PD-AAY-0[illegible]

AN EVALUATION OF THE GOALS, OBJECTIVES, AND ACTIVITIES OF THE INTERNATIONAL FERTILITY RESEARCH PROGRAM

A Report Prepared By:
SHARON L. CAMP, PH.D.
ELIZABETH CONNELL, M.D.
JAMES D. SHELTON, PH.D.
J. JOSEPH SPEIDEL, M.D.
CHRISTOPHER TIETZE, PH.D.
SAM WISHIK, M.D.
GEORGE WORTH
NICHOLAS WRIGHT, M.D.

During The Period:
JUNE 1981 - MARCH 1982

Supported By The:
U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT
(ADSS) AID/DSPE-C-0053

AUTHORIZATION:
Ltr. AID/DS/POP: 8-24-82
Assgn. No. 582106

EDITOR'S NOTE

Elizabeth Connell, M.D., Christopher Tietze, Ph.D., Sam Wishik, M.D., George Worth, and Nicholas Wright, M.D., are consultants to the American Public Health Association. Sharon Campbell, Ph.D., is affiliated with the Population Crisis Committee. James Shelton, Ph.D., and Joseph Speidel, M.D., S&T/POP, are associated with the United States Agency for International Development.

C O N T E N T S

Page

EDITOR'S NOTE i
ABBREVIATIONS iv

I. SUMMARY AND RECOMMENDATIONS 1

Introduction 1
Goals and Objectives of the IFRP 1
Staffing and Organizational Relationships 2
RAMOS and Other Long-Term Safety Studies 2
Monitoring of Maternity Care 3
Data Collection and Quality of Data 4
Technology Transfer, Technical Assistance, and Training 5
International Federation of Family Health 6
Board of Directors of the IFRP 6
Technical Advisory Committee 7
Financial Considerations 7
Conclusions 7

II. INTRODUCTION 9

III. GOALS AND OBJECTIVES OF THE IFRP 11

Evolution of Goals 11
Current Goals and Objectives 12

IV. IFRP STAFF AND ORGANIZATIONAL RELATIONSHIPS 16

Response to Early Recommendations 16
Relations with AID 17
Relations with Other Institutions 18
Recommendations 18

V. RAMOS AND OTHER LONG-TERM CONTRACEPTIVE SAFETY STUDIES 20

RAMOS 20
Long-Term Safety Studies 22
Recommendations 23

VI. MONITORING OF MATERNITY CARE 24

Recommendations 26

Page

VII. QUALITY OF DATA 27

Recommendations 28

VIII. TECHNICAL ASSISTANCE, TRAINING, AND TECHNOLOGY TRANSFER . . . 29

IX. INTERNATIONAL FEDERATION OF FAMILY HEALTH 32

X. BOARD OF DIRECTORS OF THE IFRP 33

Recommendations 36

XI. TECHNICAL ADVISORY COMMITTEE 37

Recommendation 37

XII. FINANCIAL CONSIDERATIONS 38

Recommendations 38

XIII. CONCLUSIONS AND SUMMARY OF RECOMMENDATIONS 40

Summary of Recommendations 40

ADDENDUM

ABBREVIATIONS

AID	Agency for International Development
AID/W	Agency for International Development, Washington
APHA	American Public Health Association
BKKBN	National Family Planning Coordination Board (Indonesia)
FRP	Fertility Research Program
FY	Fiscal Year
IFFH	International Federation of Family Health
IFRP	International Fertility Research Program
IUD	Intrauterine Device
LDC	Less Developed Country
MCH	Maternal and Child Health
MCM	Maternity Care Monitoring
NIH	National Institutes of Health
OB/GYN	Obstetrics and Gynecology
RAC	Research Advisory Committee
RAMOS	Reproductive Age Mortality Surveillance Study
TAC	Technical Advisory Committee
TBA	Traditional Birth Attendant
UNFPA	United Nations Fund for Population Activities

I. SUMMARY AND RECOMMENDATIONS

Introduction

The International Fertility Research Program (IFRP) was established on July 1, 1971, under an Agency for International Development (AID) contract. Its stated goal was to conduct comparative field trials of new fertility control methods, especially in developing countries. To accomplish this goal, a widespread international network of research collaborators was established to conduct a large number of clinical trials.

In 1977, the IFRP's proposal for renewal was reviewed by the Research Advisory Committee (RAC) of AID. At that time, funding was not approved, pending further study. At AID's request, a RAC subcommittee reviewed the program and later that year made its recommendations. Following receipt of the subcommittee report, a number of changes were made in both staffing and administrative procedures, many of them in line with the RAC's recommendations.

Also in 1977, support for a wider range of objectives was sought to pursue new lines of interest to the IFRP. This support was secured in the form of an AID grant. Meanwhile, funds continued to be made available through the contract.

In 1980, the American Public Health Association (APHA) recruited an evaluation team to review the IFRP and its activities. The team's general impression was that, although a number of improvements had been made since the 1977 RAC review, the IFRP's organization, staffing, and research could be strengthened further. The team made a series of recommendations to this end.

The current report, of which this is a summary, is the result of a detailed review of the IFRP and its program by a new and enlarged APHA team. It is based on firsthand observation. On this occasion, the evaluators visited research investigators in Asia, Africa, and Latin America, as well as the IFRP. The two earlier evaluation teams had not done so.

The IFRP and its major programs are described briefly below. In each section of the report, recommendations are offered where, it is believed, additional improvements can be made.

Goals and Objectives of the IFRP

The IFRP is heavily focused on IFRP- and AID-initiated Phase III clinical field trials of contraceptives in developing countries. However,

its portfolio has been expanded to include a larger proportion of studies in the United States, long-term contraceptive safety studies, non-clinical studies, and technical assistance to institutions in less developed countries (LDCs).

Staffing and Organizational Relationships

Certain problems identified by the earlier evaluators have been either partially or fully resolved by the appointment of new personnel, the transfer of existing personnel to other departments, and the resignation of persons who are unable to function effectively within the IFRP's current organizational structure. Some residual, unresolved problems remain, however. These are addressed in the following recommendations:

1. Additional measures are still needed to improve the scientific and medical leadership in the Research Department. Staff competence in biostatistics and epidemiology in the Research Department needs to be upgraded further.

2. Further efforts need to be made to upgrade the technical expertise of some field staff.

3. The IFRP's ability to initiate and monitor overseas activities has been enhanced by field offices in Africa and Latin America. The establishment in Asia of field capabilities that are appropriate to that region should be considered.

4. The IFRP should strengthen its staff by imaginative use of part-time and temporary contract personnel.

5. Current staff should be upgraded through formal training in relevant disciplines.

6. Additional ways should be found to strengthen collegial ties with neighboring scientific and academic institutions in the Research Triangle.

RAMOS and Other Long-Term Safety Studies

The IFRP began to address issues of the longer-term safety of contraceptives in 1979, identifying deaths among women of reproductive age and attempting to assess the possible relationship of these deaths to use of contraceptives. These activities, including the reproductive age mortality surveillance studies (RAMOS) and other method-specific studies, represent a small percentage of current activities. (RAMOS represents 4.1 percent of the 1982 IFRP budget.)

The evaluators recognize the need for the kinds of data that these studies provide, but they differ in their opinions about the ability of RAMOS-type studies to provide valid information on important questions. Therefore, they recommend that the following action be taken:

1. The RAMOS study currently under way in Bali should be completed.

2. The protocol of the RAMOS study in Egypt should be modified in accordance with changes suggested by RAMOS review groups convened by the IFRP. A recommendation to discontinue the project is conceivable.

3. No other RAMOS projects should be initiated until the current studies provide evidence to warrant extension of this part of the IFRP program.

4. The IFRP should continue to develop studies of longer-term contraceptive safety, using appropriate designs and carefully drawn protocols to answer specific hypotheses.

Monitoring of Maternity Care

In the study of maternity care monitoring (MCM), a standard questionnaire on reproductive health, medical care, and contraceptive use is administered to hospitalized maternity patients. The resulting data are then fed into the IFRP's computer and analyzed. To date, more than 400,000 women in more than 60 hospitals in 35 countries have been interviewed.

Over the last two years, MCM activities have been curtailed substantially, partly in response to earlier evaluators' recommendations. They now represent 3.2 percent of the IFRP's 1982 budget and are being concentrated increasingly in Africa.

