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INTERIM EVALUATION OF

FAMILY HEALTH INTERNATIONAL

by

Richard J. Derman, M.D., M.P.H., F.A.C.O.G
Forrest C. Greenslade, Ph.D.
Judith Rooks, M.S., M.P.H., C.N.M.
Rochelle N. Shain, Ph.D.

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Edited and Produced by:

Population Technical Assistance Project
International Science and Technology Institute, Inc.
2033 M Street, N.W., Suite 300
Washington, D.C. 20036
Phone: (202) 466-7290
Telex: 275445/TSI UR

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THE TEAM

Richard J. Derman, M.D., M.P.H. (Team Leader) a practicing clinician, is an assistant professor of obstetrics and gynecology at Cornell Medical School. He has long been involved with the issues of contraceptive development, clinical trials, and the establishment of priorities and support services for developing nations.

Forrest C. Greenslade, Ph.D., President of Hunterdon Biomedical Reseearch Center and Senior Consultant to The Population Council, is a pharmaceutical consultant with experience in health care product research, development and introduction, and the private sector.

Judith P. Rooks, C.N.M., M.S., M.P.H., President of the American College of Nurse Midwives, is an epidemiologist with orientation to reproductive health and developing country family planning programs.

Rochelle N. Shain, Ph.D., Associate Professor in Ob/Gyn at The University of Texas Health Science Center at San Antonio, is a social scientist who is knowledgeable in contraceptive development with emphasis on acceptability studies in developed and developing countries.

GLOSSARY

APHA	American Public Health Association
AVS	Association for Voluntary Sterilization
BKKBN	National Family Planning Coordinating Board (Indonesia)
CBD	Community Based Distribution
CDC	Centers for Disease Control
FDA	Food and Drug Administration
FHI	Family Health International
FHRC	Family Health Research Center
FP	Family Planning
FRP	Fertility Research Program
IFRP	International Fertility Research Program
IND	Investigational New Drug
INTRAH	Program for International Training in Health
IPPF	International Planned Parenthood Federation
IUD	Intrauterine Device
JHPIEGO	Johns Hopkins Program for International Education in Gynecology and Obstetrics
LDC	Lesser Developed Country
MCA	Methyl Cyanaocrylate
MCH	Maternal Child Health
MCM	Maternity Care Monitoring
NET	Norethindrone
NFP	Natural Family Planning
NIH	National Institutes of Health
OC	Oral Contraceptive

PIACT	Program for the Introduction and Adaptation of Contraceptive Technology
PARFR	Program for Applied Research on Fertility Regulation
PID	Pelvic Inflammatory Disease
RAC	Research Advisory Committee
RTSA	Regional Training Service Agency
TAC	Technical Advisory Committee
TBA	Traditional Birth Attendant
STD	Sexually Transmitted Disease
WHO	World Health Organization

EXECUTIVE SUMMARY

The Evaluation

A team assembled by the International Science and Technology Institute (ISTI) conducted a one-week interim evaluation of Family Health International 1/ (FHI) at its Research Triangle Park facility in North Carolina in August, 1984. This interim evaluation was requested as a follow-up to the recommendations of an in-depth evaluation organized by an American Public Health Association (APHA) Team in 1982. The Team focused its attention on FHI's organizational decision-making and research management practices and attempted to judge these practices against the backdrop of the goals set for the institution by AID in Contract AID-DPG-0537-C-00-1028-00 and Grant AID/pha-G-1198 and the recommendations of the APHA evaluation.

Scope of Work

The Team's investigations were guided by a fairly lengthy scope of work which requested information on status of key programs; FHI organization and staffing; assessment of publications and of FHI project approval procedures; and FHI relations with AID and other organizations. Particular emphasis was given to assessing FHI's ability to apply for approval for new drugs from the Food and Drug Administration (FDA). The separate chapters of the report deal with these various issues. The Team also added a chapter on evolution into new areas of research in response to an informal suggestion from AID.

Methodology

The evaluation was conducted primarily through interviews with key staff members, individually or in groups. In addition to briefings by the President, Executive Vice-President and Director of Development, discussions were held with the directors and key staff members of all research operations departments. In preparation for these discussions, the Team requested that each director prepare summaries outlining the objectives, accomplishments and future goals within their respective areas of responsibility.

In addition to a review of the previous evaluation and AID's contract and grant, the Team had access to a selection of documentation including two previous FHI annual reports to AID and Directions 1983-1984, an FHI document delineating the goals and work of the organization.

Constraints

Due to the limited time available, the Team found it necessary to limit its inquiries mainly to managerial issues. No attempt was made to evaluate scientific details or interpretations of research output. Furthermore, since the evaluation took place only at the Research Triangle Park facility, limited insight at best could be gained concerning operation of any of FHI's six Family Health Research Centers (FHRC) or the work of its collaborators.

1/ Formerly International Fertility Research Program (IFRP).

Summary of Observations and Findings

The Team's major conclusion was that little fault could be found either with FHI's decision-making process or its research management practices, and that the major credit should go to the outstanding caliber and commitment of its 100-odd staff members. Despite the few vacancies noted, the staff functions in a collegial, flexible and creative manner to set the priorities, select the projects, and manage the research activities which comprise the main focus of FHI's work. Its decisions in all areas are made with appropriate input from AID, so that its current research agenda is compatible with AID's own goals.

The growing complexity and diversity of FHI's initiatives met the approval of the Team. FHI currently allocates almost 50% of all funds for those programs specifically linked to contraceptive research and safety. Support services and programs that impact on public policy, as well as those concerned with reproductive health, which includes the area of natural family planning, complement the overall programming strategy.

As its research agenda has expanded, so too have FHI's research capabilities. Although it remains the public sector research organization best suited for the conduct of large-scale trials, FHI has strengthened its ability to monitor and analyze data from all levels of investigation, from the pre-clinical phase through Phases I-III to post-marketing surveillance. In addition, because of its large and wide-spread network of investigators, FHI is well equipped to introduce new contraceptive technology throughout the world. Most important, it is growing in its ability to prepare applications for approval by FDA.

Findings and Recommendations for Specific Areas

Organization and Staff

A. Observations and Findings

While the staff are of uniformly high calibre, the problem of attracting and retaining gifted personnel persists. In addition, the mix of staff at a few critical levels could be adjusted to provide for an infusion of appropriate skills. Finally, the problem of assuring that the field provides adequate input in the priority setting process has become more acute with the closing of FHI's two existing overseas offices.

B. Recommendations

1. As a means of attracting and retaining gifted clinicians, physician incentives should be explored with AID. The most feasible approach might be to request AID's Office of Contract Management to lift the ceiling on an individual basis for top level positions.

2. Priority attention should be given to filling the top-level vacancies including the Vice-President for Medical Affairs, the Medical Director and the Director of Quality Assurance. The latter vacancy in particular deserves attention, given FHI's growing responsibilities in the area of seeking FDA approval

for new contraceptive products and to resolve significant discrepancies which have, on occassion, been reported between centers.

3. Consideration should be given to filling one policy-making position with a non-medical specialist. The Team has some reservations concerning the appropriateness of filling the entire top scientific decision-making and policy-setting level solely with physicians. It is important that FHI's long-term policy and strategies not become excessively provider-oriented at the expense of the perspective and needs of potential users. The Team has suggested that if Dr. Jack Lippes were shifted to the position of Director of Medical Affairs, his current post of Vice-President for Research could be filled by a non-medical person.

4. An ob/gyn specialist should be added to work with the clinical trials group. The individual to fill the job should be well grounded in all management aspects of clinical trial work and have a strong background in obstetrics and gynecology. The position should be filled as soon as possible.

5. The work of the Biostatistical Unit should be integrated within that of the Department for Quality Assurance. Currently the Biostatistical Unit is not properly integrated into day-to-day operations of FHI. Partly because it does not have approval authority over individual projects, its potential to provide project support is often overlooked. The unit's work could most profitably be utilized by the Department of Quality Assurance.

6. The Technical Advisory Committee (TAC) should be strengthened by the addition of a nurse or nurse-midwife and/or a second behavioral scientist. This addition would fill the gap at the advisory level of an individual who could focus on the need for the Reproductive Health Division to expand its research initiatives to the non-physician provider level.

7. FHI should give high priority to seeking new ways to assure increased field participation. Although not prepared to expand the number of national FHRCs, FHI may wish to reconsider the utility and importance of re-establishing resident professionals abroad. For example, a culturally sensitive resident professional in a given country might be designated as an individual country representative. Other models should be similarly explored, such as regional meetings with leaders in the field of family planning. FHI should be provided the flexibility of perhaps utilizing a different system for field support in different geographic areas.

8. A field visit by external consultants or members of this evaluation Team is recommended to suggest specific new models for field participation.

9. Additional emphasis should be given to the increased utilization of Third World consultants.

The Decision-Making Process

A. Observations and Findings

FHI determines its research agenda in a flexible and democratic manner, which assures the incorporation of views from its own advisory bodies and staff as well as from AID, both at headquarters and in the field.

B. Recommendations

The Team's recommendations essentially call for continuation of existing procedures, as follows:

1. FHI should continue to utilize AID as well as its own senior staff, Board of Directors, and Advisory Committees in setting research priorities.

2. FHI should continue to be responsive to suggestions regarding specific projects generated by USAID missions.

3. Although FHI's first priority should be to conduct large-scale clinical trials, it should continue to increase its capabilities regarding trials at all levels from pre-clinical testing through Phases I-IV, to permit a flexible response should opportunities arise for testing at any point in the development of a new product, and as a means for attracting private sector interest.

4. FHI should continue to give primary attention to projects offering the opportunity for cooperation with other research institutions or industry.

Research Management

A. Observations and Findings

The Team found that FHI had taken initial steps to develop the capacity to manage clinical research in a manner suitable for preparation of submissions for FDA approval. On the other hand, two problems at earlier stages of research should be addressed. One is that discrepancies generally arise in the findings from different centers conducting research on the same product and utilizing the same protocol, and the other is the failure to address the acceptability issue, except in a very limited way, at the Phase II level, with the consequence that funds may be earmarked for the development of products which are ultimately not acceptable to users. An infusion of expertise in the social sciences at both the headquarters and field levels might help solve both these problems.

B. Recommendations

The first three recommendations would contribute to strengthening FHI's capacity to prepare submissions for FDA approval. They include:

1. Continued formalization of monitoring and auditing procedures would ensure that discrepancies, omissions and errors in research activities are corrected.

2. Preparation of a set of written clinical practices, including the formalized procedures in (1) above would help provide an additional quality assurance instrument in the implementation of future research.

3. The newly-initiated staff training in "good clinical practices" and regulatory affairs should be continued, to reduce insofar as possible the need to hire additional staff for preparing FDA submissions.

The following three recommendations are geared towards the improvement of the quality of research design.

4. New models for research in the social sciences need to be explored to address such issues as discrepancies in site-generated research data and contraceptive acceptability.

In some cases, personnel from the Reproductive Health Division could provide the insights required on these issues. In other cases, a full- or part-time social scientist might be added to the staffs of local FHRCs.

5. Discrepancies between site-generated data should be addressed. These discrepancies should be explored at the field level during Phase II studies and such findings explained within the body of the final submissions.

6. Additional information on the various components of acceptability should be incorporated early in the development of a new contraceptive technology. If a more comprehensive acceptability component is built into Phase I and II trials, FHI could learn which aspects of any given technology are particularly satisfactory or unsatisfactory (even among continuers) so that possible modifications could be incorporated from the user perspective early in a product's development, or at least addressed more fully in later trials.

Relationships With Other Organizations

A. Observations and Findings

The Team was impressed with the progress FHI has made in its contacts with other development organizations, both public and private. While remaining the public sector research organization best suited for large-scale clinical trials, FHI has increased its collaboration with others in this field on specific product development. At the same time, it has strengthened its ties with academic institutions and corporations in the Research Triangle Park and beyond. The Team's recommendations essentially urge FHI to continue its present efforts to communicate and work with other organizations, with specific emphasis on collaborating more effectively with AID-funded programs.

B. Recommendations

1. FHI should place priority on increased communication, perhaps on a regular basis, with representatives of other international research and provider agencies. Relationships with AID-funded training programs should be formalized, perhaps through annual meetings under the auspices of AID's Training Division.

2. Continued emphasis on linkages to academic institutions and private corporations adjacent to FHI's headquarters should remain a high priority.

Dissemination of Research Findings

A. Observations and Findings

It was clear to the Team that FHI is proceeding in the right direction in its publication and information dissemination program. More could be done, however, to strengthen existing efforts to influence national policies, particularly through the selective sponsorship of conferences.

B. Recommendations

1. Efforts to duplicate, translate and disseminate important papers on contraception from non-FHI sources should be expanded. The library staff at FHI should make efforts to augment its collection of its own published papers with relevant articles from international journals. Such reprints should be distributed not only to FHI's network of collaborators but equally important to key opinion leaders and government officials who may elect to alter priorities based upon such information.

