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<td>Authors</td>
<td>(101) Int. Fertility Research Program, Research Triangle Park, N.C.</td>
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**Abcmmum** 

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INTERNATIONAL FERTILITY RESEARCH PROGRAM

SIX MONTH REPORT

August 2, 1977 - January 31, 1978

A.I.D.
Reference Center
Room 165

AID Contract AID/pha-C-1172
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INTRODUCTION

The following report summarizes the activities of the IFRP for the first six months of the subject contract. The information is presented in a consistent format so that activities in different study areas are readily comparable.

The study areas that IFRP has been engaged in during this six month period include:

1. Intrauterine Contraception
2. Systemic Contraception
3. Female Sterilization
4. Male Sterilization
5. Barrier Contraception
6. Menstrual Regulation and Pregnancy Termination
7. Epidemiological Studies
8. Equipment Integral to Fertility Management
9. Program Evaluation

Each study area, when appropriate, has been subdivided into the following activities:

1. Protocols
2. Instruction Manuals
3. Data Collection Instruments
4. Scientific Papers
5. Consultant Reports
6. Clinical Trials

After each of these activities is a notation indicating whether the activity is continuing or was completed during the six months included in this report. A special analysis was completed, at the end of the first 120 days of the contract, assessing the input of all IFRP contributors. Those studies that were adjudged to be of low quality, or the information being gathered did not substantially add to the body of knowledge on fertility regulation, were closed out. Research Centers have now been reduced to less than 75 with a total number of contributors less than 250 persons. Tables and a schematic classification of contributing centers and studies are incorporated in Section X of the six month report.

Tables are also included which summarize the number of data forms processed, IFRP personnel transactions and total expenditures for the reporting period.
I. INTRAUTERINE CONTRACEPTION

Protocols

Immunological Response to IUDs - Completed; additional work will not be performed by IFRP.

1. To study serum IgG, IgM and IgA levels in women wearing IUDs of varying size and composition and a control group after one month, three months, six months and one year.

2. Correlate immunoglobulins IgA, IgG and IgM assay on cervical mucous to systemic levels, it may yield further clues as to the possibility of an immunologic basis for the mechanism of action of the device.

3. To study the biological effect of the presence of these immunoglobulins on sperm transport through the cervical barrier.

General Protocol - Comparative IUD Studies - Revised

1. To evaluate the continuation rates and specific complications of each IUD under study.

2. To evaluate which IUDs are the most acceptable over a period of one, two or three years to women of different parity groups, age, postpartum and other selected demographic characteristics.

Instruction Manuals

Instruction Manual - IUD Study Patient Record Forms - Completed

(IUD General Protocol - Comparative IUD studies)

Data Collection Instruments

Retrospective Szontagh IUD Study Form - Completed
Retrospective Szontagh IUD Study - PID Form - Completed
Retrospective Szontagh IUD Study - Spotting/Bleeding Form - Completed
Retrospective Szontagh IUD Study - Pregnancy Form for Deliveries (IUD in situ) - Completed
Retrospective Szontagh IUD Study - Ectopic Pregnancy (IUD in situ) - Completed
Retrospective Szontagh IUD Study - Fertility After IUD Removal - Completed
IUD Hysterosalpingography Studies Method List - Completed
I. Intrauterine Contraception, cont'd.

IUD Study - Supplementary Form for Postabortion IUD Insertions - Completed
IUD Study - Abnormal Odor or Discharge Supplementary Form - Completed
Pregnancy Confirmation Form - Completed

Scientific Papers

Two Modifications of the Pleated Membrane. Batar, I.;
Thomas, M.; Lampe, L.; Kessel, E. - Completed

Behilovic, B.; Thomas, M. - In Process

Hydron vs. Plain Spring Coil. Randic, L.; Thomas, M. - In Process

Szontagh Device and Szontagh Device with Copper.
Annus, J.; Thomas, M. - In Process

U-Coil with Progesterone. Behilovic, B.; Thomas, M. - In Process

The Ypsilon Experience in Debrecen. Batar, I.; Thomas, M. - In Process

Wheeler, R.; Yacout, M. and Tolbert, M. - In Process

Prescribing IUDs according to Acceptor Characteristics.
Wheeler, R. and Bhiwandiwala, P. - In Process