The perceived values of a MCM study are educational and technical. Collecting data is an educational experience, as is learning to use data to improve recordkeeping, identify clinical problems--and, subsequently, improve patient care--and illuminate the potential role of contraception in reproductive health.

The team recognizes the need for the kind of information a MCM study can provide, but it has doubts about the value of further widespread and continued data collection. It also is concerned about the apparent lack of impact on policymakers in a number of areas where the study was carried out. It therefore recommends the following action:

1. In accordance with earlier evaluators' recommendations, the IFRP has decreased emphasis on maternity care monitoring, particularly routine MCM activities. The team recommends that this trend be continued.

2. Existing data are being analyzed and fed back to various investigators. The IFRP should seek to improve the utility of standard computer printouts on MCM for collaborating investigators, emphasizing a highly selective choice of data for specific contributors, to increase the contributors' comprehension and use of the information. Collaborators' suggestions should be considered.

3. In attempting to address the issue of the representativeness of data collected solely from a hospital source, the IFRP should explore methods to collect data from outside the hospital. For example, it should try to gather data on deliveries by traditional birth attendants (TBAs) and attempt to collect comprehensive data for an entire geographic area.

4. The large amount of MCM data now available to the IFRP should be exploited selectively.

5. Additional training in the collection and use of types of MCM data should be given to investigators.

6. Where the MCM system is proving to have an impact on health care, continued data collection should be encouraged, as long as it has value, but the countries' own resources should be used.

Data Collection and Quality of Data

The IFRP has developed a series of forms to collect data and computer programs to analyze the methods of fertility regulation that it has investigated. The team believes that these instruments are appropriate for a multi-center research group and that the quality of data is as high as can be expected in as large and as diverse an operation as the IFRP has undertaken; however, it believes also that with stronger scientific leadership, greater flexibility and more sophisticated statistical analysis can be achieved. The team recommends the following action.

1. In future IFRP publications, more emphasis should be placed on absolute or attributable differences or risks; confidence limits, rather than standard deviations, should be used; and findings that are not statistically significant because of small numbers should be so identified.

2. The IFRP's data should be utilized more fully in periodic and general reports on selected major topics, following the deletion of data from studies with inadequate follow-up or other defects.

3. New contributors should be selected with great care; delinquent contributors should be separated without undue delay; and projects should be terminated when the required information has been obtained.

Technology Transfer, Technical Assistance, and Training

The IFRP continues to promote the introduction of new contraceptive technology into family planning programs through clinical trials, training, "detailing," and publication. Additional training programs and plans to provide equipment are being implemented to support and increase the capacity of fertility research programs (FRPs) to design studies and process and analyze their own data. The expansion of the system of FRPs has strained the IFRP's scientific resources, however, and may also have outreached the capacity of several individual FRPs to implement planned activities. Given these considerations, the team recommends that the following steps be taken:

1. The team commends the IFRP on its carefully designed plan to transfer data processing equipment to several fertility research programs, but it suggests that the process will proceed more slowly than is now anticipated and also will require many more follow-up visits than are planned at this time. The budget for these activities is too modest.

2. The promising efforts in training for research design, applied epidemiology and statistics, and data analysis need to be expanded, keeping in mind the need to go beyond the requirements of IFRP protocols and move toward independence in research.

3. The current network of seven FRPs has expanded rapidly, and, in some cases, individual FRPs have had difficulty conducting planned research activities. In addition, the need for extensive technical support for the FRPs is straining the IFRP's resources. For both these reasons, the team advises either stabilizing or contracting FRP activities. Alternatively, the IFRP should allocate additional scientific staff to provide technical assistance and consider the placement of a resident scientist in Asia, where needs are greatest.

4. The team supports the IFRP's continuing efforts to introduce new contraceptive technology through written communications, meetings (formal and informal), and short training sessions. Collaborating

scientists in, and even outside, FRPs should organize and participate in these activities as much as possible, especially in their own regions.

International Federation of Family Health

The International Federation of Family Health (IFFH) was organized in 1977-1978 to support the new fertility research programs and other international collaborators interested in contraceptive and related research on maternal and child health (MCH). A prestigious group of senior researchers has met regularly since then to exchange information on new findings, policy developments, and leads for further research. The IFFH's secretariat has been moved from Research Triangle Park, in North Carolina, to Bandung, Indonesia. It is hoped that financial independence can be attained through support from member countries and donors other than the IFRP.

To date, efforts to secure other sources of funds have not been productive. Nor has it been possible, perhaps because donors' resources are declining, to begin an ambitious program of research in maternal and child health issues. Although the future is uncertain and the history of coordinating agencies in the developing world is difficult, the team visualizes a technical assistance and research planning role for the IFFH once the secretariat has been consolidated and fully staffed, and after independent funding has been secured.

Board of Directors of the IFRP

Beginning in 1978, the IFRP's Board of Directors gradually began to change; initially a small group of IFRP staff and close colleagues and contributors, it has become a large, fully independent group with a diversity of skills and interests.

To continue this expansion and increase the effectiveness of the Board, the following steps should be taken:

1. The IFRP should continue to expand gradually the membership of its Board of Directors, giving special attention to the need for greater representation from the developing countries, collegial institutions in North Carolina, and the social sciences.

2. The IFRP should analyze the ability of the Board, as it is currently structured, to assist in the future diversification of the organization's income. Additions to the Board should

reflect the IFRP's need for more non-AID resources. The Board should assume greater responsibility in this area.

3. The IFRP should seek to deepen the Board's understanding of IFRP programs and should reserve additional time at Board meetings for substantive discussions of programmatic priorities.

Technical Advisory Committee

Earlier teams of investigators pointed out that the Technical Advisory Committee (TAC) did not provide systematic reviews of IFRP research. It meets only once a year, receives minimal information in advance, and thus serves only an overview function. In response to criticisms, the IFRP initiated a series of TAC scientific expert meetings on specific topics. The results of these meetings were distributed, with additional relevant materials, to TAC members in advance of the most recent meeting.

The team believes that the changes in the TAC and its procedures are of great value to the IFRP. It recommends that such efforts be continued and, where necessary, augmented.

Financial Considerations

The IFRP has been experiencing a period of considerable funding austerity. In 1982, the IFRP is expected to receive approximately $3.6 million for contract activities and approximately $1.1 million for the grant. These figures represent a marked reduction in support for the grant and reflect the higher priority accorded to contract research. In response to this situation, the IFRP has instituted budget-tightening procedures and is allocating resources more efficiently. The organization also has successfully diversified its support from non-AID sources; the sources now represent 15 percent-20 percent of the overall budget.

The team recommends that the IFRP continue its efforts to ensure the appropriateness of funding for specific IFRP projects and to broaden and diversify financial support. In dealing with the current funding shortfall, the IFRP should place the strongest emphasis on contract activities (including Phase IV studies) directly aimed at assessing the safety, efficacy, and acceptability of current, improved, and new methods of contraception throughout the world.

Conclusions

In general, the team has found that the IFRP is fulfilling the mission mandated by AID under the terms of the current AID grant and contract.

The team recognizes that progress has been made, particularly in improving personnel and management, expanding the Board of Directors and increasing its effectiveness, and using outside technical advice. During the evaluation, the team identified a number of areas that need to be strengthened further and made a series of recommendations. The IFRP is giving attention to these areas at this time so that it can continue to satisfy the future needs of AID.

II. INTRODUCTION

The International Fertility Research Program was established on July 1, 1971, with funding from the Agency for International Development. Its initial goal was to conduct comparative field trials of the short-term safety and effectiveness of new fertility control methods in less developed countries. To meet this objective, it established a widespread network of more than 250 research collaborators working in more than 30 countries throughout the developing world. These persons conducted a large number of clinical trials, using both straight and comparative methods of evaluation. In so doing, they enhanced their own research capabilities and the quality of the institutions in which they worked.

The original trials were conducted primarily on oral contraceptives, intrauterine devices (IUDs), menstrual regulation, pregnancy termination, and male and female sterilization. To amass useful information from these trials, the IFRP developed standard methods for gathering, reporting, and analyzing data. Thus, it was able to document safety and effectiveness and also to determine the relative appropriateness of the different methods and procedures for varying types of cultural and medical environments.

In March 1977, the IFRP's proposal for renewal was reviewed by the Research Advisory Committee of AID. At that time, a number of issues were raised and funding was not approved, pending further study. At AID's request, a RAC subcommittee made a site visit to the IFRP, evaluated the staff and program, and made a series of recommendations. Following receipt of the subcommittee's report and after consultation with AID, the IFRP made a number of changes in staffing and administrative procedures, and funding was renewed under a new contract.

