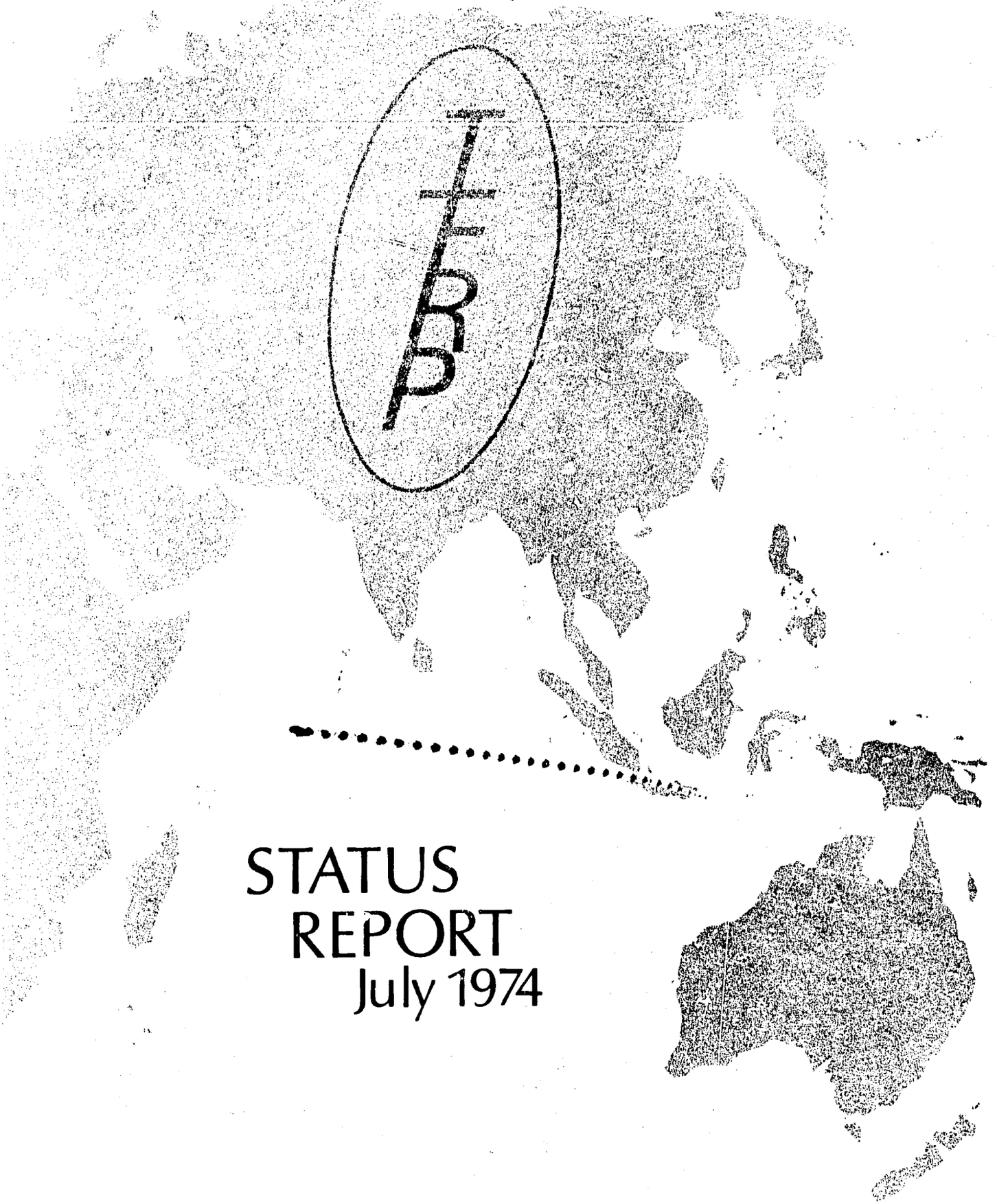
IFRP PN-AAF 392



STATUS REPORT
July 1974

International Fertility Research Program

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D. C. 20523

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INTERNATIONAL FERTILITY RESEARCH PROGRAM

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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:

1) Scientifically field test promising developments in fertility regulation.
2) 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.
3) 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 165 carefully selected Contributors (clinicians as well as program administrators) in 39 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:

1. Patient identification. These data are collected for use at the study center and are not transmitted to the IFRP.
2. Patient characteristics. A similiar set of socio-demographic characteristics is recorded for all patients in all study areas.

3. Methods. Specifics of the method of fertility regulation used, and details of all related complications and difficulties are recorded in this section.
4. 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 this follow-up section.

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

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:

1. Methods are randomly assigned to subjects to avoid bias in selection.
2. The physician who performs the method is always a different physician than the one who is responsible for follow-up care and evaluation of the patients.
3. 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.

4. All subjects are required to sign an appropriate consent form which explains the risks and benefits of the study.
5. 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 Chairman of the Department of Obstetrics and Gynecology, Medical School of the University of North Carolina at Chapel Hill, and two special University Committees --the Committee on the Protection of the Rights of Human Subjects and the Research Review Committee. These two Committees review and approve the comparative studies on the basis of both research design and patient safety.

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 pre-test stage of development, are given in Appendix A. Using the Fertility Survey and 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 to the IFRP 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.

1. 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.

2. Committee on the Protection of the Rights of Human Subjects (University of North Carolina School of Medicine) and Research Review Committee (University of North Carolina, Office of the Vice Chancellor, Health Sciences). These Committees review and approve all comparative protocols and evaluate the appropriateness of the protocols, their research design, and the potential risks and benefits to the subjects.

3. IFRP's Area Coordinators and Studies 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 Studies Review Committee evaluates the scientific merit, study design, and appropriateness of ongoing and proposed studies.

4. 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, its scientific merit and the protection of the interests of human subjects are of prime importance. Only new methods of fertility regulation, which have the potential for improving the acceptance, efficacy, and safety of existing methods, are recommended as worth any potential increased risks to the human volunteers.

IV. DIVISIONS OF THE IFRP

A. 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 (exluding India), India, the Middle East (excluding Iran), 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.

B. 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 onto a data file, using a remote medium speed input/output terminal connected to IBM 360/75 and IBM 370/165 computers, is 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:

1. 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.

2. 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.

3. 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 by 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.

4. Other Computer Outputs. The IFRP has a staff of experienced programmers who provide support to the IFRP's research staff and Contributors for non-standard data output requests.

Since July 1971, the volume of processed forms has steadily increased as well as the amount of computer useage time (see Figure 1). 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 IFRP staff and Contributors.

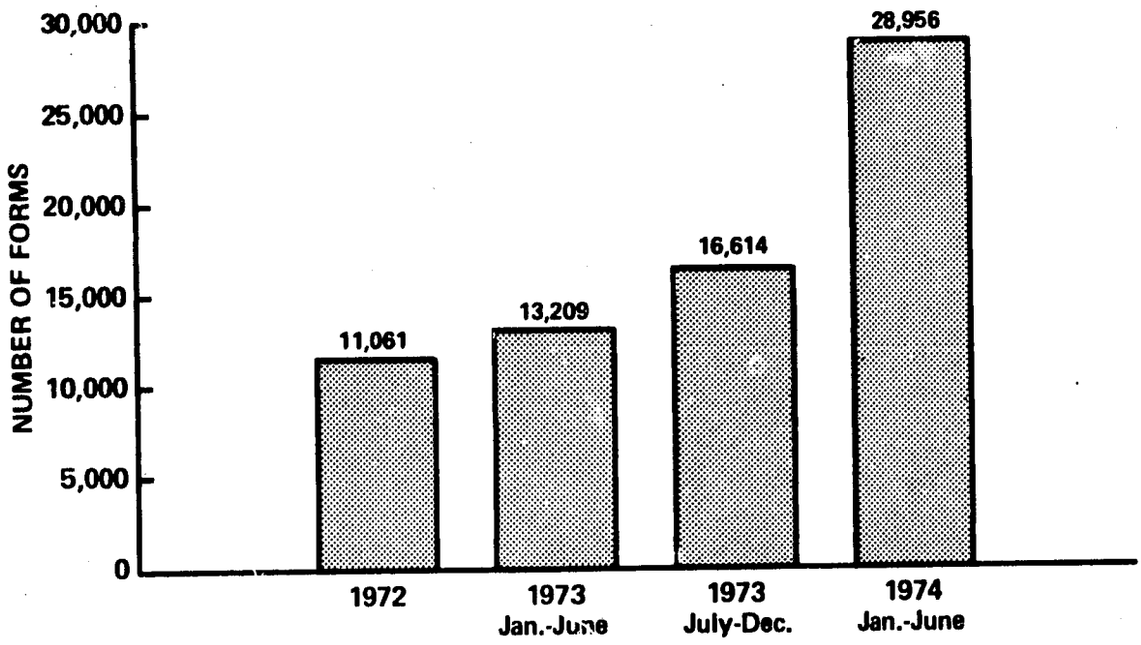


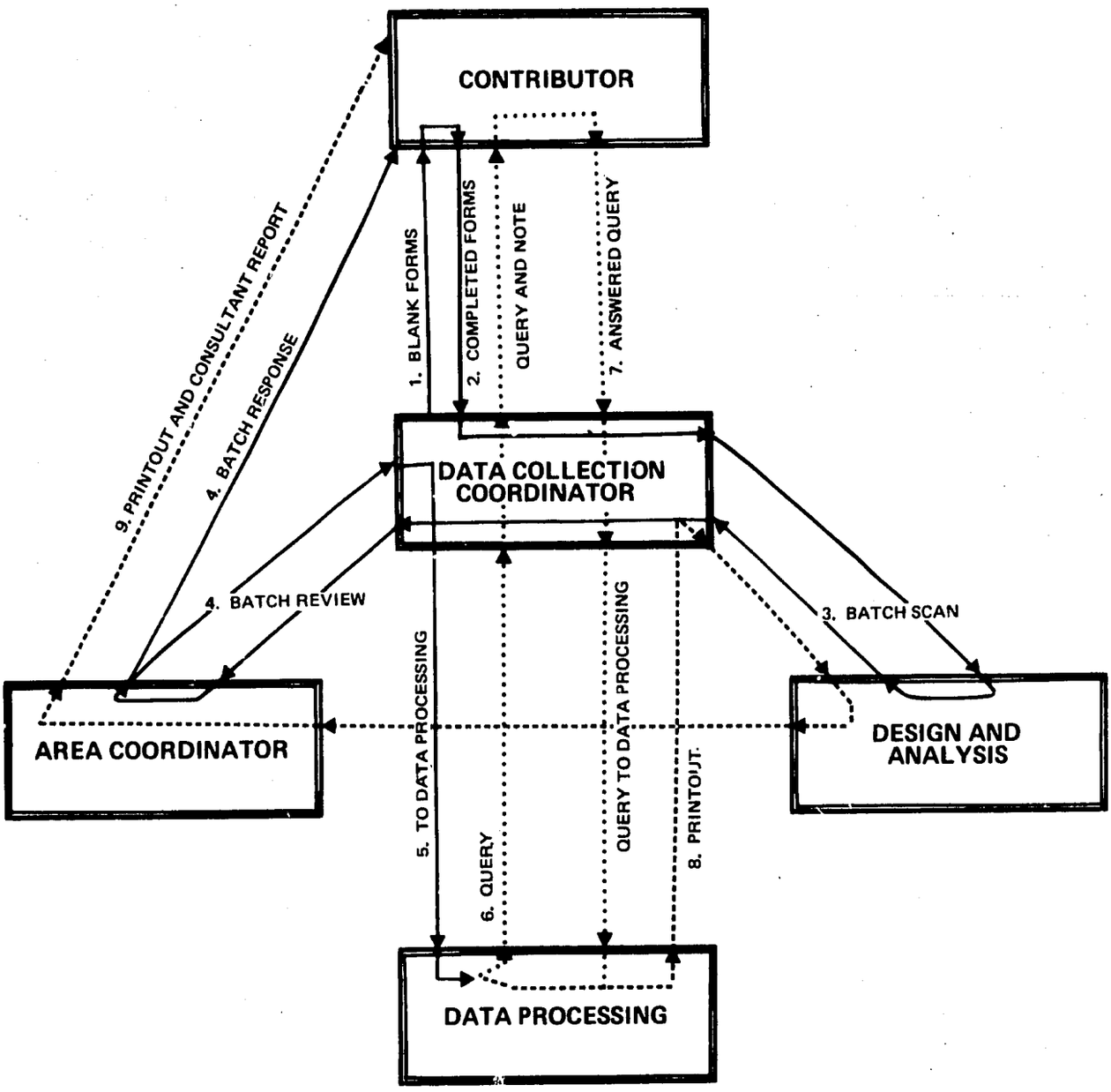
Figure 1. Number of Forms Processed by Time Period, 1972 through June, 1974.

