A. Report of Workshop Number 3: IUDs Present and Future. To be published in the proceedings of the VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974.
- IUD-11** Goldsmith, A. The IUD in Clinical Practice. Presented: VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974.
- IUD-12** Lampe, L., Randic, L., Thomas, M.N., and Kessel, E. One-Year Evaluation of the Spring Coil IUD in Debrecen, Hungary and Rijeka, Yugoslavia. VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974. To be published in the proceedings.
- IUD-13** Madrigal, V., Thomas, M.N., Goldsmith, A., and Edelman, D.A. A Two-Year Evaluation of the Dalkon Shield Intrauterine Device in San Salvador. VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974.
- IUD-14** Thomas, M.N., Laufe, L., and Wheeler, R. Experiences with a New Intrauterine Device: The Pleated Membrane. VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974. To be published in the proceedings.
- IUD-15** Kessel, E., Bernard, R.P., and Thomas, M.N. IUD Performance and Hypothesis Testing in International Clinical Trials. International Conference on Intrauterine Contraception, Cairo, Arab Republic of Egypt, December 12-14, 1974.
- IUD-16** Ragab, M.I. and Senna, I.A. The Spring Coil IUD as a Carrier for Copper, Progesterone, and Mestranol. International Conference on Intrauterine Contraception, Cairo, Arab Republic of Egypt, December 12-14, 1974.
- IUD-17** Quan, A., Edelman, D.A., Goldsmith, A., Thomas, M., and Zappala-Badia, D. Immediate Post-Abortion Insertion of the Dalkon Shield. Contraception. (In Press).
- IUD-18** Wheeler, R., Laufe, L., and Thomas, M. Concepts in the Design and Evaluation of the Pleated Membrane. 13th Annual Scientific Meeting of the Association of Planned Parenthood Physicians, Los Angeles, April 17-18, 1975.
- IUD-19** Thomas, M. and Mitra, M. The Dalkon Shield: A Multi-Clinic Study of 5100 Users. 13th Annual Scientific Meeting of the Association of Planned Parenthood Physicians, Los Angeles, California, April 17-18, 1975.

SYSTEMIC SERIES

- SYS-1** Mullick, B.C., Chi I-cheng, Pachauri, S., and Kessel, E. Follow-Up Study of Oral Contraceptive Acceptors in Howrah District, India. 102nd Annual Meeting of the American Public Health Association, New Orleans, Louisiana, October 20-24, 1974.

PROGRAM EVALUATION SERIES

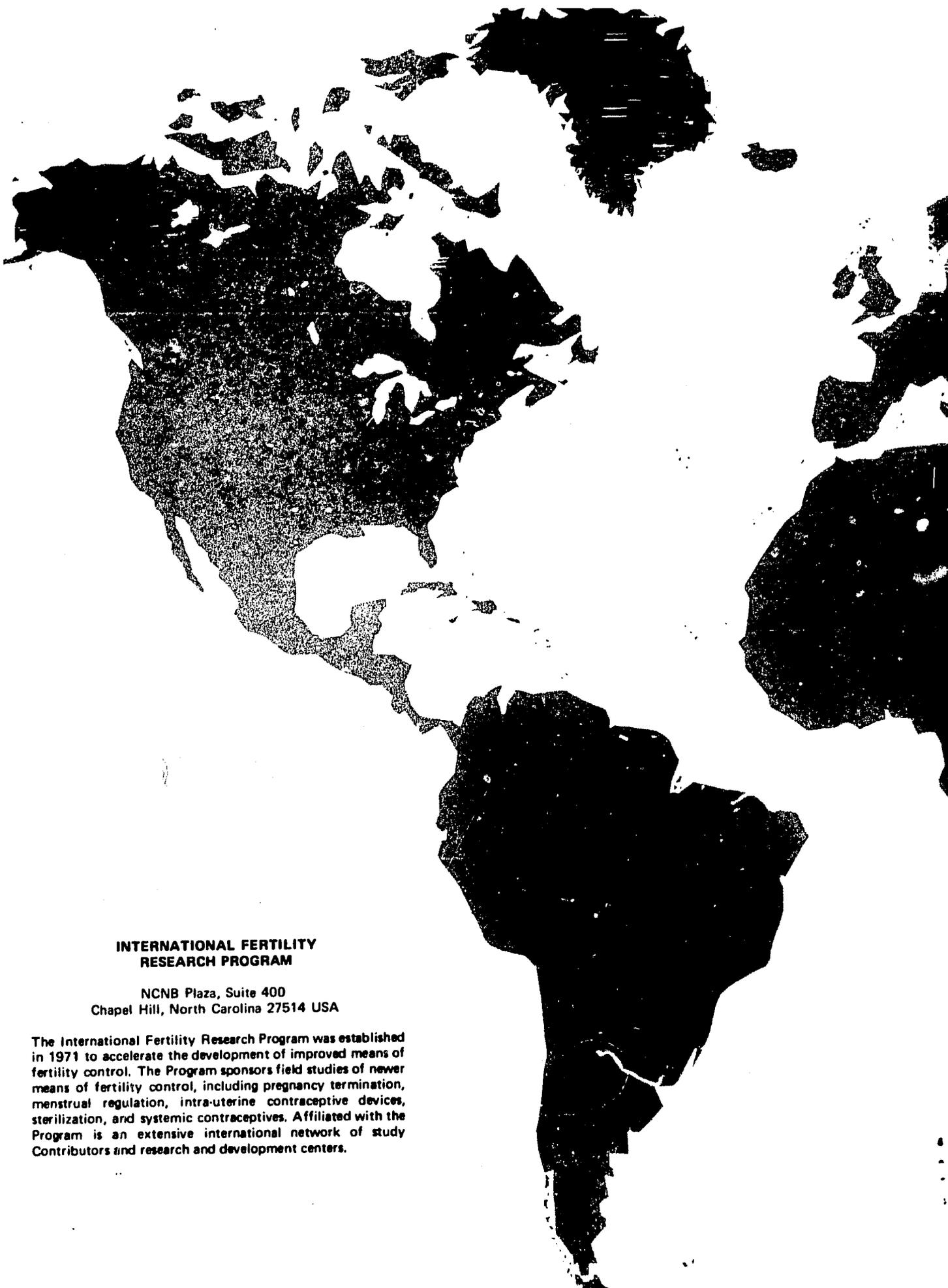
- EVAL-1** David, P. Rural Family Planning Project, Allahabad Agricultural Institute, Allahabad, India. VII World Congress on Fertility and Sterility, Tokyo and Kyoto, October 17-25, 1971.
- EVAL-2** Kessel, E. and Bernard, R.P. Evaluation of a Family Health Program: Indices Derived from Structure, Prevalence and Incidence. Conference on the Teaching and Practice of Family Health, Kampala, Uganda, November 29-December 3, 1971.