As the interests and activities of the IFRP developed and evolved, AID was asked to support a wider range of program objectives. A grant was awarded for this purpose in September 1977, and subsequently was extended for four years.

In September 1980, the American Public Health Association (APHA) recruited, at AID's request, an evaluation team to review the IFRP and its activities. Individual and group interviews were held with staff members, both at the offices of the IFRP and in New York. In addition, the team talked to members of the Board of Directors and the Technical Advisory Committee.

Following its review, the team concluded that the IFRP had made a considerable number of improvements since the earlier RAC evaluation. It felt, however, that organization, staffing, and research could be strengthened further and made numerous recommendations on specific changes.

In 1981, the RAC was given a renewal proposal for the IFRP. It again raised a number of questions about the IFRP, its activities, and the direction it was taking. To resolve the issues, the RAC recommended that the IFRP be reevaluated, this time by a larger group with specific areas of expertise. It was decided that, this time, the evaluators would visit the sites of IFRP programs in LDCs.

Over the past ten months, the team met several times in Research Triangle Park, North Carolina, and Washington, D.C. In addition, individual members visited IFRP investigators in Bangladesh, Indonesia, Thailand, Sri Lanka, Egypt, Sudan, Mexico, and Brazil.

The following report contains a summary of the general impressions of the team. Where opinions about the value of particular projects differed, divergent views are indicated. The current report deals in greatest detail with those areas about which the RAC expressed concern. The parts of the IFRP program that were covered in depth in the October, 1980, report, especially the chapters on the various contraceptive studies, are summarized only, because, the team felt, there were no major changes requiring further elaboration.

III. GOALS AND OBJECTIVES OF THE IFRP

Evolution of Goals

When the IFRP was established nearly ten years ago, its primary goal was to determine the short-term safety and efficacy of various methods of fertility regulation (including major and minor innovations in existing technology) in use in developing countries. To accomplish this task, the IFRP initiated a large number of LDC-based clinical trials (both straight and comparative studies), using standardized research protocols. Data typically were collected in the field on IFRP forms; all tabulations and analysis were performed in North Carolina; and data from individual centers and countries frequently were pooled in scientific papers.

Particularly in the mid-1970s, the IFRP's research objectives largely reflected the need of the Office of Population of AID to evaluate quickly alternative contraceptive drugs and devices which might be purchased and supplied by AID and others to family planning programs in LDCs. The IFRP's early work on IUDs and sterilization techniques reflected AID's need to assess for LDCs' use a stream of innovations in both these methods. As the IFRP's work progressed, however, the organization developed its own capacity to innovate. It also established a widespread network of research collaborators throughout the developing world. As these persons gained experience in clinical trials, they contributed to both the process of innovation and the articulation of research needs, which later was extended beyond clinical trials to encompass program design, users' attitudes, and other related issues. Thus, although research priorities continue to be strongly influenced by the needs of AID/Washington for timely evaluations of contraceptive drugs and devices, new technology originating from the IFRP and its collaborators (e.g., the postpartum IUD and quinicrine sterilization technique) and the expressed needs of program managers in the field are increasingly helping to establish scientific direction and strategy.

The IFRP's new emphasis on long-term contraceptive safety, for example, reflects needs felt both in Washington and the field. It also reflects a strong, independent commitment to reproductive health care among the IFRP's senior staff, many of whom have spent their entire professional lives in this field. To some extent, this profusion of sometimes competing demands on the IFRP's scientific resources makes it more difficult to define the IFRP's research goals, but it should be viewed (with certain caveats) as the understandable and logical outcome of ten years of institutional development in the IFRP and its network of collaborators.

The IFRP's founders shared with the AID donors the belief that a second goal of the organization was to seed new contraceptive technology

more rapidly into ongoing family planning programs in LDCs. It was envisioned that the IFRP's network of LDC collaborators would become the natural vehicle for rapid dissemination of new contraceptive technology. The IFRP thus consciously sought to recruit as principal collaborators those LDC institutions and individuals who, through their positions or level of commitment, would be most likely to influence program decisions (realizing the limitations of the influence of clinical investigators on policy decisions). Although it now appears that early optimism about the number of totally new contraceptive techniques available for testing and dissemination was somewhat misplaced, the IFRP's collaborative network has indeed helped to speed acceptance of available techniques and to spread incremental improvements by generating indigenous data on safety and efficacy through and for local health professionals. Even where the scientific contribution of local research activities has been minor on a global scale, the impact on national family planning often has been singularly important.

The IFRP's third major goal has grown in importance as the network of collaborators has expanded and become more sophisticated and as the need to transfer research skills and initiative to LDC investigators has become apparent. Although the conduct of LDC-based clinical trials has of necessity implied some minimum commitment to training in research methodology and clinical practice, the IFRP now provides considerably more support of this kind than is required to maintain its own research activities. Both the IFRP and AID believe that the organization should actively seek to improve, for their own sake, the research capabilities of IFRP investigators in the developing countries and the quality of the institutions in which they work. Over the last four years, the IFRP has encouraged its LDC collaborators to form national and international associations, to accept more responsibility for the design of research protocols and the analysis of data, and to disseminate the results of research. The IFRP supports the institutions with funding, technical assistance, and, most recently, sophisticated computer hardware. Although the level of technical sophistication and enthusiasm varies greatly among the collaborating institutions, a number of them want and can use training in highly technical kinds of data analysis. Training would allow the institutions to pursue their own research objectives. Demands for training and other assistance have placed additional pressures on the IFRP's resources in recent years.

Current Goals and Objectives

As the interests and skills of the organization evolved, support from AID for a wider range of objectives was sought and secured. At this time, support from AID encompasses both grant and contract funds. The grant, which was awarded in September 1977, and subsequently extended, has been the principal mechanism of support for IFRP activities not directly related to clinical trials of contraceptive methods. AID contract funds

support, in general, the activities encompassed under the first goal--the evaluation of new and existing contraceptives for safety (both short- and long-term) and efficacy, with special reference to conditions in developing countries. Grant funds are used primarily to support the third goal, which includes training, institution-building, and dissemination of information. Both grant and contract funds are used to support activities related to the second goal--the seeding of new contraceptive technology into programs--because these activities often straddle scientific and programmatic concerns.

Both grant and contract funds have been used also to support studies on other aspects of reproductive health care and family planning service delivery. These include hospital studies on the impact on health of illegal abortion, the maternity care monitoring system, operations research on community-based contraceptive distribution, and contraceptive prevalence surveys. Some of these activities have been initiated by AID/Washington or AID field missions to fill needs which could not be met at the time by other AID-funded agencies. The IFRP has increased its capabilities to respond to the broader needs of AID and its missions.

In the last several years, the organization has, with encouragement from the Board of Directors, sought to diversify its income. This effort has had some minor effects on the IFRP's portfolio and may have more substantial effects in the future, particularly if AID funding for contraceptive development declines. To date, non-AID funding has been sought and received from the National Institutes of Health (NIH) and several philanthropic institutions. Under current contracts with NIH, the IFRP's focus has shifted slightly toward U.S. domestic clinical trials and barrier methods of contraception. Foundation grants have not shifted measurably the IFRP's focus. However, in the future the IFRP may seek some commercial contracts with U.S. pharmaceutical firms to test contraceptives and non-contraceptive products and may submit proposals to NIH and AID (both centrally and in the field) on projects in the wider field of family health.

After a thorough review of IFRP documents and discussions with the staff, directors, and AID officials, the team summarized the IFRP's current objectives and activities, which are:

1. To initiate and direct third-stage multi-center clinical trials of new contraceptive methods and new adaptations of existing methods for the purpose of evaluating short-term safety and efficacy.

2. To initiate and direct epidemiological studies of the impact on health of fertility regulation methods, including assessment of mortality and morbidity associated with induced and spontaneous abortion and evaluation of long-term risks and benefits associated with use of modern contraceptive drugs and devices.

3. To initiate or collaborate in studies which demonstrate short-term contraceptive efficacy, safety, and acceptability in particular settings in developing countries to speed adoption of appropriate contraceptive technology (both existing and new methods) by LDC policymakers.

4. To initiate and direct, or collaborate in, non-clinical studies on contraceptive use, including contraceptive prevalence surveys and operations research on contraceptive delivery systems.