2. FHI's newsletter NETWORK is a valuable publication and efforts to expand its distribution should be continued.

3. The use of country-specific service manuals as a medium of dissemination should be continued.

4. Additional technical assistance should be provided in the rewriting and submission of papers.

5. FHI-sponsored research conferences, perhaps regional in scope, should be expanded. Such conclaves would serve as a vehicle to expand FHI's impact on national policies by: (i) reinforcing the prestige value of FHI's in-country research efforts and permitting the invitation of those opinion leaders whose presence would offer the best chance for policy change; and (ii) laying the groundwork for the dissemination of future research information to this select group, with the likelihood that such materials would be more closely read. Such meetings might focus on general contraceptive research, or more specifically focus on a single issue -- e.g., oral contraception.

Evolution Into New Areas of Research

A. Observations and Findings

The Team found that while about half of FHI's budget is allocated to technical trials and contraceptive safety, nearly 30 percent is being spent on research in reproductive health and natural family planning, new areas in relation to its originally mandated concentration on contraceptive technologies. The Team found this new emphasis appropriate, particularly in view of Africa's special needs.

B. Recommendations

1. FHI's program mix is appropriate, particularly its new emphasis on reproductive health and natural family planning. While the attention given to breastfeeding is in order, more study is needed to determine the appropriate time for transition from breastfeeding to other family planning methods and the most suitable method to be adopted. More attention also should be directed to male methods of fertility regulation.

2. In Africa, FHI should be encouraged to continue to explore new models of research on family health issues. Models might include additional documentation of health problems associated with high parity and illegal abortions; clarification of the role of breastfeeding; and issues relating to sexually transmitted diseases and infertility. Such studies should also identify and investigate the role played by indigenous fertility regulation methods and the reasons women fail

to use available family planning services. The information generated from such studies would provide useful documentation to MCH policy makers and lay the groundwork for successful introduction of FP programs.

3. FHI should continue to conduct non-family planning studies in countries with pro-family planning policies, AID missions, and internal institutions interested in developing family planning services. Countries should be considered high priority because of their large size, rapid population growth, and high rates of maternal and infant mortality.

4. For non-family planning studies, FHI should be encouraged to explore the potential for receiving for ancillary funding from AID's Office of Health and/or Office of Nutrition. The population-related activities of the Office of Health include Primary Health Care Centers, vaccines and oral rehydration, while the Office of Nutrition has programs related to breastfeeding. The Office of Nutrition might be the more likely candidate for ancillary funding.

I. INTRODUCTION

I.1 Project Background

Family Health International (FHI), formerly the International Fertility Research Program (IFRP), was established on July 1, 1971, in Research Triangle Park near Raleigh-Durham in North Carolina, under a contract issued by the Agency for International Development (AID). Its original mandate was to conduct field trials related to new contraceptive technologies, especially in developing countries. IFRP established a network of collaborative investigators in several countries as a mechanism for accomplishing this objective. More recently it helped create six national Family Health Research Centers (FHRCs) which conduct local family planning (FP) research. In 1977, the IFRP's renewal proposal was reviewed by the Research Advisory Committee (RAC) of AID. After further review by a RAC subcommittee, and following a number of staffing and administrative changes, additional lines of endeavor were funded by an AID grant. Funds for IFRP also continued through the contract. In 1980, the American Public Health Association (APHA) assembled an evaluation team to review the IFRP and its programs. That team reported that, although a number of improvements had been made since the 1977 RAC review, the IFRP should be strengthened further. A second, enlarged APHA team conducted an in-depth evaluation during the period June 1981 to March 1982. Members of this team visited collaborative investigational sites and interviewed investigators in Asia, Africa and Latin America, as well as the IFRP facility in North Carolina. That team concluded that, in general, the IFRP was fulfilling the mission mandated by AID under the terms of the AID grant and contract.

In 1982, IFRP officially changed its name to Family Health International, signifying its increasing work in multiple facets of reproductive health. Hereafter, all references will be to Family Health International (FHI).

I.2 FHI's Current Agenda

FHI's primary role was and is the initiation and monitoring of clinical trials, with a particular emphasis on new contraceptive technology. Of the seven 1/ major public sector organizations currently engaged in contraceptive development, FHI is the one best equipped to conduct large-scale Phase III clinical trials throughout the developing world. 2/

1/ The others are: (i) The Special Programme of Research, Development and Research Training in Human Reproduction of the World Health Organization, HRP/WHO; (ii) The International Committee for Contraception Research of the Population Council, ICCR; (iii) The Program for Applied Research on Fertility Regulation of Northwestern University, PARFR; (iv) Indian Council for Medical Research, ICMR; (v) Contraceptive Development Branch, Center for Population Research of the National Institute for Child Health and Human Development, NICHD; and (vi) The Program for the Introduction and Adaptation of Contraceptive Technology, PIACT.

2/ In the U.S., a clinical study of a new drug is conducted in three stages. The initial exposure to the drug is limited with respect to both dose and dura-

Over time, FHI's initiatives have become more complex and multi-focused. The organization now addresses a wide range of issues related to family health, particularly those related to reproductive health and natural family planning (NFP). In part, the new functions are an outgrowth of contraceptive technology research; monitoring of contraceptive safety, for example, is closely allied to development of new contraceptive technology. In part, the new functions have emerged as the FHRCs have become increasingly able to conduct clinical trial work independently. As a result, to some degree FHI's role has shifted to provision of training and technical assistance information.

As its research agenda has expanded, so too have FHI's research capabilities. It remains preemimently suited for conducting large-scale trials. It has, however, also strengthened its ability to monitor and analyze data from all levels of investigation, from pre-clinical trials through to post-marketing surveillance, with particular improvement at the Phase I and Phase II levels. Also, because of its large and wide-spread network of investigators, FHI is well equipped to introduce new contraceptive technology throughout the world. Most important, it has sharpened its capabilities in the area of preparing applications for approval by the Food and Drug Administration (FDA).

I.3 The Evaluation

I.3.1 Purpose of Evaluation

I.3.1.1 A team assembled by the International Science and Technology Institute (ISTI) conducted a one-week interim evaluation at FHI's Research Triangle Park facility in August, 1984.

This interim evaluation was requested as a follow-up to the recommendations of the 1982 evaluation and because it was deemed beneficial to on-going project performance.

I.3.1.2 In light of the brief time allotted for the evaluation, the Team decided to limit its activities to assessment of FHI's organizational, decision-making and research management practices, as they relate to the goals set out for the institution by AID. Specifically, while the previous evaluation team made a number of program-related recommendations, the present evaluators were more concerned with the process utilized by FHI to (i) determine the broad base of its research priorities; (ii) implement, maintain, and evaluate research programs on a global scale; (iii) offer appropriate clinical support and training

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tion. As the drug's development reveals more and more safety information from animals and man, the clinical experience with the drug can be broadened. Phase I studies are restricted with very low doses administered to approximately ten well subjects. These studies assess tolerance and acute absorption and excretion kinetics of a given drug. Based on these data, Phase II studies incorporating approximately 50 subjects may be conducted to determine the safety and effectiveness of the drug. Phase III trials permit testing of increasing numbers of subjects from 200 to several thousand, under conditions more similar to the general use of the product. Phase IV trials provide surveillance data after the product has been marketed.

to project grantees; and (iv) develop systems geared toward overall clinical trial management, which could provide for Food and Drug Administration (FDA) approval of new technology and encourage financial interest on the part of non-governmental groups.

I.3.2 Scope of Work

The Scope of Work contained a list of nine problems and issues to be considered by the Evaluation Team (see Appendix I). These have been incorporated as chapters in the report, as follows:

Chapter IV. Organization and Staff (covers issues 4 on FHI's reorganization and 6 on assessment of FHI staffing).

Chapter V. Status of Key Programs (covers issues 1, 2 and 3).

Chapter VI. The FHI Decision-Making Process (covers issue 7, assessing the process of FHI project approval).

Chapter VII. Research Management at FHI (provides information requested in issue 8 regarding application for regulatory approval in the larger context of research activity management).

Chapter VIII. Relationships with other Organizations (includes information on relationship with AID requested in issue 9, as well as a review of FHI's relationship with other research organizations, drug companies and academic institutions in Research Triangle Park).

Chapter IX. Dissemination of Research Findings (addresses issue 5, which requests assessment of publications produced or supported by FHI).

Chapter X. Evolution into New Areas of Research (this chapter was added in response to an informal suggestion from AID personnel in the Office of Population).

I.3.3 Methodology

Interviews: The evaluation was conducted primarily through interviews with key staff members, individually or in groups. In addition to briefings by the President, Executive Vice-President and Director of Development, presentations on three major program areas (institution building in developing countries, long-acting steroidal contraceptive development, and projects in Africa) were given by FHI staff.

Discussions were held with directors of all research operations departments, along with key staff members. In preparation for these discussions, the Team requested that each director prepare summaries outlining the objectives, accomplishments and future goals of each program area. These summaries are presented in Chapter V, Status of Key Programs. The interviews and discussions centered on goals and the management processes necessary for their accomplishment.

These experiences also provided an opportunity to gain some useful information, i.e., whether staff members at several organizational levels were cognizant of institutional goals and whether they were aware of how their individual assignments and roles related to the whole. The degree of integration of activities across departmental lines and among field and home operations staff was a primary focus.

In addition to interviews, the Team reviewed the curricula vitae of all professional staff at the department director level and above. The CVs for all professional staff were reviewed for two sample departments, Clinical Trials and Reproductive Health.

Two AID staff members, Russel J. Thomsen, M.D., and Laneta Dorflinger, Ph.D., were available to the Team as resources during the evaluation.

Materials: The Team also reviewed a wide selection of documentation. It focused attention on the mandate for FHI delineated by AID in the Contract and Grant; it was also aware of the program description contained in the cooperative agreement currently under consideration by AID (see Chapter II). It used as prime references the Scope of Work and the 1982 APHA evaluation. The Team also reviewed two previous FHI annual reports to AID and Directions 1983-1984, an FHI document setting out the goals and work of the organization, as well as a number of other FHI publications, internal reports, strategy white papers, and papers published by selected staff members.

I.3.4 Constraints

As stated in section I.3.1.2, the Team found it necessary to limit its inquiries mainly to managerial issues. No attempt was made to evaluate scientific details or interpretations of research output. Furthermore, since the evaluation took place only at the Research Triangle Park facility, limited insight at best could be gained concerning operation of any of the in-country research centers. In addition, the Team's judgments regarding the appropriateness of FHI's program mix (see X.3.1) were made without benefit of field observation and were based instead on their global view of contraceptive development.

I.3.5 Conclusions

It is most unusual for an evaluation team to offer words of praise toward the organization they are assessing; however, we would be remiss were we not to do so. Clearly, FHI's evolution has been timely and meaningful and the caliber and commitment of its staff appears outstanding.

Particularly in relation to the special concerns with which the Team approached this evaluation (see I.3.1.2), FHI seems to have made considerable progress. The appropriate utilization of the FHI Board of Directors, together with input from AID both in Washington and at the mission level and from FHI senior staff, ensures adequate attention to the setting of priorities. FHI currently allocates almost 50% of all funds for those programs specifically linked to contraceptive research and safety. Support services and programs that affect public policy, as well as those concerned with reproductive health, which (including the area of NFP), appear to complement the overall programming strategy.

Despite the clearly recognizable positive changes which have taken place within FHI, it remains that international programming is a dynamic process which often requires new models for implementation. Furthermore, research, by virtue of its labor intensive approach, mandates the need for ongoing technical assistance. Finally, an organization staffed by more than one hundred individuals can usually benefit from external suggestions. It is in this spirit of cooperation that the evaluation Team offers the recommendations which are included in the body of this report.

II. THE AID MANDATE FOR FAMILY HEALTH INTERNATIONAL

II.1 Among the Team's endeavors, a prime aim was to assess FHI's organizational decision-making and research management practices in the context of the goals delineated by AID. These goals are embodied in the contract (AID-DPE-0537-C00-1028-00), first signed in 1971, and the grant (AID/pha-G-1128) signed in 1977. The contract delineated the guidelines for basic research and clinical trials that represent the bulk of FHI's work. The grant provided for institutional stengthening and for a variety of related activities, including training, equipment, maternity care monitoring (MCM) and others.

Since the evaluation, AID completed negotiations with FHI on a cooperative agreement (DPE-0537-A-00-4047-00) incorporating provisions of both the contract and the grant. The agreement provides for a five year commitment to FHI. Funding will be provided on an annual basis.

II.2 The Contract

II.2.1 Under the provisions of the contract, FHI is directed by AID to serve as a center for (1) maintaining a network of international investigators; (2) developing study designs and research data collection instruments to study various means of fertility control under use conditions and their long-term effects; (3) analyzing and evaluating research data which are collected from various countries and cultural settings by contributors conducting field trials; (4) conducting studies to evaluate fertility control methods and develop such methods to the level where clinical trials are appropriate, and developing prototypes of equipment which show promise for future use; and (5) disseminating information and technology on methods of fertility control.