C. Design and Analysis Division

The primary responsibilities of this division are to:

1. design all data collection instruments, the basic data management systems and standard computer tables,
2. design protocols for comparative and straight studies,
3. monitor the overall quality of incoming data,
4. assist and train Contributors in the analysis and interpretation of their study results,
5. prepare brief reports on completed studies for the Contributors,
6. assist Contributors in the preparation of manuscripts for presentation at national or international meetings or conferences, and
7. present and/or publish individual methodological papers as well as papers based on pooled data from two or more similar studies.

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 Studies 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 which is diagrammed in Figure 2.



Data Collection

1. Blank Forms sent to Contributor
2. Completed Forms — From Contributor to Data Collection Coordinator (DCC)
3. Completed Forms — Through DCC to Design & Analysis for batch scan and back to DCC
4. Completed Forms — Through DCC to Area Coordinator and back to DCC for batch review and le
5. Completed Forms — Through DCC to Data Processing for processing

Data Processing

6. Query—Through DCC to Contributor
7. Answered Query returned to Data Processing

Feedback

8. Printout through DCC to Design & Analysis
9. Tables and Consultant Report to Contributor via Area Coordinator

Figure 2. Review System for Processing Data Collection Forms.

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 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:

1. Conference on Abortion Techniques and Services, June, 1971, New York, New York.
2. Seventh World Congress on Fertility and Sterility, October, 1971, Tokyo, Japan.
3. International Planned Parenthood Federation Indian Ocean Regional Conference, December, 1971, Tokyo, Japan.
4. International Conference on Voluntary Sterilization, February, 1972, Geneva, Switzerland.
5. Twenty-second Iranian Medical Congress, September, 1973, Ramsar, Iran.
6. Menstrual Regulation Conference, December, 1973, Honolulu, Hawaii.
7. All India Congress of Obstetrics and Gynecology, February, 1974, Agra, India. (sponsor India Fertility Research Programme)
8. Sixth Asian Congress of Obstetrics and Gynecology, July, 1974, Kuala Lumpur, Malaysia.

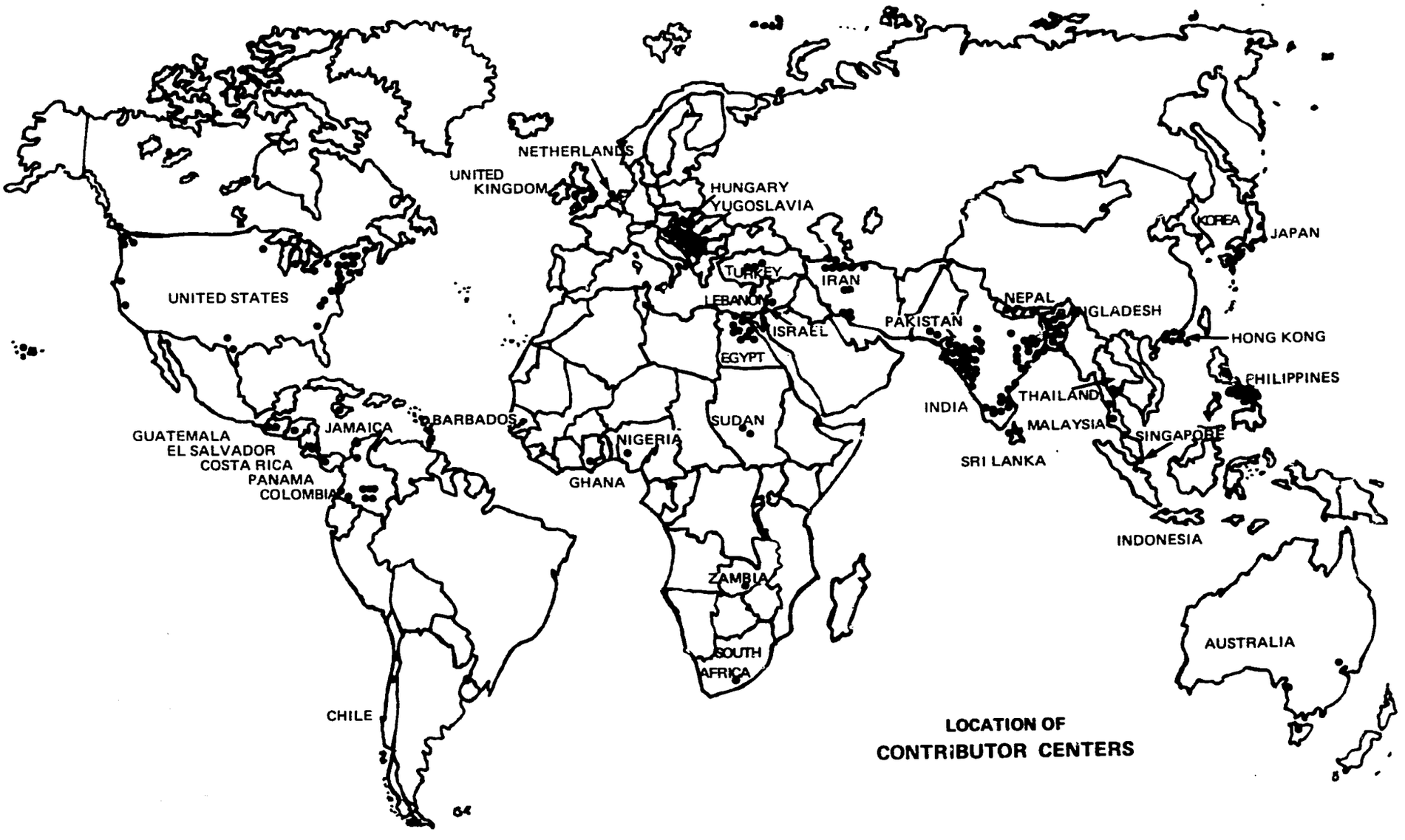
The IFRP is presently affiliated with 165 Centers in 39 countries. Of these 165 Centers, 87 Centers in 21 countries are currently active. Table I gives a breakdown of these Centers and the studies they are conducting by country. The India Fertility Research Programme is now processing forms from Centers in India.

Table I

NUMBER OF ACTIVE CENTERS, NUMBER OF STUDIES IN EACH STUDY AREA AND FORMS RECEIVED BY COUNTRY

Country	Active Centers	Number of Studies by Study Area						Total	
		PT	MR	IUD	FS	MS	SYS	Number of Studies	Forms Received
U. S. A.	12	3	5	3	3	1	1	16	4274
England	3	1	3	—	1	—	—	5	609
Hungary	2	—	1	2	—	—	—	3	3317
Yugoslavia	4	3	—	2	—	—	—	5	1932
Egypt	5	1	—	1	2	—	—	4	940
Iran	12	3	1	3	3	—	1	11	1443
Turkey	3	2	—	1	2	—	—	5	1185
Africa	1	1	—	—	—	—	—	1	46
India	16	12	6	2	7	—	—	27	9846
Philippines	6	2	2	2	3	—	—	9	3144
Pakistan	1	—	1	—	1	—	—	2	75
Singapore	1	1	1	—	1	—	—	3	4347
Korea	1	—	1	—	—	—	—	1	52
Hong Kong	1	—	—	3	—	—	—	3	1058
Indonesia	3	1	1	2	1	—	—	5	3208
Thailand	2	1	—	—	2	—	—	3	1444
Ceylon	2	—	—	—	2	—	—	2	229
Chile	1	1	—	—	—	—	—	1	49
Colombia	9	1	—	—	—	—	—	1	1299
El Salvador	1	—	—	1	1	1	—	3	5285
Costa Rica	1	—	—	—	1	—	—	1	60
All Countries	87	33	22	22	30	2	2	111	43842

PT = Pregnancy Termination
MR = Menstrual Regulation
IUD = Intrauterine Contraceptive
FS = Female Sterilization
MS = Male Sterilization
SYS = Systemic Contraceptive



INTERNATIONAL FERTILITY RESEARCH PROGRAM

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 the Department of Obstetrics and Gynecology and at other Institutions where specific training, skills and procedures are available. Two areas of training experience are emphasized:

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

Since July, 1971, 46 Contributors, or members of their staffs, from 19 countries have come to Chapel Hill for training (Table 2). 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 IFRP intends to develop regional and country programs capable of conducting studies utilizing the IFRP data collection instruments and study protocols. Such regional programs will be autonomous with scientific, colleague relationships with the IFRP-Chapel Hill.

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 transfered to the regional center. Although this latter approach would provide each regional center with a complete data processing and analysis capability, it may not be the most economical approach since revisions to the IFRP's computer programs are made on a continuing basis.

The first step in regionalization was accomplished when Contributors from India elected to organize a non-profit society under India law, entitled the India Fertility Research Programme. The India Fertility Research Programme presently has full capability for data collection and processing. Their interim central office is in Calcutta and computer facilities are located at the Computer Centre of Delhi University.

Table 2

FELLOWS PARTICIPATING IN IFRP TRAINING PROGRAMS BY COUNTRY

July, 1971 - June, 1974

Country	Fellow
Bangladesh	Lt. Col. A.M.F. Burhanuddin
Colombia	Dr. Alfonso Hoyos
Hungary	Dr. F.E. Szontagh
India	Dr. Sreemanta Banerjea
	Dr. Rohit V. Bhatt
	Dr. J.K. Chatterjee
	Dr. Sam X. Charles
	Dr. S.A. Dass
	Dr. Vimala Isaac
	Dr. Kamakshi Kabir
	Dr. S. Kanitkar
	Dr. S.D. Khandwala
	Dr. B.C. Lahiri
	Dr. P.E. Mallika
	Dr. Ajit Mehta
	Dr. Shirin Mehaji
	Dr. Biral Mullick
	Dr. S.D. Mulye
	Dr. V. Rahmathulla
	Dr. N.G. Shaila
Indonesia	Dr. Abdulrauf
	Dr. Arie Doodoh
	Dr. Shelley Jubhari
Iran	Dr. Y. Behjatnia
	Dr. Sheitaneh Soroudi Moghadam
	Dr. R. Mortazavi
	Dr. Manssour Raji
	Dr. S. Sadri
Jamaica	Dr. Gene Burkett
Korea	Dr. Sung-bong Hong
Malaysia	Dr. Jose Catindig
Pakistan	Dr. Bilquis Malik
Philippines	Dr. Virgilio Oblepias
Singapore	Dr. Lim Teck Beng
	Dr. Tan Wee Khin
	Dr. Seng Kwang Meng
	Dr. D. Vengadasalam
Thailand	Dr. Suporn Koetsawang
Turkey	Dr. Eflatun Goksin
Yugoslavia	Dr. Ljubomir Antonovski
	Dr. Toso Cizelj
	Dr. Ziva Novak
	Dr. Milan Kupresanin

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, and 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 an 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 future data submitted. The IFRP 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.

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:

1. Standard Computer Summary Tables. These are readily available to the Contributors upon request for any data set or selected parts of the data set.

2. 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.

3. 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.

