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REPORTS OF CONSULTANTS
FOR THE EVALUATION OF THE
INTERNATIONAL FERTILITY RESEARCH PROGRAM
IFRP - AID/csd - 2979

A.I.D.
Reference Center
1100 15th St

Submitted By

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OVERVIEW OF THE EVALUATION REPORT ON
THE INTERNATIONAL FERTILITY RESEARCH PROJECT

Michael S. Burnhill, M. D., M.Sc.

This overview is based on a site visit to Chapel Hill, N. C., a field trip that covered a visit to 13 contributors in eight different countries, and attendance at an international meeting held in Palm Springs, California. This report is my personal account which will later be integrated with the reports of the three other evaluators.

The International Fertility Research Project currently is supervising investigations at 91 centers located in 21 countries. Details of the types of investigations and centers are outlined in the Status Report, April 1975. Page one of this report includes the objectives of the IFRP. These are to:

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

It is against the framework of these objectives that the evaluation will be carried out.

A. Overall Attainment of Stated Objectives

1. Scientific Field Testing: The IFRP appears to be performing an excellent job in testing promising developments.
2. Shortening the Introductory Time of Innovations: The IFRP appears to be doing an excellent job in assisting the introduction of innovations.

3. Dissemination of Information: It is difficult for me to assess the impact of current IFRP techniques in dissemination of information. The distribution of preprints, and self-printed papers apparently reaches a limited but highly selected audience. Many of the papers are not of sufficient importance for publication in major international journals because of their limited scope or nature. It would be advantageous to assist contributors to publish in their local, national or regional journals as this might have more impact in the innovation introduction. A similar comment may be made about participation in meetings. It is perhaps even more expensive to use a number of IFRP staff to present these papers. Greater efforts should be made to continue the work of presenting concurrent workshops, or having contributor presentations at regional meetings where their work can be discussed and disseminated in the area. Contributors workshops and meetings appear to be popular and valuable to the cooperating centers and should be encouraged. It would be desirable (fortuitous and economical) if more of these could be appended to regional and international meetings.

B. General Administrative Procedures

1. A number of problems appeared during the site visits. These are, in part, related to the separation of IFRP from the University of North Carolina, which resulted in the disruption of a number of administrative channels and the necessity for

developing new procedures and policies. However, other problems related to poor, sluggish, and indifferent processing of communications from the contributors.

These communications may be through direct correspondence or by conference with area coordinators, or other members of the IFRP staff.

2. Amongst the procedures which need clarification with the contributors are:
 - a. Contractual Confusions and Problems: Individualization of contract costs, and form reimbursement.
 - b. Provision for inflation, especially as it relates to airmailing of forms.
 - c. Clarification that agreement between contributor and IFRP does not constitute authorization to begin a project until a signed contract by AID has been returned to the contributor.
 - d. Development of a mechanism to suspend or terminate unauthorized studies.
 - e. Development of some alternate payment arrangements to allow for start-up costs on larger scale projects, particularly in the well-established field testing centers. This might involve a combination of an initial payment, followed by the "form-filled payments".
 - f. Clarification with the investigators of the informed consent clauses, and the means of recording and retaining these consents.

- g. Payments: Many complaints about late, missing, or incomplete payments were made. Efforts should be made to speed up bookkeeping procedures and to handle contributor complaints about reimbursement.
3. Data Processing - Forms: A number of investigators noted that the forms were either too long (especially menstrual regulation) or not locally selective (did not selectively code for local ethnic groups or religions). With respect to the latter it was not made clear to them that these items could have been coded in "Additional Studies". Another frequent complaint was the difficulty and cost required to use bilingual coders and interviewers. It would be very helpful to have all forms translated into the local language and use the identical coding process to simplify local problems. It also appeared quite possible in a number of centers to have cards key punched locally and a type prepared on a local computer. This holds promise of markedly reducing key punching costs, mailing costs and processing time. Delays in shipping forms have produced problems.
4. Equipment Problems: Many contributors are having problems repairing equipment and obtaining supplies. In some cases In some cases the IFRP could assist by providing supplies and equipment rather than cash to the contributors. In other cases, it might be advantageous to locate repair sources or develop a regional repair facility to help these programs.

5. Evaluatory Feedback: Several contributors complained that they had not received printouts in a long time, or that they received printouts without any accompanying consultant report, or that they did not know that they could request printouts or additional types of tabular material from the data already in the computer. There did not seem to be clarity on the part of all the contributors as to the nature or extent of information which they could ask for or which they could receive from IFRP regarding their contributions. In particular, some statements regarding comparative performance appeared to be very important to them. The ability of IFRP to supply this data, to evaluate the quality of the material and to outline when and how much feedback would be provided should be clarified.
6. Role of the Area Coordinators: Several contributors seemed puzzled by the area coordinators. Communications given them relating to the state of a contract, fee payments, problems with equipment, seem to have been poorly handled. In some instances, the area coordinator visited the area without visiting the contributor, on other occasions the contact was made over the telephone or in the hotel. The role of the coordinator in transmitting communications, assisting the contributor with his studies, reviewing his work in progress and supplying the contributor with progress reports should be more rigorously defined and complied with.

C. Publications and Presentations

1. Several investigators complained of some pressure for joint authorship of papers having been applied.
2. On at least one occasion travel for presentation of a contributor's paper was turned down while it was approved for an area coordinator who had little personal experience with the technique and who would have been inappropriate to present the paper. It would appear to be generally more beneficial if presentations were given by the contributor, except for pooled investigations.

D. Medical Questions

1. One investigator questioned the carrying out of an investigation after it had been shown to have inferior results. It would appear prudent to terminate poor result studies even if the target number of cases has not been reached.

Spent all day reviewing policy program and objectives with Dr. Kessel, Michael Thomas and other members of the staff. Numerous programs were reviewed. Some questions were raised about late payments. These were supposedly resolved. The mechanisms for key punching, and error detection on IFRP forms were discussed. These related to internal control of quality and not to the quality of data filled on the form, accuracy and reliability of the material submitted.

The reliability of the investigators was to be determined by area coordinators who are responsible for on-site inspection. We were assured by Michael Thomas that the computer programs recognized consistent errors in coding and that review of the print-outs revealed obvious errors of omission such as lack of pregnancies with IUDs or complications with menstrual regulation.

A considerable amount of material was given to us for review before our evaluation and for use during the trip. These included IFRP status reports, Annual Report 1974, Financial Statement June 1975. Some proposed study outlines, a code list for all studies, a status report for each center that we were to visit, indicating whether the contracts were signed or pending, the number of forms received, payments made and status of the study.

Numerous reports of field trips by IFRP staff. Internal memos relating to validity checks on IFRP data, a statement of compliance with A. I. D. requirements for human subjects' rights and welfare.

The subject of apportionment of funds for writing and developing new proposals was discussed. The question arose over time spent writing up a K.A.P. proposal. It was pointed out to them that proposal development funding should be derived from their general administrative overhead funds.

The possibilities of cooperation with FIGO were discussed as well as the developments in India towards an independent regional data collecting and processing center.

LONDON - OVERVIEW 9/15/75

Visited Richard Beard and Brian Lieberman at St. Mary's Hospital and reviewed IFRP matters. They had no payment problems in the last few months. The method of recording informed consent was discussed. They use oral consent after a discussion by the resident. They felt adequately visited by IFRP. They had had problems with one batch of clips that were defective. Following the discussion a clip procedure was observed at Samaritan Hospital (performed by Dr. Lieberman). He used a two punch technique using a new Rocket applicator that appeared well-designed.

In the afternoon we had a discussion with Ian Craft and his resident. He had some complaints about the Band Equipment and one band that shredded on loading. He felt that the IFRP form was too long. After his hospital ethics committee approved a project the patients had only to sign a routine sterilization form.

PROBLEMS:

1. Some treatment problems with quality control of clips, bands, original clip applicators, fogging of the laproscope lens.
2. IFRP form too complicated for widespread use.

RECOMMENDATIONS:

1. Feedback and correction mechanism for new equipment.
2. Review of necessity for all the items on IFRP forms.

This report is based on a site visit conducted 9/18 and 9/19. The fertility Institute facilities were examined and the abortion service at the maternity hospital. History taking, two vacuum aspiration procedures under paracervical block, the recovery rooms were observed. The state of the projects and the relationships to the IFRP were discussed at length with Dr. Andolsek and some of her staff.

PROBLEMS:

1. Investigation does not receive evaluatory feedback as to the comparative results obtained. No discussion as to significance of results in print-outs.
2. Mechanism for terminating studies with obviously inferior or morbid results not clear.
3. IFRP requests removal of some IUDs at end of study whether or not patient is content with IUD. Seems to lack sensitivity to patient's needs and wishes in study.
4. Postage for airmailing of forms not included in processing cost.
5. Processing costs do not have a provision for inflationary changes.
6. Frequent requests from IFRP for additional data, including non-IFRP material, are burdensome to staff, both financially and in terms of interrupting their ongoing work load.

RECOMMENDATIONS:

1. A. Progress reports to investigation after 3-6 months or as needed, interpreting data trends and giving clinical evaluation as to quality of work.
B. Investigators meetings to discuss details of studies.
2. Provision for either IFRP or investigator to terminate studies for cause without completing contractual number of cases.
3. Patient given continuation option for IUD studies.
4. Include (lump sum pre) payment for postage.

5. Include provision for advance payment/form.
6. Decrease frequency of data requested.
7. Switch to combined contract and "form filled" payment methods.