FHI is directed to focus on, but not be limited to, fertility control technology under use conditions in nine major areas: (1) intrauterine devices; (2) systemic contraceptives; (3) female sterilization; (4) male sterilization; (5) barrier contraceptives; (6) fertility awareness; (7) equipment integral to fertility control technology; (8) appropriate special studies including a limited amount of Phase I and II research; and (9) Phase IV studies including epidemiologic safety studies.

II.3 The Grant

The specific objectives of the grant are:

1. To provide limited clinical training, equipment and evaluation services and to facilitate introducing improved contraceptive technology into new or existing programs in lesser developed countries (LDCs).

2. To provide initial core costs for newly established national fertility research programs in Africa, Asia, and Latin America, in order to strengthen institutional capabilities in LDCs.

3. To provide limited supplies not available in LDCs so that contributors may continue programs initiated in field trials until other sources of supply can be developed.

III. RESPONSE TO RECOMMENDATIONS IN 1982 APHA EVALUATION

In conducting its evaluation the Team sought to analyze how effectively FHI had responded to the recommendations in the APHA 1982 evaluation. While covering a range of managerial and program-related issues, that evaluation focused on the organizational area. Noting that progress had already been made, particularly in improving management and personnel, expanding the Board of Directors, and increasing the use and effectiveness of external expertise, the APHA Team offered the following six recommendations:

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

During the current evaluation, the Team determined that FHI had meaningfully addressed five of the six stated concerns. The most important staffing changes included:

1. An increase in both the number and quality of senior staff with priority given to the disciplines of epidemiology and biostatistics.

2. The addition of a new director of clinical trials with private sector credentials in clinical monitoring and with important linkages to industry and operations of the U.S. Food and Drug Administration.

3. An appropriate use of expert committees and consultant services to address more effectively issues of project design and evaluation, particularly as they relate to new contraceptive technology.

The Team also noted upgrading of staff through in-house training and improvement of collegial ties with academic organizations in Research Triangle Park. Overall, the team felt that FHI's professional staff was well organized, both in terms of job definitions and overall structure, and that its current structure both allows for accountability and provides systems for direct support of field services. The only major problem concerned the area of field offices.

Given the untimely dissolution of the Latin American and African field offices since the last evaluation, the suggestion of adding one in Asia requires a critical reassessment. This issue is discussed in Chapter IV.

To summarize, the Team determined that FHI had succeeded in acquiring the caliber of personnel, the technical expertise and the leadership it needs to fulfill its mandate.

IV. ORGANIZATION AND STAFF

IV.1 Organization

IV.1.1 FHI's organization is well suited to accomplish the goals set forth by AID (Figure 1). Its President, a recognized leader in international family planning, plays an active role in research planning, institution building and in guiding FHI's professional staff. Operational organization is administratively facilitated by an Executive Vice-President, broadly experienced in public and private sector management.

IV.1.2 At the senior policy level are Vice-Presidents for Research and for Medical Affairs, with a Medical Director attached to the Office of Vice-President for Medical Affairs. At the time of the evaluation, all three posts were vacant. Since the Team's visit, however, Dr. Jack Lippes has accepted the position of Vice-President for Research. Dr. Lippes' administrative skills, vast knowledge of technology and academic credentials should prove invaluable in guiding FHI's expanded initiatives, particularly in view of FHI's growing capacity to attract enterprise in the entire realm of new technology evaluation and the initiation and monitoring of human clinical trials from Phase I through Phase IV (see I.2).

IV.1.3 At the operations level, four departments or units deal with specialized aspects of FHI's operations: Administration, Quality Assurance, Scientific Support Services, and Biostatistics. At the time of evaluation, the post of the Director of Quality Assurance was vacant and there were problems regarding underutilization of the Biostatistics Unit.

IV.1.4 Research Operations

At the heart of FHI are the Research Operations Departments charged with the accomplishment of the institution's major goals:

- Clinical Trials - development and introduction of contraceptive technology and assessment of health consequences of contraceptive technology;
- Contraceptive Safety - identification and quantification of the health risks and benefits associated with contraceptive use;
- Field Development and Training - technical assistance and training in research, information dissemination and field support to the ongoing programs;
- Natural Family Planning Research - evaluation of NFP and breastfeeding as approaches to family planning; and
- Reproductive Health - assessment of the method and use-effectiveness of contraceptives; evaluation of acceptability and channels of distribution; monitoring of maternal care and traditional health practices; collection of information on maternal morbidity and mortality.

With the hiring of additional staff, particularly in the clinical trials and contraceptive safety divisions (see IV.2.3), strong performance is the norm in all research areas. The addition of at least one senior professional at the supervisory level of Research Operations, however, would further enhance coordination among the various Research Operations departments.

IV.1.5 Day-to-day management is the responsibility of the three following standing committees: Executive, Administrative, and Science Committees. The Science Committee, composed of the Research Operations Department Directors and chaired by the President, meets monthly and constitutes the primary interdepartmental mechanism in establishing priorities and in the evaluation of new research ideas (see VI.3.2). Each project has a written strategy with a time line, predetermined goals and a budget. These are addressed on a monthly basis by the President and the appropriate operational department director.

IV.1.6 Computer Programming

Strong departments assure adequate administrative maintenance as well as data management and analysis functions. While the evaluation Team's expertise was not in the area of computer programming, the Team was nonetheless impressed by the staff, facilities and available technology. It is clear that the development of microcomputers is being handled selectively and under a rigid set of guidelines. The Team views the sharing of this technology most favorably but emphasizes a particular need for technical assistance at the field level.

IV.1.7 Three advisory committees guide the institution's activities:

- An independent Board of Directors meets twice a year. Subcommittees of the Board meet on a more frequent basis (see VI.2.2).

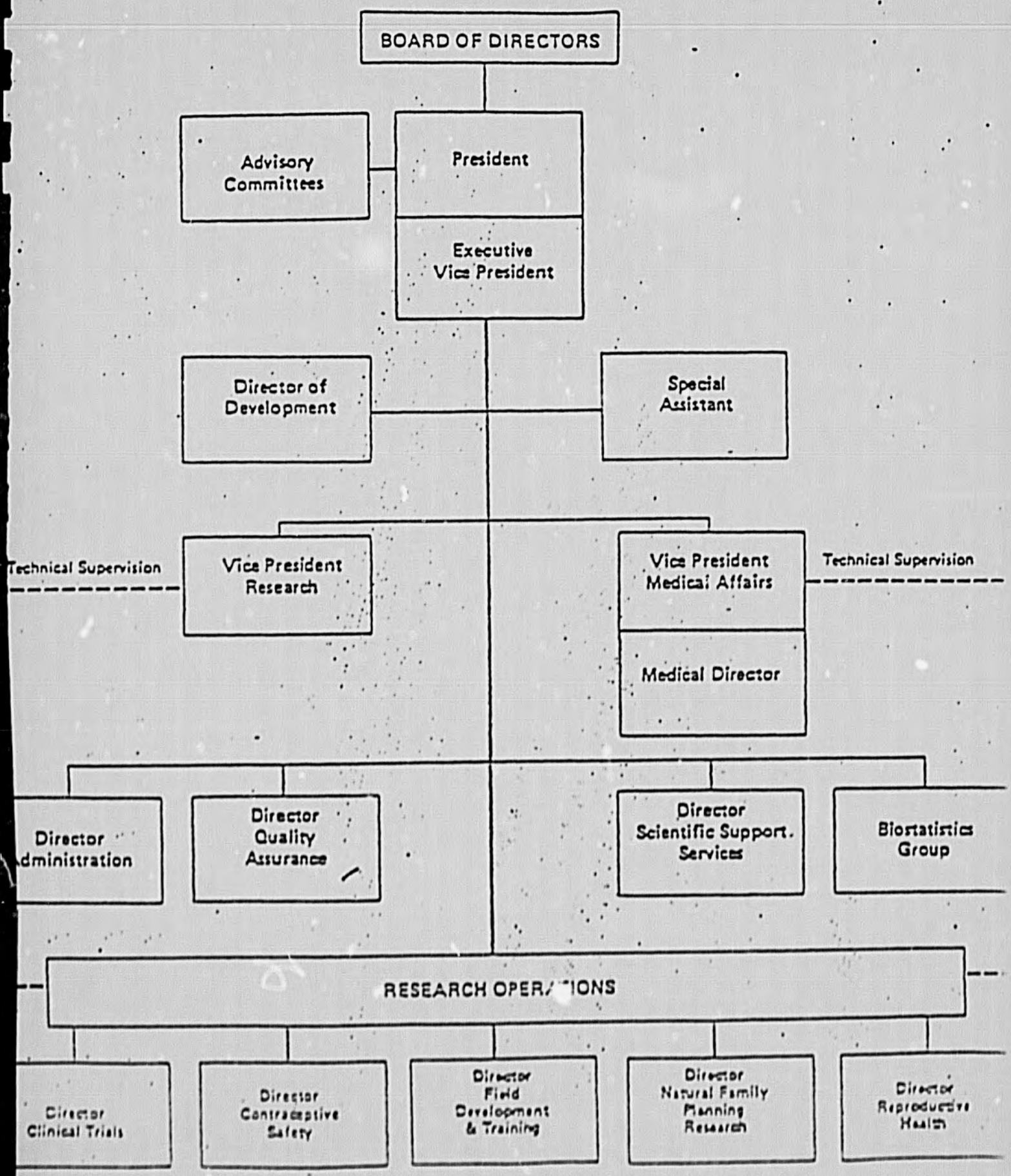
- Technical Advisory Committee (TAC), made up of clinical experts, biological scientists and one behavioral scientist, meets once a year to review overall programs. Subcommittees are dedicated to specific projects (e.g. chemical female sterilization and breastfeeding) and meet periodically. A special Standing Committee on Natural Family Planning which reports to the TAC has been established to provide guidance to this relatively new program area (see VI.2.2).

- An appropriately constituted Protection of Human Subjects Committee is completely independent and consists of medical and legal representatives. Recently, committee members representing social science and minority groups were added.

The Team feels that FHI's current approach to Family Planning Services Delivery (see V.6.4) needs broadening and suggests that additions to TAC might help. Specifically, the Team noted that FHI's research, despite the key role that mid-level health workers such as nurses and midwives play in the delivery of MCH services in LDCs, has so far focused mainly on the work of physicians, pharmacists and indigenous health workers such as traditional birth attendants (TBAs). Inputs at the policy level from individuals who understand the importance of the role of the mid-level health worker would help to fill a gap in the expertise currently available to FHI through the TAC.

FIGURE 1

FAMILY HEALTH INTERNATIONAL



Approved June 26, 1984

IV.1.8 The organizational structure described above promotes flexibility and responsiveness to changing needs. For example, if a research area requires particular emphasis, it can be dealt with either within departments or as a separate department, as was the case with Natural Family Planning. This department, although small, benefits from input and expertise of professionals throughout the institution and uses consultants to conduct a significant amount of its research (see IV.1.7).

IV.2 Staff

IV.2.1 The organizational structure also facilitates high levels of interaction and communication among the professional staff. Most projects receive continuous input from specialists in medicine and the biological and behavioral sciences. Moreover, professional relationships among the staff are supportive and collegial. There was evidence that staff at all levels were well aware of both the objectives and current status of individual projects. Accountability appears to be good.

The Team was consistently impressed by the quality and enthusiasm of FHI staff. The organization apparently benefits from the policy of advancing productive individuals to positions of greater responsibility. The Team was gratified to see women in positions of leadership and decision making.

IV.2.2 The Team reviewed the types and levels of training of current FHI staff (see Table IV.2.2 below).

TABLE IV.2.2 - MOST ADVANCED DEGREE ATTAINED

	Humanities Administration, Secretarial	Bio-medical	Behavioral, Public Health	Systems, Math
Associates/Other	23	0	0	6
Bachelors	15	1	5	3
Masters	1	3	20	2
Doctorates	0	6	6	2

IV.2.3 Addition of New Staff

A review of the CVs of most of the professional staff, and impressions gathered during interviews and discussions, convinced the Team that FHI has significantly strengthened its research and management capabilities since the 1982 evaluation. Adding to the excellent backgrounds in public health and behavioral science, FHI has hired new professionals with training and experience in biomedical science. A new director of clinical trials brings to FHI private sector credentials in pharmacology and drug development management and experience in the workings of the Food and Drug Administration (FDA). A reproductive biologist, recently hired, will provide important scientific input and help prepare documents for regulatory submission. Contraceptive safety and clinical trials

areas have been strengthened by the addition of three physicians skilled in epidemiology and public health and three biostatisticians who will strengthen the data management and analysis capabilities within these two departments.

The use of consultants and part-time personnel on a project basis has been expanded in an effort to address more effectively issues of project design and evaluation, particularly as they relate to contraceptive safety. More, however, could be done to use host-country consultants (see Appendices IX and XII a and b).