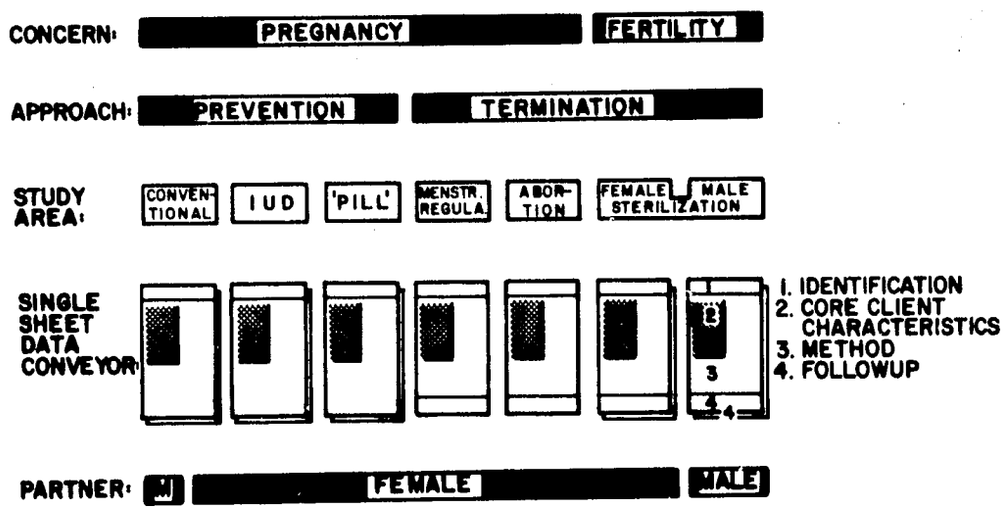
4. Journal Articles. Contributors and the IFRP staff frequently submit joint or independent articles to journals for publication. The IFRP provides editing services to the Contributors and the IFRP staff so that articles are in appropriate format. A reprint series of journal articles is maintained by the IFRP for wide distribution.

5. 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 C.

APPENDIX A

DATA COLLECTION INSTRUMENTS



STANDARDIZED DATA COLLECTION INSTRUMENTS
FOR ALL SEVEN IFRP STUDY AREAS

ORIGINAL

INTERNATIONAL FERTILITY RESEARCH PROGRAM–CAROLINA POPULATION CENTER

I.U.D. STUDY–ADMISSION RECORD

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) 4. Husband's Name _____

5. Address _____ 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 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) Caucasoid 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 [ ] 24; number of females [ ] 25 *(8 or more = 8)*
21. Number of Additional Children Wanted: [ ] 26
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 Before This Insertion: 0) none 1) IUD 2) orals 3) tubectomy 4) vasectomy 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other _____ [ ] 31

PREGNANCY AND MENSES

26. Ever Pregnant: 0) no 1) yes [ ] 33
27. Date Last Pregnancy Ended: [ ][ ] day [ ][ ] month [ ][ ] year 34–39
28. 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 _____ [ ] 40
29. Breastfeeding Now: 0) no 1) yes [ ] 41
30. Menses Since Last Pregnancy: 0) no → *SKIP to Item 38* 1) yes [ ] 42
31. Date Last Menses' Onset: [ ][ ] day [ ][ ] month [ ][ ] year 43–47

OVER LAST THREE PERIODS

32. Average Length of Cycle: *(in days)* 88) irregular [ ] 48–49
33. Average Duration of Flow: *(in days, 8 or more = 8)* [ ] 50
34. Average Amount of Flow: 1) scanty 2) normal 3) excessive [ ] 51
35. Dysmenorrhea: 0) no 1) mild 2) moderate 3) severe [ ] 52
36. Intermenstrual Bleeding: 0) no 1) staining/spotting 2) moderate 3) severe [ ] 53
37. Intermenstrual Pain: 0) no 1) mild 2) moderate 3) severe [ ] 54

Interviewer's Name _____

EXAMINATION AND INSERTION

38. Uterus Position: 1) anteverted 2) retroverted 3) midposition [ ] 56
39. Uterus Sounded: *(98mm. or more = 98)* 99) not done [ ][ ] 57–58
    External Os to Fundus *(in mm.)* [ ][ ] 59–60
    External Os to Internal Os *(in mm.)* [ ] 61
40. Cervical Erosion: 0) no 1) mild 2) severe
41. Type of Device Inserted Today:
    CAUTION: If study is blind, leave type and size blank—proceed to Item 42.
    Type _____ [ ][ ] 62–63
    Size _____ [ ] 64
42. Difficulty at Insertion: 0) no 1) yes, describe _____ [ ] 65
43. Time Between Last Pregnancy's End and Today's Insertion: 0) never pregnant 1) under 2 hours 2) 2-24 hours 3) over 24 hours [ ] 66
44. Who Fitted the Device: 1) doctor 2) nurse 3) midwife 8) other _____ [ ] 67 [ ] 79

ADDITIONAL STUDIES *(To be Filled in Upon Request)*

45. Hematocrit: 99) not done [ ][ ] 11–12
46. Hemoglobin in Grams: 99) not done [ ][ ] 13–14
47. Weight in kg.: *(98 and over = 98)* [ ][ ] 15–16
48. Height in cm.: [ ][ ] 17–19
49. _____ [ ][ ] 20–21
50. _____ [ ][ ] 22–23
51. _____ [ ][ ] 24–25
52. _____ [ ][ ] 26–27
[ ][ ] 28–29

53. Today's Insertion Date: [ ][ ] day [ ][ ] month [ ][ ] year 30–34
54. Date Set for First Follow-up Visit: *(Usually after 1 month)* [ ][ ] day [ ][ ] month [ ][ ] year 35–40

Insertor's Name _____

NO. _____ 42–49

REMARKS *(treatment, etc.)*: _____

IFRP APR/73

AIRMAIL TO: International Fertility Research Program, Carolina Population Center, NCNB Plaza, University of North Carolina at Chapel Hill, Chapel Hill, N.C. 27514 USA

16

ORIGINAL

INTERNATIONAL FERTILITY RESEARCH PROGRAM–CAROLINA POPULATION CENTER

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 _____ (day month year)

3. Patient's Name _____ (family first maiden) 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 8) other _____ [ ] 20
12. Date (This) Contact: [ ][ ] [ ][ ] [7][ ] 21–25
13. Date (Last) Contact: [ ][ ] [ ][ ] [7][ ] 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: _____ (day month year) *(Add 14 days to start of last menses.)*
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 [ ][ ] [ ][ ] [X][ ] 62–66 (day month year)

Examiner's Name _____

I.F.R.P. USE ONLY

49. Termination Type: [ ] 70
50. Termination Date: [ ][ ] [ ][ ] [X][ ] 71–75 (day month year)

[ ] 79

REMARKS _____

IFRP APR/73

AIRMAIL TO International Fertility Research Program, Carolina Population Center, NCNB Plaza, Chapel Hill, N.C. 27514 U.S.A.

17

ORIGINAL

INTERNATIONAL FERTILITY RESEARCH PROGRAM–CAROLINA POPULATION CENTER

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) 4. Husband's Name _____

5. Address _____ 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 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) Caucasoid 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) orals 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

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: 0 1 2 3 4 [ ] 66
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

Coding
0. not used
1. single used
2. single repeated
3. combined first used
4. combined last used

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 _____ [ ] 79

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) orals 3) tubectomy 4) vasectomy 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other _____ [ ] 24
61. Admission Date: [ ][ ] [ ][ ] [X][X] 30–31
62. Initiation Date: [ ][ ] [ ][ ] [X][X] 32–33
63. Completion Date: [ ][ ] [ ][ ] [X][X] 38–42
64. Final Discharge Date: [ ][ ] [ ][ ] [X][X] 44–48 (day month year)
65. Nights in Hospital: [ ][ ] 50–51
66. Time Between Initiation and Completion: *(99 hours or over = 98:59)* [ ][ ] [ ][ ] 52–55 (hours minutes)

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) orals 3) tubectomy 4) vasectomy 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other _____ [ ] 52
69. Bleeding Requiring Curettage: 0) no 1) yes [ ] 57
70. Fever Requiring Antibiotics: 0) no 1) yes [ ] 58
71. Other Complications _____ [ ][ ] 59–60
72. Readmission Related to Termination: 00) no [ ][ ] 61–62; number of nights [ ][ ]
73. Date of Follow-up Visit: [ ][ ] [ ][ ] [X][X] 64–68 (day month year)
74. Completed Weeks From Discharge to Follow-up: [ ][ ] 70–71

IFRP APR/73 NO _____ 54–61

Recorded By _____

AIRMAIL TO: International Fertility Research Program, Carolina Population Center, NCNB Plaza, University of North Carolina at Chapel Hill, Chapel Hill, N.C. 27514 USA

18

ORIGINAL

INTERNATIONAL FERTILITY RESEARCH PROGRAM—CAROLINA POPULATION CENTER
MENSTRUAL REGULATION 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* 4. Husband's Name _____

5. Address _____ 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 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) Caucasoid 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 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) orals 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

PROCEDURES

37. Vacuum Aspiration: 0) not used 1) single first used 2) single repeated 3) combined first used 4) combined last used _____ 59
38. Curette Check Performed: 0) no 1) yes _____ 60
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 Millimeters: 00) not dilated _____ 67–68
44. Prostaglandin: Complete IFRP Drug Administration Form *(Use item 37 codes)* _____ 69
45. Other Drug: *(Use item 37 codes)* _____ 70
46. Other Method _____ *(Use item 37 codes)* _____ 71
47. Concurrent Surgery: 0) none 1) IUD 2) tubectomy 8) other _____ 72

Operator's Name _____ 1 76–80

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) orals 3) tubectomy 4) vasectomy 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other _____ _____ 27
63. Admission Date: _____ *day month year* 28–30
64. Initiation Date: _____ 31–33
65. Completion Date: _____ 34–40
66. Final Discharge Date: _____ 41–51
67. Nights in Hospital: _____ 52–54
68. Time Between Initiation and Completion: *(99 hours or over = 98:59)* _____ *hours minutes* 55–58

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) orals 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: decidua, etc. 2) products of conception identified 3) results not known 9) exam not done _____ 57; _____ 58
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 _____ 64–66
77. Date of Follow-up Visit: _____ *day month year* 67–71

Recorded by _____

IFRP/MR 8/73 NO. _____ 72–75

2 80

AIRMAIL TO: International Fertility Research Program, University of North Carolina, NCNB Plaza, Chapel Hill, N.C. 27514 U.S.A.

19

ORIGINAL

INTERNATIONAL FERTILITY RESEARCH PROGRAM–CAROLINA POPULATION CENTER
FEMALE STERILIZATION STUDY–ADMISSION RECORD

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 *family first maiden* 4. Husband's Name

5. Address Telephone

6. Relative/Friend's Name 7. Address

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 12
12. Age: *(years completed)* 13–14
13. Gainfully Employed: 0) no 1) yes 15
14. Race: 1) Caucasoid 2) Mongoloid 3) Negroid 8) other 16
15. Religion: 0) none 1) Buddhist 2) Catholic 3) Hindu, caste 4) Jewish 5) Muslim 6) Orthodox 7) Protestant 8) other 17
16. Marital Status: 1) never married 2) currently married 3) formerly married 8) other 18
17. Patient's Education *(school year completed)* 19–20
18. Husband's Education: *(school year completed)* 21–22
19. Total Live Births: 23–24
20. Children Now Living: number of males *(8 or more = 8)* 25; number of females 26
21. Age of Youngest Child *(8 or more years = 8)* 27
22. Total Number of Abortions 28–29
23. Number of Spontaneous Abortions *(8 or more = 8)* 30
24. Total Stillbirths *(8 or more = 8)* 31
25. Contraceptive Method Mainly Used Before this Operation 0) none 1) IUD 2) orals 3) tubectomy 4) vasectomy 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other 32
26. Patient Status: 1) private 2) nonprivate 33
27. Patient Scheduled as: 1) outpatient 2) inpatient 34

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 36
29. Date Last Pregnancy Ended: 37–42
30. Date Last Menses' Onset: 43–47 *day month year*
31. Currently Pregnant: 00) no number of weeks 48–49
32. Average Length of Cycle: *(in days)* 88) irregular 50–51
33. Average Duration of Flow: *(in days; 8 or more = 8)* 52
34. Average Amount of Flow: 1) scanty 2) normal 3) excessive 53
35. Dysmenorrhea: 0) no 1) mild 2) moderate 3) severe 54
Interviewer's Name *(print)* 55–56

MEDICAL DATA

36. Weight in kg: *(98 and over = 98)* 57–58
37. Height in cm: 59–61
38. Hematocrit: 99) not done 62–63

MEDICAL HISTORY

39. Abdominal Surgery: 0) no 1) yes: specify 70
40. Pelvic Surgery: 0) no 1) yes: specify 71
41. Systemic Disease: 0) no 1) yes: specify 72
42. Other Complaints 73–74