Dr. Rhagab spent a morning with us. The visit took place in his private office. He kept most old IFRP forms in a difficult to reach closet. His IFRP records were in cubby holes all over the office. Additional IUD construction equipment was present in the office. No visit to his clinical facilities took place. Dr. Rhagab stated that he filled out the forms himself. He also indicated that he paid the doctors, nurses, social workers, and air mail postage personally with daily cash payments.

Dr. Rhagab stated that he had received no payments in 1975. IFRP status summary supplied to AID just before evaluation indicated four to five payments were made, and that studies already completed in 1974 were not completely paid for. He showed us a completed menstrual regulation study (Study 443) for which no AID approval or signed IFRP contract was available. He apparently began the study based on a letter passed on to him by K. Omran, noting that IFRP had requested contract approval from AID.

Dr. Rhagab seemed confused regarding questions and needing to show us IFRP related materials. His planning for the visit was poor though he claimed he had not gotten E. Kessel's detailed letter of instructions. No other contributor meetings were arranged or scheduled. Letter from Kessel to Rhagab which Rhagab denied receiving had requested Cairo contributors be convened. Rhagab made no attempt to contact any, even after our arrival.

ADDITION: K. Omran has visited Rhagab project three times in the past year. Discussions with her as to how these matters were considered appears warranted. Informed consent is clearly not obtained (Rhagab states he was told he did not need to retain and file consents obtained. He stated only information given to patient is "This is the only up to date abortion you can get." He says he wouldn't get patients if he explained risks.

EVALUATION PROBLEM:

1. Details of notifying contributor regarding signing of IFRP contract seemed confused, especially in respect to Project 443.
2. Contributor not advised to stop sending forms or to stop study pending approval of contract (Study 443) after IFRP received first batch of forms.
3. Airmail requests for forms not compensated for.
4. No outline of bookkeeping requirements seemed available at onset of studies.
5. Clinical facilities and staff not seen or reviewed.

RECOMMENDATIONS:

1. Clearly advise contributors of contract signing and project start-up times.
2. Immediately stop all unapproved projects.
3. Allow for costs of airmailing forms.
4. Outline fiscal requirements and procedures for participants.
5. Have an independent clinical evaluation of program as to the contributor and his projects.
6. Evaluate adequacy of communications of IFRP area coordinator with contributor.

ASSIUT - 9/22/75

Dr. Fathalla and Dr. Morad gave us a tour of the maternity hospital and endoscopy unit. We were permitted to observe the application of a yoon band on a woman who had had an incomplete abortion. A discussion of the IFRP project was held with the addition of Dr. Shaaban and two other physicians. Dr. Fathalla indicated that they were pleased with the IFRP forms, with the instruction and information delivered by Dr. Omran and by Dr. Kessel's contributions to the Alexandria endoscopy meeting. They did indicate that they were not clear on the fiscal requirements. They had recently sent 10 completed menstrual regulation forms, along with 27 other forms for initial processing. They were awaiting more M. R. forms to continue with the study.

PROBLEMS:

1. Fiscal methods not completely outlined by IFRP.
2. Informed consent not completely outlined by IFRP.

RECOMMENDATIONS:

1. Outline requirements re disposition of funds.
2. Outline requirements re informed consent.

Visited Dr. Suporn Koetsawang at the Sirirat Hospital. Watched him perform a Yoon Band Sterilization, a tubal cauterization, and his resident a mini lap. His unit has modified the IFRP form to provide additional data. They are prepared to key punch their own data cards if they could obtain a key punch machine. A Thai key puncher gets approximately \$100 a month.

FINDINGS:

1. They appreciate IFRP assistance in writing papers and getting them published.
2. Payment for forms received very late.
3. Like the contributors meetings held in conjunction with other Asian Conferences.
4. Do not get back much evaluation interpretation or comparative interpretation of their material.

RECOMMENDATIONS:

1. Prompter payments.
2. Regular contributors regional meetings.
3. Review by IFRP of their material by statistician or area coordinator, etc., for trend analysis, and comparative statements.

Dr. Kambeang Chaterrachinda at the Ramathibodi Hospital arrived unexpectedly as he had not gotten IFRP letter. Reviewed techniques and instruments for mini laproscopy with Dr. Vitong.

PROBLEMS:

1. Received only one payment check for 1975 without response to inquiry.
2. Could not perform comparative study because forms arrived late (used Xeroxed copies for a while).
3. No personal contact with center. Dr. Saha has not visited - only communicated from hotel.

4. Have not received print-out of material sent to IFRE since 1973.

RECOMMENDATIONS:

1. Speed payments, improve financial handling.
2. Better, prompter form shipments.
3. Visit to site at least once a year.
4. Print-out and comparative evaluations at regular intervals.

Kandang Kerbau Hospital - Visited with Dr. Lean and his staff.

Had an extensive discussion each day. Watched menstrual regulation Clinic Monday -- Dr. Vengadasalam performed three sterilizations on 9/30. Checked our Xeroxed IFRP records against their records. One IFRP form missing. Five hospital records could not be located.

PROBLEMS AND COMMENTS:

1. Late payment; too low with inflation.
2. A long delay between promise and delivery of new equipment.
3. Gets comparative data.
4. Need regular feedback on inconsistencies.

RECOMMENDATIONS:

1. Speed payments; improve financial handling.
2. Expedite delivery or make more realistic.

GENERAL COMMENTS BY DR. LEAN:

1. Questions about using local key punching and local data processing.
2. Possibilities of regional centers for teaching, data assembly, technical development.
3. Question about using IFRP as clearing house for private sector drug testing.
4. Quality of middle management, i. e., area coordinators -- means of recruiting and employing senior management in areas such as advertising, board review, etc.
5. Questions about cost of publishing in U. S., binding, etc., higher than local area printing.

JAKARTA - OVERVIEW 10/1/75

Visited the Raden Saleh Clinic which is the old maternity clinic of the General Hospital now designated as the Human Reproduction Center. It is being rebuilt with funds generated from M. E. and sterilization. A conference was held with the staff, including Dr. Sudraji Sumapnata, the Director, Dr. Arie Doodoh, Dr. Rahadi Santo and one other person. A culdoscopy pomeroy type sterilization was observed. Minor difficulties were encountered due to breakdown of the retractor light. It was stated that one of their laproscopes was out of repair. No local repair facilities are available.

We then visited the Suka Mulya Clinic, a private facility. We were taken on a tour and then we watched a menstrual extraction performed with atropet premedication, using a Chinese vacuum pump.

After this, a visit to the National Family Planning Coordination Board where the demographic aspects of Indonesian family planning programs were discussed. They appear to be falling 30% short of their goals this year.

PROBLEMS:

1. Considerable difficulty in filling out forms in English.
2. Not all IFRP forms coded to local demographic categories.
3. Not all local Family Planning methods coded.
4. Study 433 completed while contract was pending; not stopped by IFRP.
5. No consent note on charts for M. E.
6. Problems getting equipment repaired and obtaining additional equipment.

RECOMMENDATIONS:

1. Translate form to local language.
2. Add local religions, races, as needed.
3. Check for additional local needs.
4. Clarify contract procedure.
5. Allow payment in the form of equipment purchases against their grant receipts.

JAKARTA - 10/2/75

Had a tour of the General Hospital and conference with Dr. Hanifa Wiknjosastro and his staff. Dr. Hanifa and Dr. Sudraji noted that of 11 government medical schools only three had expressed interest in a women's reproduction center and of these only the Raden Saleh was in actual operation. The laproscopy unit was being directed by a Hopkins trained gynecologist. The unit production of sterilization was low due to high volume of complicated gyn and ob. work at the hospital, and the presence of only one laproscope. The menstrual regulation unit at the hospital is in the same space as the Family Planning Clinic and is quite cramped. For political reasons M. R. is being kept as a low profile and being done as a "study". The Family Planning Clinic had fewer patients in 1974 than in 1973, with the greatest drop in IUD insertions. Apparently the CU 7 and CU T are reviving interest in IUDs.

At the discussion both Dr. Hanifa and Dr. Sudraji felt that data collaboration was important in establishing credibility for M. R. and also was somewhat politically protective. The latter was also of great interest to the BKKFN.

Dr. Sudraji requested all possible assistance in the administrative aspects of a Human Reproduction Center.

Dr. Burnhill discussed possibility of using an administrator with a business administration background to help develop and run the clinic. The possibilities of using clinic fees to assist in clinic development was raised as well as the question of whether the World Bank would offer credit for developing self-sustaining Reproductive Health Centers. The motivation to obtain and pay for M. R. appears to be quite high.

The need to emphasize the negative and harmful effects of illegal abortion, and to present data on the economic, social, and medical costs of the problem were suggested as a possible political strategem.

Mr. Suryochondro, Managing Editor of the Indonesian Journal of Obstetrics and Gynecology and an attorney interested in population problems was present at the meetings and maintains an office adjacent to the Ob/Gyn Library.

PROBLEMS:

1. Data collection on the IFRP model, especially for M. R., is a politicized issue.
2. Administrative and technical guidance is needed to assure success of Raden Saleh Clinic.
3. Insufficient data currently available on abortion problems in Indonesia.

RECOMMENDATIONS:

1. Retain Raden Saleh in IFRP data collection system.
2. Try to provide technical assistance to Raden Saleh.
3. Develop general technical background material on harmful effects of induced abortion.

4. Try to provide Raden Saleh with sufficient equipment to expand the volume of sterilizations and serve as a training center for Indonesian gynecologists.
5. It may be advisable to provide an administrative internship for one non-physician (i. e., PPNYC, Sanger Center).

Visited Dr. Astawa and Dr. Tjitarsa at the BKBBN office.