IV.3 Field Operations

IV.3.1 Field Offices

At the time of the 1982 evaluation, FHI had field offices in Africa and Latin America staffed by well qualified, indigenous physicians. The prior evaluation team recommended (as did the 1980 team) developing similar field capabilities in Asia. Since 1982, however, both the African and Latin American offices have been dismantled because of political exigencies within the host countries and an Asian office has not been created.

IV.3.2 National Family Health Research Centers (FHRCs)

Although recent years have seen a diminution of staff representation overseas, the network of independent national Family Health Research Centers (FHRCs) has grown. Currently there are six sister centers, located in Indonesia, Bangladesh, Egypt, Thailand, Sudan and most recently in Sri Lanka (see V.4.1 and Appendices VIII, IX and X a and b). These centers conduct research which affects family planning policies in their countries. They are supported through multiple funding sources. FHI provides strong technical assistance, training and support, designed to make these centers capable of conducting research at internationally-accepted standards.

Although FHI is pleased with the evolution of these six institutions, it is not currently prepared to expand their number.

IV.4 Recommendations

IV.4.1 Staff Vacancies

(i) Consideration should be given to redesigning FHI administrative procedures to permit physician incentives and greater job security for all staff.

The issue of FHI staffing has surfaced on each evaluation and each team has noted the evolution of progressively more qualified personnel possessing additional skills. Nonetheless, the problem of attracting and retaining gifted staff persists, even at the highest levels (see IV.1.2 and IV.1.3). Noncompetitive salaries and job security are two issues which for some professionals weigh against accepting employment with FHI.

Specifically, history has indicated that it is difficult to recruit and hold exceptional clinically-oriented physicians at a salary level previously approved by AID. Perhaps even more damaging is the yearly process which in the

past two years FHI has had to undergo to assure continued funding. It is doubly difficult to recruit staff of professional excellence when in some cases job security is on a year-to-year basis. In addition, staff time required to submit contract or grant request documentation could be used more profitably in those areas which AID has originally mandated.

In light of these problems, the team makes the following recommendations:

(i)(a) As a means of attracting and retaining gifted clinicians, physician incentives should be explored with AID.

The most feasible approach might be to request the Office of Contract Management to lift the ceiling on an individual basis for top level positions.

(i)(b) A long-term funding commitment should be established.

(ii) Priority attention should be given to filling top-level vacancies including Vice-President for Medical Affairs, Medical Director (see IV.1.2) and Director of Quality Assurance (see IV.1.3).

The position of Director of Quality Assurance in particular deserves attention, given FHI's growing responsibilities in seeking FDA approval for new contraceptive products (see Ch.VI). In addition, a Director of Quality Assurance is needed to resolve the significant discrepancies which often occur in findings between centers. The Director of Quality Assurance would represent an independent authority to audit data collection, management, analysis and reporting functions, regarding studies related to regulatory submission and earlier phases in the research process. The Director should have approval authority over each new project.

(iii) An obstetrics/gynecology specialist should be added to work with the clinical trials group (see IV.1.4).

A physician with a specialty in obstetrics and gynecology is needed to work closely with the clinical trials department. S/he should assume oversight responsibility for all clinical aspects of the trials especially safety assessment. The Team noted a number of approaches to this personnel need. The position of Medical Director could be filled with an ob/gyn specialist with interest in clinical research. Alternatively, physicians from the Research Triangle area could be utilized in a consultant capacity. The individual should be well grounded in all clinical aspects of clinical trial work. The position should be filled as soon as possible.

(iv) Consideration should be given to filling one policy-making position with a non-medical specialist.

Top FHI management has identified the need for prestigious U.S.-based obstetric and gynecological specialists to provide continuous guidance and medical leadership in policy development, interactions within the international population community and with governmental decision-makers, including regulatory officials. The Team believes that these issues are consistent with AID's goals for FHI. It further stresses filling such vacancies with minimal disturbance of the well functioning operational level.

The Team has some reservations concerning the appropriateness of filling the entire top scientific decision-making and policy-setting level solely with physicians. It is important that FHI's long-term policy and strategies not become excessively provider-oriented at the expense of the perspective and needs of potential users. The evaluation team suggests that Dr. Lippes be considered for the Vice President for Medical Affairs position, thus allowing him more flexibility in serving the organization and permitting the recruitment of non-M.D. for the Vice President of Research position (see IV.1.1).

IV.4.2 Organizational Changes

(v) The work of the Biostatistical Unit should be integrated within that of the Department for Quality Assurance (see IV.1.3).

Currently the Biostatistical Unit is not properly integrated into daily FHI operations. Partly because it does not have approval authority over individual projects, its potential to provide project suport is often overlooked. The unit's work could most profitably be utilized by the Department of Quality Assurance. The Director of this Department should have umbrella authority over the Biostatistical Unit; the Director of Quality Assurance should also have authority to approve all proposed projects (see paragraph IV.1.2).

(vi) The TAC should be strengthened by the addition of a nurse or nurse-midwife and a second behavioral scientist (see IV.1.7).

IV.4.3 Field Participation

(vii) FHI should give high priority to seeking new ways to assure increased field participation (see IV.3.1).

Although not prepared to expand the number of national FHRCs, FHI may wish to reconsider the utility and importance of re-establishing resident professionals abroad. FHI staff do not believe an Asian office is practical because of the large territory to be covered. However, they do believe that a culturally sensitive resident professional in a given country might be designated as an individual country representative, particularly in a nation such as Egypt, which hosts an unusually large number of FHI projects. Such an individual could provide technical assistance, marshall additional in-country technical resources, and facilitate and monitor projects.

Political constraints aside, FHI must seek to locate field offices in receptive nations. While the country representative idea may have merit for a particular country (or countries), other models should be similarly explored. A second suggestion might be to convoke regional meetings with international family planning leaders to solicit their views on needs. In any case, FHI should be provided the flexibility of utilizing different systems for field support in different geographic areas.

It is imperative, however, that these issues be addressed to ensure that research priorities established at headquarters reflect the full gamut of indigenous resources and realistic needs (see Ch. VII).

(viii) A field visit by external consultants or members of this evaluation team is recommended, to suggest specific new models for field participation (see vii).

(ix) Additional emphasis should be given to the increased utilization of Third World Consultants (see IV.2.3).

V. STATUS OF KEY PROGRAMS

V.1 The Scope of Work called for an assessment of progress for the 11 FHI programs listed below. The first eight of these are funded under the AID contract and the remaining three under the grant.

As the initial step in evaluation, the Team asked each operational division to prepare a brief, outlining objectives, key overall accomplishments, accomplishments since the 1982 evaluation, and future directions for each of the following programs:

1) female sterilization;
2) male sterilization;
3) systemic oral contraception;
4) long-term injectable contraception;
5) long-term implant contraception;
6) barrier contraception;
7) natural family planning, birth spacing, breastfeeding;
8) epidemiologic studies including contraception safety, cancer and contraceptive use, and contraception and sexually transmitted diseases;
9) national Fertility Research Programs;
10) technical assistance and training, particularly in the area of microcomputer technology; and
11) studies of social aspects of family planning.

These briefs were reviewed by the Team prior to interviews and discussions with staff members in each department. The Team asked FHI to integrate the briefs into a status summary, which is presented here. The Team also requested a budget breakdown according to the above program areas. It is presented in Chapter X.

The following summary, which was drafted by FHI and reviewed by the Evaluation Team, describes FHI's work. The summary is organized according to the tasks of the five Research Operations Departments: (i) Clinical Trials; (ii) Contraceptive Safety; (iii) Field Development and Training; (iv) Natural Family Planning Research; and (v) Reproductive Health (see Appendix II).

V.2 Clinical Trials

V.2.1 Surgical Female Sterilization

V.2.1.1 Accomplishments. FHI has been a leading organization in encouraging and documenting the switch from routine laparotomy under general anesthesia with several days of hospital stay to the use of minilaparotomy or laparoscopy. FHI studies have been associated with practically every aspect of this important evolution. FHI was the first to test the Yoon (Falope) ring worldwide; FHI also tested various laparoscopes, evaluated the Hulka Clemens Clip, investigated air insufflation used in place of CO_2, studied suprapubic endoscopy, and documented the advantages of minilaparotomy over endoscopy in low volume, peripheral facilities.

V.2.1.2 Current Objectives. FHI's primary objective is to further simplify sterlization procedures, thereby increasing access and safety. Currently, FHI is evaluating the safety, ease of use and effectiveness of the Filshie Clip, the curved upper arm of which may facilitate occlusion of thick fallopian tubes, thus making the Filshie Clip more suitable than other clips for postpartum and postabortion procedures. Another important area of research involves collecting long-term (over 24 months) follow-up data on female sterilization cases by a variety of techniques. FHI is also analyzing data for studies funded by the Program for Applied Research on Fertility Regulation (PARFR), of an Intra Tubal Device, a nylon plug inserted at the tubal ostia which may be removed to restore fecundity. FHI is currently collaborating with BioNexus and plans to work with Pfizer International and Femcare, Incorporated, on Filshie Clip studies.

V.2.1.3 Future Directions. FHI will evaluate the safety and efficacy of new occlusive techniques and assess the acceptability of female sterilization in new populations. The Filshie Clip may be evaluated in the U.S. for FDA approval. In addition, FHI plans to conduct studies of a new device for determining tubal patency which will be valuable both for voluntary sterilization and the treatment of infertility - FEMTEST. Final plans are being developed for the study of piroxicam (FELDENE) as a single dose, long-acting analgesic for post-surgical pain.

V.2.2 Nonsurgical Female Sterilization

V.2.2.1 Accomplishments. Animal studies on the toxicology of intrauterine quinacrine have been completed, as well as experimental and toxicological work on the use of tetracycline as a sclerosing agent. FHI has supported studies demonstrating the feasibility of non-surgical sterilization in women using three applications of 250 mg. quinacrine pellets at monthly intervals.

More recently, three and four year follow-up studies have shown the intrauterine insertion of quinacrine pellets to be an effective and safe non-surgical procedure. (FHI's involvement in these studies has been limited to data analysis only). Preliminary data from trials utilizing methyl cyanoacrylate (MCA) have shown a low pregnancy rate and few complications or complaints associated with the method. A Phase I trial of quinacrine inserted transcervically 24 hours prehysterectomy was completed in May 1984 with no abnormal findings.

V.2.2.2 Current Objectives. Efforts are being made to identify and develop a simple, non-surgical method of female sterilization which, if necessary, could be performed by paramedical workers in primary health clinics.

FHI is collecting long-term (over 24 months) follow-up data on women sterilized by the transcervical application of MCA to the fallopian tubes. In addition, under separate Investigational New Drug applications, (INDs), quinacrine hydrochloride and tetracycline hydrochloride as sterilization agents are being evaluated in Phase I trials in women who have been scheduled for a hysterectomy.

V.2.2.3 Future Directions. Attention will be focused on the further simplification of chemical sterilization, attempting to achieve high rates of tubal closure with a single insertion of a drug. FHI will investigate such variables as dose, release rate and adjunctive therapies.

Quinacrine and tetracycline will continue to be evaluated in Phase I trials. Quinacrine will be administered 30 days prehysterectomy and tetracycline will be inserted at both 24 hours and 30 days prehysterectomy. Phase II trials are dependent upon successful outcome of these studies.

V.2.3 Male Sterilization

V.2.3.1 Accomplishments. FHI's work has documented the safety, effectiveness and low cost of vasectomy and thus helped increase its acceptability. FHI-supported research demonstrated that there was no association between vasectomy and any diseases that are manifestations of atherosclerosis.

More recently, study of vas ligation and excision in Brazil completed in 1983 revealed no technical failures or surgical injuries and only four (0.4%) complications. This study was pivotal in documenting the acceptability of sterilization among men of various socioeconomic levels in Brazil.

V.2.3.2 Current Objectives. The focus of FHI's research is surveillance of the long-term effect of vasectomy with particular attention to the relationship between clinical outcome, clinical training and location of the surgery. Currently, work is being undertaken to explore the possibility of a trial of percutaneous vas occlusion, which eliminates the need for a surgical incision.

V.2.3.3 Future Directions. Percutaneous vas cautery has undergone initial clinical testing independent of FHI using microdiathermy needles developed in collaboration with FHI. Elimination of the surgical incision holds the promise of reducing potentially painful and serious side effects associated with surgery.

V.2.4 Oral Contraceptives (OCs)

V.2.4.1 Accomplishments. FHI has conducted studies on Norinyl 1/35 versus Brevicon which have shown a higher incidence of breakthrough bleeding, discomfort and headaches among acceptors of Brevicon. These findings prompted AID to review the supply of this brand of OCs. A study of progestogen-only OCs has been instrumental in introducing this form of contraception to lactating women. It is expected that an increasing number of local health authorities will be responding to the needs of breastfeeding women by providing this form of contraception.

More recently, progestogen-only studies have been initiated at three sites; the remaining centers will start patient recruitment within the next three to four months.