5. To improve the capacity of investigators in LDCs to collaborate in IFRP studies and to initiate and implement their own studies through the provision of technical assistance and training in research methods and clinical practice, medical equipment and supplies, and, where relevant, software and hardware for data analysis.

6. To design, test, and transfer to developing countries maternity care monitoring systems which demonstrate the relationships between fertility and maternal and child health.

7. To disseminate (in refereed journals, newsletters, seminars, and conferences) and aid in the dissemination of research findings for program and policy development at both national and international levels to facilitate rapid acceptance of new information.

8. To encourage, through grants and technical assistance, the strengthening of selected permanent research institutions in developing countries with the capacity to help set and respond to national research priorities in contraceptive technology; to generate and independently test indigenous hypotheses; to disseminate results of research; and to encourage professional links among research institutions in LDCs.

The enumeration of the IFRP's current objectives suggests that the organization continues to be heavily focused on IFRP- and AID-initiated third-stage clinical trials of contraceptives in developing countries; it suggests also that the IFRP has expanded its portfolio to include a larger proportion of studies in the United States, long-term contraceptive safety studies, clinical and non-clinical studies on reproductive health, and technical assistance to LDC institutions. These trends are a response to changes in the needs of AID and its field missions, to the needs or interests of the IFRP's developing-country collaborators, and to the IFRP's own need to sustain itself as an independent research organization with a secure, diversified base of funding. In general, the IFRP's objectives correspond to a large degree to those of AID's population research program.

The expansion of the IFRP's objectives into non-AID concerns, which has occurred in recent years, should not jeopardize the IFRP's utility to AID, as long as the organization retains its capacity and shepherds its resources to perform well and to the degree necessary in its traditional roles.

IV. IFRP STAFF AND ORGANIZATIONAL RELATIONSHIPS

To determine the adequacy of the IFRP's current staffing pattern in light of AID's requirements under the contract and grant, the team reviewed biographical information on all personnel in the top three grade levels, examined closely the patterns of supervision and communication on technical matters, and assessed the quality of scientific output of a number of key personnel.

Some recurrent problems have been partially or fully resolved by the appointment of new personnel, the transfer of existing personnel to other departments, and the resignation of persons unable to function effectively within the IFRP's current organizational structure. Although, ideally, the IFRP should seek to recruit additional senior personnel for both its scientific and field activities, financial constraints are likely to limit the number of additional full-time permanent employees that can be hired in the near future. Careful consideration should, therefore, be given to the range of activities that can be covered satisfactorily, and priorities should be established. The IFRP should, moreover, seek to strengthen its staff by imaginative use of part-time and temporary contract personnel.

Response to Early Recommendations

The team notes with satisfaction the following recent improvements in staffing patterns, which reflect responses to earlier evaluators' recommendations:

1. Scientific and, specifically, medical supervision of the IFRP's field staff was improved measurably by the transfer of a senior physician to the International Projects Department and use of mechanisms permitting closer cooperation between regional coordinators and scientific staff. Further efforts need to be made, however, to upgrade the technical expertise of some field staff.

2. The IFRP's sensitivity to developing countries' needs and its ability to initiate and monitor activities overseas have been enhanced by the establishment of two field offices in Latin America and Africa, staffed by well-qualified, indigenous physicians. The IFRP should consider developing similar field capabilities in Asia.

3. The resignations of some senior personnel have eliminated major sources of friction within the organization. The result has been more open, collegial relationships and better communication

among staff. In addition, lines of authority and organizational priorities have been clarified.

4. The appointment of a deputy executive director with extensive management experience has put the IFRP on a sound administrative footing, improved communications, and freed the executive director to provide more active leadership in scientific activities. Budgeting, accounting, personnel, and other systems have been revamped and are highly professional. No major improvements in these areas are deemed necessary.

5. The IFRP has hired a competent demographer-biostatistician, with relevant developing country experience, to be a "data quality coordinator." Authorized to approve all research methodologies and review all results of studies, this person has substantial control over the quality of scientific output. The team feels, however, that staff competence in biostatistics and epidemiology still needs to be upgraded, particularly for studies, such as RAMOS, on contraceptive safety.

6. The somewhat unwieldy Research Department has been reduced in size through the transfer of individual personnel and some subunits to International Projects and Administrative Services. The transfers appear to have smoothed working relationships and should leave the associate director for research with more time and energy to direct the work of the IFRP's senior scientists. Additional measures are needed, however, to improve the medical and scientific leadership of the Research Department.

7. Some of the problems related to the selection of studies and research designs have been solved by strengthening subject-area task forces and the Research Strategies Committee. Participation of senior research staff has increased measurably, improving supervision, communication, and coordination between senior scientists and more junior scientists and between research staff and field personnel. Such efforts should be strengthened further, with intimate interaction encouraged during design of research proposals, development, operation, analysis, evaluation, and reporting.

Relations with AID

Working relationships between IFRP staff and professionals in the AID Office of Population are characterized by a high degree of cooperation and collegial interaction. This situation benefits both AID and the IFRP and ensures that IFRP activities are in harmony with AID goals and objectives. However, two kinds of communications problems exist that merit attention.

First, IFRP staff feel that they do not always receive information on their institution on time and that this affects their ability to plan and to respond adequately to concerns expressed by AID. The team recommends that AID look for ways to ensure the earliest possible flow of information to the IFRP on matters relating to IFRP activities.

Second, from AID/Washington's perspective, the burden of communication on scientific collaboration, program planning, and recommendations for decisions is concentrated in one or two people in the Office of Population. Ways should be sought to relieve this burden and to involve higher-level AID personnel in the review of the IFRP's program priorities.

Relations with Other Institutions

In the Raleigh-Durham area, where the IFRP is headquartered, there are several universities and research institutions with resources that could aid the IFRP's work. In the past several years, interaction between IFRP staff and these institutions' personnel has improved. The team feels, however, that the IFRP needs to make a more conscious effort to build institutional ties with the North Carolina research community. The election to the Board of a senior academician from North Carolina would be a useful first step.

Recommendations

To improve staffing and organizational relationships, the IFRP should implement the following recommendations:

1. Additional measures are still needed to improve the scientific and medical leadership in the Research Department. Staff competence in biostatistics and epidemiology in the Research Department still needs to be upgraded further.

2. Further efforts need to be made to upgrade the technical expertise of some field staff.

3. The IFRP's ability to initiate and monitor overseas activities has been enhanced with the addition of field offices in Africa and Latin America. The establishment of field capabilities in Asia that are appropriate to that region should be considered.

4. The IFRP should strengthen its staff by imaginative use of part-time and temporary contract personnel.

5. The current staff should be upgraded through formal training in relevant disciplines.

6. Additional ways should be found to strengthen collegial ties with neighboring scientific and academic institutions in the Research Triangle.

V. RAMOS AND OTHER LONG-TERM CONTRACEPTIVE SAFETY STUDIES

RAMOS

Recognizing that clinical trials could answer only a limited range of questions about safety among contraceptive users, the IFRP began to address the issues of longer-term safety in 1979. The largest undertaking, the RAMOS program, represents 4.1 percent of the IFRP's 1982 budget. The initial strategy was to use principles of surveillance, already well-established in public health and clinical practice, to identify deaths among women of reproductive age and to determine what relationship those deaths might have had to contraceptive use. The first reproductive age mortality surveillance study was organized in Bali, beginning in late 1980, and the second in Egypt in late 1981. Both sites were expressly chosen to maximize the likelihood of relatively accurate and complete mortality reporting. In Egypt, the existing civil mortality reporting system was thought to be virtually complete. In Bali, however, it seemed that the addition of a relatively light supervisory support system to an existing, and uniquely pervasive, social network in the villages would be sufficient to promote complete reporting of deaths.

A more difficult task, clearly recognized in the planning phase, was to establish a cause for each reported death. In some instances, as in cases of homicide, accidents, or deaths during childbirth under medical supervision, this is relatively easy. In other cases, however, proximate causes of death have to be deduced from the symptoms of the patient during her final illness, as related by relatives and friends shortly after the event. Although clearly not the histopathological detective work of the university hospital, this more sympto-anthropological approach to autopsy was, it seemed, serviceable for field-testing. This was fortunate, because the more sophisticated approaches to medical diagnosis were not feasible.