Dr. Astawa has a chart locating F. P. clinics on Bali as well as a breakdown on new acceptors by method and location. He indicated extensive correspondence and problems with IFRP relating to funding. A letter from E. Kessel dated February 1974 indicated a commitment for a study at \$3.50 a case, including histopathology. An advance of \$250 was sent -- no money since then though they have completed the original series.

They received a signed contract for a 1975-76 study to begin in October 1975 at a slightly higher contractual rate. In the meantime they apparently owe money on the histopathology. The original technique was demonstrated by Dr. Laufe when a team visited in February 1974. The technique has become very popular. Apparently by word of mouth 200-300 are being performed per month. They are distressed by lack of back-up equipment for the syringes and an impending shortage of cannulas. They have had cannula breakage and sterilize the cannulas in formalin. One of the gynecologists on the island is opposed to M. R. but in favor of sterilization. The other is for both procedures.

They have read a printout for their first 412 cases and a letter indicating they (IFRP) would help them write a paper with Judith Fortney as co-author. She is expected to visit in the near future.

They would prefer a closer source of information and training such as Dr. Hanifa's Raden Saleh Clinic in Jakarta, which is very highly considered in Indonesia.

We visited Dr. Tjitarsa's private office in the evening where Dr. Darney saw an M. R. performed. Facilities are rudimentary though the patients were uncomplaining. They paid 1,000 Rupiahs (\$2.50) for the procedure.

PROBLEMS:

1. Contractual and fiscal difficulties.
2. Back-up equipment not available.
3. Purchase source for cannulas not known.
4. Money owed for histopathology from previous contract.
5. Problems using MFRP form in English.

RECOMMENDATIONS:

1. Clarify continental assignments.
2. Supply Battelle Hand Pump.
3. Supply IPAS Information.
4. Pay back monies.
5. Translate form.

We met with Tom Harriman from the AID mission and were briefed on the progress of the Korea Sterilization Program. Of particular interest was the effectiveness of the JHIPIEGO Program and the problems of distributing laproscopic equipment. We then proceeded to the Korean Institute for Family Planning where we were briefed by Mr. Donaldson from Population Council and then met the KIFP Deputy Director, Dr. Dae-Woo Han Kap Suk Koh, Director of the Evaluation Division, and several members of their staff. A lengthy discussion as to the possibilities of using the IFRP forms and/or consultation ensued. It was recommended that KIFP develop their own briefer form that would be coded as the IFRP form so that they would be compatible. A sample of their form was reviewed but was too rudimentary for real consideration.

In the afternoon we met with Dr. Hyun-Mo Kwok from Yonsei University. He had just returned from Japan where he presented a paper on his experience with the Fallop Ring. He had his own tabulations for this study as an IFRP print-out was not available. He didn't seem to realize that he could have requested one prior to the paper. He also expressed the usual problems with filling out forms in English, airmailing processed forms. He reported spending an afternoon with Dr. Saha at her last visit to Seoul. He was very pleased with the Fallop Ring technique -- so far having both fewer complications and a lower complication rate than with the cauterization. He showed us a program indicating that both Saha and Pachauri were listed as co-authors of a paper at the Association of Gynecologic Laproscopists. He indicated some discussion regarding IFRP processing data for him with Saha but no relevant response to date.

In the evening he invited us to dinner with Jae-Mo Yang, Dean of Yonsei University, President of PPF of Korea and Director of the Yonsei Center for Population and Family Planning, along with members of his staff. Some of the demographic problems of Korea were discussed.

The role of Yonsei in training Korean M.D.s was explored during both the afternoon and evening discussions. Dr. Kwak indicated that he felt mini-lap. was better for rural areas and that surgeons of all types could be trained in the procedure.

10/8/75

We met with Dr. Chang at the Seoul National University. He had first completed a personal series of 1000 tubal cauterizations and presented his results at a Japanese Gyn Society Meeting. He also was going to be training Korean physicians for laproscopic sterilization. So far he had not been paid by IFRP, or gotten any print-outs from them.

Dr. Saha had not visited him on her last Korean visit. He too has had difficulties with the forms being in English. He needed additional equipment to do training for the JHPIEGO Program. He would have liked some training films on laproscopy.

We discussed some problems with Keun-ding Rhoa, Chairman of the Department, who had just presented their results with menstrual regulation in Japan. They felt that the IFRP form for M. R. was more complicated than the procedure.

PROBLEMS:

1. Late payments.
2. Forms in English.
3. Failure to clarify IFRP supplying of print-outs for paper presentation.
4. Inclusion of IFRP staff members as authors of paper.

5. Failure to further explore data processing capabilities of KIFP.

RECOMMENDATIONS:

1. Prompter payments.
2. Translate form into local language.
3. Careful elucidation as to rules, and requirements for pre-paper print-outs.
4. Delineating ground rules for including IFRP staff as co-authors of a paper.
5. Further exploration of local data processing to reduce cost of IFRP overhead.

Members of the staff of IFRP and Investigators presented papers at the 1975 International Family Planning Research Association Meeting in Palm Springs, California.

The first session of the meeting was devoted to international speakers. The session covered nine papers and lasted approximately two hours and 15 minutes. Six of these papers were under IFRP auspices. Four were accompanied by pre-prints. Five members of the IFRP staff attended the meeting. Three contributors were present. There were 156 professionals registered at the meeting. The names and authors sponsored by IFRP are listed below:

1. "A Comparison of Metal and Plastic Cannulae for Performing Vacuum Aspiration During the First Trimester of Pregnancy"
Speaker: Sheitaneh Soroudi Moghaddam, M. D., MPH
Co-authors: Javad Vakilzadeh, DVM, MPH and Eva Miller, MA
2. "Sterilization by Minilaparatomy"
Speaker: Anjali Saha, M. D.
Co-authors: Ashley G. S. Dassenaike, M.D. and Margaret F. McCann, M.S. U.S.A.
3. "A Study of Abortion in Countries Where Abortions are Legally Restricted"
Speaker: Dr. Chi J-Cheng
Co-authors: Eva Miller, MA, Judith Fortney, Ph.D., Roger P. Bernard, M. D. Taiwan
4. "Medical and Socio-Demographic Implications of Abortion at Felix Bulner Hospital in Santiago, Chile"
Speaker: Rafael Viada, M. D.
Co-authors: H. Eyzaguirre, M. D., Francisco Frenter, MD, Alfred Goldsmith, MD, and Eva Miller, MA Chile
5. "Laparoscopic Sterilization Immediately After Term Delivery: An Analysis of 200 Cases"
Speaker: Cecelio Aranda, M. D. Costa Rica
6. "A New Technique for Outpatient Female Sterilization"
Speaker: Alfredo Goldsmith, M. D., MPH USA

Two papers (Dr. Viada's and Dr. Aranda's) were read by the investigator. The other four were read by IFRP staff members. From a statistical standpoint, the study on metal and plastic cannulae was

somewhat confusing, as numerically the plastic cannulae appeared to have more complications than the metal ones. However, according to the authors there was no statistical difference (though the test for significance was not specified). Dr. Viada's pre-print was marred by a proofing error that included a table from another study.

On Wednesday morning at the second session of the International speakers program three more IFRP sponsored studies were read. Titles and authors are listed below:

1. "The Use of IUDs as Carriers of Medicaments to Control Bleeding"
Speaker: M. I. Ragab, M.D. Egypt
2. "The Use of Trained Midwives in a Copper-T IUD Insertion Program"
Speaker: J. Vakilzadeh, M. D.
Authors: M. Mitra, M. D., M. Loghmani, M. D. U.S.A.
3. "A New Look at An Old Technique: Sterilization by Infundibu-
lectomy"
Speaker: Anjali Saha, M. D. U.S.A.

No pre-prints were received. Approximately 49 registrants were in the audience for the session which lasted approximately 1 hour and 15 minutes. Dr. Ragab, the investigator, read his paper which clearly explained the theoretical basis for decreasing bleeding, using AMCA carried in silastic tubing within a spring coil IUD. In 200 women studied for six months there were no pregnancies; 1.1 expulsions, 1.1 hwy. removals for bleeding and pain. This was compared to the spring coil with 700 mm. of copper. The latter device also had no pregnancies; 0.5/hwy. expulsions but this had a bleeding; pain removal rate of 9.9/hwy. The paper took eight minutes to deliver and there was no discussion.

PROBLEMS:

1. Question relative cost effectiveness of this number of speakers traveling to a small meeting.
2. Question IFRP staff reading papers dealing with surgical procedures or

investigations that they are not intimately involved with.

RECOMMENDATIONS:

1. Assess more carefully selection of meetings for presenting papers with some emphasis on area presentations.
2. Select member of staff traveling to meetings more carefully in relation to impact of meetings.

MEMORANDUM

TO: Howard E. Hough, Project Coordinator, Division of International
Health Programs, American Public Health Association
FROM: Philip D. Darney, M.D., Consultant in Population Planning Program
Evaluation
SUBJECT: IFRP Evaluation of Sept. 16 - Oct. 5, 1975
DATE: Nov. 17, 1975

Attached you will find a report of my evaluations of ten IFRP study sites and a summary of observations and recommendations.