Comparison of Plain and Hydron Coated Spring Coils. Randic, L.
and Thomas, M. - In Process

Electrochemical Effects of Metals on IUDs. Zipper, J.;
Wheeler, R.; Silvia, A. and Adrian, H. - Completed

An Epidemiological Analysis of Intrauterine Contraceptive Devices--
A Preliminary Report. Chi, I-cheng, Kessel, E. and Mitra, M. In:
Risks, Benefits and Controversies in Fertility Control, Sciarra, J.,
Zatuchni, G. and Speidel, J., eds. - Completed

An Overview of IUD Research and Implications For the Future.
Congress of Fertility and Sterility, Miami Beach, Florida, April
12-16, 1977. - Completed

IUD Insertions By Midwives: Five Year's Experience in Santiago,
Chile. Pastene, L.; Rivera, M.; Zipper, J; Medel, M. and Thomas, M.
Presented: IX World Congress of Fertility and Sterility, Miami Beach,
Florida, April 12-16, 1977. - Completed
I. Intrauterine Contraception, cont'd.

Experience With Postpartum IUDs at Jose Fabelia Memorial Hospital, Manila. Apelo, R. and Ramos, R. IX World Congress of Fertility and Sterility, Miami Beach, Florida, April 12-16, 1977. - Completed

La Membrana Intrauterina (Un Dispositivo Intrauterino Experimental) en el Post-Abortion Precoz. Quan, A., Edelman, D., Ventura, T. and de Badia, D. - Completed

The Use-Effectiveness of Copper IUDs. Edelman, D.; Goldsmith, A.; Zipper, J. and Medel, M. - Completed

Contraceptive Effectiveness of Copper IUDs. Ghorbani, F. and Wheeler, R. - Completed

Assessment of Intrauterine Device Contraception. Goldsmith, A. and Taylor, B. 1st International Seminar, Recent Advances in Fertility Control, Sao Paulo, Brazil, September 23-26, 1977. - Completed

Consultant Reports - Completed

Uterine Structure and Device Design in Relation to IUD Performance. Kamal, I.

The Anderson Leaf: A Developmental Analysis. Anderson, I.

The Monterrey IUD: A Postpartum Experiment. Garcia Flores, R.

Comparison of the Bioactive Latex Leaf with two other Bioactive Devices Copper T and Copper 7 - and with the Plain Leaf. Agoestine, T.
II. SYSTEMIC CONTRACEPTION

Protocols

Ramadan Pill - to determine continuation rates of women starting oral contraceptives during Ramadan. - Completed

Lactation Pill - In Process

1. To determine acceptability of progesterone only pills among lactating women.
2. To determine differences in weight gain among infants of women on progesterone only oral contraceptives vs. infants of women on non-hormonal contraception.

Husband Pill - In Process

1. To determine if continuation rates improve when husbands participate in oral contraceptive program.
2. To determine if husbands have an accurate understanding of their wife's health status.

Instruction Manuals

Ramadan Pill form instruction manual (Ramadan Pill Protocol) - Completed

Instruction Manual for Systemics forms (changes in instructions for abbreviated forms) - In Process

Ramadan Pill form instruction (Ramadan Pill Protocol) - In Process

Data Collection Instruments

Ramadan Pill Form (Ramadan Pill Protocol) - Completed

Abbreviated Systemics Admission Form - In Process

Abbreviated Systemics Follow-up Form - In Process

Lactation Pill Form - In Process

Husband Pill Form - In Process
II. Systemic Contraception, cont'd.

**Scientific Papers** - Completed

Pattern of Breakthrough Bleeding Associated with Oral Contraceptive Use.


Probability of Side Effects With Ovral, Norinyl 1/50 and Norlestrin.
Berger, G. and Talwar, P.

The Risks and Benefits of Hormonal Contraception. Edelman, D.
1st International Seminar, Recent Advances in Fertility Control, Sao Paulo, Brazil, September 23-26, 1977.

Effects of Study Design on Reported Rates of Symptoms Associated with Oral Contraceptives. Talwar, P.