The underlying design of RAMOS is to ascertain whether or not contraceptive use is associated with increased mortality and whether such mortality is due to biologically plausible proximate cause(s) of death. At both study sites, information on prevalence of current contraceptive use is available for comparative purposes. At one site, information on past use also is available. It is assumed, again on the basis of pilot studies, that mortality associated with pregnancy and childbirth can be identified and analyzed separately from other deaths to women of reproductive age. The two RAMOS projects are meant to yield information on causes of death in traditional societies among women between 15 and 45 and, if, as is expected, the enumeration of deaths is reasonably complete, reliable age-specific mortality rates.

Because the RAMOS project in upper Egypt had only just begun, it was felt that a site visit would be premature. The details of the project

were discussed with the director while he was in the U.S.; this person, with one exception, seemed to be familiar with and to understand the protocol. One problem was the need for local review of the symptomatic histories of the decedents by medically-trained persons who are unaware of the deceased persons' past contraceptive practices. The uncertainty over this important issue was pointed out to the IFRP project monitor for correction.

The team gave much more attention to the Bali project than to the project in Egypt. The team visited the site to assess almost one year of field operations there. Significant problems, many of which had been anticipated earlier, emerged. For a variety of reasons, reporting of deaths to married women between 15 and 45 has been seriously incomplete. And, because of uncertain baseline population data, the expected number of deaths is not firm.

Allowing for this uncertainty, however, the level of reporting does not seem to be higher than 70 percent. Although evidence points to increasing reporting over the brief life of the project, 70 percent at this stage of implementation must be considered less than desirable. Analyses for reporting bias by contraceptive use, diagnosed cause of death, and maternity status will soon be undertaken to assess any possible impact on the principal research objectives. With this information it should be possible to interpret any findings with a higher level of confidence.

The site visit made plain that the system organized to reinforce the unique village banjars in collecting death reports was not functioning optimally, perhaps because the same supervisors are used for a variety of developmental service and research projects. Nor was overall supervision adequate to cover the entire island with sufficient frequency to prompt adherence to the protocol for reporting deaths and conducting detailed interviews about the deaths with relatives, friends and, less frequently, health providers. In addition, but less seriously, there was a backlog of interview data on deaths awaiting diagnostic review. There was a backlog because of the recent extended illness of the project coordinator.

With the cooperation and concordance of local project staff, the team made several suggestions to strengthen the project. The recommendations were implemented and strengthened by thorough follow-up visits by a member of the IFRP staff and (separately) the National Family Planning Coordination Board (BKKBN), based in Jakarta, Indonesia. Bali was divided into two areas, according to project intensity. In the strengthened area, nearer to project headquarters, more training of village leaders and more supervision at several levels will be undertaken. Reporting of deaths will be facilitated by new forms. In the other area of Bali, the project will go forward according to the original protocol.

Given the evident problems with implementation, these changes increase the likelihood that supervision will be strengthened (and reporting of deaths increased) over half the island's population in the second year

of the project. The results of these changes should be clear quickly and, if they go in the expected direction, they will permit both comparative and sequential analyses for bias in death reporting by the characteristics mentioned above. Such internal analysis is expected to strengthen understanding of the project's efficiency and will be indispensable in interpreting the final results.

Long-Term Safety Studies

In addition to the RAMOS studies, the IFRP has supported three cohort-type investigations into the long-term effects of vasectomy (California) and Depo-Provera (Bandung, Indonesia, and Atlanta, Georgia). A case-control study of atherosclerotic heart disease and its possible relation to vasectomy in the developing world is being planned. Because there are few opportunities for research of this kind in the developing world, such studies typically take advantage of unique situations and opportunities.

Two of the cohort studies seem to be well-founded, but the third, in Indonesia, is vulnerable to criticism. In a follow-up study of a relatively small group of current and former users of Depo-Provera, endometrial biopsies are being performed to assess the frequency of non-malignant changes. It is already clear that the study will not have sufficient power to detect risk of endometrial cancer, and, in the absence of a specific hypothesis, it must be regarded as a marginal "fishing expedition." This alone might be a reasonable point from which to proceed, provided enough long-term users are available, but the number of women recruited could be much smaller still, causing less inconvenience, risk, and expense. It is not clear that a power curve was done before this particular study was organized. A thorough statistical appraisal during the planning phase might have altered the design in beneficial ways.

Given the IFRP's extensive involvement in female sterilization programs and the follow-up studies that already have been published by staff, the basis for longer-term studies of sterilized women seems to be well-established. Active follow-up of part of the extensive group of women now kept under observation for the two years following surgery might be one approach to these studies.

A neglected area of concern, not now being addressed in the developing world by other agencies, is infertility following contraceptive use. This is of special concern in programs where the prevalence of IUD use is significant, and it might be approached as a case-control study in a hospital setting where infertility workups are performed.

Finally, new hypotheses will emerge from the literature, from IFRP training efforts, and also from surveillance efforts. Simple systems of passive surveillance (in contrast to the active surveillance of RAMOS)

may be expected to generate additional research on possible long-term safety risks. Such systems are relatively easy to set in motion and deserve a trial country-wide in the developing world.

Recommendations

The following steps should be taken to ensure that the IFRP's work in contraceptive safety and related issues produces useful information:

1. The team commends the IFRP for its careful development of the RAMOS approach to measuring serious contraceptive risk, but it is not sure that the design will enable the IFRP to reach all its objectives. The RAMOS project in Bali should be completed as planned, but the study in Egypt should proceed only with the approval of the RAMOS consultative group, which is expected to meet for the second time in April 1982.

2. No other RAMOS projects should be initiated until the current two efforts have demonstrated their feasibility and scientific merit.

3. The team supports the IFRP's efforts to develop other studies on longer-term contraceptive safety, using appropriate designs and carefully drawn protocols to answer specific hypotheses.

VI. MONITORING OF MATERNITY CARE

Among the activities undertaken when the IFRP broadened its scope beyond studies on contraceptive methods was the MCM project. For this, a standard questionnaire form is used to compile, input, and analyze data on hospitalized maternity patients. More than 400,000 cases in more than 60 hospitals in 35 countries have been covered.

Progress also has been made in developing comparable forms to collect data for maternal health centers and in designing a pictorial record form for traditional birth attendants. The analyses of data from hospitals were done directly at the IFRP, and reports were fed back to the contributing institutions. A number of scientific papers were produced by IFRP staff and overseas collaborators. Over the last two years, MCM activities have been curtailed substantially, partly in response to earlier evaluators' recommendations. They now represent 3.2 percent of the IFRP's 1982 budget and are being concentrated increasingly in Africa.

Several obvious benefits accrue to participating hospital personnel that have implications for their practices. The mere completion of forms is an educational process and a constructive discipline. Attaching a copy to each woman's hospital case record improves the quality and likely utility of recordkeeping. Feedback with statistical summaries on clinical procedures and outcomes, especially with epidemiological associations to those outcomes, should help to alert institutional personnel to the need for changes in their practices. Particular emphasis is given to the potential roles of contraception in maternity care. The extent of actual changes that result from presentations of data has not been documented and is difficult to determine.

Of perhaps greater importance is the fact that data also expose deficiencies in preventive maternity care provided outside the hospital. Bringing these deficiencies to the attention of responsible public health authorities is not so automatic, however; and it is less likely that correction will be stimulated in these instances than when intramural hospital considerations are brought to light.

Once the MCM system was initiated in 1977 and 1978, it snowballed. The IFRP's aim seems to have been to encompass more and more hospitals in more and more countries, and eventually to compile information on childbirths throughout the world. Correspondingly, costs mounted, and expected returns diminished. Tight supervision on accuracy, completeness, and continuation of reporting became more onerous. The team did not obtain trend data on these aspects or on the IFRP's analysis of the backlog that occurred during the life of the project. It is not clear to what extent the IFRP succeeded in involving and shifting responsibility to other

agencies and groups. In any event, the routine collection and analysis of large amounts of underutilized data should be discontinued.

The team would admit that for each hospital that is included, the opportunity to make corrections increases, and each country opens itself to improvement in preventive maternity care. But the IFRP cannot be expected to be the agent that spreads the gospel around the world. The MCM activity must be constricted and focused and tied to specific steps for capitalizing on the information in a planned and systematic fashion.

The collection of epidemiologic data by other than precise sampling calls for completeness or near completeness of reporting. Not only must accurate and complete hospital data be gathered, but comprehensive information on the extra-hospital situation--the women delivered at home by TBAs and the women who die in such circumstances--must also be obtained. Hospital data alone are valuable, but they give only a partial and distorted picture, the magnitude of the distortion remaining uncertain. The IFRP has moved in the right direction in planning, with the United Nations Fund for Population Activities (UNFPA), the design of one or more country projects in which comprehensive data will be collected across the different levels and settings of maternal health service. The development and testing of such a model will be very useful.