EXAMINATION AND SURGERY

43. Pelvic and Operative Examination: 1) normal 2) adhesions 3) prolapse 4) fibroid 5) cyst 6) combination 8) other 75
44. Pelvic Infection: 0) none 1) yes, acute 2) yes, chronic 76
45. Anesthesia: 0) none 1) analgesia only 2) local 3) regional 4) general 5) 1+2 6) 2+4 8) other 77
1 79–80
46. Planned Procedure: 1) culdoscopy 2) vaginal ligation 3) vaginal hysterectomy 4) laparoscopy 5) abdominal ligation 6) abdominal hysterectomy 7) transcervical 8) other 12
47. Performed Procedure: *(Use Item 46 Codes)* 13
48. Technique Used 14–15
49. Difficulties at Surgery 16–17
50. Pregnancy Termination This Admission:
0) (no) 1) concurrent with sterilization 2) preceding sterilization 3) after sterilization 18
51. Pregnancy Termination Procedure: 1) D&C 2) vacuum aspiration 3) intra amniotic 4) hysterotomy 5) cesarean 6) vaginal delivery 8) other 19
52. Pregnancy Termination Outcome *(Use Item 28 Codes)* 20
53. Other Surgery This Admission *(Use Item 50 Codes)* 21
specify procedure 22–23
54. Surgical Time *(From incision through closure) (in minutes, 98 minutes and over = 98)* 24–25
55. Prophylactic Antibiotics Given: 0) no 1) yes 26

COMPLICATIONS: STERILIZATION TO DISCHARGE

56. Any Complications Related to Sterilization Procedure
0) (no) 1) yes, no additional hospitalization required 2) yes, additional hospitalization required 28
57. Excessive Blood Loss: 0) no 1) yes 29
58. Blood Transfusion Given: 0) no 1) yes ml 30
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 31
60. Fever 38°C /100.4°F. or Over, 24 Hours After Surgery: 0) no 1) yes 2) yes, requiring antibiotics 32
61. Anesthesia Complications: 0) none 1) apnea 2) vomiting 3) convulsions 4) shock 5) aspiration 6) headache 7) combination 8) other 33
62. Other Complications 34–35
63. Death: 0) no 1) yes, cause 36
64. Admission Date 38–42
65. Surgery Date 43–47
66. Discharge Date 48–52 *day month year*
Surgeon's Name *(print)*

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 64
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 65
69. Reason For This Contact: 1) scheduled follow up 2) emergency 8) other 66
70. Number of Additional Contacts Related to Sterilization *(8 or more = 8)* 67
71. Readmission Related to Sterilization: 00) no number of nights 68–69
72. Fever Requiring Antibiotics: 0) no 1) yes 54
73. Other Complications 55–56
74. Resumption of Full Work or Household Activities: 0) no 1) yes 57
75. Have You Recommended Sterilization To Anyone Since Your Operation? 0) no 1) yes 58
76. Date of This Follow up Visit 60–64
77. Date Set For Next Follow up Visit 65–69 *day month year*

IFRP FS FEB/73 No 71–78

2 80

AIRMAIL TO: International Fertility Research Program, Carolina Population Center, NCNB Plaza, Chapel Hill, N.C. 27514, U.S.A.

20

ORIGINAL

INTERNATIONAL FERTILITY RESEARCH PROGRAM--CAROLINA POPULATION CENTER
FEMALE STERILIZATION STUDY--FOLLOW-UP RECORD
PRETEST

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_____ (family first maiden) 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 No. [ ][ ][ ][ ][ ][ ] 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 [ ][ ] 27-28
number of days after sterilization
18. Dyspareunia: 0)no 1)yes [ ] 29

SPECIAL STUDIES

19. _____ [ ][ ] 31-32
20. _____ [ ][ ] 33-34
21. _____ [ ][ ] 35-36
[3] 80

22. Follow-up Visit: 1)6 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: [ ][ ] [ ][ ] [X][X] 21-25
27. Date (Last) Contact: [ ][ ] [ ][ ] [X][X] 26-30
(day month year)

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: [ ][ ] [ ][ ] [X][X] 43-47
(day month year)
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: *(or 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
[4] 79-80

IFRP/FS fu/2-74

AIRMAIL TO: International Fertility Research Program, Carolina Population Center, NCNB Plaza, Chapel Hill, N.C. 27514 U.S.A.

21

ORIGINAL

INTERNATIONAL FERTILITY RESEARCH PROGRAM—CAROLINA POPULATION CENTER

SYSTEMIC CONTRACEPTIVE STUDY—ADMISSION RECORD

PRETEST

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) 4. Husband's Name _____

5. Address _____ 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 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) Caucasoid 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: *(If no living children SKIP TO ITEM 22)* number of males *(8 or more = 8)* [ ] 24; number of females [ ] 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: 0) no 1) yes [ ] 43
32. Date Last Pregnancy Ended: [ ][ ] [ ][ ] [ ][ ] 45–50 (day / month / year)
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: 0) no → *SKIP TO ITEM 43* 1) yes [ ] 54
36. Date Last Menses' Onset: [ ][ ] [ ][ ] [X][ ] 56–60 (day / month / year)

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) normal 3) excessive [ ] 65
40. Dysmenorrhea: 0) no 1) mild 2) moderate 3) severe [ ] 66
41. Intermenstrual Bleeding: 0) no 1) staining/spotting 2) moderate 3) severe [ ] 67
42. Intermenstrual Pain: 0) no 1) mild 2) moderate 3) severe [ ] 68

Interviewer's Name _____ [ ] 70

MEDICAL DATA

43. Hematocrit 99) not done [ ][ ] 11–12
44. Hemoglobin in Grams: 99) not done [ ][ ] 13–14
45. Blood Pressure: Systolic [ ][ ][ ] 15–17; Diastolic [ ][ ][ ] 18–20; 999) not done
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; [ ][ ] 34–35
51. Number of Cycles Given This Visit: *(in months)*
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: [ ][ ] [ ][ ] [X][ ] 38–42 (day / month / year)
54. Date of Starting Contraceptive: [ ][ ] [ ][ ] [X][ ] 44–48 (day / month / year)
55. Who Prescribed the Contraceptive: 1) doctor 2) nurse 3) midwife 8) other _____ [ ] 50
56. Date Set For First Follow-up Visit: [ ][ ] [ ][ ] [X][ ] 52–56 (day / month / year)

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

COMMENTS: _____

IFRP APR/73

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22

DUPLICATE

INTERNATIONAL FERTILITY RESEARCH PROGRAM–CAROLINA POPULATION CENTER

SYSTEMIC CONTRACEPTIVE STUDY–FOLLOW-UP RECORD

PRETEST

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 *family first maiden* 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 12-17
9. Follow up Visit Number 18-19

CONTACT DATA

10. Type of Contact 1) clinic visit 2) home visit 3) moved 4) unable to locate 5) died, cause 8) other 21
11. Reason for This Contact 1) routine 8) other 22
12. Date (This) Contact *day month year* 7 24-28
13. Date (Last) Contact *day month year* 7 30-34
14. Date Contraceptive Started *(first follow up visit only)* *day month year*
    Never Started (·) *SEE MANUAL*

MENSES

15. Menses Since Last Visit 0) (no) 1) yes 36
    16. Date Last Menses' Onset *day month year*
    17. Average Length of Cycle *(in days)* 88) irregular 37-38
    18. Average Duration of Flow *(in days 8 or more 8)* 39
    19. Average Amount of Flow 1) scanty 2) normal 3) excessive 40
    20. Dysmenorrhea 0) no 1) mild 2) moderate 3) severe 41
    21. Intermenstrual Bleeding 0) no 1) staining spotting 2) moderate 3) severe 42
    22. Intermenstrual Pain 0) no 1) mild 2) moderate 3) severe 43

PREGNANCY

23. Breastfeeding Now 0) no 1) yes 44
24. Pregnancy Since Last Visit 0) (no) *SKIP TO ITEM 29* 1) yes 45
25. Pregnancy Diagnosed By 1) pregnancy test 2) physical examination 3) history only 4) combination 8) other 46
26. Date of Conception *(Add 14 days to start of last menses)* *day month year*
27. Pregnancy Outcome 0) currently 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 8) other 47
28. Date of Termination *day month year*

MEDICAL DATA

29. Hematocrit 99) not done 49-50
30. Hemoglobin in Grams 99) not done 51-52
31. Blood Pressure Systolic 999) not done 53-55
    Diastolic 56-58
32. Weight in kg *(98 and over 98)* 59-60
33. Primary Current Medical Condition 61-62

ADDITIONAL ITEMS *(To Be Filled in Upon Request)*

34 63-64

35 65-66

CONTINUATION DATA

36. Contraceptive Identification by Name or Code 68-71
37. Contraceptive Type
    1) daily (·) *SKIP TO BOX A*
    2) non daily (·) *SKIP TO BOX B* 72

BOX A DAILY CONTRACEPTIVE

38. Maximum Number of Consecutive Days Missed Last Cycle 73-74
39. Total Number of Days Missed Last Cycle 75-76
    SKIP TO ITEM 43 79

BOX B NON DAILY 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 0) (no) 1) yes 28
    44. Date of Last Use *day month year* 7 30-34
    45. Decision to Discontinue Made By 1) patient 2) doctor 8) other 36
    46. Primary Medical Reason for Discontinuing 37-38
    47. Primary Non-medical 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 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 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other 40 41
    49. Primary Reason for Irregular Use 0) not irregular 1) forgetfulness 2) side effects 3) supply not available 4) temporarily not needed 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 Method to Anyone Since Last Visit 0) no 1) yes 44
    52. Date Set For (Next) Follow up *day month year* 7 46-50

Interviewer's Name

Comments

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27

ORIGINAL

INTERNATIONAL FERTILITY RESEARCH PROGRAM—CAROLINA POPULATION CENTER
MALE STERILIZATION STUDY—ADMISSION RECORD FORM

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 _____ (last / first / middle) 4. Wife's Name _____

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. Wife's Age: *(years completed)* [ ] 15–16
13. Patient's Education: *(school year completed)* [ ] 17–18
14. Wife's Education: *(school year completed)* [ ] 19–20
15. Patient's Occupation: 0) unemployed 1) retired/student/housewife 2) professional 3) manager/farmer 4) clerical 5) craftsman 6) operative 7) laborer 8) other _____ [ ] 21-22
16. Wife's Occupation: *Use Item 15 Codes* [ ] 23-24
17. Religion: 0) none 1) Buddhist 2) Catholic 3) Hindu 4) Jewish 5) Muslim 6) Orthodox 7) Protestant 8) other _____ [ ] 25
18. Race: 1) Caucasoid 2) Mongoloid 3) Negroid 8) other _____ [ ] 26
19. Marital Status: 1) never married 2) formerly married 3) multiple marriages *(Codes 1–3 Skip to Item 30)* 4) currently married, one wife — *answer items 20–27* [ ] 27

COMPLETE FERTILITY HISTORY OF WIFE

20. Latest Pregnancy Outcome: (0) never pregnant
    1) currently pregnant 2) live birth 3) still birth 4) induced abortion 5) spontaneous abortion 6) ectopic [ ] 28
21. Date Last Pregnancy Ended: [ ][ ] day [ ][ ] month [ ][ ] year 29–34
22. Total Live Births: [ ][ ] 35–36
23. Children Now Living: *(8 or more = 8)* number of males [ ] 37; number of females [ ] 38
24. Age of Youngest Living Child: *(8 or more years = 8)* [ ] 39
25. Total Number of Abortions: [ ][ ] 40–41
26. Number of Spontaneous Abortions: *(8 or more = 8)* [ ] 42
27. Total Stillbirths: *(8 or more = 8)* [ ][ ] 43–45
28. Total Living Children Fathered:
29. Contraceptive Method Mainly Used During Past 12 Months: 0) none 1) IUD 2) orals 3) tubectomy 4) vasectomy 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other _____ [ ] 48
30. Primary Reason for Choosing This Operation: 1) socio-economic 2) medical 3) eugenic 4) contraceptive failure 5) does not like/trust other methods 8) other _____ [ ] 49
31. Referral Source: 1) self/wife 2) family planning staff 3) other health staff 4) private physician 5) other agency 6) operated person 7) unoperated person 8) other _____ [ ] 50
32. Where Operated: 1) hospital/clinic (static team) 2) hospital/clinic (mobile team) 3) sterilization camp 4) doctor's office 8) other _____ [ ] 51
33. Who Paid For Operation: 1) self 2) insurance 3) public agency 4) private agency 8) other _____ [ ] 52