Effects of Cross-over from High Estrogen to Low Estrogen Combination Oral Contraceptives. Talwar, P.
III. FEMALE STERILIZATION

Protocols

Quinacrine Hydrochloride, a Nonsurgical Method of Female Sterilization. The study seeks to determine whether pellet insertion is an improvement over solution instillation in terms of complications and pregnancy rates and to determine a preliminary estimate of complication and pregnancy rates associated with transcervical application of the pellets. - In process

A Preliminary Study of IUD use and fallopian tube inflammation in women undergoing sterilization. The study is being conducted to further elucidate the etiology of pelvic inflammatory disease and its relationship to the use of IUDs, as well as which IUDs, if any, are associated with a higher risk of PID. - In process

Instruction Manuals

Revised Instruction Manual for the Female Sterilization Study (FS General Comparative Protocol) - In process

Instruction Manual for the Female Sterilization Study Patient Summary Form (No Protocol) - In process

Instruction Manual for the Female Sterilization Reversal Study (No Protocol) - In Process

Data Collection Instruments

FS Admission and Follow-up Forms revision (FS General Comparative Protocol) - Completed

Postabortion FS Study Method List revision (No Protocol) - Completed

Postpartum FS Study Method List revision (No Protocol) - Completed

Comparative FS Study Method List - Sections A&B (Spanish) (FS General Comparative Protocol) - Completed

Chemical FS Pre-Hysterectomy Study Form (No Protocol) - Completed
III. Female Sterilization, cont.

Tubal Specimen Study of Post-Sterilization Pregnancies Form (No Protocol)
- Completed

FS Patient Summary Admission and Follow-up Forms (No Protocol) - In Process

FS Reversal Admission, Follow-up and Supplement Forms (No Protocol)
- In Process

Comparative FS Method List - Section A&B (FS General Comparative Protocol)
- In Process

Scientific Papers


Minilaparotomy--The Procedure. Laufe, L. - Completed


Is Minilaparotomy Appropriate in the United States? McCann, M. and Bhiwandiwala, P. Annual Scientific Meeting of the Association of Planned Parenthood Physicians, Atlanta, Georgia, October 12, 1977. - Completed

The Fimbrial Prosthesis. Laufe, L. - Completed


En Anillo de Yoon en el Postparto Inmediato. Quiñones, R. and Muñoz, R. - Completed.
III. Female Sterilization, con't.

Nonelectric Female Sterilization Procedures and Their Potential Reversibility. Laufe, L. First International Seminar, Recent Advances in Fertility Control, Sao Paulo, Brazil, September 23-26, 1977. - Completed


Experience with the Tubal Ring for Female Sterilization. Quinones, R., Edelman, D., Alvarado, A., and Ley, E. - Completed

A Comparison of Interval and Post "Spontaneous" Abortion Laparoscopic Sterilization with Tubal Rings. de Badi, D., Edelman, D., Quan, A., and Llort, R. - Completed

Laparoscopic Tubal Ring Sterilization at the Chelsea Hospital for Women. Craft, I. and McCann, M. - In Process


Consultant Reports - Completed

Female Sterilization by Culdoscopy. Matin, M.

Female Sterilization by Minilaparotomy. Sheikholislam, T.

Female Sterilization by Minilaparotomy. Thambu, J.

Female Sterilization at the Tri-Service General Hospital. Chen, F.

Female Sterilization at Kasr El-Aini Hospital. Talaat, D.

Female Sterilization at the Maternidad Alexander Fleming. Lins, E.

Comparative Anesthesia Study. IGCC—Multiple Asian Centers
IV. MALE STERILIZATION

Protocols

Vas Flushing: This study is being conducted to document the effectiveness, complications and technical ease of the use of various spermicidal and nonspermicidal solutions for flushing and eliminating residual sperm in the distal portion of the vas. - In Process

Wives' Menstrual Pattern: This study is being conducted to gather menstrual pattern data on a control group of women whose husbands are being sterilized. These data will be compared with menstrual pattern data of women who are being sterilized. - In Process

Data Collection Instruments - In process

Vas Flushing Method List.

Wives' Menstrual Pattern Method List.