At this time, the IFRP sits on a mountain of MCM data that should be exploited, but not mined exhaustively. Although a number of papers were presented at international meetings that described the MCM concept and its application in different countries, in the several years since the project began, relatively few analyses of findings have appeared. A number have been clinical, on such topics as sterilization, breech deliveries, cesareans, and postpartum contraception. Others have been epidemiologic, concerned with maternal and perinatal mortality, low birth weight, adolescent pregnancy, and identification of risk groups. These analyses are, in large part, useful contributions to the literature. At times, however, there has been a tendency to play with numbers, and not to give time selectively to important questions. In such instances, the findings have been what one would expect.

The IFRP should make the MCM data available to overseas collaborators, so that they can use them to write their own reports, and also to other independent investigators. Care should be exercised in any pooling of data from multiple sources. All reports should give numbers of cases, as well as percentage distributions; precise information should be provided also on extent of incompleteness in reporting cases, answering specific questions, and addressing other biases in the material. A special effort should be made to identify and highlight in simple, focused feedback reports indications for extramural preventive steps (e.g., primary health care projects) by public health authorities. Suggestions for action do not emerge clearly from scientific publications and do not reach the most relevant audiences.

Recommendations

The evaluators recommend the following to improve monitoring of maternity care:

1. In accordance with earlier evaluators' recommendations, the IFRP has decreased emphasis on maternity care monitoring activities, particularly routine activities. The team recommends that this trend be continued.

2. Existing data are being analyzed and fed back to various investigators. The IFRP should seek to improve the utility of MCM standard computer printouts for collaborating investigators, emphasizing a highly selective choice of data for specific contributors, to increase contributors' comprehension and use of the information. Collaborators' suggestions should be considered.

3. In attempting to address the issue of the representativeness of data collected solely from a hospital source, the IFRP should explore various methods for collecting data outside the hospital. For example, it should try to gather data on deliveries by traditional birth attendants, and attempt to collect comprehensive data for an entire geographic area.

VII. QUALITY OF DATA

Over the years, the IFRP has developed a series of forms to collect data on the several methods of fertility regulation it has investigated and computer programs to detect internal inconsistencies and to tabulate results. The evaluation team believes that these forms and programs are appropriate for a multi-center research enterprise and that the quality of the data that are collected and processed is as high as can be expected in an operation as large and as diverse as that undertaken by the IFRP. It is hoped, however, that with stronger scientific leadership, greater flexibility and greater sophistication of statistical analysis will be achieved.

Certain features in the IFRP program warrant particular statistical sophistication and caution in analysis. They require that the IFRP:

--rely on cases that are not selected at random;

--draw inferences from small case numbers and incomplete data;

--involve large numbers of collaborators with limited research experience;

--seek long-term associations among data from different sources;

--give consultation on research design to overseas collaborators;

--pool data from different investigators and institutions; and

--work in many different and alien cultural settings.

For the immediate future, the team believes that, wherever possible, IFRP publications should emphasize absolute or attributable differences or risks, in addition to relative risks; use confidence limits instead of standard deviations, which may be quite misleading; and identify findings which are not statistically significant because the number of cases is small (e.g., those that offer a less than 80 percent chance of detecting a relative risk of 2.0 or a difference considered clinically or programmatically important).

The evaluation team also believes that the IFRP's "data bank" should be used more fully, perhaps for periodic or occasional reports on selected major subjects. This would require the identification and exclusion of data from studies with inadequate follow-up or other defects. The feasibility of making the "data bank" available to outside scholars should be explored.

The team applauds the IFRP's recent efforts to verify the completeness and accuracy of data and recording by field visits. The team urges that new contributors be selected with great care, that delinquent contributors be separated without undue delay, and that specific projects be terminated when the information required has been obtained.

The team anticipates that any decentralization of research planning and data analysis to national FRPs or individual investigators will result, at times, in confusion, misdirected efforts, and lower standards. The IFRP should be prepared and equipped to offer adequate training and technical assistance in a transitional period, the duration of which cannot be predicted with confidence.

Recommendations

The evaluators recommend the following action to improve and ensure the quality of data:

1. In future IFRP publications, more emphasis should be placed on absolute or attributable differences or risks; confidence limits should be used instead of standard deviations; and findings that are not statistically significant because of small numbers should be so identified.

2. The IFRP's data should be used more fully in periodic and general reports on selected major topics, following the deletion of data from studies with inadequate follow-up or other deficits.

3. New contributors should be selected with great care; delinquent contributors should be separated without undue delay; and projects should be terminated when the required information has been obtained.

VIII. TECHNICAL ASSISTANCE, TRAINING, AND TECHNOLOGY TRANSFER

The 1981-1982 IFRP Directions devotes four pages to technical assistance and institutional development. Emphasized are the provision of microcomputers and appropriate software; training in research design; data collection and report writing; support for fertility research programs in LDCs and their networks of local collaborators; and support for the International Federation of Family Health. (The IFFH is discussed in a separate chapter.)

Plans are well-advanced to provide the microcomputers and specially-designed software to several of the FRPs. The LDCs eagerly await this equipment, often without fully recognizing the inevitable problems and delays that can be anticipated. Great care has been taken by IFRP staff to arrange for the purchase of cost-effective equipment that can be serviced in the developing countries. Software packages are being designed in North Carolina, and careful training is planned to introduce the software when the hardware comes on line. Initially, the programs will be aimed at current IFRP-sponsored studies, mostly clinical trials or surveillance-type efforts, and will be compatible with data processing systems at the IFRP. After introduction, follow-up visits by technically trained IFRP staff will almost certainly be required to increase comfort with the equipment and procedures, and also to solve problems. Eventually, the IFRP plans to make available more comprehensive software packages to permit analysis of studies using a wider variety of designs (e.g., case-control and longitudinal and cohort studies). It can be expected that these introductions will proceed more slowly than is now anticipated and that the ongoing technical assistance that will be needed to bring and keep the equipment productively on line will be time-consuming and expensive.

The IFRP recognizes that some in-country networks are more "ready" than others. The team feels that the IFRP should undertake to provide technical assistance in one or two "ready" countries first, making sure that the budget for follow-up is adequate before it proceeds. In this deliberate way, unanticipated problems that emerge can be solved without straining human and financial resources.

Recently, the IFRP initiated efforts to strengthen significantly the capacity of the FRPs and other collaborators in research design. Short-term training courses in epidemiological and statistical approaches to fertility research have now been held in three countries. No complaints of "research imperialism" were expressed to the team, but such feelings may not be far from the surface and may well emerge in response to IFRP-designed protocols that enlist collaborators as part, often a small part, of an international study. The team thinks it is reasonable to anticipate a growing movement, precipated by locally-generated hypotheses, toward independence in research. Also anticipated is increasing need for either local funding for research or, as in Indonesia, direct

arrangements with donors that give local family planning organizations and universities increased responsibility for evolving their own bio-medical research strategies.

There is considerable interest in formal, short-term training and, compared to even a year ago, the IFRP's capacity to provide expertise in epidemiology and biostatistics has increased significantly. Outside resources, often in the developing country, can and should be mobilized by the IFRP to teach these courses, especially when the teaching should not be only in English. In addition, the IFRP might wish to sponsor trainees attending suitable courses run by other technical assistance agencies, (e.g., The Population Council). The team believes that the IFRP should continue to offer training courses in the logic of research and biomedical data analyses and provide a manual for students. The courses might touch on specific problems of data management for IFRP-sponsored research, though this should not be the main focus of the teaching. The main emphasis, in the team's view, should be the development of protocols around locally developed hypotheses, or ideas which indigenous researchers think are relevant to the local setting.

The IFRP's commitment to support FRPs has been increasing. It is important to recognize that the national fertility research programs are aimed at enhancing the capabilities of developing countries to design, implement, monitor, and evaluate high-quality fertility control research of all kinds to speed and improve the evaluation, introduction, and diffusion of the latest methods of fertility control and systems for their delivery. The national fertility research programs were established on the sound idea that having a central coordinating body would maximize the resources available for biomedical research. Clearly, the FRPs welcome assistance from the IFRP; they want more extended visits--and by technically qualified persons. This is especially true of the FRPs that have made the most progress toward independence in research. Short administrative visits are no substitute for what is desired locally. Nor can AID population missions often provide the most appropriate kind of recurring, long-term technical help. The team feels that more consideration should be given to placing a suitably trained junior scientist as the IFRP's field representative, probably in Asia. Ideally, this person would be based in a country FRP to provide continuous on-the-job training and technical assistance. (S)he would be available to perhaps one other active country FRP. Of the four FRPs in Asia, two either can find this help through other agencies or are not far enough advanced to profit from it at this time.