- EVAL-3** Kessel, E. Evaluation of a Sterilization Program. Second International Conference on Voluntary Sterilization, Geneva, Switzerland, February 25-March 1, 1973. Published in the proceedings.
- EVAL-4** Brenner, W.E. Evaluation System for Postcoital Contraceptive Methods. Seminar on Voluntary Sterilization and Post-Conceptive Regulation, Bangkok, January, 1974.
- EVAL-5** Kessel, E. Evaluation of Sterilization and Post-Conceptive Regulation Programmes. Presented: Seminar on Voluntary Sterilization and Post-Conceptive Regulation, Bangkok, January, 1974. In: Seminar on Voluntary Sterilization and Post-Conceptive Regulation (Bangkok: Planned Parenthood Association of Thailand, 1974), pp. 93-104.
- EVAL-6** Bernard, R.P. and Kessel, E. Voluntary Sterilization Program Statistics – Collection and Evaluation. In: Advances in Voluntary Sterilization: Proceedings of the Second International Conference, M.E. Schima, I. Lubell, J.E. Davis, E. Connell, eds. (Princeton: Excerpta Medica, American Elsevier Publ. Co., Inc., 1974), pp. 297-304.

METHODOLOGY SERIES

- METH-1a** Kessel, E., Omran, A.R., Bernard, R.P., Ravenhold, R.T., and Speidel, J.J. International Fertility Research Program. In: Fertility and Sterility, Proceedings of the VII World Congress, Tokyo and Kyoto, October 17-25, 1971. International Congress Series No. 278 (Amsterdam: Excerpta Medica, 1972).
- METH-1b** Bernard, R.P. Operation of a Multicenter International Clinical Network to Collect and Analyze Performance Data for IUDs. Presented: Workshop on Advances in IUD Contraception for Developing Countries, Battelle Seattle Research Center, October 18-20, 1973. Published: Intrauterine Devices: Development, Evaluation, and Program Implementation, 1974, pp. 67-77.
- METH-2** Brenner, W.E. The Technology of Post-Conceptive Regulation – Present Available Methods. Presented: Seminar on Voluntary Sterilization and Post-Conceptive Regulation (Bangkok: Planned Parenthood Association of Thailand, 1974), pp. 38-44.
- METH-3** Goldsmith, A., Edelman, D.A., and Kessel, E. Medical Research In Fertility Regulation. Contribution to: Abortion and Family Planning Practices in Latin America. To be published by PAHO/WHO.
- METH-4** Hanifa, W., Samil, R.S., Saifuddin, B.A., Sarwono, S.W., Doodoh, A., and Bernard, R.P. Seasonality of Conception in Jakarta – Meteorological and Cultural Correlates. VI Asian Congress in Obstetrics and Gynecology, Kuala Lumpur, Malaysia, July 20-27, 1974.
- METH-5** Bhatt, R.V., Bernard, R.P., Potts, D.M. and Purandare, B.N. Association Between Climate Variation and Human Reproduction in Baroda, India. VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974.
- METH-6** Kessel, E. Applied Fertility Research – What is Needed? VIII World Congress on Fertility and Sterility, Buenos Aires, Argentina, November 3-9, 1974. To be published in the proceedings.
- METH-7** Kessel, E. Research Methodology in Comparative Fertility Control Studies. 141st Annual Meeting of the American Association for the Advancement of Science, New York, January 26-31, 1975.

- METH-8** Bernard, R.P. Clinical Fertility Profiling in Obstetrics and Gynaecology. IV Sudanese Congress of Obstetrics and Gynaecology, Khartoum, Democratic Republic of Sudan, February 10-13, 1975.
- METH-9** Bernard, R.P., Shahidi, H.A., Viazi, J. and Farvar, M.T. Morbidity and Mortality Measurement by Behvarzs. Behvarz Data Collection Exercise -- I. Selseleh Regional Development Project, Alashtar, Selseleh, Lorestan, Iran. Second Asian Congress of Agricultural Medicine and Rural Health, Tehran, Iran, April 21-24, 1975. To be published in the proceedings.



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