Scientific Papers - Completed

Vasectomy as an Outpatient Procedure in El Salvador. Henriques, E., Madrigal, V. and Cole, L.
V. BARRIER CONTRACEPTION

Protocols

Pilot Studies of the Contraceptive Sponge. The hypothesis to be tested is that the polymer sponge is a safe, effective and acceptable contraceptive. Pilot Studies are to provide an initial estimate of the incidence of side effects, frequency of complaints and rate of failure. - Completed.

Evaluation of Neo-Sampoon Loop Tablets for Prophylaxis Against Gonorrhea in Females. The hypothesis to be tested is that women using Neo-Sampoon will have a significantly lower rate of gonorrhea infection than women using no vaginal preparation. - In Process

Instruction Manuals

Female Barrier Contraceptive Study - Collatex Protocol. - In Process

Female Barrier Contraceptive Study (Short Forms). - In Process

General Barrier Protocol. - In Process

Data Collection Instruments

Female Barrier Contraceptive Study - Admission Record (Collatex Protocol) - Completed

Female Barrier Contraceptive Study - Admission Record (Short Form) (General Barrier Protocol). - Completed

Female Barrier Contraceptive Study - Follow-up Record (Collatex Protocol) - Completed

Female Barrier Contraceptive Study - Follow-up Record (Short Form) (General Barrier Protocol). - Completed

Gonorrhea Prophylaxis Study Coital Log. - In Process

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VI. MENSTRUAL REGULATION AND PREGNANCY TERMINATION

Management of Incomplete Abortion: Completion by Vacuum Aspiration and Sharp Curettage, Inpatient and Outpatient Procedures. - In Process

The Objectives of this study are:

1. To evaluate the practicality of outpatient management of incomplete abortions and the relative safety of suction and sharp curettage.

2. To evaluate the practicality of initiating contraception immediately after the abortion.

Instruction Manuals

Hospital Abortion Record - PRIF Short form instruction manual (No Protocol) - In Process

Hospital Abortion Record - English (No Protocol) - In Process

Hospital Abortion Record - Spanish (No Protocol) - In Process

Data Collection Instruments

Registro de Aborto Hospitalario - APROFAM short form (No Protocol) - Completed

Formulario de Aborto Hospitalario - Muestra Nacional (PRIF) (No Protocol) - Completed

Hospital Abortion Record - Completed

Menstrual Regulation/First Trimester Abortion (No Protocol) - In Process

Hospital Abortion Record - Portuguese (No Protocol) - In Process

Midtrimester Abortion Sequelae - WHC Interview Information (No Protocol) - In Process

Hospital Abortion Record - Short form (No Protocol) - In Process

Hospital Abortion Record - Spanish - In Process
VI. Menstrual Regulation and Pregnancy Termination, cont'd.

Scientific Papers - Completed


Competing Risks of Unnecessary Procedures and Complications. Fortney, J.; Miller E.; and Kessel, E.

The Menstrual Regulation Procedure. Laufe, L.

Menstrual Regulation Performed by Nurse-Midwives. Loghmani, M.; Kay, A.; and Mohyi, M.

Menstrual Regulation as a Method of Fertility Control. Kessel, E.


VI. Menstrual Regulation and Pregnancy Termination, cont'd.

Repeat Abortion: A Problem or Not? Fortney, J.; Burnhill, M.; and Armstead, J. Annual Scientific Meeting of the Association of Planned Parenthood Physicians, Atlanta, Georgia, October 12-13, 1977.


VII. EPIDEMIOLOGICAL STUDIES

Protocols

An epidemiologic study of hospitalized cases of thromboembolic disorders in a Singapore General Hospital 1971-1974. - Completed

Scientific Papers

A case-control analysis of IUD medical removals. - In Process

Uterine perforations during sterilization by laparoscopy and minilaparotomy. - In Process

Change in Fertility Patterns Associated With Oral Contraceptive Use in Urban, Rural and Slum Areas in Howrah District, India. Mullick, B.; and Wood, J. - In Process

Effects of Birth Order by Sex on Fertility in Howrah, India. Wood, J.; Mitra, M.; and Page, S. - In Process

An Evaluation of Menstrual Regulation Services Offered in the Howrah District of India. Mullick, B.; and Taylor, R. - In Process


A Case Control Study of Pregnancies Following Female Sterilization. Chi, I-cheng; McCann, M.; and Tolbert, M. - In Process
VIII. EQUIPMENT INTEGRAL TO FERTILITY MANAGEMENT

Data Collection Instruments

Dilation Method List - Completed

Scientific Papers

Non-electric Female Sterilization Procedures and Their Potential Reversibility. Laufe, L. - Completed


Consultant Reports - Completed

The Capillary Pregnancy Test Developed by Dr. H. Lorrin Lau: An Interim Report on 1214 Cases. Lau, H.