V.2.4.2 Current Objectives. A major study is a 4500-case comparative trial of Norinyl 1/35 independently with Brevicon, Lo-Ovral and Norinyl 1/50. The evaluation of standard and low-dose OCs is important to countries where a variety of preparations are provided in the public sector and where different health infrastructures and cultural and ethnic factors are influential.

Several studies of the progestogen-only pill Ovrette are underway to evaluate its acceptability among breastfeeding women. A total of approximately 14,000 women will be enrolled in a multi-centered study. Much of FHI's OC re-

search is carried out with specific support from the pharmaceutical industry which typically donates supplies and frequently provides other assistance.

V.2.4.3 Future Directions. Additional comparative studies of standard and low-dose pill formulations will be initiated to assist governments and private organizations in making pill supply decisions and to introduce safe, effective contraceptives. An 80-case clinical trial will compare OCs with and without iron, to determine the effect of iron on side effects and continuation rates while monitoring serial hematocrits. FHI will also suppport studies of multiphasic preparations to identify a steroidal method that offers effective protection while minimizing side effects and total systemic exposure to the estrogen and progestogen components of standard OCs.

Since compliance is the most important factor affecting the efficacy of OCs and may be a particular concern with multiphasics, FHI plans to conduct a series of studies to refine methods of OC compliance assessment, to evaluate compliance in a broad population setting, and to determine whether motivational strategies will increase compliance.

V.2.5 Long-Term Injectables

V.2.5.1 Accomplishments. In association with PARFR, Stolle R&D, Ortho Pharmaceutical Corp., and AID, FHI has planned a five-year clinical development program to obtain FDA approval for injectable, biodegradable, 90-day microencapsulated norethindrone (NET). The current need is to adjust the formulation and manufacture of the microspheres to achieve adequate NET blood levels during 90 days of use. This is a prerequisite to initiation of PARFR-funded Phase I and II trials. FHI will monitor these studies and carry out data analysis. A management plan for the development of injectable NET has been finalized, liaison with industry established, and a contract prepared to cover production of NET microspheres.

Data are also being collected retrospectively from four centers to compare continuation rates and reasons for discontinuation among users of OCs and users of injectables. Almost 50% of the planned 1800 cases in the retrospective study have been evaluated since September 1983.

V.2.5.2 Future Directions. FHI will continue to manage the development of 90-day NET. Phase I evaluation of the reformulated product will be initiated in October 1984. Initiation of Phase II and III studies is planned for March 1985 and January 1986, respectively.

V.2.6 Implants

V.2.6.1 Accomplishments. Protocols and related study documents on NORPLANT implant studies and a comprehensive work plan have been developed in cooperation with the Population Council. Negotiations with investigators are nearing completion.

V.2.6.2 Current Objectives. Introductory studies of NORPLANT contra-

ceptive subdermal implants are scheduled for initiation in Sri Lanka, Nepal, Bangladesh, and the Philippines. FHI plans to expand NORPLANT implant studies to include Egypt, Morocco, Sudan, Tanzania, Turkey, Costa Rica, Guatemala, Haiti and Pakistan. FHI is also completing analysis of PARFR-sponsored Phase II studies of NET implants, comparing three-pellet to four-pellet insertions.

V.2.6.3 Future Directions. FHI's studies of NORPLANT implants will assess effectiveness and overall acceptability in a multicenter (N=1600-1800) clinical trial. Participating investigators will receive training in the insertion and removal techniques prior to study initiation, which is scheduled for October-November of 1984. Since the effective lifetime of the implants is five years, follow-up of the women will occur every six months for the complete duration of the study or until removal, whichever comes first. In addition, FHI is exploring appropriate methodologies for post-marketing surveillance of NORPLANT implants.

V.2.7 Vaginal Contraception

V.2.7.1 Accomplishments. Successful pilot studies of the Collatex sponge established the acceptability and efficacy of the sponge as a barrier method and led to NIH funding of a multicenter comparative trial of the sponge and diaphragm. This trial contributed to FDA approval of the sponge as an over-the-counter contraceptive method in the United States. FHI studies have also demonstrated clear cultural differences in the acceptability of barrier contraceptive methods.

More recently, FHI trials of foaming tablets have provided evidence that menfegol (Neo Sampoon) may lead to fewer side effects and be more acceptable than nonoxynol-9. International studies of the sponge have been successfully completed in a number of countries, and have aided in the introduction of the method to family planning programs worldwide.

FHI, working partly with private funds and partly with AID funds, is conducting *in vitro* and *in vivo* lab tests on Beta blockers as spermicides, opening up a previously unexplored category of agents as potential spermicides.

V.2.7.2 Current Objectives. FHI aims to expand the range of safe, effective vaginal contraceptives and encourage wider use through clinical trials. FHI continues to evaluate spermidical foams, diaphragms, and foaming vaginal tablets. Current emphasis is on a comparative evaluation of tablets containing the spermicide nonoxynol-9 versus those containing menfegol, a less widely used spermicide.

V.2.7.3 Future Directions. New spermidical formulations will continue to be evaluated. The effect spermicides have on the incidence of sexually transmitted diseases (STDs) will also be studied. Studies of contraceptive vaginal rings containing levonorgestrel and estradiol are planned at four sites, but initiation is pending a review of recently completed animal studies. Additional studies may be initiated to test educational materials to be developed under contract with PIACT. FHI also plans to study the use of diaphragms with and without spermicides as well as a new disposable diaphragm. Plans are also underway to conduct a retrospective survey and a prospective study of condom use in Haiti to characterize users, to learn whether condom use can be increased, and to measure efficacy and acceptability of the condom.

V.2.8 Intrauterine Devices (IUDs)

V.2.8.1 Accomplishments. Past FHI IUD research emphasized testing the efficacy and safety of many different IUD designs. Out of the many IUDs FHI helped evaluate, only a few have been identified as standards: the Lippes Loop and copper devices, including the Copper T, the Copper 7 and the Multiload.

More recently, FHI completed trials of the 'Delta' IUDs, modifications of TCu220 and the Lippes Loop designed to lower postpartum expulsion rates. The studies of the postpartum device indicated that postpartum IUD insertion is safe and effective and that the training of insertors to achieve proper fundal placement is probably a more important variable in lowering expulsion rates than modification of the architecture of the device.

Other accomplishments in the past two years include (1) the near completion of studies evaluating the TCu380Ag showing that they perform at least as well as the Multiload Cu375 and the Cu7; (2) completion of immediate postpartum studies of the Progestasert 3 and the TCu200 which indicated that the Progestasert was not an appropriate IUD to insert immediately postpartum; and (3) the completion of a study comparing the Nylon T and the Copper T in which the pregnancy rates in the Nylon T group were significantly higher than those in the Copper T group, showing that copper had a greater contraceptive effect than increased surface area.

V.2.8.2 Current Objectives. Current objectives include continuing tests of promising new IUD designs, searching for ways to reduce complications associated with IUD use, and making the IUD an acceptable contraceptive choice for a larger portion of the population in need of FP services.

Three older IUD strategies remain active. Two sites evaluating the TCu380Ag continue to collect long-term follow-up data. Studies at two sites continue to admit women to the "strings versus no strings" trial designed to evaluate the role of IUD strings in the etiology of Pelvic Inflamatory Disease (PID). Final follow-up data is being collected from three sites participating in the Hassan Wing Sound II studies.

V.2.8.3 Future Directions. Three new IUD strategies have been developed. In order of priority they are: (1) a trial of the TCu380Ag will test its acceptability in many countries, comparing it to locally used copper devices; (2) a comparison of the Merchant Copper Coil, an open ring copper device, with the current standard copper device, the TCu220; and (3) a study of the Kurz 'Adapted T' based on Dr. Kurz's technique of trimming the crossarm of TCu200 IUDs to fit the uterine dimensions of individual women.

A second phase of the "strings versus no strings" study may be done with IUDs with inverted strings (which point upward into the uterus rather than hanging down through the cervix). Implementation of this strategy is pending evaluation of the Brush IUD Retriever (developed at FHI) that would be used to remove these devices.

V.3 Contraceptive Safety (see Appendix IV)

V.3.1 Accomplishments

Several studies have been completed by the FHI year-old Contraceptive Safety group. The RAMOS study, the first attempt to ascertain causes of death for women of reproductive age in Bali, Indonesia, and Menonfia, Egypt, found the leading causes of death to be similar in both countries - cardiovascular, maternal and trauma. Most women who died because of pregnancy complications were older and of high parity, indicating that most of these deaths are potentially preventable. A study of the return to fertility after discontinuation of IUD use indicated that there are no differences among the different IUDs studied.

V.3.2 Current Objectives

Along with the Centers for Disease Control (CDC), FHI will carry out a case-control study to investigate the role of female sterilization as a risk factor for hysterectomy. FHI is also examining the hypothesis that vasectomy increases the risk of atherosclerotic disease in two studies, one of which is a retrospective cohort study in China co-sponsored by the World Health Organization (WHO). A case-control study with the Kaiser Medical Research Foundation will determine whether vasectomy is a risk factor for prostate disease. A study conceived by the National Family Planning Coordinating Board (BKKBN) in Indonesia compares the rates of surgical complications among men sterilized by paramedics and by doctors.

Various oral contraceptive studies are planned or underway. FHI will perform a clinical trial to investigate the influence of low-dose oral pills on sickle cell anemia and undertake a hospital discharge survey to explore whether women are hospitalized with problems potentially attributable to oral contraceptive use. Aided by Duke University Medical School faculty, FHI will further develop a life table model that determines the effect on life expectancy of all reported consequences of OC use.

FHI will soon initiate, with the CDC, a large randomized clinical trial in Kenya on the effect of post-IUD insertion doxycycline on the incidence of PID. A large case-control study of endometrial, breast, ovarian and cervical cancer is planned in Costa Rica, also in collaboration with the CDC. FHI and researchers at the University of Durango (Mexico) will study the relationship between cervical dysplasia and reduced levels of folate.

V.3.3 Future Directions

Further studies of long-term injectable contraceptive use are planned, including continued analysis of data from Grady Hospital in Atlanta. Preliminary analysis indicated that Depo Provera users were not at higher risk than users of other contraceptives for any of the studied diseases. A joint WHO-FHI study will follow up children exposed in utero to medroxyprogesterone acetate in Israel to examine congenital malformation rates, developmental milestones, and sexual maturation. A similar study will be conducted, together with Johns Hopkins University, on a larger sample of exposed children in Thailand. The primary focus of an FHI-CDC case-control study at the University of the West Indies will be the association between Depo Provera use and cervical cancer.

A cross-sectional chart review study of the relationship between contraceptive use and STDs has begun at Planned Parenthood - New York City. A clinical trial on the effect of the contraceptive sponge on rates of gonorrhea, chlamydia, trichomonas and candida will soon begin among a high-risk population in Bangkok, Thailand.

V.4 Field Development and Training

V.4.1 National Fertility Research Programs (FRP) and Family Health Research Centers (FHRC) (see IV.3.2 and Appendices VIII, IX, and Xa, b and c).

V.4.1.1 Accomplishments. FHI participated in development of three research institutes (in Tunisia, India, and Colombia) which continue to function without FHI support. It supports the operations of another five major research institutions in Egypt, Sudan, Indonesia, Thailand, and Bangladesh, and recently developed an additional research center at the Family Planning Association in Sri Lanka. Considerable improvement in management and research skills at existing centers also took place since the last evaluation.

V.4.1.2 Current Objectives. FHI's current objectives are: (i) to improve the research capabilities of sponsored research programs to the point where they operate consistently at internationally accepted research standards; (ii) to increase their impact on national contraceptive policy; and (iii) to improve their viability as independent, broadly funded research organizations with minimal FHI core support.

V.4.1.3 Future Directions. FHI will continue to provide strong technical assistance, training and support, working particularly toward improvement of research designs and better administration, including the handling of multiple sources of funding. Centers will be encouraged to develop new sources of research support. There will be a gradual phasing out of financial support for existing centers and development of new centers.

V.4.2 Technical Assistance and Training (excluding microcomputers) (see Appendix XI)

V.4.2.1 Accomplishments. Before the last evaluation, emphasis was on contraceptive technology training. At least fifteen separate projects received support. Innumerable technical assistance activities were also implemented.

More recently, emphasis has shifted to research training, especially in clinical trial methodology. Course curricula in epidemiologic methods and clinical trial performance have been developed.

V.4.2.2 Current Objectives. FHI's goals at present are (i) to develop cost-effective modules for training and to provide appropriate training and technical assistance in clinical trial methods, epidemiologic methods, general research, management of research, and new contraceptive technology; and (ii) to assist in the transfer of new contraceptive technology through local research, training, and information dissemination.

V.4.2.3 Future Directions. FHI will develop additional material to increase efficiency in training. There will be a new emphasis on sharply focused information dissemination for lesser developed countries (LDCs). Assistance as appropriate will be provided in the introduction of long-acting steroids outside of clinical trials.

V.4.3 Microcomputer Technology

V.4.3.1 Accomplishments. Through the placing of computer-based systems in key developing locations, FHI and the local researchers have been able to work more closely together on study data. These systems also allow local researchers to conduct their own studies. FHI has also been able to identify areas where additional training is needed (e.g., biostatistics, research methodology, epidemiology) and has tied this additional training to the use of the microcomputer for data collection, editing and analysis.