The team feels that the IFRP should not seek to expand further the FRP network in the near future. Even if the budget for subgrants permitted this, the technical resources of the staff do not seem to be sufficient, given current staffing patterns, to provide adequate technical support to an increasing number of FRPs.

In addition to the activities mentioned in the 1981-1982 IFRP Directions, the historic roots of the IFRP's effort to speed the international diffusion of the latest techniques in contraceptive technology require comment. Modeled after the Rice Research Institutes and other academically-oriented agricultural extension programs in the United States and overseas, the IFRP was founded to provide a mechanism for testing new developments in contraceptive technology under conditions peculiar to developing countries. It was felt that members of the IFRP's international network of collaborating investigators could also aid in the dissemination of the contraceptives they evaluated. The IFRP continues to support activities that provide new technology and adapt methods and procedures widely used elsewhere to new health and family planning programs in LDCs.

In addition to multi-center clinical trials to test new methods, the IFRP transfers several kinds of contraceptive technology. One of the most important activities has been the recent introduction of IUDs in Brazil. Briefly, this project provided funds to the University of Campinas to coordinate a multi-centered program trial of copper IUDs. Before this trial, IUDs were not widely available in Brazil. The IFRP project is important because all the collaborating centers in the trial are major Brazilian medical institutions. Programs were initiated at departments of obstetrics and gynecology (OB/GYN), with the cooperation of department chairpersons. Because of the sponsorship of the study and the cooperation of a large number of prestigious medical institutions, IUDs have become an increasingly legitimate form of contraception. Their acceptance would have been difficult to secure without the IFRP project.

The IFRP continues its series of conferences and demonstration and training programs in support of the introduction and transfer of new contraceptive technology. Information is also "passed" when IFRP staff visit collaborators and other, less formal contacts.

The value of the demonstration and training ("detailing") activities is considerable. Historically, many of the seminars have been extremely important, especially in Latin America, where the IFRP was able to provide a context for the open and free discussion of family planning and contraceptive techniques for professionals likely to be involved in the field. More recently, however, as information about contraceptive techniques has become widely available, the usefulness of these seminars has been questioned. The seminars continue to be useful where information is scarce and practitioners need to be upgraded and legitimized, and where personal "detailing" is more persuasive than written communication. There is continuing concern at the IFRP that such activities be tailored carefully to meet specific local needs and that presentations be scientifically correct and balanced. Working with the FRPs helps ensure that these aims are met.

IX. INTERNATIONAL FEDERATION OF FAMILY HEALTH

The IFFH was organized in 1977-1978 to support the new fertility research programs and other international collaborators interested in contraceptive and related research in maternal and child health. A prestigious group of senior researchers has met regularly since then to exchange information on new findings, policy developments, and leads for further research. The secretariat of the IFFH has been moved from Research Triangle Park, in North Carolina, to Bandung, Indonesia. It is hoped that financial independence can be attained through support from member countries and donors other than the IFRP.

To date, efforts to raise other sources of funds have not been productive. Nor has it been possible, perhaps because donors' resources are declining, to begin an ambitious program of research in maternal and child health issues. Although the future is uncertain and the history of coordinating agencies in the developing world is difficult, the team visualizes a technical assistance and research planning role for the IFFH once the secretariat has been consolidated and fully staffed, and after independent funding has been secured.

X. BOARD OF DIRECTORS OF THE IFRP

Beginning in the fall of 1978, the composition of the Board of Directors of the IFRP began to change. Initially a small working group composed of IFRP staff and a few close colleagues, the Board has become a large, fully independent unit representing a diversity of skills and interests. Staff are represented on the Board only as non-voting members. The beginning of this process of evolution corresponded to major changes in the organization and leadership of the IFRP, prompted in part by financial and management problems. These organizational changes, and the problems which helped to precipitate them, drew Board members more deeply into a wider range of management decisions than had been the case throughout most of the IFRP's history. The resolution of the problems experienced in 1977-1979 and the appointment of well-qualified management staff have allowed the Board to withdraw considerably from the oversight of day-to-day administrative and financial operations. However, the experience of the earlier years has firmly established the newly independent Board as the policymaking body for the organization. Continued additions to the Board have expanded its capacity to provide such leadership. The team believes that these developments--the establishment of an independent Board willing and able to provide direction and oversight--have measurably strengthened the IFRP's financial, management, and scientific potential.

The team recognizes, however, that the evolution of the Board of Directors is not complete and that certain additional steps should be taken to ensure better representation on the Board of certain skills or areas of interest useful to the organization. The team also believes that the IFRP must work harder to make the Board a more integrated whole and to make new Board members fully conversant with the organization's scientific programs. The present makeup of the Board (see Exhibit X-1) suggests where gaps in representation may still exist.

The team feels that with the recent additions of William Hubbard and Rodger Short, the Board now possesses much of the necessary expertise to provide adequate direction for the IFRP's scientific work in biomedicine. The Board also has a sufficient complement of members with business and program management experience (Collins, Andrews, Brown, and Hubbard) to guide the IFRP's well-qualified administrative staff. However, four possible gaps in competencies on the Board remain.

First, there is little representation from the developing countries, even though the bulk of the IFRP's work continues to be in, or on behalf of, the developing countries.

Second, the Board is not well-qualified to provide direction for the IFRP's work in the social sciences. If the IFRP is to continue, with AID's encouragement, to take on research projects involving demographic

Exhibit X-1

IFRP BOARD MEMBERS

Officers

Elected 1978 (April)	Sharon L. Camp, Ph.D., Chairman and President: American, political scientist; public policy advocate in Washington, D.C.*
Elected 1976 (October)	Hubert de Watteville, M.D., Vice President: Swiss, obstetrician-gynecologist; professor emeritus, and recognized authority on infertility; leadership roles in European and Third World MCH organizations and programs.
Elected 1974 (October)	Donald Collins, M.B.A., Treasurer: American, businessman and consultant in financial management and fundraising, with broad volunteer experience in family planning organizations.*
Elected 1979 (September)	Lise Fortier, M.D., Secretary: Canadian, obstetrician-gynecologist; medical director of Los Angeles Planned Parenthood; pioneer in Canadian family planning program; extensive publications and professional memberships.*

Members

Elected 1977 (September)	Guadalope de la Vega: Mexican, psychiatrist; founder of first highly successful family planning clinic and outreach program in northern Mexico.
Elected 1979 (September)	Torrey Brown, M.D.: American, internist; director of Ambulatory Medicine and Health Care Program and associate professor and dean for clinical programs, Johns Hopkins University; health committee chairman in Maryland House of Delegates; director of several community health programs.
Elected 1980 (February)	Brigadier General Alexander B. Andrews (U.S. Air Force, Ret.): American, attorney and businessman in Raleigh, N.C.; multiple corporate directorships in U.S. firms with operations overseas.*
Elected 1981 (September)	William Hubbard, M.D.: American, internist, president, Upjohn Co.; ties to North Carolina academic community and U.S. pharmaceutical industry; former dean, Medical School of the University of Michigan; broad professional memberships.
Elected 1981 (September)	Rodger Short, Ph.D., D.V.M.: Scottish, reproductive physiologist; director, Unit of Human Reproduction, Medical Research Council; professor, University of Edinborough; widely published.
	Malcolm Potts, M.D., Ph.D.: English, obstetrician-gynecologist; executive director, IFRP, non-voting.

---

* Member of the Executive Committee. Collins, Andrews, and Brown make up the Audit Committee.

analysis or the design of service programs, at least one additional person with recognized expertise in this field should be recruited as a member of the Board.

Third, although the Chapel Hill area is rich in academic resources which could supplement the IFRP's work in various ways, the IFRP's ties to North Carolina institutions are not strong. The addition to the Board of a person from a North Carolina university or research institution could facilitate increased interaction with local colleagues.