Interviewer's Name _____

ADDITIONAL ITEMS *(To Be Filled In Upon Request)*

34. _____ [ ][ ] 59–60
35. _____ [ ][ ] 61–62

MEDICAL HISTORY

36. Injury or Operation of Scrotum/Testis: 0) no 1) yes [ ] 63
37. Excessive Pain in Scrotum/Testis: 0) no 1) yes [ ] 64
38. Swelling of Scrotum/Testis: 0) no 1) yes [ ] 65
39. Hernia/Appendix Operation: 0) no 1) yes [ ] 66
40. Other Related History: 0) none 1) yes- specify: _____ [ ][ ] 67–68
41. Sexual History: 1) satisfactory 2) unsatisfactory, specify _____ [ ] 69

EXAMINATION

42. Height in cm.: [ ][ ][ ] 70–72
43. Weight in kg.: [ ][ ][ ] 73–75
44. Urogenital Abnormalities 0) none 1) yes, specify _____ [ ][ ] 76–77
45. Other Existing Medical Conditions: 0) none 1) psychological 2) systemic 3) combination: _____ 8) other, specify _____ [ ] 78

STERILIZATION PROCEDURE [1] 79–80

46. Anesthetic: 1) local 2) regional 3) combination, specify _____ 8) other _____ [ ] 12
47. Type of Incision: 1) single-vertical 2) single-horizontal 3) double-vertical 4) double-horizontal 8) other _____ [ ] 13
48. Sterilization Technique _____ [ ][ ] 14-15
49. Length of Vas Resected: (in mm.) 00) not done [ ][ ] 16-17
50. Vas Ligature Material Used: 0) none 1) silk 2) linen 3) nylon 4) chromic catgut 5) tantalum clip 8) other _____ [ ] 18
51. Abnormal Findings/Difficulties at Surgery: 0) none 1) yes: specify _____ [ ][ ] 19-20
52. Prophylactic Antibiotics Given: 0) none 1) local 2) systemic 3) both [ ] 21

IMMEDIATE COMPLICATIONS

53. Any Complication(s) Related to Sterilization Procedure: (0) no 1) yes, hospitalization not required 2) yes, hospitalization required [ ] 22
    54. Injury to Testicular Artery/Pampiniform Plexus: 0) no 1) yes [ ] 23
    55. Hematoma Scrotum: 0) no 1) yes [ ] 24
    56. Anesthesia Complication(s): 0) no 1) yes [ ] 25
    57. Other Complications _____ [ ][ ] 26-27
58. Surgical Time in Minutes *(98 or over = 98)* [ ][ ] 28-29
59. Surgery Date [ ][ ] day [ ][ ] month [ ][ ] year 31-36

Surgeon's Name _____ [ ][ ] 38-39

REMINDER: Retain this form and complete it at the first follow-up visit one week after sterilization. Visits occuring more than 21 days after surgery should be recorded on the follow-up form.

ONE WEEK FOLLOW-UP

60. 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 _____ [ ] 54
61. Wound Healed: 0) no 1) yes [ ] 55
62. Any Complication(s) Related to Sterilization Procedure: 0) no — *skip to item 69* 1) yes, hospitalization not required 2) yes, hospitalization required [ ] 56
63. Fever 38°C./100.4° F. or Over, 24 Hours After Surgery: 0) no 1) yes 2) yes, requiring antibiotics [ ] 57
64. Wound Septic: 0) no 1) yes [ ] 58
65. Hematoma of Scrotum: 0) no 1) yes [ ] 41
66. Abscess of Scrotum: 0) no 1) yes [ ] 42
67. Excessive Pain in Scrotum/Testis: 0) no 1) yes [ ] 43
68. Other Complications: _____ [ ][ ] 44-45
69. Date of This Follow-up Visit: [ ][ ] day [ ][ ] month [ ][ ] year 47-52
70. Date Set For Three-month Visit: [ ][ ] day [ ][ ] month [ ][ ] year 54-59

Recorded by _____

IFRP MS 8/74 No. _____ [2] 71–78 80

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24

ORIGINAL

INTERNATIONAL FERTILITY RESEARCH PROGRAM–CAROLINA POPULATION CENTER

MALE STERILIZATION STUDY–FOLLOW-UP RECORD

Circle Appropriate Numbers and Hexagons, 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 ____ *last first middle* Telephone ____

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 Record Form No. [ ][ ][ ][ ][ ][ ] 11-16
9. Follow-up Visit: 1) 3-month visit 2) 6-month visit 8) other ____ [ ] 17

CONTACT DATA

10. Type of Contact 1) clinic visit 2) home visit 3) moved out of area 4) unable to locate 5) confirmed wrong address 6) died, cause ____ 8) other ____ [ ] 18
11. Reason For This Contact: 1) routine 8) other ____ [ ] 19
12. Date This Contact: [ ][ ] *day* [ ][ ] *month* [ ][ ] *year* 21-26

CONTINUATION DATA (Since Last Follow-up)

13. General Health and Well Being: 0) no change 1) improved 2) deteriorated - specify: ____ [ ] 27
14. Contraceptive Method Mainly Used:
    (0) none 1) abstinence 2) tubectomy 3) IUD 4) orals 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other ____ [ ] 28
    15. Duration of Contraception: 0) less than one month 1) 1 month 2) 2 months 3) 3 months 4) 4 months 5) 5 months 6) 6 months or more [ ] 29
    16. Regularity of Use: 1) regular 2) irregular [ ] 30
17. Suspected Pregnancy of Partner Since Last Follow-up: 0) no 1) yes → *Complete Pregnancy Confirmation Form* [ ] 31
18. Sexual Activity Since Last Follow-up: 0) no change 1) improved 2) deteriorated 3) not yet resumed [ ] 32
19. Satisfied With Operation 0) no 1) yes 2) indifferent [ ] 33
20. Recommended Male Sterilization To Anyone Since Last Follow-up 0) no 1) yes [ ] 34

Interviewer's Name ____

CURRENT COMPLAINTS RELATED TO STERILIZATION

21. Pain in Scrotum/Testis: 0) no 1) yes [ ] 36
22. Swelling in Scrotum/Testis: 0) no 1) yes [ ] 37
23. Lower Back Pain: 0) no 1) yes [ ] 38
24. Lower Abdomen Pain: 0) no 1) yes [ ] 39
25. Painful Coitus: 0) no 1) yes [ ] 40
26. Hemospermia: 0) no 1) yes [ ] 41
27. Frequency of Nocturnal Micturition: 0) no change 1) increased 2) decreased [ ] 42
28. Other: 0) none 1) yes–specify: ____ [ ][ ] 43–44

ADDITIONAL ITEMS *(To Be Filled in Upon Request)*

29. ____ [ ][ ] 45–46
30. ____ [ ][ ] 47–48
31. ____ [ ][ ] 49–50

PHYSICAL EXAMINATION

32. Weight in Kg.: [ ][ ][ ] 51–53

(Please Record Any Abnormality Since Last Reported Contact.)

33. Epididymo-orchitis 0) no 1) yes [ ] 54
34. Funiculitis: 0) no 1) yes [ ] 55
35. Hematoma: 0) no 1) yes [ ] 56
36. Abscess: 0) no 1) yes [ ] 57
37. Sinus: 0) no 1) yes [ ] 58
38. Testicular Atrophy: 0) no 1) yes [ ] 59
39. Hydrocele/Varicocele: 0) no 1) yes [ ] 60
40. Spermatocele: 0) no 1) yes [ ] 61
41. Other Complications: 0) none 1) yes: specify ____ [ ][ ] 62-63
42. Enlarged/Tender Prostate/Seminal Vesicle: 0) no 1) yes 9) not examined [ ] 64
43. Additional Surgery Required: 0) no 1) yes: specify ____ [ ] 65
44. Hospitalization Required: 0) no number of nights: *(8 or more = 8)* [ ] 66

LATEST SEMEN TEST

45. Weeks Between Operation and Test: *(98 or over = 98)* [ ][ ] 67-68

(99) Test not done

46. Number of This Test: *(8 or more = 8)* [ ] 69
47. Estimated Number of Ejaculations Since Operation: 00) no ejaculations *(98 or over = 98)* [ ][ ] 70-71
48. Result of Test: (sperm per low power field) 00) none *(98 or over = 98)* [ ][ ] 72-73

(If sperm seen, repeat test and see instruction manual)

REMINDER: The patient should be seen for follow-up visits three and six months after surgery.

49. Date Set for Next Contact: [ ][ ] *day* [ ][ ] *month* [ ][ ] *year* 74-79

Examiner's Name ____ [3] 80

COMMENTS: ____

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25

INTERNATIONAL FERTILITY RESEARCH PROGRAM–CAROLINA POPULATION CENTER

MATERNITY SURVEY RECORD

CIRCLE APPROPRIATE NUMBERS AND FILL IN APPROPRIATE BOXES AND BLANKS. No. _____

PATIENT IDENTIFICATION: 1. Your Hospital or Clinic Number _____ 2. Admission Date _____

3. Patient's Name _____ 4. Husband's Name _____

5. Address _____ Telephone _____

STUDY IDENTIFICATION

6. Center Name _____ and Number [ ][ ][ ] 1-3
7. Study Name _____ and Number [ ][ ][ ] 4-6
8. Patient Order Number [ ][ ][ ][ ][ ] 7-11

PATIENT CHARACTERISTICS

9. Residence: 1) urban 2) rural [ ] 12
10. Wife's Age: (years completed) [ ][ ] 13-14
11. Husband's Age: (years completed) [ ][ ] 15-16
12. Wife's Occupation: 0) unemployed 1) retired/student/housewife 2) professional 3) manager/farmer 4) clerical 5) craftsman 6) operative 7) laborer 8) other _____ [ ] 17
13. Husband's Occupation: *(use Item 12 codes)* [ ] 18
14. Race: 1) Caucasoid 2) Mongoloid 3) Negroid 8) other _____ [ ] 19
15. Religion: 0) none 1) Buddhist 2) Catholic 3) Hindu, caste _____ 4) Jewish 5) Muslim 6) Orthodox 7) Protestant 8) other _____ [ ] 20
16. Wife's Education *(school year completed)* [ ][ ] 21-22
17. Husband's Education *(school year completed)* [ ][ ] 23-24
18. Marital Status: 1) never married 2) currently married 3) formerly married 8) other _____ [ ] 25
19. Total Live Births: [ ][ ] 26-27
20. Children Now Living *(8 or more=8)* number of males: [ ] 28; number of females: [ ] 29
21. Age of Youngest Child: *(8 or more years = 8)* [ ] 30
22. Number of Additional Children Wanted [ ] 31
23. Total Number of Abortions: [ ][ ] 32-33
24. Number of Spontaneous Abortions: *(8 or more = 8)* [ ] 34
25. Total Stillbirths: *(8 or more = 8)* [ ] 35
26. Contraceptive Method Mainly Used Prior to Pregnancy 0) none 1) IUD 2) orals 3) female sterilization 4) male sterilization 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other _____ [ ] 36
27. Sterilization this Hospitalization: 0) no 1) yes [ ] 37
28. Admission Date: [ ][ ] day [ ][ ] month [ ][ ] year 38-43
29. Delivery Date: [ ][ ] day [ ][ ] month [ ][ ] year 44-49
30. Discharge Date: [ ][ ] day [ ][ ] month [ ][ ] year 50-55

ADDITIONAL STUDIES

(To be filled in upon request)

31. _____ [ ] 56
32. _____ [ ] 57
33. _____ [ ] 58
34. _____ [ ][ ] 59-60
35. _____ [ ][ ] 61-62

Interviewer's Name _____

COMMENTS: _____

_____

_____

IFRP/mat. surv. 8 74

AIRMAIL TO International Fertility Research Program, Carolina Population Center, NCNB Plaza, Chapel Hill, North Carolina 27514 U.S.A.