V.4.3.2 Current Objectives. FHI will continue to concentrate on the development through training and "hands-on" experience of autonomous research capabilities. FHI offers a total system approach that includes hardware, software, documentation, training and evaluation, and builds in-country data collection, editing, and analysis of contraceptive clinical trial and maternal and child health (MCH) data.

V.4.3.3 Future Directions. FHI's prime goal is to identify new locations for technical assistance and provide them with the appropriate microcomputer system and proper support. FHI staff will continue to work with the current sites to improve their use of the technology and to continue to provide follow-up training where appropriate.

V.5 Natural Family Planning (NFP) (see Appendix VI)

V.5.1 Accomplishments

Most of FHI's NFP work started since the previous evaluation. Over the last two years, FHI organized breastfeeding research seminars in Manila, Philippines and Cairo, Egypt and prepared a special issue of the Journal of Biosocial Science on breastfeeding (forthcoming, late fall 1984, or early spring 1985) (see IX.4). FHI also collaborated in the publication of the edited volume, Natural Family Planning: Development of National Programs (see IX.2.1). FHI successfully completed a needs assessment report of a site visit on NFP programs in Kenya.

V.5.2 Current Objectives

- To support research directed toward increasing the effectiveness of NFP methods and improving their delivery.
- To support research on the contraceptive effects of breastfeeding and how these effects can be enhanced.
- To increase the ability of developing country institutions to conduct objective research on NFP methods and programs.
- To increase awareness of NFP methods and the contribution of breastfeeding to fertility control among family planning professionals and the general public through publications and professional meetings.

V.5.3 Future Directions

Thirty projects are currently in the development process. In the coming months, FHI will concentrate on initiating new projects as well as monitoring the fourteen on-going projects.

In the longer run, FHI would like to emphasize psycho-social research in NFP. For example, NFP advocates argue that NFP methods, if taught correctly, encourage marital communications and improve marital relations. Similarly, they argue that NFP methods potentially have a longer-term impact than the other methods, because no short cuts are taken in the teaching. Couples learn basic facts about reproduction, their fertility, and how to integrate FP into marital relations. FHI also plans to study the acceptability and effectiveness of NFP in a multi-method program.

V.6 Reproductive Health (see Appendix V)

V.6.1 Maternal Child Health/Family Planning (MCH/FP) Surveys

V.6.1.1 Accomplishments. Surveys conducted in several states in Brazil provided some of the first data available on contraceptive use and showed that female sterilization and OCs were the most prevalent methods and contraceptive use was higher in the most developed states and in states with community based distribution (CBD) programs.

Data from a Lagos, Nigeria, survey showed that periodic abstinence is the most important method of spacing births and that use of modern methods is very low. Results of the study in Ibadan, Nigeria, sponsored together with the Pathfinder Fund, showed that a high percentage of young adults were sexually active but that their contraceptive use was low. A high percentage of women had been pregnant (45% of sexually active women). Almost all pregnancies were terminated in abortion.

More recently, results from FHI-supported surveys have been presented at numerous seminars and meetings in the United States and in the countries where they took place. The studies and presentations have made policymakers aware of the need to improve FP services.

Numerous papers have been prepared for publication based on the results of FHI surveys. Topics include sterilization, cesarean section, contraceptive delivery systems, pill side effects and contraceptive continuation.

V.6.1.2 Current Objectives. FHI currently is paying special attention to obtaining data on use of FP methods in a non-clinical setting and on the needs of young adults. Current activities are being carried out in conjunction with CDC and Management Sciences for Health.

V.6.1.3 Future Directions. FHI will continue to support surveys that provide information on use of FP services and on non-clinic distribution programs. Particular attention will be paid to development of modules that complement other FHI activities and on obtaining data on pill-related activities among consumers.

V.6.2 Maternal and Child Health Monitoring Studies

V.6.2.1 Accomplishments. Since 1976, FHI has conducted an ongoing program of Maternity Care Monitoring (MCM) studies. At present, the MCM data set contains information on about 450,000 deliveries collected in 184 centers in 56 countries. In addition to its use in managing resources, highlighting the need for contraception and transferring research skills, the MCM system has been used for self-evaluation and training of medical personnel. In several instances, the MCM system has been used as the core for national maternity care data collection systems. The MCM system has provided information on a broad range of topics to health policy decision makers, administrators, and members of the scientific community. Publication of Childbirth in Developing Countries and Reproductive Health in Africa: Issues and Options, as well as publication of papers in scientific journals, have contributed significantly to the literature on how to improve health and FP services. At the request of the AID Africa Bureau, new studies designed to be geographically representative and to include different levels of care have begun in sub-Saharan Africa.

V.6.2.2 Future Directions. FHI will continue the expansion of monitoring activities from an institutional, delivery oriented base toward more comprehensive studies, representative of all events in a particular area. FHI will also explore new aspects of the relationship between formal and informal health care networks and monitor cohorts of mothers and infants to determine levels and patterns of infant mortality.

V.6.3 Pregnancy Wastage Studies

V.6.3.1 Accomplishments. FHI pregnancy wastage studies have been instrumental in alerting policy makers in several countries to women's desire to control fertility and the cost of existing fertility regulation practices. Recently, multi-center studies conducted in Mali and Zaire show that a high proportion of women hospitalized for complications of illegally induced abortions are young, single, nulliparous, and highly educated. In Bolivia, women with induced abortions tend to be older, less educated, married and to have children. As in Zaire, most of the women were non-contraceptors and appeared to have little knowledge of contraception.

V.6.3.2 Current Objectives. Studies planned or underway will (i) determine: the characteristics of, the complications experienced by, the resources used in treating, and the contraceptive use of women hospitalized for complications of induced abortions; (ii) compare the characteristics of women undergoing birth with those of women hospitalized for complications of induced abortion; and (iii) provide local policy-makers with data to assist in the design of programs to reduce abortions and improve health.

V.6.3.3 Future Directions. As part of the MCM efforts in Africa, information on women hospitalized for complications of spontaneous and of illegally induced abortions will be obtained in addition to the standard information on women hospitalized for childbirth. These data will provide health policy-makers with information on women hospitalized for a broad range of pregnancy-related conditions.

V.6.4 Family Planning Service Delivery

V.6.4.1 Accomplishments. Results of a survey of CBD workers in Honduras showed that their knowledge concerning the correct use of methods and their training in counseling women regarding contraindications and side effects needed to be upgraded. This information was incorporated into new training programs.

In December 1982, FHI completed an important evaluation of the Bangladesh Family Planning Social Marketing Project that included an analysis of the gap between condom sales and distribution and condom use, and an analysis of the plateauing of pill sales.

V.6.4.2 Current Objectives. FHI's present goals are (i) to determine the level of knowledge among FP providers, CBD personnel and retailers, concerning the methods they distribute or sell, and to assess their effectiveness as providers; and (ii) to analyze the attitudes of physicians and pharmacists regarding FP to determine whether programs can be designed to employ them as a more positive force.

V.6.4.3 Future Directions. FHI will undertake studies to improve information and training for suppliers of FP. Providers may affect overall use both by encouraging women to use particular methods and by providing correct instructions on how to use the various methods. As new oral and vaginal contraceptives are introduced, care must be taken to ensure that both medical and nonmedical providers know how to screen and counsel women regarding contraindications and side effects.

V.6.5 Female Sterilization

V.6.5.1 Accomplishments. FHI-supported studies have demonstrated that over half of Brazilian women who get sterilized have this surgery concurrent with a cesarean section, and, that the higher a woman's socioeconomic status, the more likely she is to have a cesarean section. The conclusion is that poor women have less access to postpartum sterilization.

FHI-supported studies have also indicated that facilities for post-partum sterilization at Ministry of Health hospitals in Honduras were unable to meet the demand for sterilization and that many unsterilized women did not return for surgery in the few months following delivery. This data indicated that if women are not sterilized postpartum, very often they will not obtain interval procedures.

Recently, FHI-supported studies in Honduras indicated that over a two-year period women interested in sterilization but unsterilized were more likely to get pregnant than they were to get sterilized. Another study showed that Brazilian women are discouraged from obtaining interval sterilizations because of the approval and followup procedures that must be followed before surgery. Both these studies promise to lend weight and credibility toward the revision of restrictive sterilization procedures.

V.6.5.3 Future Directions. Sudies are being conducted to provide information on three important female sterilization-related issues: interest and acceptance, evaluation of facilities, and long-term satisfaction. Data will also be provided on the effect, if any, of government subsidies.

VI. THE DECISION-MAKING PROCESS: HOW IS FHI's RESEARCH AGENDA SET?

VI.1 Research Goals

FHI was originally created to determine the safety, efficacy and acceptability of various contraceptive methods through clinical trials in a variety of developing countries. Although clinical trials are still the priority purpose of the organization, (representing 34 percent of the organization's total FY 1984 budget -see Ch.X),[1/] FHRCs are increasingly able to conduct more of this work with less direct assistance from FHI. Accordingly, FHI's capability and agenda have expanded to meet the changing needs for training, technical assistance, and information on reproductive health -- all necessary elements to enhance the delivery of effective FP services in LDCs.

FHI's President cited the following as the organization's current general research goals:

1. Improving contraceptive methods available through both method development and clinical trials;

2. Increasing access to FP through introduction of new methods and "detailing" (using in-country clinical trials to demonstrate safety and effectiveness and to introduce the method to indigenous medical leadership);

3. Documenting the association between contraception and health;

4. Learning more about contraceptive distribution channels and how they can be made more effective; and

5. Post-marketing surveillance of contraceptive method use to document safety and identify risks.

With this expanded research agenda, FHI conducts or participates in as many as 90 separate research-related projects in a single year.

VI.2 The Overall Research Strategy: Setting Goals and Priorities

VI.2.1 Role of FHI Staff and AID

FHI's overall goals, priorities and research strategies are established by FHI's President with substantial input from AID. Both parties agree that FHI's first priority should be clinical trials in support of development, improvement and introduction of contraceptives appropriate for use in LDCs. They also agree that FHI should be able to respond to AID's research needs in a flexible or even ad hoc manner. Indeed, in the creative, collegial environment of FHI, ideas from any staff member may feed into strategic planning. FHI's President relies on his senior staff to help set policy. For example, FHI's research in breastfeeding and other methods of NFP was initiated by the senior staff. The

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1/ This figure does not include clinical trials funded through the Field Development and Training Department's budget.

President also sees FHI's newly hired reproductive biologist as potentially playing an important role in development of FHI's strategy. To assist in the creative process, senior staff plan off-site full-day meetings once or twice yearly for purposes of long-range planning and identifying gaps and priorities in the research agenda. Each division also annually prepares a work plan that includes a statement of objectives together with a specific plan of action.

VI.2.2 Role of the Board of Directors and the TAC

The Board of Directors (see IV.1.7) meets twice yearly, with two additional meetings of the Executive Committee. The Board approves the budget and thus, in effect, approves the research agenda. They discuss the scope and direction of FHI's research program but rarely change it. The Board is influential, however; for example, individual members played a significant role in motivating FHI toward quinacrine research. The Board has also placed a (high) budgetary limit on the microcapsule work.

The TAC meets for only one day, once yearly; however, its function is augmented by the committees and meetings described in IV.1.7. The TAC reviews strategy papers for selected studies prior to each meeting. In addition, the Committee suggests new areas of research, identifies ongoing FHI research that may be of low priority, and provides FHI investigators with advice on research design and new data analysis methodology.

VI.3 Identification and Approval of Specific Projects

VI.3.1 Identification

While headquarters staff and AID set overall policy and strategy, suggestions or requests for projects may arise from staff members at any level, from any of the six FHRCs, and from within individual USAID missions. FHI has been appropriately responsive to all these parties.

Staff members: Staff members travel extensively and often return with field-generated research ideas. The lack of formal in-country representation (see IV.3.1), however, may not allow for establishment of priorities which truly reflect field needs. This possibility lends urgency to the need for exploring ways to reinstate FHI field operations (see IV.4.3 [vii] and [viii]).

FHRCs: The FHRCs help identify significant research questions. For example, the idea for the MCM program originated with a Sudanese physician who needed the information for health services planning. A researcher in Bangladesh investigated the actual use of OCs in his country. His discovery of widespread, serious and previously unrecognized disparities between prescribed and actual pill consumption is resulting in further FHI studies of contraceptive method use. The Contraceptive Safety Division's current work on the risks and benefits of hormonal contraception for women with sickle cell disease also resulted from a need identified within the FHRC network.

As the FHRCs become capable of autonomous function, it is to be expected that they will increasingly develop their own research agendas. Examination of the 1984-88 five-year plans for the FHRCs in Indonesia and Thailand (see Appendices X a and X b) indicated each had its own set of priorities. All studies in the proposed Thai list were related to contraceptive use, while only three of the

seven priority studies identified by the Indonesian center were clearly linked to this area. Instead, the emphasis in the Indonesian center has shifted to maternity-related research, a trend which is seen to be growing worldwide. It should be noted, however, that non-family planning studies pursued by the Indonesia FHRC will not necessarily be funded by FHI.