The contents of the report are as follows:

- A. St. Mary's Hospital, London, Sept 17
- B. Chelsea Hospital, London, Sept 17
- C. Family Planning Institute, Ljubljana, Yugoslavia, Sept 19-20
- D. Ain-Shams University, Cairo, Sept 21
- E. Assuit University, Assuit, Egypt, Sept 22-23
- F. Siriraj Hospital, Bangkok, Sept 25-26
- G. Ramathibodi Hospital, Bangkok, Sept 25-26
- H. Kandang Kerbau Hospital, Singapore, Sept 28-29
- I. University of Indonesia, Jakarta, Oct 1-2
- J. Private Clinics, Denpasar, Indonesia, Oct 3-4
- K. Summary of general observations and recommendations

The individual evaluations have the following format:

1. Contacts
2. Observations
 - a. background
 - b. record keeping
 - c. fiscal management
 - d. relationship with IFRP headquarters
 - e. clinical aspects
3. Recommendations

Thank you for giving me an opportunity to participate in the evaluation. I hope you will find my observations useful and my recommendations practical.

A. St. Mary's Hospital, London

1. Contacts

- a. Prof. Beard, Chairman of the Dept. of Obstetrics and Gynecology
- b. Mr. Brian Lieberman, Obstetrician gynecologist
- c. Mr. J. Paynton, Obstetrician gynecologist
- d. Ms. A. Hughes, secretary to Mr. Lieberman for IFRP project

2. Observations

- a. background - St. Mary's is a large and prestigious London hospital and medical school. Its ob gyn service is among London's most active. Prof. Beard's 4 studies (1 MR, 3 sterilization) obligate \$9800 of which \$2970 have been paid. The MR study is completed, a clip sterilization study is in progress, another sterilization study awaits A.D. approval and one other such study has been withdrawn.
- b. Record keeping - coders abstract information from hospital charts. Early on more than half of the IFRP forms were returned, often for clerical rather than significant clinical errors. Now less than 1% are sent back from Chapel Hill and time from mailing to return of incomplete forms is much shorter than previously.
- c. fiscal management - payment for completed forms is slow in coming, making hiring of coders difficult since there was no provision for start-up costs. Promptness of payment has improved over the past year. Funds are held in a departmental research account.
- d. Consent procedures - patients sign only the routine hospital consent form. They receive verbal information about the experimental nature of the clip tubal ligation. All research projects, including IFRP studies are scrutinized by the hospital Ethical Committee.
- e. Clinical aspects - Laparoscopic sterilization procedures by the Hulka clip were observed. The procedures were done by Mr. Lieberman under local anesthesia in an efficient manner and were well-tolerated by patients. Patient follow-up procedures are thorough: 199 of 200 were contacted at 3 weeks and 167 of 200 at 6 months. Mr. Lieberman reported 7 failures (only 5 of these were clearly method failures).

3. Recommendations - St. Mary's will be the coordinating center in a 5 center IFRP study. Hiring of a traveling coordinator will be expedited by advance payments for start-up costs and by prompt payment of fees for previously initiated studies. Adequacy of consent procedures should be investigated.

B. Chelsea Hospital, London

1. Contacts

- a. Mr. Ian Craft, Consultant in Obstetrics and gynecology,
- b. Mr. Bill Tingy, Sr. Registrar in Obstetrics and gynecology

2. Observations

- a. background - Chelsea Hospital has a moderate ob gyn case load which limits their single IFRP study to about 10 tubal band ligations weekly. \$3000 have been allocated for this study. Data collection began only recently and no payments have yet been received.
- b. Record keeping - Mr. Tingy, the registrar whose research project the IFRP study is, completes all the forms himself. In addition, he keeps case summaries for his own use in evaluating his data (partly because he finds many of the IFRP questions "irrelevant."). He is also personally responsible for all follow-up.
- c. Fiscal management - no funds have been received; the plan is to maintain a special research account.
- d. Consent procedures - Patients receive a verbal explanation of the tubal band, but no note of this is entered in the chart. No other special consent is required in the opinion of the hospital research committee which reviewed the IFRP study.
- e. Clinical aspects - all the procedures are done by Mr. Tingy; none were observed.

3. Recommendations - Adequacy of consent procedures should be established. Mr. Craft regards the IFRP study at Chelsea as a vehicle by which the senior registrar may publish clinical research. The study will have the full attention of a single individual who will, no doubt, do excellent work. If, however, IFRP is constrained to reduce the number of centers and studies it can fund and monitor, the smaller centers conducting studies with few subjects probably ought to be the first to be eliminated in the interest of efficiency.

1.
C. Family Planning Institute, Ljubljana

1. Contacts

- a. Prof. Lidija Andolsek, Director
- b. Majda Oven, Statistician

2. Observations

- a. background - The Family Planning Institute is a modern out patient facility where contraception and infertility evaluation are provided. The Institute is closely affiliated with the Ljubljana Gynecologic Clinic, a 470 bed hospital and clinic where Family Planning Institute physicians perform abortions. The Institute uses the computer and clinical laboratory facilities of the local university. IFRP has collaborated with the Institute in 17 studies costing a total of \$50,750. 9 of these have been withdrawn before data were submitted TO IFRP so that only \$11,163 have been paid for 3 complete and 4 active studies. An additional study is pending AID approval. The Institute is presently conducting IUD and first trimester abortion evaluations.
- b. record keeping - social workers complete most of the items on the IFRP forms. The forms are later edited by coders. The institute does not keep separate summary sheets but depends completely on IFRP for data handling. They do use the university computer for statistical analysis of the data IFRP provides. DR. Andolsek and Ms. Oven find IFRP response to their requests for data to be very prompt - usually about 4-6 weeks. IFRP forms do not always contain the information needed for particular studies. In such cases Dr. Andolsek conducts chart reviews.
- c. fiscal management - The Institute has conducted studies with WHO, Population Council and the Pathfinder Fund and is therefore familiar with managing funds from several sources. They find IFRP payments prompt, but, because of inflation, don't believe the payments are adequate to cover the cost of completing and, especially, mailing the forms by air.
- d. relationship with IFRP - about 3 IFRP staff members visit each year. IFRP is sometimes very slow to respond to letters. Dr. Andolsek has not, for example, received a response to her written complaints about increased costs of completing and mailing forms.
- e. clinical aspects - The institute's facilities are outstanding. Patients are assured privacy, waiting times are short, instruction sessions are well planned and conducted, and equipment is excellent. The Gynecological Clinic, where abortions are performed, is less modern and appealing, but the procedures observed were done competently and very efficiently under local anesthesia in the company of the social worker who had previously explained the procedure and completed the IFRP form with the patient.
- f. collaborator's comments - Dr. Andolsek mentioned that she had little contact with other IFRP collaborators in Yugoslavia and had not seen pooled data. Such data had

C. Family Planning Institute, Ljubljana, continued

proved useful when Population Council and WHO provided it in the past. She wondered if additional studies of already thoroughly-evaluated IUDs like the Lippes D and Cu 7 were needed. She asked if other collaborators shared her concern that IFRP might not be responsive enough to early indications that a particular IUD did not warrant further evaluation. IFRP studies had introduced new technology, she said, but after the study ended there might be no way of continuing to employ the new and better methods either because the equipment would not be available or because medical committees would not approve the new methods.

3. Recommendations - IFRP should discuss with Dr. Andolsek the problem of rising overhead costs and the possibility of revising payment rates. The value of retrospective IUD studies, further studies of proven devices, and discontinuation of evaluations of IUDs found early on to be unsatisfactory are issues that IFRP ought to address. The importance of encouraging communication among collaborators by distribution of pooled data and other methods should be assessed.

D. Ain-Shams University, Department of Obstetrics and Gynecology

1. Contacts - Prof. Ismail Ragab

2. Observations

- a. Background - At Ain-Shams University Dr. Ragab has collaborated with IFRP in 18 different studies which have a total obligation of \$68,600. 8 of these are active studies, 6 of them are completed, 2 are inactive, and 2 are pending AID approval. They include investigations of pregnancy termination, menstrual regulation, and of various IUDs. Dr. Ragab has long been interested in IUD and equipment design and several of the studies are concerned with his own abortion cannula, prostaglandin infusion pump, and IUDs. No information regarding the clinical facilities was provided and the party did not have an opportunity to visit them. Discussions were held in Dr. Ragab's private office.
- b. record keeping - IFRP forms are retained in the hospital until follow-up is complete. We did not, therefore, have an opportunity to observe the forms in use. When follow-up is concluded the forms are stored by type of study in Dr. Ragab's office loft. The forms are completed at the hospital by the physician who performs the procedure. The complexity of the IFRP forms necessitates use of a physician to complete them. In addition to copies of the IFRP forms, Dr. Ragab had retained treatment summaries with the time at which specified doses of prostaglandin, for example, were administered. Dr. Ragab has not requested or received tabulations of the data he has submitted.
- c. fiscal management - Dr. Ragab's comments focused on funding. He complained that he had received no payments since September, 1974, despite repeated appeals to Chapel Hill. Because IFRP funds are exhausted he no longer maintains a separate account for IFRP money. He pays the secretary, who serves as an administrator, three physicians, one full-time and 3 part-time social workers, and several part-time nurses from his personal funds, usually on a piece-work basis. He admits that his practice of out-of-pocket payments makes cost accounting difficult, but asserts that he sent a cost breakdown to IFRP. Although promised payment if a cost breakdown was provided, he still has not received money for studies completed months ago. He cited studies 3, 302 and 309 as examples. He said that he was never advised by IFRP that cost accounting would be necessary and was never given instructions as to how it should be carried out.
- d. relationship with IFRP - IFRP agreements are directly with Dr. Ragab, not with Ain-Shams University. He appeared not to understand that studies could not be initiated without AID approval. The evaluators cited 443 and 444 as examples of studies still pending AID approval but for which Dr. Ragab had submitted forms. He replied that IFRP had told him to begin collecting data for these studies. He cited long-standing difficulty in

D.. Ain-Shams University, Dr. Ragab, continued

mail communications with IFRP, objecting particularly to slow replies and the cost of air mailing great numbers of forms and letters.