INTERNATIONAL FERTILITY RESEARCH PROGRAM--CAROLINA POPULATION CENTER

FERTILITY SURVEY RECORD

Circle Appropriate Numbers and Fill in Appropriate Boxes and Blanks. NO. _____

FAMILY IDENTIFICATION: 1. Your Hospital or Clinic No. _____ 2. Interview Date _____ *day month year*

3. Head of Household _____ *last first middle* 4. Spouse's Name _____

5. Address _____ Telephone _____

STUDY IDENTIFICATION

6. Center Name _____ and Number [ ] 1-3
7. Survey Name _____ and Number [ ] 4-6
8. Family Order in Survey [ ] 7-13

FAMILY CHARACTERISTICS

9. Residence: 1) urban 3) rural [ ] 14
10. Husband's Age: *(years completed)* [ ] 15-16
11. Wife's Age: [ ] 17-18
12. Husband's Occupation: 0) unemployed 1) retired/student/housewife 2) professional 3) farmer/fisher 4) clerical 5) craftsman 6) operative 7) laborer 8) other _____ [ ] 19
13. Wife's Occupation: *(use Item 12 codes)* [ ] 20
14. Race: 1) Caucasoid 2) Mongoloid 3) Negroid 8) other _____ [ ] 21
15. Religion: 0) none 1) Buddhist 2) Catholic 3) Hindu, caste _____ 4) Jewish 5) Muslim 6) Orthodox 7) Protestant 8) other _____ [ ] 22
16. Husband's Education: *(school year completed)* [ ] 23-24
17. Wife's Education: [ ] 25-26

18. Marital Status:
    0) never married
    1) formerly married
    2) currently married and formerly married
    3) currently married, more than 1 spouse
    SKIP to Item 25
    4) currently married one spouse only [ ] 27
19. Total Live Births: [ ] 28-29
20. Children Now Living: *(8 or more = 8)* number of males [ ] 30; number of females [ ] 31
21. Number of Additional Children Wanted: [ ] 32
22. Total Number of Abortions: [ ] 33-34
23. Number of Spontaneous Abortions: *(8 or more = 8)* [ ] 35
24. Total Stillbirths: *(8 or more = 8)* [ ] 36
25. Contraceptive Method Mainly Used During Past Six Months: 0) none 1) IUD 2) orals 3) female sterilization 4) male sterilization 5) condom 6) withdrawal/rhythm 7) foam/diaphragm/jelly 8) other _____ [ ] 37

ADDITIONAL ITEMS

26. _____ [ ] 38-39
27. _____ [ ] 40-41

Interviewer's Name _____

Remarks: _____

NO. _____ 74-80

IFRP/FS 9-73

AIRMAIL TO: International Fertility Research Program, Carolina Population Center, NCNB Plaza, Chapel Hill, N.C. 27514 U.S.A.

INTERNATIONAL FERTILITY RESEARCH PROGRAM--CAROLINA POPULATION CENTER

PREGNANCY CONFIRMATION FORM--PRETEST

Circle Appropriate Numbers and Fill in Appropriate Boxes and Blanks.

PATIENT IDENTIFICATION: 1. Your Hospital/Clinic No. _____

2. Patient's Name _____ (*family* *first* *maiden*) 3. Husband's Name _____

4. Address _____ Telephone _____

STUDY IDENTIFICATION: *(Code for the Study in which the patient was enrolled when pregnancy is suspected to have occurred.)*

5. Center Name and Number _____ [ ][ ][ ]

6. Study Name and Number _____ [ ][ ][ ]

7. Patient Order No. [ ][ ][ ][ ]

8. IFRP Admission Form No. [ ][ ][ ][ ][ ][ ]

(If suspicion and confirmation reported earlier, SKIP to Item 22.)

PREGNANCY SUSPICION: *(Fill out at first contact at which pregnancy is suspected.)*

9. Reason For This Contact: [ ]
   1) scheduled follow-up
   2) suspected pregnancy
   8) other _____

10. Pregnancy First Suspected By: [ ]
    1) doctor at this center
    2) doctor elsewhere
    3) patient
    8) other _____

11. Reason For Suspicion: [ ]
    1) missed menses
    8) other _____

12. Menstruation Since Last Contact: 0) no 1) yes [ ]

13. Date of Last Menses Onset: [ ][ ] [ ][ ] [ ][ ] *day month year*

14. Additional Contraceptive Used Since Last Contact: [ ]
    0) none 1) abstinence 2) IUD 3) orals 4) condom
    5) withdrawal/rhythm 6) foam 7) diaphragm/jelly
    8) other _____

15. Date of This Contact: [ ][ ] [ ][ ] [ ][ ] *day month year*

PREGNANCY CONFIRMATION: *(If uncertain at time of contact, hold form and complete in one month.)*

16. Diagnostic Method Used: [ ]
    0) pregnancy already terminated → *SKIP TO ITEM 22*
    1) pregnancy test, specify name _____
    2) pelvic examination
    3) 1 plus 2
    8) other _____

17. Result of Diagnosis: [ ]
    0) not pregnant → *SKIP TO ITEM 29*
    1) pregnancy confirmed

18. Estimated Gestational Age: [ ][ ]
    (number of weeks from last menstrual period)

19. Estimation of Whether Pregnancy Occurred Before or After Last Procedure/Method Used: [ ]
    1) definitely before } *Fill in Reasons and*
    2) probably before } *SKIP TO ITEM 21*
    3) uncertain
    4) probably after
    5) definitely after

Reasons for this Estimation:

_____

20. Possible Reasons for Contraceptive/Procedure Failure: _____

21. Date of This Contact: [ ][ ] [ ][ ] [ ][ ] *day month year*

PREGNANCY OUTCOME:

22. Termination Decision: [ ]
    0) no termination at this contact--pregnancy will continue to term } *SKIP TO ITEM 29*
    1) lost contact
    2) pregnancy terminated

23. Pregnancy Outcome: [ ]
    1) spontaneous abortion
    2) induced by patient
    3) induced at this center
    4) induced elsewhere
    5) stillborn
    6) live birth--premature
    7) live birth--mature
    8) other _____

24. Congenital Malformation: [ ]
    0) no 1) yes 9) unknown

25. Estimated Gestational Age at Termination: [ ][ ]
    number of weeks 00) patient not pregnant

26. Re-estimation of Whether Pregnancy Occurred Before or After Last Procedure/Method Use: [ ]
    1) definitely before } *SKIP TO ITEM 27*
    2) probably before
    3) uncertain
    4) probably after
    5) definitely after

Reasons for Above Estimation, Based on Termination:

_____

27. Additional Reasons for Possible Contraceptive/Procedure Failure, Based on Termination:

_____

28. Date of Termination: [ ][ ] [ ][ ] [ ][ ]

29. Date of This Contact: *(if other than above)* *day month year*

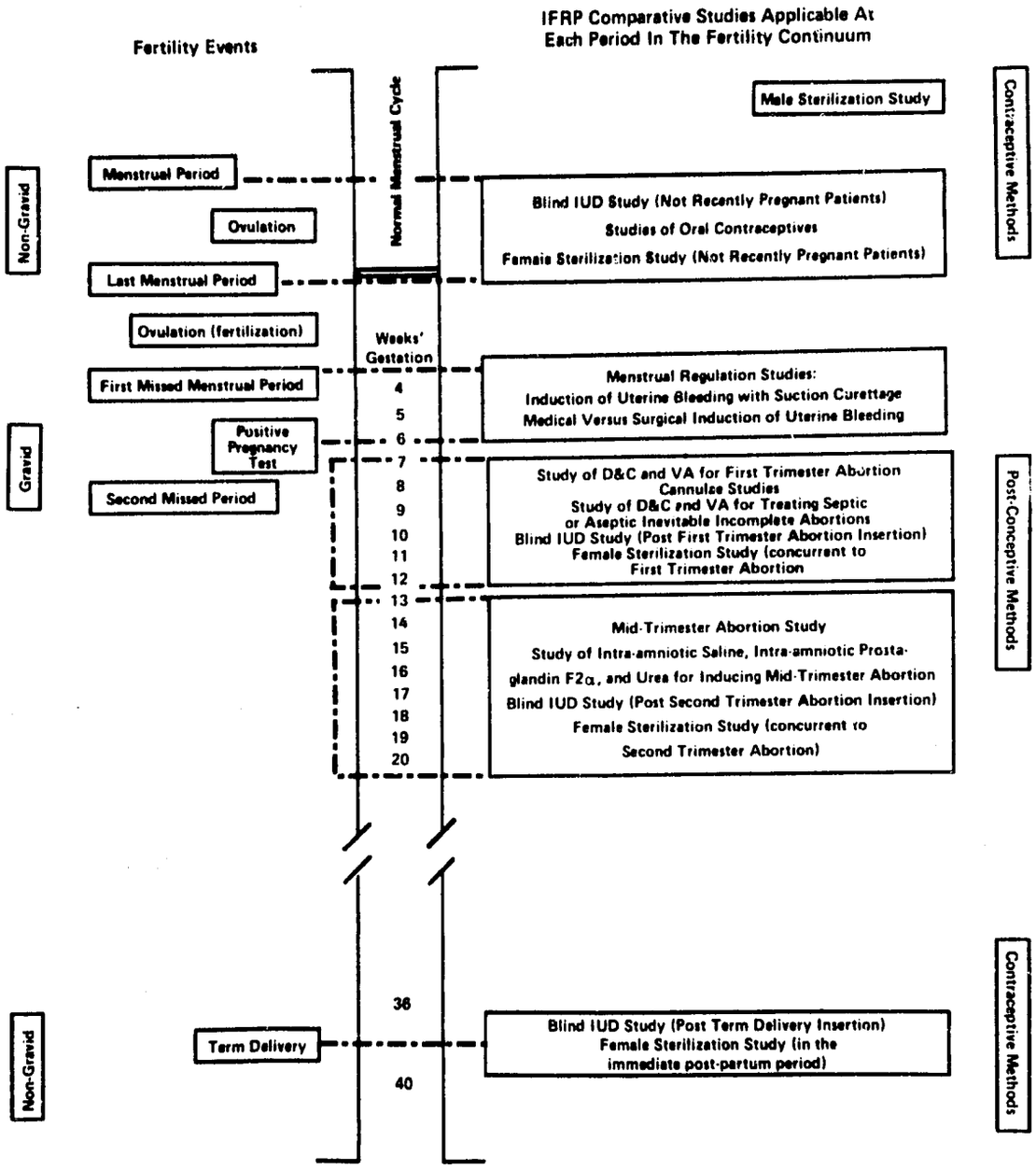
COMMENTS _____

IFRP/ PC / 9-73

AIRMAIL TO: International Fertility Research Program, Carolina Population Center, NCNB Plaza, Chapel Hill, N.C. 27514 U.S.A.

APPENDIX B

SUMMARIES OF IFRP STUDIES AND PROTOCOLS



I. AN OUTLINE OF THE PROTOCOLS

For all study areas (abortion, menstrual regulation, female and male sterilization, IUDs, and oral 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 oral 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. Method 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 two additional forms: the Method List and Consent Form. The principal purpose of the Method List is to record the method assigned to the subject and 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 Committee for the Protection of Rights of Human Subjects of the University of North Carolina School of Medicine which must approve all of IFRP's comparative protocols.

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. 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.