USAID Missions: USAID missions often suggest projects based on perceived individual country needs or within the context of the country's long-term planning process. FHI must balance these requests against the potential of such research for practical application.

VI.3.2 Approval

Every study proposed by a division must be reviewed and approved by the Science Committee. This committee meets monthly (see IV.1.5). One-page summaries of new or revised proposals are distributed to Committee members for advanced review. Each summary requires a brief project description, discussion of possible significance, and information on location, duration, estimated costs and collaborative plans. Approximately two-thirds of all proposals are ultimately approved, sometimes after significant revision. Once a project has passed review, a strategy paper is developed to submit for AID review and approval.

VI.4 Considerations Governing Selection of Projects

While field and AID-generated projects tend to reflect country-specific priorities, FHI's strategic decisions are also governed by the level of interest in a particular initiative in the research community at large. The joint undertakings described in Chapters V and VIII with WHO, PARFR, and the Population Council and to a lesser degree other donors, represent some of FHI's most promising and important endeavors. Projects promising financial or product contributions by industry are also attractive, since these reflect a sufficient level of commitment to suggest the possibility of ultimate marketing -- should initial trials prove satisfactory (see VIII.2). While AID-suggested programs should not be relegated to a lesser category, those programs where dual interest and involvement are evident must receive primary attention.

VI.5 Recommendations

(i) FHI should continue to utilize AID as well as its own senior staff, Board of Directors and Advisory Committees in setting research priorities.

(ii) FHI should continue to be responsive to suggestions regarding specific projects generated by USAID missions.

(iii) Although FHI's first priority should be to conduct large-scale clinical trials, it should continue to increase its capabilities in regards to trials at all levels from pre-clinical testing through Phases I-IV, to permit a flexible response should opportunities arise for testing at any point in the development of a new product and to attract private sector interest.

(iv) FHI should continue to give primary attention to projects offering the opportunity for cooperation with other research institutions or industry.

VII. RESEARCH MANAGEMENT

VII.1 Key Elements of the Research Management System

FHI has developed several organizational strengths that enhance its capacity to conduct research in a variety of countries, manage and evaluate data, and disseminate research findings to a range of audiences. The key elements of this system are:

i. An extensive network of investigators and institutions around the world, especially in developing countries (see Appendix III);

ii. Linkages for monitoring the ongoing activities of the investigative sites;

iii. A mechanism for providing technical assistance and training in research methodology;

iv. Staff experienced in managing clinical, epidemiological and behavioral research; and

v. Facilities and staff for data processing and analysis.

VII.2 Clinical Trials Department

Since conducting Phase III clinical trials is a priority goal for FHI, the Team selected the Clinical Trials Department to determine the effectiveness of the various elements which comprise the research management system. This department uses a project team approach. A project team (typically including a project manager, medical expert, statistician, study field monitor, and data assistants) is assigned to each clinical strategy. Protocol development and the design of case record forms constitutes inputs from each team member as well as from behavioral science colleagues. Selection of collaborating investigators depends on several criteria including the power requirements of the study, geographical considerations, and the performance record of investigators at specific sites.

Data quality is monitored at the investigational site by selected checks of source documents during visits by FHI staff. Case records are extensively checked at the Research Triangle Park facility, and discrepancies, omissions and errors corrected by communication with the investigator. The Team stressed that this step must be carefully documented, especially in studies designed for regulatory submission. Data are double entered for computer processing, with internal consistency checks.

The monitoring and auditing procedures have been formalized considerably, and a set of written clinical practices is planned.

The department has begun a program of good clinical practices training for its staff. Selected individuals have taken specific training programs, and plans are underway to establish an in-house program for FHI staff and ultimately for investigators within the international network.

By adherence to the procedures described above, FHI has strengthened its ability to conduct both Phase II and Phase III clinical trials and to prepare comprehensive reports for the FDA[1]. By sending its newly appointed reproductive biologist to a training course in writing FDA submissions, FHI is increasing its capability even further. With continued training of existing staff, only minimal additional personnel will be required as FHI's contraceptive development projects proceed toward regulatory submission.

VII.3 Reproductive Health Department

VII.3.1 Research Management

In general, Reproductive Health staff participate in clinical trials at the level of actual use of the technology in the field. Use-effectiveness, accessibility, availability, and methods of distribution are primary concerns.

Typical studies conducted by behavioral scientists in the Reproductive Health Division incorporate cross-sectional or longitudinal household surveys. Correct research procedure is followed: census tract information is first obtained and a random sample (sometimes stratified to include rural and urban components) is chosen for door-to-door solicitation of participation. Information desired by individuals in decision-making positions (managers in the health delivery systems, policymakers in the Ministry of Health, etc.) are incorporated into the data collection instrument. These individuals also assist with the translation of all questions into culturally appropriate language.

Indigenous interviewers are trained by an independent coordinator who is also responsible for the logistics of fieldwork operations. An FHI monitor oversees initial training stages and observes interviewers in the field. The usual stay for FHI field staff varies between one and four weeks, depending on the need.

Before proceeding to the final survey, pretesting occurs to test the interview schedule, the substance and clarity of questions, and interviewer skill. Consistency and completeness of response is ensured by the supervisor who rechecks all questionnaires. As much of the data as possible is processed in the field. The final report generally is written by FHI with collaboration of indigenous investigators.

VII.4 Integration of Social Science Research Into Clinical Trials

In at least two instances, issues have arisen in the course of technological research which could perhaps best be resolved with the assistance of a behavioral research social scientist. Specifically, (i) discrepancies in the results of research from different sites may have sociological explanations and (ii) the study of acceptability of various contraceptive methods is not sufficiently comprehensive; it should address all aspects of the user's perspective.

1/ It should be noted that FHI conducted the trials that led to FDA approval of a contraceptive vaginal sponge product.

The 1982-83 Annual Report documents at least two examples of inconsistent or significantly divergent data emerging from different sites in Phase II multi-center trials. In one instance women using the contraceptive sponge had a 12-month gross cumulative life-table pregnancy rate of 25.9 compared to 9.2 for another center. In another example, there were marked differences in the discontinuation of the progesten-only pill related to decrease in milk production. It is highly likely that these differences (if not due to faulty record keeping) could be accounted for by provider-related or cultural factors.

FHI currently examines the acceptability issue mainly at Phase III clinical trials with only the issues of continuation rates and reasons for discontinuation addressed at the Phase II level. Under these conditions, it is not surprising that sometimes a new product with clinically proven high effectiveness may have poor consumer acceptability, raising a question regarding the funding priority given to that particular research concept.

VII.5 Recommendations

VII.5.1 Clinical Trials

FHI has taken initial steps to develop the capacity to manage clinical research and prepare submissions for FDA approval. High priority should be given to strengthening these operations through the following steps:

(i) Continued formalization of monitoring and auditing procedures would ensure that discrepancies, omissions and errors in research activities are corrected.

(ii) Preparation of a set of written clinical practices, including the formalized procedures in (i), would help provide an additional quality assurance instrument in implementing of future research initiatives.

(iii) The newly-initiated staff training in "good clinical practices" and regulatory affairs should be continued, to reduce insofar as possible the need to hire additional staff for preparing FDA submissions.

VII.5.2 Integration of Social Science Considerations Into Clinical Research

(iv) New models for research in the social sciences need to be explored to address such issues as discrepancies in site-generated research data and contraceptive acceptability.

In some cases, personnel from the Reproductive Health Division could provide the insights required on these issues. In other cases, a full or part-time social scientist might be added to the staffs of local FHRCs.

At present even where FHI country-specific programs exist (Bangladesh, Thailand, Sri Lanka, Sudan, India, Egypt), most social science research is not a basic component. This may reflect available skill categories; however, the addition of a full- or part-time social scientist within these offices (or at least with access to the individual FHIs) should prove to be highly cost effective.

(v) Discrepancies between site-generated data should be addressed.

These discrepancies should be explored at the field level during Phase II studies and such findings explained within the body of final submissions prior to initiating Phase III work.

(vi) Additional information on the various components of acceptability should be incorporated early in the development of a new contraceptive technology. If a more comprehensive acceptability component is built into Phase I and II trials, FHI could learn which aspects of any given technology are particularly satisfactory or unsatisfactory so that possible modifications could be incorporated from the user perspective early in a product's development, or at least addressed more fully in later trials.

VIII. RELATIONSHIPS WITH OTHER ORGANIZATIONS

VIII.1 International Research Groups

Out of the large number of organizations engaged in the development of contraceptive technology (see footnote 1 section I.2), FHI is the one best qualified to conduct large-scale clinical trials. Its large and widespread network of investigators has a unique capacity to introduce new contraceptive technology throughout the world. In addition, FHI has an increasing ability to monitor and analyze data from all levels of investigation, from the pre-clinical phase through post-marketing surveillance.

As a result, many of the major research organizations have called on FHI to assist in product development at the stage when large-scale testing is required. Chapter V contains many examples of collaborative efforts between FHI and the contraceptive developers. For example:

(i) PARFR, whose main capabilities include soliciting, funding, initiating, developing and monitoring Phase I and Phase II studies, has used FHI to (a) analyze data for PARFR - funded studies on an Intra-Tubal Device (see V.2.1.2); and (b) analyze PARFR - sponsored Phase II studies of NET implants (see V.2.6.2). In addition, AID has directed FHI to play a major role at an earlier phase of product development, by monitoring studies of NET injectables needed as a prerequisite to initiation of PARFR-funded Phase I and II Trials (see V.2.5.1). This activity requires FHI to focus greater attention on good clinical practices and the quality control of its data collection systems.

(ii) The Population Council, which, in its development of NORPLANT[R] implants, called on FHI for assistance in conducting pre-introductory trials (see V.2.6.1).

Collaborative activities also exist betweeen FHI and NIH (e.g., testing of the contraceptive sponge (see V.2.7.1); CDC (e.g., a case-control study of breast, ovarian, endometrial and cervical cancer in Costa Rica; Pathfinder (adolescent sexuality survey in Ibadan); PIACT (pharmaceutical bulletin on contraceptive side effects in Egypt); and UNFPA (research methods training workshop in Gambia).

Most recently, FHI has begun to establish collaborative links with WHO. Although long part of an inter-agency group (WHO, PARFR, Population Council, NIH) on long-acting steroids, FHI has otherwise collaborated only minimally with WHO. FHI's particpation in a WHO-initiated study concerning the relationship between atherosclerosis and vasectomy in China (see V.3.2), however, may signal the start of a number of collaborative ventures. It is likely that as relationships between the two organizations strengthen, WHO will begin to utilize the FHI network of individual investigators, practitioners and governmental bodies to supplement WHO's own network, which is limited to governments.

FHI has also collaborated with a number of organizations which engage in training as well as research (International Planned Parenthood Federation [IPPF], Johns Hopkins Program for International Education in Gynecology and Obstetrics [JHPIEGO], and the Program for International Training in Health [INTRAH]). As FHI and particularly the FHRCs become involved in practitioner training in the process of introducing new contraceptive technologies, new opportunities may arise for collaborative training efforts.

VIII.2 Research Triangle

FHI is to be congratulated for its continuing efforts to utilize interested professionals from local seats of excellence in the Research Triangle vicinity (i.e., Duke University, the University of North Carolina), within the confines of its research and training programs. The quality of technical assistance which can be provided by members of these faculties cannot be overstated.

Similarly, the burgeoning private sector within and beyond the Research Triangle presents another opportunity for FHI. A portion of FHI's budget each year is derived from private foundations and from business with pharmaceutical companies. These companies, although providing only 1-2 percent of FHI's annual income, have undertaken noteworthy collaborative work with FHI (e.g., Stolle Research and Ortho Pharmaceuticals - NET injectables [see V.2.5.1]). More important, business with the pharmaceutical industry serves to stimulate FHI's entrepreneurial drive and to ensure that companies will later be interested in manufacturing the new contraceptive products being developed by FHI. The team is pleased to see one pharmaceutical corporation president presently serving on the FHI Board. Interactions with the professional and business communities are to be encouraged if FHI is to continue to explore the opportunities for non-governmental funding.

VIII.3 AID

The relationship between FHI and the AID Office of Population and AID contract-level personnel appears to be excellent, i.e., cordial and mutually responsive. FHI staff feel that AID is as cooperative as possible given the federal bureaucracy and the necessary dependence on congressional mandates. The team also feels that FHI is making significant efforts to comply with AID requests and goals.

VIII.4 Recommendations

VIII.4.1 International Research Organizations

(i) FHI should place priority on increased communication, perhaps on a regular basis, with representatives of other international research and provider agencies. Relationships with AID-funded training providers should be formalized.