- e. clinical aspects - The evaluators had no opportunity to observe the hospital or clinic. Procedures are not done in Dr. Ragab's private office, although he showed equipment he uses to fabricate IUDs. He said that he uses university hospital operating rooms and pays the staff and maintenance costs himself. In addition, he must hire physicians, usually his own assistants and students, to remain with midtrimester abortion patients because the regular hospital staff would not have time to attend to the patients or to complete the IFRP forms.
 - f. collaborators comments - As mentioned above, Dr. Ragab stated that he did not understand the delays in making payments for forms already submitted. He commented several times about a planned trip to "the Palm Springs meeting" that had been withheld because of misunderstandings with IFRP.
3. Recommendations - Dr. Ragab requires instruction in the need for and in the techniques of cost accounting, if his relationship with IFRP is not to degenerate completely. Although the evaluators did not have an opportunity to observe patients or procedures, Dr. Ragab's remarks led us to believe that consent procedures are casual and that some patients may, in effect, be bribed to participate. These impressions need thorough investigation. The initiation of studies prior to AID approval also deserves scrutiny

E. Assuit University Medical School, Department of Obstetrics and Gynecology

1. Contacts

- a. Prof. A.A. Hammouda, Chairman of the Department
- b. Prof. M.F. Fathalla, Director of the Endoscopy Unit
- c. Dr. M. Morad, Director of the Cytogenetics Laboratory
- d. Dr. M. Shaaban, Assistant Professor

2. Observations

- a. background - The department uses Mabarrah Hospital in the City of Assuit as its training institution. Dr. Fathalla has established a laparoscopic unit in the outpatient department of the hospital. It is used mostly for sterilization procedures but also for diagnostic laparoscopy by both the gynecologists and internists. The department has agreed to participate in 2 IFRP sterilization studies and 1 menstrual regulation study. The agreements are signed and approved by AID and a few forms have already been submitted. In addition to the IFRP studies, the Department participates in WHO and Ford Foundation projects. The latter provides equipment and travel funds. IFRP obligation is \$630.
- b. record keeping - IFRP forms are completed by the resident physician who interviews patients on their arrival in the endoscopy unit. The residents have encountered no problems in using the forms and feel adequately instructed in their use. Dr. Fathalla sees the principal advantage of the IFRP form as providing easily retrieveable data storage. He plans to also keep records of his own design. He has used these records to store data in previously published reports about sterilization procedures in Assuit. He is interested in using the IFRP forms for the WHO "Joint study of female sterilization. There have been contacts between WHO and IFRP regarding such use of IFRP forms but no agreement as yet.
- c. fiscal management - Because IFRP, unlike Ford and WHO, provides funds on a per form rather than a project basis, Dr. Fathalla has devised different methods of handling money from these different sources. He received no advice about handling funds from IFRP, but plans to keep IFRP money in a separate departmental account. He was interested in receiving payment in equipment rather than cash. The rate at which the department will be paid per form submitted to IFRP was decided by IFRP. There was no attempt to assess the cost of completing and mailing the forms. The investigators appeared to understand the system of editing and returning forms for proper completion although they had not yet received forms for correction.
- d. relationship with IFRP - Dr. Fathalla has met with IFRP representatives once in Assuit and again in Alexandria. Because his department has only recently begun to submit forms, he had no comments about promptness of payment, responsiveness to problems, or accuracy of estimates of the cost of completing the IFRP forms.

E. Assuit University Medical School, continued

- e. clinical aspects - The endoscopy unit is well-equipped and includes a Yoon Band laparoscope provided by IFRP. Laparoscopy is carried out under satisfactory conditions and in standard fashion except that intravenous equipment was not obviously available. Dr. Fathalla assured me that it could be easily obtained if needed. The procedures were carried out under local anesthesia and after a 2 to 3 hour recovery period patients were sent home. Because the populace regard surgery with fear, the laparoscopic unit avoids any association with an operating room approach. This avoidance means that patients do not receive the information the evaluators regarded as desirable for truly informed consent. About 3 to 5 sterilizations are done each day. Dr. Hamman's surveys suggest that among rural families 10% regard sterilization as an acceptable way of controlling family size. Dr. Fathalla has no difficulty recruiting patients, however.
3. Recommendations - Payments from IFRP should be made in equipment if the collaborator so desires. Here, as in several of the other sites evaluated, the problem of cultural, as well as legal, differences in what constitutes medical consent was apparent. It may not be practical to obtain in Assuit and elsewhere the informed consent required in the USA. If, however, such consent is necessary, then collaborators obviously need more information about it. Here, as elsewhere, the investigator appeared to be poorly informed about cost accounting procedures and about the sort of data output and analysis he could expect from IFRP.

F. Siriraj Hospital, Mahidol University Medical School, Bangkok

1. Contacts

- a. Suporn Koetsowang, M.D., Director, Family Planning Unit
- b. Thavatchai Pinpuvidol, Wyeth Co. representative, Bangkok

2. Observations

- a. Background - Siriraj Hospital and Mahidol University Medical School are among the most respected medical institutions in Thailand. The Family Planning Unit is well-known and extremely active. During the month of August, 1975, for example, the unit saw 190 new contraception patients, recorded 3,025 revisits, and performed 406 sterilizations, 314 of them postpartum. IFRP studies in collaboration with Dr. Suporn were initiated in Sept., 1972, and had an initial obligation of \$32,550. \$8,996 had been paid as of Sept., 1975. Two IUD studies are complete, 2 sterilization studies are active, 3 IUD studies were cancelled, 1 sterilization study is inactive and another new one has just been initiated. An additional D&C vs. vacuum curettage abortion study was cancelled. Dr. Suporn previously worked with Pathfinder Fund when Drs. Kessel and Barnard were there. He now works with WHO as well as IFRP.
- b. Record keeping - IFRP forms are completed by interviewers and nurses. The investigator's copy is stored separately from the patient record. Forms are rarely returned because of errors or incompleteness. An additional form, which is kept with the patients clinic record, collects information not required by IFRP. Dr. Suporn has this data punched on cards and uses it to amplify the data he receives from IFRP. He would like to have a key punch machine to encode both his own and IFRP forms. He could then send either cards or tape to IFRP. The several projects in Bangkok might, he believes, be able to share the same punching facilities.
- c. Fiscal management - Funds received from IFRP are kept in a special account. Payments arrive about 6 months after forms are submitted.
- d. Relationship with IFRP - Even though Dr. Suporn collects data for clinical studies using his own forms and performs independent data analyses and would carry out his investigations without IFRP support, he had several positive comments regarding IFRP. He has received summaries of the activities of other centers (few of the sites visited had done so), he uses IFRP data for the first draft of papers, he believes that IFRP facilitates communication among investigators by organizing meetings and encouraging publications. Dr. Suporn had no complaints about the responsiveness of IFRP to his requests.
- e. Clinical aspects - The evaluators observed the family planning clinics, which were pleasant and efficient and adequately staffed with well-trained personnel, and the operating rooms where mini-laparotomy and laparoscopic sterilizations were performed under local anesthesia.

F. Siriraj Hospital, Bangkok, Dr. Suporn, continued

Dr. Suporn and his resident were considerate of patients and conducted the sterilization procedures in standard fashion with speed and skill. Their equipment was modern and well-maintained. Para-medical support was excellent.

3. Recommendations - Dr. Suporn and his staff are obviously capable of collecting, storing, and analyzing large amounts of data in an efficient fashion. With or without the participation of IFRP the unit would contribute useful information. Mailing of IFRP forms to Chapel Hill is probably, as Dr. Suporn suggests, not sensible, because the data is less accessible than it would be if processed in Bangkok, where facilities are adequate, and because mailing is expensive and time-consuming. Savings in mailing costs alone would quickly pay for key-punching services for all the IFRP contributors in Thailand. Data tapes might then be mailed to IFRP or IFRP tabulating programs sent to Bangkok and summary data returned to IFRP. Such data processing services need not be located at Siriraj Hospital nor must IFRP necessarily purchase the processing equipment, but Bangkok seems like a promising place to begin decentralization of Chapel Hill's data processing chores.

1. Contacts

- a. Vitoon Osathanondh, M.D., Ph.D., Chief, Population/Family Planning Unit, Dept. of Obstetrics and Gynecology
- b. Kamheang Chaturachinda, M.B., Ch.B. M.R.C.O.G., Consultant Obstetrician Gynecologist, Dept. of Obstetrics and Gynecology

2. Observations

- a. Background - Ramathibodi Hospital, a medical establishment of considerable reputation, has been an IFRP collaborator only since Jan., 1975. One active and 2 new sterilization studies obligate \$9,000, of which \$1,002 have been paid. These studies compare various laparoscopic techniques and evaluate methods of tubal occlusion in minilaparotomy. Dr. Vitoon is one of the principal developers of the latter method of sterilization and has a world-wide reputation.
- b. Record keeping - IFRP forms, which Dr. Kamheang considers more than adequate, are completed by 2 nurse assistants who are paid from IFRP funds. Clinical items are completed by physicians who perform the procedures. A small proportion of the 500 forms submitted to IFRP have been returned, usually because of clerical rather than substantive errors. Dr. Kamheang finds mailing costs burdensome and believes that it would be more efficient and cheaper to process data in Bangkok. He mentioned that the first IFRP forms arrived more than 5 months after agreement to begin study 621.
- c. Fiscal management - Dr. Kamheang received an advance of \$1,000 for start-up costs. This money has been used to pay the two nurse assistants who are responsible for completing forms and patient follow up. Although he has sent 500 forms for study 621, he has not received additional payments. Money is necessary, he says, to retain the services of the nurse assistants, and he urgently needs the additional \$4,000 owed the department. In addition to the \$1,000, Dr. Kamheang's department has received a single Yoon Band laparoscope. IFRP funds are retained in a separate research account. Dr. Kamheang received no instruction or advice regarding funds management or the need for cost accounting. He could perform a cost analysis if such were required, however.
- d. Relationship with IFRP - Dr. Kamheang has found communication with IFRP to be difficult. He did not, for example, know that the present evaluators were visiting him until they had arrived at his office. Even though the area coordinator often passed through Bangkok, there had not been a single site visit at Ramathibodi until the present unannounced one. He had been called to meet with the area coordinator in a hotel on one occasion and had done so. He had expected that IFRP would provide summary reports that would assist him in preparing papers and keep him informed about the work of other investigators but, he said, had received only the annual report. He

G. Ramathibodi Hospital, Dr. Kamheang, continued

has not requested reports. He has used his own record keeping system for preliminary data analysis.