F. Supplies

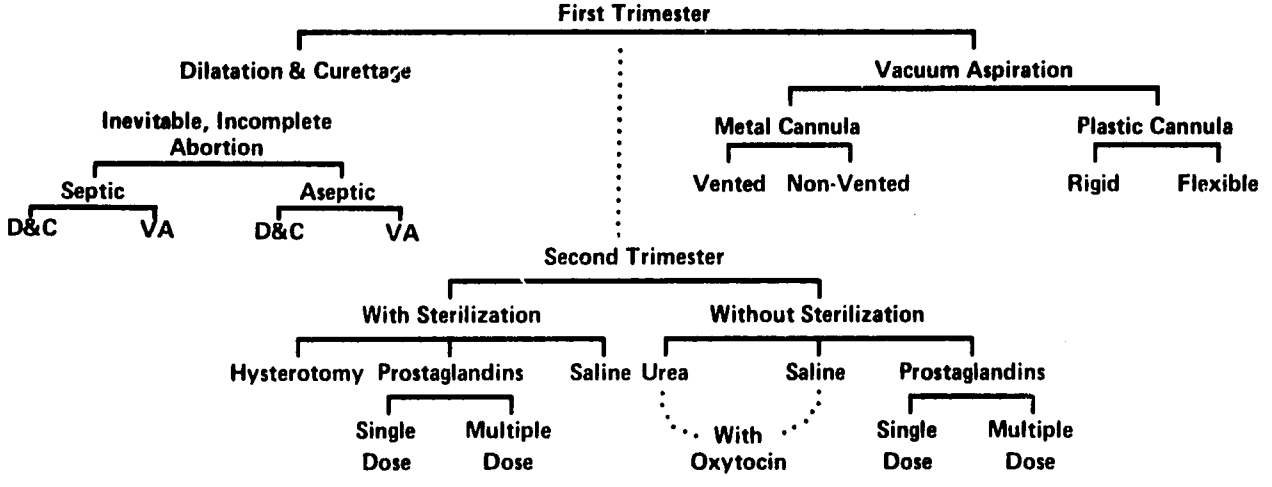
Prior to the start of a comparative study the principal investigator will receive from the IFRP all necessary supplies (forms and medical supplies) for the study.

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

1. C.H. Hendricks, M.D., Chairman, Department of Obstetrics and Gynecology, UNC School of Medicine
2. Research Review Committee (UNC Office of the Vice Chancellor for Health Sciences)
3. Committee on the Protection of the Rights of Human Subjects (UNC School of Medicine)
4. IFRP's Medical Advisory Committee
5. Studies Review Committee (IFRP)

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

II. PREGNANCY TERMINATION STUDIES



31

A. First Trimester Abortion Studies

Comparative Study of Ragab's Cannula

The objectives of this study are to compare Ragab's 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. These objectives are evaluated in a "blind" study design with a random allocation of methods (cannula with or without the jet stream) to subjects. One hundred and fifty subjects will be aborted by each method. All subjects will be required to return for a follow-up physical examination 2-4 weeks after the abortion. The data will be recorded on standard forms and sent each month to the IFRP.

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 generally physically healthy women requesting an artificial abortion will be studied. Standard procedures for performing the vacuum aspiration will be followed. All subjects will be required to return for a follow-up physical examination 2-4 weeks after the abortion. The data will be recorded on standard forms and sent each month to the IFRP for review.

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. The objectives are evaluated in a "blind" study design with random allocation of cannulae to subjects. Generally, physically healthy women requesting a therapeutic termination of pregnancy will be included in the study. Each type of cannulae 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 subjects gestational age. All subjects will be required to return for a physical examination 2-4 weeks after the abortion. The study will be conducted at a number of different hospitals, and the data will be recorded on standard forms and sent each month to the IFRP for review.

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. The procedures -- D&C or VA -- are randomly assigned to subjects in a "blind" study design. 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.

*Ragab, M.I., Jet Ejector Vacuum Cannula for Abortion: A New Engineering Principle. Contraception 4: 199, 1971.

32

Standard procedures for performing D&C and VA will be followed. All subjects will be required to return for a follow-up visit and physical examination 2-4 weeks after the abortion. All data will be recorded on standard forms and sent to the IFRP at monthly intervals for review.

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. The objectives are evaluated in a "blind" study design where the procedures--D&C or VA--are randomly allocated to subjects. Only generally physically 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 will be required to return for a physical examination 2-4 weeks after the surgery. The study will be recorded on standard forms and sent each month to the IFRP for review.

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 will be required to return for a follow-up visit and physical examination 2-4 weeks after the abortion. All data will be reported on standard forms to the IFRP at monthly intervals for review.

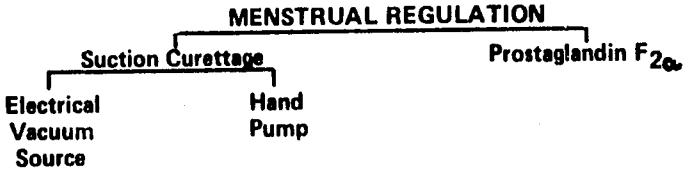
Comparative Study of Intra-amniotic Saline, Intra-amniotic Prostaglandin $F_{2\alpha}$, and Urea for Inducing Mid-Trimester Abortion

The objectives of the study are to compare the effectiveness and com plications 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 intra-

33

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 intra-venous oxytocin (200 mu/min). The study will also evaluate whether with each of the above abortion methods the administration of intra-venous 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 amnioinfusion 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 by the appropriate conventional therapy. All subjects will be required to return for a follow-up examination 2-4 weeks after the abortion. The data will be recorded on standard forms and sent each month to the IFRP for review.

III. 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 (Berkely 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. The objectives of the study are evaluated in a "blind" study design where the different MR procedures are randomly assigned to the subjects. 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 will be 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. The study will be conducted at a number of different institutions, and the data will be recorded on standard forms and sent each month to the IFRP for review.

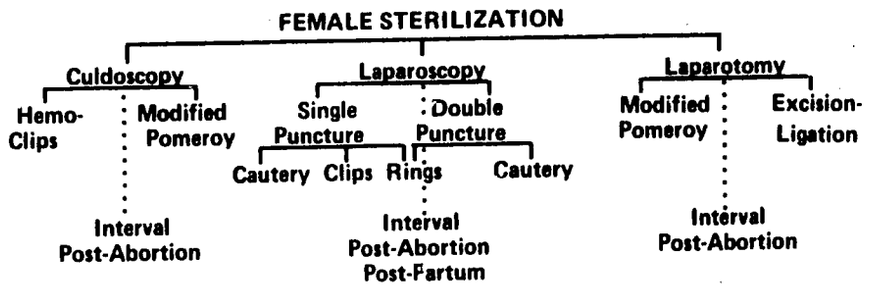
34

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. The study objectives are evaluated in a study design where the different MR procedures are randomly assigned to subjects. For each MR procedure 100 subjects will be studied. Only generally physically 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 meriperidine 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 plastic (Karman type) cannula and a 50 cc Karman syringe. All subjects will be 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. The study will be conducted at a few carefully selected institutions, and the data will be recorded on standard forms and sent each month to the IFRP for review.

IV. 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 methods of sterilization are: Modified Pomeroy, Shaw-Vienese, hemoclip, spring-loaded clip, silastic ring and cautery. The surgical approaches are laparotomy, 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. These objectives are evaluated in a study design where methods

are randomly assigned to subjects. A total of 150 subjects will be sterilized by each method. Only generally physically 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 hours emergency care and will be requested to return for follow-up examinations at 7-21 days and 6 months and 1 year after the surgery. Standard forms will be used to report the data which will be reviewed at monthly intervals.

B. Male

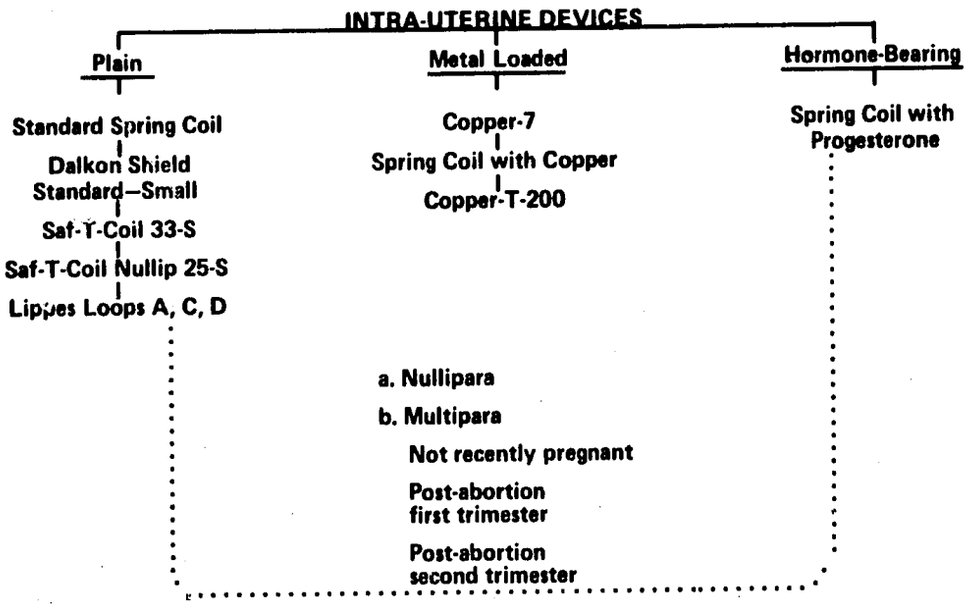
COMPARATIVE VASECTOMY TECHNIQUES

1. **Excision & Ligation of the Cut Vas Ends (Standard technique)**
2. **Cutting of the Vas, Proximal (testicular) Segment Folded and Ligated, Distal Segment Ligated Only**
3. **Excision of Vas, Ligation of Proximal (testicular) Segment and Covering of Distal Segment with Fascial Sheath**
4. **Tantalum Clip Application**
5. **Fulgarization of the Lumens of Cut Vas Ends (Schmidt technique)**

Comparative Male Sterilization Study

The objectives of the study are to compare the complications and failure rates of the sterilization techniques listed above. Each investigator selects two of the above 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 or not less than one month 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 at least one month later or after at least 5 ejaculations. All subjects will be required to return for a physical examination and semen test six months post sterilization. Standard forms will be used to report the data to the IFRP.

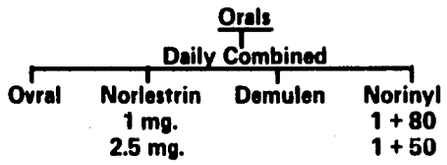
V. INTRA-UTERINE CONTRACEPTIVE DEVICES



Comparative "Blind" IUD Study

The objectives of the study are to compare the continuation rates and the specific complications associated with two or more IUD's over a two-year period. Only women with no gynecologic abnormalities and who have not previously used an IUD will be studied. The principal investigator will select two or more IUD's for study using one patient category. The study IUD's 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, and Copper T-200. Other IUD's will be included as they are developed. The patient categories are: Immediate post-abortion, immediate post-delivery, not recently pregnant (multigravida), and nulligravida. All IUD's are inserted within 1 week of the first day of the subject's last normal menstrual period, abortion, or delivery. IUD's are randomly assigned to subjects in a "blind" study design, with each study IUD assigned to 450 subjects. IUD's 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. Standard forms are used to report all data to the IFRP for review at monthly intervals.