Fourth, the IFRP needs to analyze the Board's ability to contribute to the diversification of the organization's income through contracts with government agencies other than AID, commercial contracts with the pharmaceutical industry, or grants from philanthropic institutions. The IFRP would benefit from the addition of persons with experience in or ties to any of these potential sources of income. Although, from AID's perspective, the first three areas of under-representation on the Board may be more important, the long-term viability of the IFRP as an independent research organization may depend on the organization's success in generating income. Therefore, the team recognizes that, from the IFRP's perspective, the recruitment of Board members with fundraising abilities may have higher priority.

The team also recognizes that the IFRP cannot add new Board members rapidly without risk to the level of commitment, knowledge of the organization, and close cooperation which characterize the Board at this time. Two members elected in late 1981 will attend their first meeting in 1982, and two or three additional new members will be considered for election at that time. The new candidates are Fred A. Coe, Jr., retiring chairman of the Board of Burroughs-Wellcome Company (a major international pharmaceutical firm headquartered in Research Triangle Park), and R. Payton Woodson, III, an international businessman from Raleigh with ties to corporate philanthropic activities in a number of developing countries.

The consolidation of this growing Board into a working unit will require special care. New Board members should be given ample opportunity to immerse themselves in IFRP programs through special briefings, site visits, attendance at technical meetings and workshops, etc. Further additions to the Board probably should not be made at a rate of more than one or two persons each year.

The minutes of IFRP Board meetings indicate that a large portion of the Board's time is taken up with administrative, financial, and personnel issues. Although the team recognizes that this preoccupation with "housekeeping" is, to some extent, unavoidable, it feels that other areas may be receiving too little attention. These areas include research priorities and strategies, the composition of international activities and programs, and development of a long-term plan for diversification of income. The team notes that over the last year, many financial and management issues have been delegated--with good effect--to the Executive Committee and the new

Audit Committee. But the IFRP needs to make more room on the agendas of full Board meetings for substantive discussions of IFRP programs and, without unnecessarily duplicating the role of the Technical Advisory Committee, to find ways to immerse Board members more deeply in the technical aspects of the IFRP's scientific work. The involvement of Board members in technical meetings and on-site evaluations of subgrantees are examples of activities which can help to immerse Board members in IFRP programs. In the last two years, Board members have been involved in on-site evaluations in Brazil, Colombia, India, Malaysia, and Thailand. In addition to expanding the Board to include additional persons with expertise related to the IFRP's work, the IFRP should consider increasing, within budget constraints, the level of the Board's involvement in field visits. Such visits help to increase the Board's understanding of specific IFRP projects and programs.

The full Board holds regularly scheduled meetings twice each year. At these times, the Audit Committee and Nominations Committee also meet. The Executive Committee meets four times each year. In the past, the full Board held as many as four meetings a year, but it is not expected that this pattern will be repeated.

Recommendations

The team recommends that the IFRP implement the following steps to improve the composition and capabilities of the Board of Directors:

1. The IFRP should continue to expand gradually the membership of the Board of Directors, giving special attention to the need for greater representation from the developing countries, collegial institutions in North Carolina, and the social sciences.

2. The IFRP should analyze the ability of the Board, as it is structured at this time, to assist in the future diversification of IFRP income. Additions to the Board should reflect the organization's need to bring in more non-AID resources. The Board should assume greater responsibility in this area.

3. The IFRP should continue to try to deepen the Board's understanding of IFRP programs and should reserve additional time at Board meetings for substantive discussions of programmatic priorities.

XI. TECHNICAL ADVISORY COMMITTEE

The TAC was established originally to provide periodic outside review of IFRP projects and programs. At the time of the 1977 evaluation, it was pointed out that the TAC did not provide systematic reviews of IFRP research projects. Moreover, the earlier TACs were a mix of staff members and outside consultants, a number of whom were IFRP grantees.

The 1980 APHA team found that the membership of the TAC had been diversified and strengthened. However, the TAC meets only once a year, receives minimal or no information in advance, and carries out no detailed project reviews. Thus, it serves only an overview function. The team strongly recommended that all research proposals be subjected to thorough and rigorous review by a revitalized and reoriented TAC.

In response to this recommendation, the IFRP initiated a series of meetings on specific research topics. Outside experts in the relevant areas participated in these meetings. The results of the meetings were distributed, with additional relevant materials, to TAC members before their meeting in July 1981.

Recommendation

The team believes that changes in the membership and procedures of the TAC have resulted in substantial improvement. Continuation of this new format, with augmentation where necessary, is, therefore, recommended.

XII. FINANCIAL CONSIDERATIONS

Like many AID projects, the IFRP has been experiencing a period of considerable funding austerity. Funds for fiscal year (FY) 1982 will be approximately $4.7 million, as compared to $4.9 million in FY 1981. Of the $4.7 million, approximately $3.6 million will be applied to the contract, and approximately $1.1 million will go to grant activities. These figures represent a decrease in funding for the grant, which has been funded at an average of almost $2 million per year for the last three years. They represent a slight increase in funding for the contract, which has been averaging just over $3 million per year for the last three years. This funding pattern is consistent with the opinion of AID and earlier evaluators that contract research should have the highest priority.

The IFRP has undertaken a number of actions in response to cuts in funding. It has instituted considerable belt-tightening, particularly in personnel, installed a more rigorous budgeting and accounting system, and secured significantly increased financial support from sources other than the AID Office of Population. This diversified support (approximately 15 percent to 20 percent of the budget) includes funds from private sources, the NIH, and the AID mission in Indonesia (for local activities).

The newly instituted budgeting process requires the complete allocation of and control over all funded activities. It includes a progress reporting system with specific milestones and the measurement of progress against milestones. Thus, all projects are under continuous review. The system fully ensures that the funding levels for particular projects are appropriate.

These changes improve the efficiency of the organization, but they do not obviate the clear problem of a shortfall of funds. Funds received from AID are almost entirely committed to ongoing projects, and there is very little flexibility to pursue new opportunities that arise. When faced with difficult funding decisions, the IFRP should give highest priority to research to assess the safety, efficacy, and acceptability of new and improved methods of contraception. Other priority areas should include training and institution-building to raise the level of competence of IFRP staff and contributors in the field.

Recommendations

The team recommends that the IFRP continue its efforts to ensure the appropriateness of funding for specific IFRP projects and to broaden and diversify financial support. In dealing with the current funding shortfall, the IFRP should place the strongest emphasis on contract activities

(including Phase IV studies) directly aimed at assessing the safety, efficacy, and acceptability of current, improved, and new methods of contraception throughout the world.

XIII. CONCLUSIONS AND SUMMARY OF RECOMMENDATIONS

In general, the IFRP is fulfilling the mission mandated by AID under the terms of the current AID grant and contract. The team recognizes that progress has been made, particularly in improving personnel and management, expanding and enhancing the capabilities of the Board of Directors, and using outside technical advice. During the evaluation, the team identified a number of areas that need to be strengthened further and made a series of recommendations. The IFRP is addressing some of these areas at this time so that it can continue to satisfy the future needs of AID.

Summary of Recommendations

To recapitulate, the following action is recommended:

1. Additional measures are still needed to improve the scientific and medical leadership in the Research Department. Staff competence in biostatistics and epidemiology in the Research Department needs to be upgraded further.

2. Further efforts need to be made to upgrade the technical expertise of some field staff.

3. The IFRP's ability to initiate and monitor overseas activities has been enhanced with the addition of field offices in Africa and Latin America. The establishment of field capabilities in Asia that are appropriate to that region should be considered.

4. The IFRP should strengthen its staff by imaginative use of part-time and temporary contract personnel.

5. The current staff should be upgraded through formal training in relevant disciplines.

6. Additional ways should be found to strengthen collegial ties with neighboring scientific and academic institutions in the Research Triangle.

ADDENDUM

SAMUEL M. WISHIK M.D.
2401 SOLEDAD COURT
LA JOLLA, CA 92037
(714) 454-1772

Since, unfortunately, I could not attend and participate in the final meetings at which the IFRP report was drafted and since my name is attached to the report because of my earlier contributions to it, I find it necessary to make the following statement for attachment to the report record.

I am in general accord with the report, but am more negative in several respects. My major concern is the tremendous scope of content the IFRP is attempting to cover and the diminishing emphasis on medical and technical aspects of contraceptive development. It is also important to call particular attention to IFRP's failure to act upon criticisms concerning quality of leadership in research design and methodology that have been made repeatedly by site visit teams over a period of five years.

I concur in the report made by the Subcommittee of the AID Research Advisory Committee and the recommendations passed by the Committee as a whole at its April, 1982 meeting. At that time, I made additional comments and submitted a written statement for the record.

June 29, 1982