- e. Clinical aspects - The evaluators unannounced visit did not allow the Ramathibodi staff time to prepare for observation of sterilization procedures. The cases had been completed earlier in the day. Drs. Kamheang and Vitoon did, however, show photographs of their procedures and provided considerable information about techniques and complication rates. They believe that mini-laparotomy is much more satisfactory for use in rural areas than is laparoscopy. They organize rural training centers in the procedure and train each medical student in its execution. Laparoscopy, they contend, because the equipment is complicated and the complications are occasionally life threatening, should not be used in medically unsophisticated regions. They agree that minilaparotomy is best performed for slender patients. Dr. Vitoon has, however, performed the procedure for patients weighing up to 200 lbs. 70% of patients receive only IV analgesia. The remainder are equally divided among no medication at all, local anesthetics, and general anesthetics. Operative injuries occur in about 0.6% of minilaparotomy patients, while wound infections or hematomas complicate about 0.4% of such cases. Prophylactic antibiotics are not used. Drs. Vitoon and Kamheang seemed very concerned about the demographic impact sterilization procedures might have in Thailand.
3. Recommendations - The IFRP collaborators at Ramathibodi Hospital deserve more attention than IFRP has given them. Although they have only recently enrolled in IFRP, Drs. Kamheang and Vitoon have substantial reputations in fertility control investigations and, no doubt, will continue to make important contributions with or without IFRP's attention. IFRP can, however, profit from Ramathibodi's enthusiastic collaboration and ought, therefore, to inform Dr. Kamheang of payment policies, routine and special data summary reports available to him, and of the activities of other IFRP investigators of minilaparotomy and laparoscopic sterilization. In addition, the area coordinator might benefit from a visit to Ramathibodi at the next opportunity. As at Siriraj Hospital the gynecologists at Ramathibodi are capable of managing the processing of their own data. Perhaps the two institutions and Dr. Charanpet's group might arrange to share data processing facilities and thereby achieve economies in postage and processing, and efficiency in analysis.

H. Kandang Kerbau Hospital, Unit of the Senior Obstetrician and Gynecologist (A), Singapore

1. Contacts

- a. Prof. T. H. Lean, Head and Senior Consultant Obstetrician Gynecologist
- b. Dr. D. Vengadasalam, Consultant Obstetrician Gynecologist
- c. Dr. S. H. Kee, Senior Registrar
- d. Dr. T. B. Lim, Senior Registrar
- e. Dr. W. K. Tan, Senior Registrar
- f. Dr. C. B. Parandare, Visiting Assistant Professor of Obstetrics and Gynecology

2. Observations

- a. Kandang Kerbau Hospital (KK) is the principal obstetric and gynecologic hospital in Singapore and one of the largest such hospitals in the world. Its services are divided among units A, B, and U - the latter is Singapore University Medical School's Department of Obstetrics and Gynecology. Unit A, the only IFRP collaborator at KK, is thus responsible for one-third of medical services rendered at KK and, in 1974, accounted for 11,101 deliveries, 726 major gynecologic operative procedures, 1,348 therapeutic abortions, and 1,695 female sterilizations. Although Units A, B, and U share equal clinical responsibilities at KK, they are fiscally and administratively autonomous and differ considerably in the way in which their responsibilities are discharged. For example, interval sterilization is performed primarily by supra pubic laparotomy in A, laparotomy in B, and culdoscopy in U. There is little exchange of clinical information among the 3 units. Prof. Lean has collaborated with IFRP since 1971. As of Sept., 1975, IFRP had paid his group \$36,557 of \$75,600 originally obligated. In 1974 Unit A recorded 2,061 procedures on IFRP forms, making it the single largest IFRP contributor for that year. Of 20 different studies initiated, Prof. Lean's group has completed 6, 7 are currently active (1 of which remains unsigned by AID as of Sept. 1975), 1 is inactive, 5 are new studies for which IFRP has not yet received forms, and 1 other is pending AID approval.
- b. Record keeping - Unit A uses IFRP funds to pay 3 coders who review hospital clinical records in order to complete the IFRP forms. The forms are completed from the record alone - no special interview or procedures are required. The collaborator copy of the IFRP form is not used unless the unit receives queries from Chapel Hill. Prof. Lean feels the IFRP form is adequate for his purposes. He collects additional information for special studies and has data processed by the Family Planning Board. In order to evaluate the recording process at Unit A, the evaluators brought 30 copies of IFRP forms originally completed at Unit A. In the Unit A files 29 copies of the 30 were found. In the hospital record room, 25 of 30 charts of patients previously reported to Chapel Hill

were quickly found on routine search. The ready availability of these records led the evaluators to conclude that data procedures at Unit A are efficient.

- c. Fiscal management - Unit A maintains a central research funding pool in which IFRP payments are retained. Therefore, although IFRP payments arrive late, in the opinion of Dr. Vengadasalam, the unit is able to draw on other resources to pay the IFRP form coders. The unit receives the majority of its research support from the Singapore Medical Research Council. Prof. Lean was told what IFRP could pay for completed forms. The decision on their cost was not based on estimates of the actual costs of completing the forms. He was not made aware that cost accounting might be necessary, but he believes that he could easily itemize his use of IFRP funds.
- d. Relationship with IFRP - Unit A of KK has had a long standing and, apparently, mutually profitable relationship with IFRP. Prof. Lean is a member of the IFRP Medical Advisory Committee. Perhaps because of these relationships, Dr. Vengadasalam and Prof. Lean had more comments and criticisms of the IFRP central organization than did collaborators at any other site visited. Prof. Lean generally approves of the idea to regionalize processing of IFRP forms. He says, for example, that all data processing could easily be done in Singapore. He presently collects data for special studies in addition to IFRP studies. This data is processed by the Singapore Family Planning Board data processing unit. Prof. Lean has special interest in and knowledge of regionalization of IFRP activities because he has been very active on the Inter-Governmental Co-ordinating Committee - South-East Asian Regional co-operation in Family and Population Planning (IGCC). He sees the IFRP role as that of data processing consultant and project designer, but is concerned that the central (Chapel Hill) staff has emphasized data collection and has not given enough consideration to project planning and data analysis. He is not certain that IFRP has enough personnel who are competent to plan studies and suggest innovative analytic approaches. He suggested that increased staff competence might be achieved if higher level personnel, area coordinators, for example, were screened by the Medical Advisory Committee or a Board of Directors, so that the IFRP Director might pick from a panel of qualified applicants. Prof. Lean approves of the publication and conference program as the best approach to disseminating information among collaborators and to others, but he has reservations about the IFRP plans to use the Journal of the International Federation of Obstetrics and Gynecology as a principal organ for communication. He believes the Journal is of questionable quality and reputation. In addition, Prof. Lean suggested that, in its effort to rapidly expand the number of collaborators, centers of undetermined quality had been enrolled in IFRP. He believes that collaborator quality rather than quantity should be emphasized.
- e. Consent procedures - The unit has recently adopted a research consent form provided by IFRP in addition to the routine KK consent form which does not specify research procedures. Such procedures are explained to the patient prior to surgery.

- f. Clinical aspects - The evaluators observed laparoscopic and mini-laparotomy sterilization procedures and a session of the menstrual regulation clinic. Sterilization procedures were conducted under local anesthesia and included use of both the Hulka clip and the Yoon band. Prof. Lean performed all the procedures observed with speed and skill. He explained that the procedures he performed would be evaluated in patient follow up interviews by Dr. Vengadasalam, and that he would evaluate the procedures that Dr. Vengadasalam performed. The menstrual regulation (generally abortion under 6 weeks of gestation) were done in an efficient manner without anesthesia in an out-patient clinic. Two urine HCG tests were performed for each patient (Prognosticon Dri dot and the Lau capillary tube urine HCG) and the uterine aspirate was sent to the pathologist for examination. Evacuations were done without dilatation using the Karman cannula and hand-held syringe. Patients received no premedication. Like sterilization operations, these abortion procedures are performed by one member of the staff and evaluated by another. Unit A provides contraception to its patients, but Prof. Lean believes that KK is not a good place to evaluate preconceptive methods because the Family Planning Board provides the great bulk of contraception to the women of Singapore.
3. Recommendations - Prof. Lean is a long-standing and productive IFRP collaborator. In addition he is a member of the IFRP Medical Advisory Committee and a leader in the IGCC. Prof. Lean is, therefore, a collaborator whose comments and criticisms should be of special concern to IFRP. His ideas about the reorganization of IFRP on a regional basis, his suggestions for upgrading personnel recruitment processes, and his reservations regarding particular IFRP staff members deserve attention. Prof. Lean is the only non-American member of the Medical Advisory Committee, but he has not yet had an opportunity to attend a meeting. His observation that IFRP staff members travel with frequency through Asia while the only Asian member of the Medical Advisory Committee has yet to attend a meeting is a significant one because it was made by other Asian investigators who noted frequent but not always productive visits by IFRP staff. Perhaps IFRP should consider spending more on travel by carefully selected collaborators and less on staff travel. Several collaborators echoed Dr. Vengadasalam's and Prof. Lean's opinions that contact among investigators took place most effectively at meetings and that these were best held in Asia for Asian collaborators, rather than in the USA. As did other collaborators, Prof. Lean greatly appreciated provision of equipment by IFRP. Since cash payments are made slowly, and since many collaborators need equipment more than they need cash, IFRP might do well to consider the suggestion, made by several collaborators, that payments be made in the form of equipment until centers were considered adequately supplied with laparoscopic and other equipment.