VI. SYSTEMIC CONTRACEPTIVES

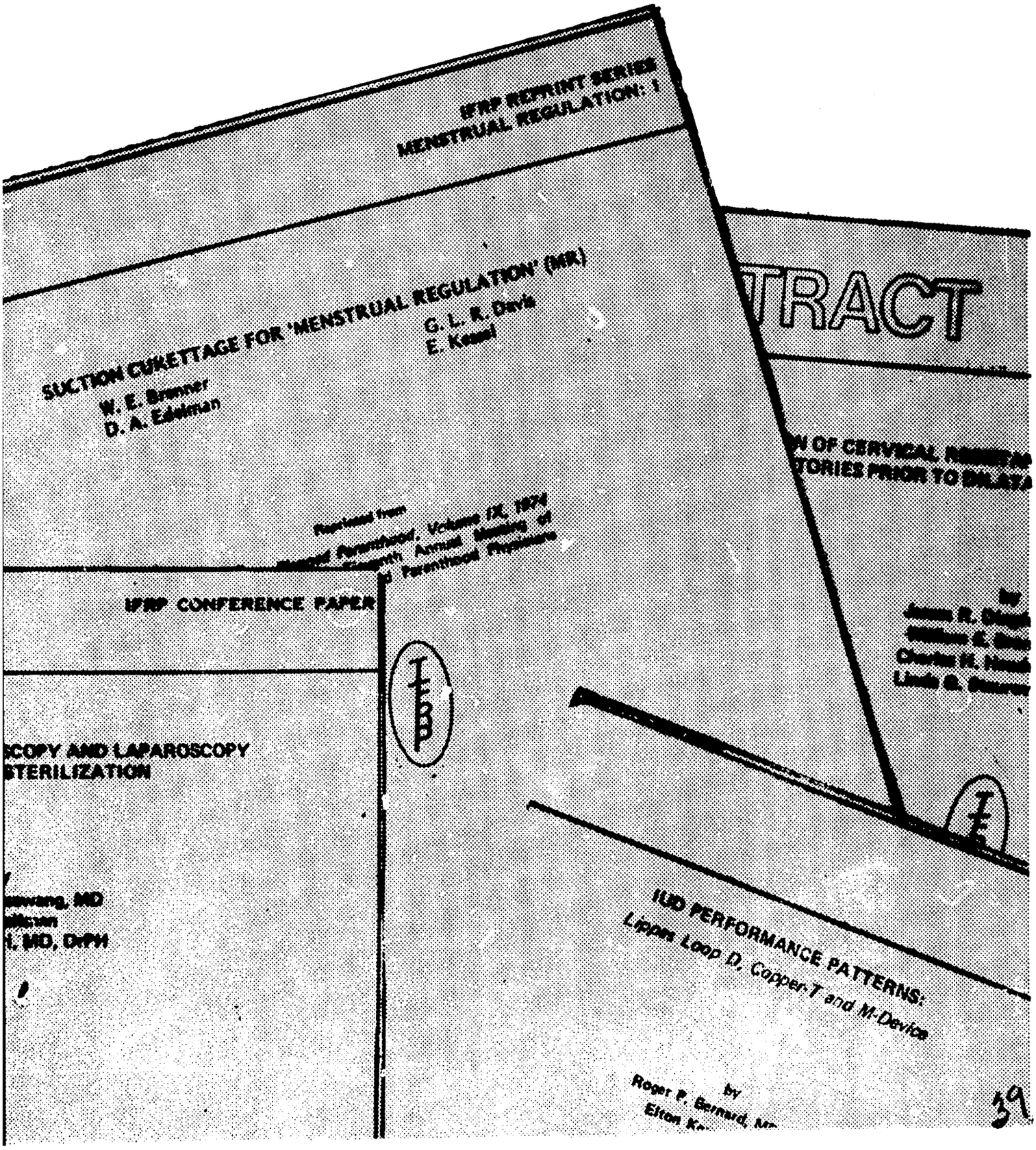


Comparative Studies of Oral Contraceptives

The objectives of the studies are to compare continuation rates due to medical reasons and the incidence of specific side-effects for two or more oral contraceptives. Generally physically healthy women between 15 and 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. All study drugs 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. Oral contraceptives are randomly assigned to subjects in a "blind" study design. Each study drug is assigned to 305 subjects. Standard forms are used to report all data to the IFRP for review at monthly intervals.

APPENDIX C

IFRP REPORTS AND PUBLICATIONS



INTERNATIONAL FERTILITY RESEARCH PROGRAM

PUBLICATIONS

1. Berger, G.S.; Edelman, D.A.; and Kerenyi, T.D. Oxytocin Administration, Instillation-to-Abortion Time, and Morbidity Associated with Saline Instillation. Accepted for publication in Amer. J. Obstet. Gynec.

2. Berger, G.S. and Kerenyi, T.D. Analysis of Retained Placenta Associated with Saline Abortion: Clinical Considerations. Accepted for publication in Amer. J. Obstet. Gynec.

3. Braaksma, J.T.; Brenner, W.E.; Fishburne, J.I., Jr.; and Staurovsky, L.G. Published: Amer. J. Obstet. Gynec., 114: 511-515, 1972.

4. Brenner, W.E.; Hendricks, C.H.; Braaskma, 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.

5. Brenner, W.E.; Hendricks, C.H.; Braaksma, J.T.; and Fishburne, J.I., Jr. Prostaglandin $F_{2}a$ 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.

6. Brenner, W.E.; Hendricks, C.H.; Braaskma, J.T.; and Fishburne, J.I., Jr. Intravenous Prostaglandin F_2 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.

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8. 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_{2a} 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.

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10. Brenner, W.E.: Hendricks, C.H.; Braaksma, J.T.; Fishburne, J.I., Jr.; and Staurovsky, L.G. Vaginal Administration of Prostaglandin $F_{2\alpha}$ for Inducing Therapeutic Abortion. Presented: District IV ACOG Meeting, Atlanta, Georgia, October 24, 1972. Published: Prostaglandins, 1:455-467, 1972.

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22. Edelman, D.A.; Brenner, W.E.; Davis, G.L.R.; and Childs, P. An Evaluation of the Pregnosticon Dri-Dot Test in Early Pregnancy. Published: Amer. J. Obstet. Gynec., 119:521-524, 1974.

23. Fishburne, J.I., Jr.; Omran, K.F.; Hulka, J.R.; Mercer, J.P.; and Edelman, D.A. Tubal Application of Lidocaine with Local Anesthesia for Laparoscopic Clip Sterilization. To be published in Fertility and Sterility.

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25. 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_{2a} 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.

26. 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.

27. Hendricks, C.H.; Brenner, W.E.; Ekbladh, L.; Brotanek, V.; and Fishburne, J.I., Jr. Efficacy and Tolerance of Intravenous Prostaglandins F_{2a} and E_2. Presented: Ninety-Fourth Annual Meeting of the American Gynecological Society, Phoenix, Arizona, April 14-17, 1971. Published: Amer. J. Obstet. Gynec. III:564-579, 1971.

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35. 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.

36. Berger, G.S. and Kerenyi, T.D. Control of Morbidity Associated with Saline Abortion. Association of Planned Parenthood Physicians, Memphis Tennessee, April 16-17, 1974. To be published in Advances in Planned Parenthood.

37. 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.

38. Brenner, W.E.; Hendricks, C.H.; Fishburne, J.I.; Dingfelder, J.R.; Staurovsky, L.G. Phase II Clinical Trials of Prostaglandin F_{2a}. Symposium on Methods of Evaluating New Drugs in Man, New Orleans, Louisiana, March 24, 1973.

39. Brenner, W.E.; Edelman, D.A.; Davis, G.L.R.; Kessel, E. Suction Curettage for Menstrual Regulation. American Association of Planned Parenthood Physicians, Houston, Texas, April 11-13, 1973. Published in Advances in Planned Parenthood, 1973.

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42. Brenner, W.E. The Technology of Post-Conceptive Regulation. Present Available Methods. Seminar on Voluntary Sterilization and Post-Conceptive Regulation, Bangkok, Thailand, January 31, 1974.

43. Brenner, W.E. Report of the Workshop on Complications of Menstrual Regulation. Menstrual Regulation Conference, Honolulu, Hawaii, December 18, 1973. Reported in: Proceedings of the Menstrual Regulation Conference.

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52. Hendricks, C.H.; Brenner, W.E.; Fishburne, J.I.; and Braaksma, J.T. Second Trimester Abortions Induced by Prostaglandin F_{2a}. VII World Congress of Obstetrics and Gynecology, Moscow, August 13, 1973.

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59. Kumarasamy, T. Laparoscopic Sterilization with Spring-Loaded Clips. The First Scientific Congress in Family Planning, The Family Planning Association of Sri Lanka, January, 1974. To be published in the Proceedings.

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OCCASIONAL PAPERS

74. 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. Submitted for publication.

75. Berger, G.S.; Edelman, D.A.; and Kerenyi, T.D. Fetal Crown-Rump Length and Biparietal Diameter in the Second Trimester of Pregnancy. Submitted for publication.

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77. Bernard, R.P. and Mehta, A.C. Clinical Abortions and Abortees in 1971 in India, the U.S.A., and Yugoslavia.

78. Brenner, W.E. Evaluation System for Postcoital Contraceptive Methods.

79. Brenner, W.E. The Use of the Karman Cannula with Vacuum Aspiration.

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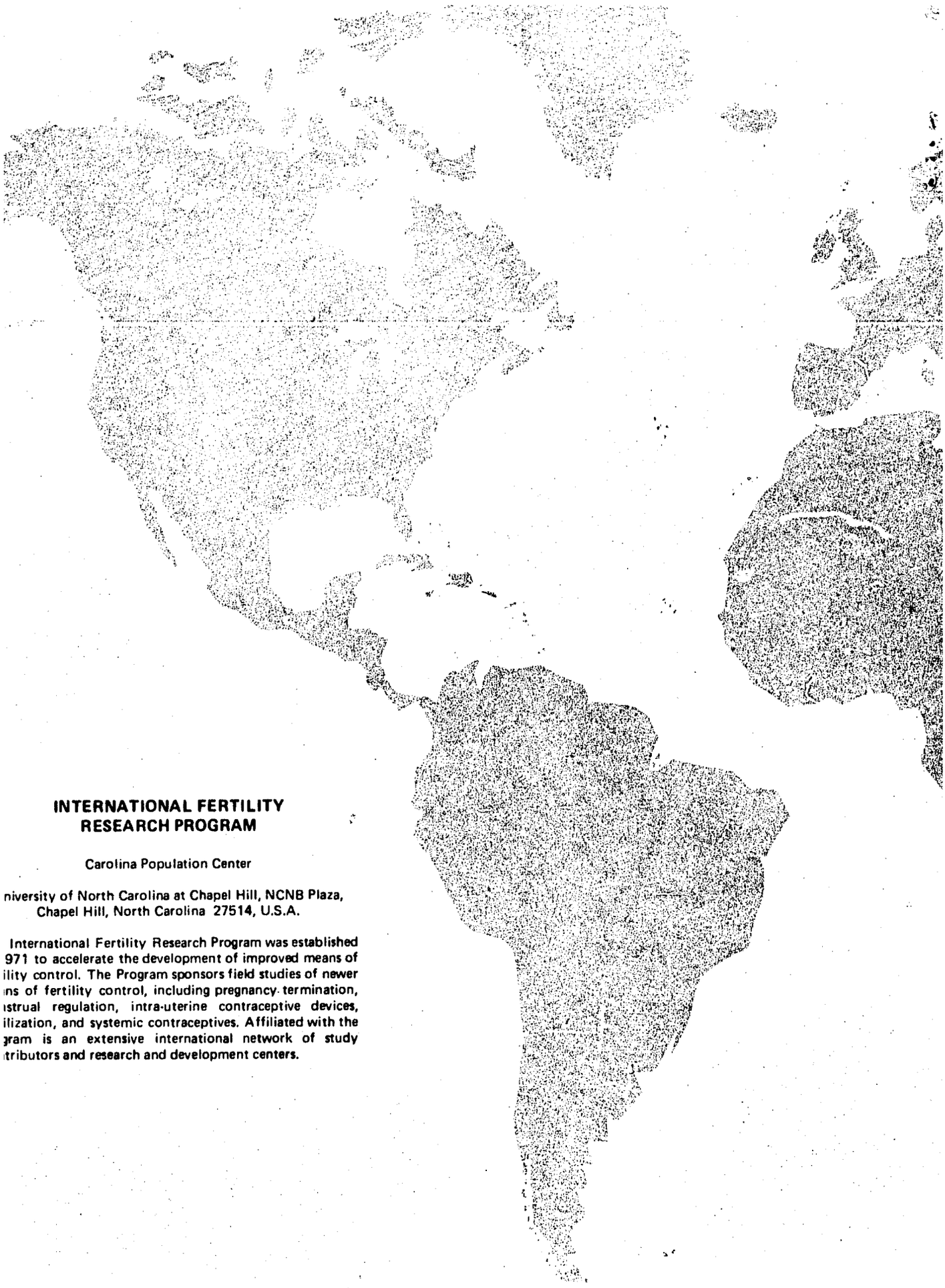

INTERNATIONAL FERTILITY RESEARCH PROGRAM

Carolina Population Center

niversity of North Carolina at Chapel Hill, NCNB Plaza,
Chapel Hill, North Carolina 27514, U.S.A.

International Fertility Research Program was established 971 to accelerate the development of improved means of ility control. The Program sponsors field studies of newer ns of fertility control, including pregnancy termination, strual regulation, intra-uterine contraceptive devices, ilization, and systemic contraceptives. Affiliated with the gram is an extensive international network of study tributors and research and development centers.