Regression Analysis of Hand Pump Performance. Williford, J.

Uterine Caliper and Sound. Zipper, J.
IX. PROGRAM EVALUATION

Instruction Manuals

Family Planning Clinic Record, December, 1977. - Completed
Community-Based Distribution. - Completed

Data Collection Instruments

Family Planning Clinic Record. - Completed
Bangladesh Family Planning Association: Clinic Record. - Completed
Farsi - Family Planning Admission Record - Completed
Family Planning Follow-up Record - Completed
IPPF - Family Planning Admission Record. - Completed

Birth Attendant Surveillance - Register of Births Attended
Birth Attendant Referral Card - In Summary of Birth Attendant Process Activities

Community Health Worker Record - Family Survey
Community Survey
Patient Register
Patient Register Codes
Patient Register Summary - In Diary of Activities Process
Performance Evaluation
Referral Card

Multipurpose Health Worker - Family Survey
Community Survey
Patient Register
Register of Community Level - In Activities Process
Status Report
Health Worker Information

Community-Based Distribution - Couple Registration Record
Follow-up Record
Daily Register
Status Report - In Special Status Report for Concerned Women, Da'cca, Bangladesh
IX. Program Evaluation, cont'd.

Scientific Papers

The Evolution of the Korean Family Planning Program. Donaldson, P. - Completed


The Interrelationship Between Marital Dissolution and Fertility. Janowitz, B., Koo, H. - In Process


Newer Developments in Female Methods of Fertility Control. Kessel, E. 1st International Seminar, Recent Advances in Fertility Control, Sao Paulo, Brazil, September 23-26, 1977. - Completed

Effect of Study Design on Reported Rates of Symptoms Associated With Oral Contraceptives. Talwar, P. and Berger, G. - Completed


Consultant Reports - Completed

Use of the Family Planning Clinic Record for Program Management and Evaluation. Castañeda Rugamas, L.; Arqueta, G.; Amador, M. and Bode, S.

Use of the Family Planning Clinic Record at the Asociacion Demografica Salvadoreña Clinic in San Salvador. Arqueta, G.; Castañeda Rugamas, L.; Amador, M.
IX. Program Evaluation, cont'd.

Clinical Trials

IPPF/IFRP Depo-Provera Monitoring

1. Surigao City Health Department
   Dr. Bernardo T. Mora, Sr.
   Surigao City, Philippines
   Family Planning Clinic Record
   - In Process

2. Bangladesh Family Planning Association
   Dr. Mozammel Hoque
   Dacca, Bangladesh
   Family Planning Clinic Record
   - In Process

3. Family Planning Association of Honduras
   Dr. Joaquin Nunez
   Tegucigalpa, Honduras
   Family Planning Clinic Record
   - In Process

4. Family Planning Association of Hong Kong
   Dr. Ho-Kei Ma
   Hong Kong
   Family Planning Clinic Record
   - In Process
X. IFRP CENTERS AND STUDIES

Figure 1
SCHEMATIC CLASSIFICATION OF IFRP CENTERS

CONTRIBUTOR NETWORK

PROPOSED GENERAL CENTERS

ACTIVE GENERAL CENTERS

INACTIVE AND ACTIVE RESEARCH CENTERS

ACTIVE RESEARCH CENTERS
### TABLE 1

**INTERNATIONAL FERTILITY RESEARCH PROGRAM CENTERS BY GEOGRAPHIC REGION**

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### Table 2

INTERNATIONAL FERTILITY RESEARCH PROGRAM STUDIES BY COUNTRY AND REGION

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**Subtotal: 84**
# Table 2

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XII. PERSONNEL TRANSACTIONS

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