I. Department of Obstetrics and Gynecology, University of Indonesia
Medical School, Prof. Hanifa Wiknjosastro, Head

1. Contacts

- a. Prof. Hanifa Wiknjosastro, Head of the Department and Head of Staff, Dr. Tjipto Mangunkusumo General Hospital
- b. Dr. Sudraji Sumapradja, Chief, Division of Human Reproduction and Director, Raden Saleh Clinic
- c. Dr. Harru Harahup, Chief, Family Planning Clinics
- d. Dr. Rahadi Santo, Lecturer and Director, Suka Mulia Clinic and Hospital
- e. Dr. Arie Doodoh, Coordinator of IFRP Studies at Mangunkusumo General Hospital and Raden Saleh Clinic
- f. Prof. Suwardjono, Chairman, National Family Planning Coordinating Committee (BKKBN)
- g. H. Harjono, Ph.D, Chief, Division of Reporting and Analysis, BKKBN

2. Observations

- a. Background - The University of Indonesia Medical School is the country's largest and most influential medical school and the Dr. Tjipto Mangunkusumo General Hospital is Jakarta's largest institution for the care of the indigent. In addition, the Raden Saleh Clinic is the only institution engaged in out-patient sterilization and abortion and oriented to training practitioners in these skills. The Suka Mulia Clinic, unlike Raden Saleh, serves only private patients who are relatively well-to-do, but it also has an innovative approach and provides a source of training for interested practitioners. These 3 institutions are involved in Prof. Hanifa's departmental collaboration with IFRP. No where else in Indonesia are studies likely to be as competently conducted as in this department. The eight studies originally planned obligated \$11,450, of which \$1400 have been paid. A retrospective Lippes Loop study (433) and a general (001) study are completed, although the department has not received payment for the latter. A Dalkon retrospective (415) and a clip sterilization study (621) are inactive. An early trimester abortion study (305) is proposed and awaits AID approval and a second abortion study (302) was cancelled. A minilaparotomy study (430) will soon be started. Most of the patients will be seen at the Raden Saleh clinic. The proposal for this clinic, whose objective is to encourage innovative approaches to family planning and to evaluate "non-conventional" methods in a country where abortion and sterilization are illegal, is well-conceived and carefully and convincingly presented in a document entitled, "Raden Saleh Clinic Project," dated May 11, 1974. Much progress has been made since that time and the clinic may actually serve as a catalyst to encourage the acceptance of sterilization and abortion as family planning methods, both by practitioners and politicians. It should certainly provide a model for other medical schools' efforts in family planning.
- b. Record keeping - IFRP forms processing was examined at Raden Saleh and Suka Mulia Clinics. At both places it appeared that forms were efficiently completed for each patient at the time of her visit (rather than from chart review). The clinics have no plans to keep records in addition to those of IFRP. The collaborators will depend on IFRP for all data processing and

I. University of Indonesia Medical School, Prof. Hanifa, continued

analysis. Because the forms are in English, physicians, commonly the only English-speaking personnel at the clinics, must complete all items on the forms. In order to facilitate completion by paramedical personnel, Dr. Sudraji has translated the IFRP Menstrual Regulation form into Indonesian and has included items that are appropriate to the Indonesian culture. He wondered why IFRP could not provide translated forms that included appropriate questions for such items as race, religion, education, self-induced abortion, and traditional methods of family planning. The department has not encountered serious problems in completing the forms to IFRP satisfaction.

- c. Fiscal management - IFRP funds are kept in an account in Prof. Hanifa's name and used to pay paramedical personnel and such incidental items as postage - as at most sites, a considerable expense. The department was not informed of the possible need for cost-accounting. The payment per form was determined by IFRP. Payment for study 432 (completed before receiving AID approval) has not been received nor do records show payment for 001, the only other completed study.
- d. Relationship with IFRP - The department members did not have particular comments or criticisms regarding IFRP. They were not distressed by late payments for submitted forms because, they said, they were pleased to receive the data and analyses for their reports. They did wonder at the long delay in printing Indonesian translations of IFRP forms. When asked to comment on the assertion that the Yoon band might be a reversible method (suggested in IFRP Asia Area Coordinator, dated Feb 21, 1975.) Dr. Sudraji said he was aware that reversibility had not been demonstrated and did not promise or suggest reversibility to patients. He had not questioned IFRP regarding the reversibility of tubal band sterilizations.
- e. Consent procedures - Consent for menstrual regulation is verbal only. A written consent is obtained for sterilization procedures.
- f. Clinical aspects - Both Raden Saleh and Suka Mulia clinics have operating and treatment rooms where the evaluators observed culdoscopic sterilization and early abortion procedures, respectively. Because there are only 2 laparoscopes for the department, and 1 is broken, only culdoscopic sterilizations are performed at the clinics. The one such procedure witnessed was competently done by a resident although the culdoscope lighting system mal-functioned. Mini laparotomies are done in the hospital only as post partum sterilizations. Only early 1st trimester abortions are performed and are considered to be menstrual regulation. Karman cannulae and either Berkeley or the much cheaper Chinese (\$2,000 vs \$400) vacuum pumps are used. The procedure is free for indigent women and costs only \$7 for those who can pay at the Raden Saleh Clinic. The cost for private patients at Suka Mulia is \$50. Costs are similar for sterilization. All procedures are performed under local anesthesia without intravenous fluids, although there are provisions for initiating such therapy when required. The standard premedication is 10 mg of diazepam and 100 mg of meperidol IV. Proper attention to sterile technique was observed and the physicians denied encountering frequent infections following culdoscopy.

In terms of likely demographic impact, the efforts of these 2 clinics are very small, but the increase in the numbers of procedures is impressive and the centers have already served to train practitioners who would not otherwise have been exposed to modern techniques of abortion and sterilization. The number of abortions performed at Raden Saleh increased from 13 in Dec. 1974 to 418 in July, 1975. At Suka Mulia Clinic, 1081 abortions were done in the last 5 months of 1974, while 1,477 were done in the first 5 months of 1975. There are only 3 sterilization procedures daily at Raden Saleh, and even fewer at Suka Mulia.

3. Recommendations - IFRP ought to provide Indonesian translations of records. It would also be in the interest of IFRP's objectives to provide additional laparoscopes and culdoscopes (perhaps in lieu of cash payments) to the department. Research and training capacities are severely limited by difficulties in obtaining and repairing equipment. There should be more emphasis of mini laparotomy as an interval sterilization technique. Here, as well as elsewhere, IFRP representatives should be cautious about promoting sterilization techniques as reversible. The initiation (and, here, completion) of studies prior to AID approval deserves examination, as does the long delay in making payments. Although data processing facilities exist in Jakarta (IBM, Pansystems) they are not nearly as sophisticated as services in Bangkok, Singapore and elsewhere. IFRP should probably continue to process and analyze data from Indonesia.

J. Private clinic of Dr. I. B. Tjitarsa, Denpasar, Bali, Indonesia

1. Contacts

- a. Dr. I.B. Tjitarsa
- b. Dr. Astawa, Director, Bali Provincial BKKBN
- c. Mr. I.B. Permana, Secretary to the Director, Bali Provincial BKKBN

2. Observations

- a. Background - Dr. Tjitarsa is responsible for 3 menstrual regulation studies at 3 different clinic sites. Two are now inactive and one is complete. IFRP's initial obligation was \$4,075 of which \$250 have been paid. Both Dr. Tjitarsa and Dr. Astawa have principal responsibilities in public health, both have MPH degrees from the University of Hawaii, and both, as do nearly all government physicians in Indonesia, work in their own private clinics during the evenings. These clinics are the IFRP study sites. Neither the Medical School or Health Department clinics perform abortion or sterilization because the procedures are illegal and, in the opinion of the local gynecologist, immoral. Illegal abortion is common: there were about 1500 hospitalizations for suspected illegal abortion complications at the general hospital and about 9000 births in 1974. Fourteen other clinics had performed "menstrual regulation" in the past, but a shortage of cannulae has forced them to stop.
- b. Record keeping - IFRP forms are completed by the physician for those patients who meet study criteria - less than 2 weeks post last menstrual period. Most abortion procedures are done for women further along in gestation but these patients are not recorded. About 10% of the forms sent to Chapel Hill are returned for corrections. Dr. Tjitarsa agreed that forms printed in Indonesian would save physician time. He received for the first time in February a computer report of his IFRP forms. There was no explanation or review of the results but he found the report understandable. In February, the Area Coordinator had promised, at the time of her visit, a draft of a paper describing the abortion experience in the clinics. Dr. Tjitarsa has not received one but is still interested in doing so.
- c. Fiscal management - Dr. Tjitarsa and Dr. Astawa were considerably distressed by late payments from IFRP. Although the IFRP Study Status list records no payments to Dr. Tjitarsa, he received a \$250 advance payment in February, 1974. He has not been paid since, although he has submitted a total of 526 forms. Since the menstrual regulation study requires a pathologic diagnosis, he has contracted for cytopathology for which he now owes \$1100. He has now ceased contributing forms to IFRP because he cannot afford a greater debt for pathology services. He claims that he explained this problem to the area coordinator at her last visit and was promised partial payment in March, 1975. When payment did not arrive, he wrote, but received a confusing reply. IFRP funds will be kept in Dr. Tjitarsa's account. IFRP established the payment rate. He is not aware of special costing procedures.
- d. Relationship with IFRP - Although IFRP has only small projects in Bali, there are frequent IFRP visits to Denpasar. Collaboration was initiated in July, 1974, and there have been 3 visits by IFRP

J. Private clinics of Dr. I. B. Tjitarsa, Denpasar, Bali, Indonesia

staff. Another is scheduled for Oct 10, 1975. Dr. Tjitarsa was unaware of its purpose, but hoped that it would resolve his problem of the cytopathology debt since the previous visit of February had not. Dr. Tjitarsa also finds obtaining menstrual regulation kits from IFRP to be a problem. When asked why a study (761) had been started without AID approval, Dr. Tjitarsa replied that IFRP had asked him to begin the study.

- e. Consent procedures - consent is verbal without a chart record.
- f. Clinical aspects - Abortion procedures were observed at Dr. Tjitarsa's private clinic which is sparsely equipped compared to the hospital sites previously visited, but well adapted to very early pregnancy termination. If the uterus is too large on pelvic examination, Dr. Tjitarsa does not proceed, no matter what the menstrual history. He uses Karman cannulae up to 10 times after which they tend to break at the tip. Cannulae and other equipment (Tenaculae and speculae) are kept in separate antiseptic soaking trays. IV solutions are not available, but various injectable drugs are. Abortion is free to contraceptive failures and about \$2.50 to others. Dr. Tjitarsa says that other physicians have a similar policy. In 1974 Dr. Tjitarsa performed 811 early abortions and menstrual regulations. In the first 9 months of 1975 he did 2122. Many more could be done, he says, if more cannulae were available. In order to perform abortions beyond 6 weeks from last menstrual period, he would like to have a vacuum pump - either an electric or hand model.

- 3. Recommendations - Dr. Tjitarsa's problem of the debt for pathology services as a result of his participation in IFRP studies must be resolved by prompt payment of funds owed him. Promises to assist him in preparing a report should also be fulfilled. Whether a continued relationship with such small private clinics is worthwhile from either the standpoint of research or disseminating information is problematic. It seems unlikely that such clinics can contribute knowledge about well established procedures and unwise to introduce procedures that have not yet won general acceptance (like prostaglandin abortions, as an area coordinator suggested to Dr. Tjitarsa) in a place where mid trimester uterine evacuation is not available. There is obviously a great demand for early abortion procedures, and at least part of the demand must result from the interest provoked among practitioners by IFRP's teaching session and studies in Bali. However, a disproportionately large investment was necessary to achieve this small success and further collaborations with private clinics in Bali seem unwarranted.

K. General summary of observations and recommendations

1. Observations - Although each of the ten IFRP study sites visited was unique with regard to some aspects of background, record keeping, fiscal management, relationship with IFRP, and clinical procedure, several observations were common to all sites and, therefore, lead to some general recommendations. The general observations are as follows:
 - a. Record keeping
 - 1) Forms are printed in English only and include items culturally inappropriate to some of the countries visited. Because forms are in English, they can be completed only by physicians in countries where only highly educated people read English.
 - 2) A small proportion of forms are returned to study sites for trivial clerical errors. Such return delays processing by months and doubles already high postage costs.
 - 3) Forms are all processed at IFRP in Chapel Hill even if a particular country or city has several collaborators and sophisticated data processing capacity.
 - 4) Costs of mailing forms are high and rapidly rising. They comprise a large proportion of IFRP collaborator expenses.
 - b. Fiscal management
 - 1) Payments for submitted forms are often slow in coming. This delay works a considerable hardship for some collaborators, especially those who do not have other research funding sources, who find it difficult to retain staff and pay debts resulting from their IFRP work.
 - 2) There are no uniform cost accounting procedures. It would be very difficult for some collaborators to pass a routine audit because they have received no instructions regarding handling of IFRP funds.
 - 3) Lack of a provision for start-up costs has delayed initiation of work at some sites.
 - 4) Because IFRP sets the payment rate, some collaborators have failed to estimate prior to beginning data collection the cost of completing, mailing, correcting, and remailing forms.
 - c. Relationships with IFRP
 - 1) IFRP is generally slow to respond to letters from collaborators.
 - 2) Studies are initiated without waiting for AID approval.
 - 3) Data (collaborator-specific and pooled) are not regularly or widely distributed.
 - 4) Site visits by area coordinators or other IFRP central staff are frequent but not always productive.
 - 5) Some of the more experienced collaborators have reservations about the research and clinical competence of some IFRP staff members and believe, therefore, that recruitment procedures are not rigorous.
 - d. Clinical aspects
 - 1) The procedures observed at the various sites were expertly performed in standard fashion.
 - 2) Consent procedures varied widely among collaborators - from providing no information at all to patients to use of forms that would meet USPHS standards for informed consent.

- 3) Some collaborators badly needed more equipment in order to meet IFRP objectives of field testing, data accumulation, and information dissemination.
- 4) Some sites were pursuing investigations of already thoroughly evaluated modalities, e.g., Lippes loop.
- 5) The larger centers visited were conducting fertility control research prior to IFRP collaboration. It is therefore difficult to assess just how much IFRP has contributed to their work, except to provide a standard basis for comparing results. The smaller centers might not have conducted research without IFRP encouragement.

2. Recommendations - Suggestions for each of the sites visited are made above. (A-J) The following recommendations are based on observations common to the sites and concern the work of the IFRP central staff:

a. record keeping

- 1) When there are several collaborators working in a country where English is not widely spoken, IFRP should provide translations of forms. The forms should take into account cultural, racial and religious characteristics of the particular population so that the data gathered will be maximally useful to the local investigators.
- 2) Trivial errors should be corrected by competent editors at IFRP so that time and money will not be wasted transmitting otherwise complete forms.
- 3) IFRP should accelerate its consideration of decentralized data processing in those regions where adequate facilities are available. Indigenous resources could be used to process forms, tabulate data using IFRP programs, and disseminate information more rapidly and much more economically than IFRP can. Local or regional funding might eventually be available to support these projects.
- 4) Mailing costs could be reduced by performing data entry procedures locally and mailing tapes or microfilm to IFRP until local data processing capacity exists.

b. Fiscal management

- 1) IFRP should make payments more promptly and resolve disputes regarding payments expeditiously, especially when collaborators have incurred debts in conducting IFRP research.
- 2) Collaborators should be instructed in a uniform approach to cost accounting and funds management.
- 3) It is appropriate for IFRP to make moderate advance payments to cover collaborator's start-up costs.
- 4) Payment rates for forms submitted should be based on the collaborators' costs as well as IFRP's resources.

c. IFRP relationships with collaborators

- 1) IFRP central staff should respond promptly to inquiries from collaborators and make special efforts to resolve financial problems expeditiously.
- 2) Collaborators should be instructed not to initiate data collection until IFRP notifies them of AID approval of studies. They should be told that data will not be processed nor payments made for forms completed prior to AID approval.

- 3) Collaborators should regularly receive interim data summaries of all studies in progress. The frequency of such reports should depend on rapidity of data accumulation. IFRP should also provide on a regular basis summaries of pooled data from collaborators conducting similar studies in the same region. The content of these reports should be standardized unless collaborators have special needs and interests. Collaborators should be made more aware of the processing, reporting, and analytic services IFRP can provide.
- 4) IFRP area coordinators and other staff, prior to site visits, should make collaborators aware of the visit plan, including specific objectives agreed upon by IFRP and the collaborator. Site visits should then specifically address these objectives and visit reports should summarize progress toward them. There should be a standardized, business-like approach to site visits by area-coordinators.
- 5) Personnel recruitment processes, especially those for area-coordinators, should be standardized. High level positions should be filled by applicants who have been screened by the Board of Directors or the Medical Advisory Committee.

d. Clinical aspects

- 1) Although the clinicians who were observed were expert at the sterilization and abortion techniques they employed in IFRP studies, they were often unaware of different techniques employed by other IFRP collaborators in their country or region. IFRP should improve communication among collaborators by distributing analyses of pooled data and by sponsoring regional meetings of collaborators. Compared to travel by IFRP staff and collaborators to and from the USA, such meetings would be economical, and, most of the clinicians interviewed agreed, more productive.
- 2) Consent procedures should be clearly specified to collaborators after appropriate standards are determined.
- 3) Collaborators should be asked and area coordinators required to determine equipment needs. Payments should be made in needed equipment when possible and if desired by the collaborator.
- 4) Studies, especially retrospective ones, of already thoroughly evaluated modalities should be terminated. Procedures for quickly terminating studies of modalities found to be unsatisfactory by other investigators should be developed.
- 5) Priorities should be set for IFRP sponsorship so that highly competent centers can become independent as soon as possible and small centers of questionable competence can be eliminated if they are seen not to advance the IFRP objectives of field testing, data accumulation, and information dissemination. A system for establishing priorities by giving appropriate weights to the degree to which a given center has met these objectives ought to be established. For example, Prof. Hanifa's project has done little field testing or data accumulation but is a successful disseminator of information at the local level.