While FHI has made considerable progress in its dialogues with international research groups such as PARFR, the Population Council, and the WHO, coordination with provider agencies could be strengthened further, particularly where research results may have an impact on these agencies' initiatives, or where training funds already exist and can be effectively utilized by more than one organization. Perhaps the concept of periodic donor agency meetings should be instituted to prevent overlap and provide further collective support.

In addition, the Team recommends formalizing relations with organizations such as JHPIEGO, INTRAH, Development Associates, and the University of Hawaii Regional Training Service Agency (RTSA) which focus specifically on training family planning providers. Annual meetings under the auspices of AID's Training

Division would provide opportunities for trainers to include introduction of new technologies in a timely manner into training programs. FHI's strengths might best be utilized in evaluating the results of these collaborative training efforts.

VIII.4.2 Research Triangle

(ii) Continued emphasis on linkages to academic institutions and private corporations adjacent to FHI's headquarters should remain a high priority.

IX. DISSEMINATION OF RESEARCH FINDINGS

IX.1 A primary purpose of family planning research is to produce results that are understood and used by policymakers and providers so as to increase the effective and safe use of contraceptive technology. FHI achieves this objective in a wide variety of ways, each of which is described below.

IX.2 Publications

IX.2.1 Published Materials

FHI investigators publish research results extensively in a timely fashion in journals such as the American Journal of Obstetrics and Gynecology, Fertility and Sterility, Social Science and Medicine, Contraception, Journal of Biosocial Science, American Journal of Public Health, Contraceptive Delivery Systems, Studies in Family Planning, Journal of Reproductive Medicine, and the International Journal of Gynecology and Obstetrics. Based on reading a small non-random sample of articles, the Team believes that the quality of FHI-published information has improved in recent years. In addition to publishing in major journals, FHI staff have published eight monographs addressing major FHI projects, have written chapters in books edited by non-FHI staff and have assisted in the editing of monographs by non-FHI personnel (e.g., Natural Family Planning: Development of National Programs [see V.8.1]). In addition, the proceedings of the annual meetings of the FHRCs are published.

FHI subsidizes 500 subscriptions (sent to collaborating investigators and institutions) to the International Journal of Gynecology and Obstetrics and in an attempt to upgrade the Journal, edits 15 articles annually from foreign investigators (regardless of their participation in the FHI network). FHI has however, reduced somewhat its involvement with this publication because of an editorial policy in line with an expansion of all aspects of gynecology and obstetrics. The Team, however, feels that a continued commitment to the Journal by FHI is appropriate. Team concurs with FHI's decision.

FHI disseminates synopses of its own work and that of other investigators through its quarterly newsletter, Network. This publication is written clearly, concisely and professionally, and in non-technical language so as to be understandable to individuals outside the English-speaking world. Its selection of topics is commended by the Team. Over 220 individuals and institutions (e.g., governments, libraries, universities, FP programs and health facilities) in North America, Africa, Asia, Europe, Latin America and the Pacific receive this publication. The mailing list, which includes collaborators and individuals in decision-making positions, is being constantly expanded.

In order to maximize the dissemination of important research results, FHI selectively translates such work into different languages. For example, three cancer and steroid hormone studies published by the CDC were translated into French and Spanish and sent to collaborators and relevant institutions in Francophone Africa and Latin America. FHI believed it was very important to alleviate mass fears that oral contraceptives cause cancer and to publicize the beneficial effects of steroidal contraception.

In another dissemination effort, FHI participates in incorporating research findings within service manuals. For example, since 1980, FHI has collaborated with the Egyptian Fertility Care Society in producing bulletins on contraceptive technology so as to periodically update pharmacists', nurses' and physicians' knowledge of contraindications and side effects of contraceptive methods.

IX.2.2 Preparation of Materials for Publication

Approximately 60 percent of FHI publications are co-authored by collaborating investigators, with a member of the FHI staff usually the primary author.

In many cases, the individual research site prepares, often with technical assistance by FHI, its institutional summary. These data obtained from individual sites are reviewed by FHI, and, where appropriate, combined with data from other domestic and international research centers utilizing the same protocol. The final paper bears the names of the individual investigators; however, if it is a multi-center study, final preparation occurs at FHI headquarters. Thus, the primary author in most cases remains a member of the FHI staff. This approach is not unreasonable in a collaborative effort.

FHI also encourages the in-country publication of single-site data, in an effort to provide decision-makers in a particular country national information upon which they may choose to act. Some of this research is also utilized by collaborators to satisfy requirements for master and doctoral level degrees.

All FHI-funded proposals require a written report on research results. A problem in utilizing locally produced materials, however, is that the writing ability of many host country collaborators is below standard. As part of its program to provide technical assistance, FHI offers formal courses in analytic and writing skills, both in the field and at FHI. Investigators are sometimes brought to FHI to write up their research results. Ad hoc technical assistance in writing is also provided in the field. Moreover, an FHI-fellowship program was recently created to provide foreign collaborators with extended experience in data analysis and writing.

IX.3 Conferences

International training seminars and conferences are routinely supported and coordinated by FHI. These meetings serve as important vehicles for information dissemination and frequently offer collaborators the opportunity to present their own data. Individuals from all over a given country are brought together; particular attention is paid to selecting participants who are judged likely to conduct research or who have some effect on decision making. Usually 70 to 80 percent of attendees follow up with their own research. Proposal writing is required in many training workshops; individual proposals are then submitted to FHI for possible funding.

FHRCs also hold conferences on an annual basis, the proceedings of which are published. Since typically FHRCs are composed of individuals who have an impact on policy, those meetings provide participants with data which they can use to attempt to affect national policy.

IX.4 Mass Media

FHI tries to inform public officials of relevant research results with the hope of increasing public awareness. For example, Egyptian President Mubarek discussed results of the RAMOS study (see V.3.1) on public television. FHI "expert meetings" occasionally serve this purpose as well. A 1983 conference on breastfeeding in the Philippines, and a similar 1984 meeting in Egypt, attracted the attention of the mass media and thus served to promote breastfeeding in these countries (see V.5.1).

IX.5 Informal Communication

IX.5.1 Collaborating investigators

The dissemination locally of the results of research projects is key to the usefulness of these studies. The involvement of decision-makers in government and health facilities on developing research protocols guarantees that these important audiences are involved at the start with any research undertaking. In order to maximize utilization of research findings, initial results are processed in the field and final results are returned to the field as quickly as possible.

The means for further dissemination may depend on the local situation. In Zaire, for example, a local advisory committee, consisting of representatives from different organizations, was formed to advise researchers and to disseminate results of a study on pregnancy wastage. This study found that women who either wanted or needed FP services did not usually return postdelivery for contraception. As a result of this study, FP nurses now provide needed FP information and services in delivery rooms. In Mali, policy change is currently under consideration as a result of a similar pregnancy wastage study.

IX.5.2 Population Organizations

Information is also disseminated to other population organizations on an informal basis. For example, an FHI sterilization study in Honduras showed insufficient availability of services. FHI contacted The Association for Voluntary Sterilization (AVS), which subsequently addressed this need.

IX.6 Recommendations

It is clear that FHI is proceeding in the right direction in its publication and information dissemination program. More could be done, however, to strengthen existing efforts to influence national policies, particularly through holding of conferences. Specific recommendations include:

IX.6.1 Publications

(i) Efforts to duplicate, translate and disseminate important papers on contraception from non-FHI sources should be expanded.

The library staff at FHI should make efforts to augment its collection of its own published papers with relevant articles from international journals.

Such reprints should be distributed not only to FHI's network of collaborators but equally important to key opinion leaders and government officials who may elect to alter priorities based upon such information.

(ii) FHI's newsletter NETWORK is a valuable publication and efforts to expand its distribution should be continued.

(iii) The use of country-specific service manuals as a medium of dissemination should be continued.

(iv) Additional technical assistance should be provided in the rewriting and submission of papers.

FHI staff have suggested the sponsorship of FHRC research analysts at the Institute of Population Studies, University of Exeter for formal extended training. The Team believes this idea has merit and should be pursued.

IX.6.2 Conference

(v) FHI-sponsored research conferences, perhaps regional in scope, should be expanded.

Such conclaves would achieve several goals, primarily since they would serve to expand FHI's impact into the area of national policies. Specifically, such conferences could

1. Permit the invitation of those opinion leaders whose presence at these presentations offers the best chance for policy change;

2. Lay the groundwork for the dissemination of future research information to this select group, with the likelihood that such material would be more closely read;

3. Provide experience for individuals to arrange similar meetings within their own medical community; and

4. Reinforce the prestige value of FHI's in-country research efforts.

To increase credibility for such efforts, both papers by FHI collaborators and by pre-eminent researchers from throughout the field of reproductive medicine should be presented. The AVS experience with this approach has been notable, and we see no reason why similar successes in a parallel areas cannot be achieved by FHI. The Team recognizes the financial considerations inherent in this recommendation and urges AID to allocate appropriate funding for its implementation.

X. EVOLUTION INTO NEW AREAS OF RESEARCH

X.1 Analysis of FHI budget

To determine the extent to which FHI has moved into new areas of research, the Team turned to FHI's budget. The Team focused particular attention on expenditures for MCM (see V.6.2) in light of concerns expressed in the APHA evaluation.[1/] It also compared the 1982 and 1984 levels of expenditure on contraceptive technology and contraceptive safety with those for reproductive health and natural family planning and it analyzed shifts in priorities among different contraceptive methods.

During the current fiscal year, FHI's budget was allocated among the five Departments of Research Operations as follows: 34 percent to clinical contraceptive trials; 13 percent to contraceptive safety studies to describe and quantify health benefits and risks associated with method use; 24 percent to field development and training activities (most of which is used to enhance the ability of LDC medical research institutions to conduct clinical trials autonomously); 11 percent to studies to enhance the effective utilization of NFP methods, including breastfeading; and 18 percent to Reproductive Health Department activities.

Nearly half (47 percent) of all funds are earmarked directly for programs specifically linked to contraceptive research and safety and another 24 percent to LDC medical research institutions whose prime task is to conduct clinical trials. Together, NFP and reproductive health activities represent the remaining 29 percent of the total budget.

Table X.1 represents AID-supported expenditures according to research area, regardless of which FHI department was involved. For example, the line item, Female Sterilization, includes funds from three departments: Contraceptive Trials, Contraceptive Safety, and Reproductive Health. Between 1982 and 1984, the proportion of expenditures on various types of research changed as follows:

- Research dollars related to IUDs decreased from 18 percent to 7 percent;
- Research dollars related to female sterilization decreased from 12 percent to 8.5 percent;
- The percent of funds for male sterilization decreased from 2 percent to 1 percent;
- Research funds related to barrier methods decreased from between 5 and 7 percent to 4 percent;
- Dollars for research-related to hormonal contraception increased from 6 percent to 11 percent;

1/ The APHA evaluation recommended that FHI decrease its MCM data gathering and seek instead to analyze in a meaningful way the information already gathered.

Table X.1

SUMMARY OF FHI EXPENDITURES BY RESEARCH AREA
(AID Budget Only) - Fiscal Year 1982-1984

Research Area	FY82		FY83		FY84		FY84[6]
	$	%	$	%	$	%	% of PoP$
Intrauterine Devices	783,000	17.54	751,000	16.19	395,000	6.78	6.92
Female Sterilization	535,000	11.98	432,000	9.31	490,000	8.40	8.59
Male Sterilization	80,000	1.79	97,000	2.09	54,000	0.93	0.95
Barriers	225,000	5.04	322,000	6.94	241,000	4.13	4.22
Systemics[1]	267,000	5.98	458,000	9.87	640,000	10.98	11.21
NFP/Breastfeeding	129,000	2.89	374,000	8.06	634,000	10.87	11.10
Contraceptive Safety	317,000	7.10	297,000	6.40	713,000	12.23	12.49
In-Country Research Institutes	895,000	20.05	660,000	14.22	857,000	14.70	15.01
Evaluation/Needs Assessment	380,000	8.51	271,000	5.84	404,000	6.93	7.08
Technology Assistance/ Training[2]	367,000	8.22	432,000	9.31	702,000	12.04	12.29
Maternity Care Monitoring	339,000	7.59	424,000	9.14	546,000[5] 426,000[6]	9.37	7.46
Programmatic Studies	33,000	0.74	41,000	0.88	52,000	0.89	0.91
Information Dissemination	114,000	2.55	81,000	1.75	102,000	1.75	1.79
	4,464,000	99.65	4,640,000	100.0	5,830,000[4,5] 5,710,000[6]	100.0 (all funding)	100.02

FY=Fiscal Year

Notes:
1. Includes OCs, long acting steroids and implants.
2. Includes microcomputer technology development and transfer.
3. Includes IJGO and NETWORK.
4. $4,996,000 from 1 October 1983 - 31 July 1984.
5. Includes $120,000 Africa Bureau Money.

- Research related to NFP increased from 3 percent to 11 percent, and now consumes the same proportion of FHI funds as hormonal contraception;

- Funds for MCM remained stable at about 7.5 percent (but increased to over 9 percent, if the special Africa Bureau funds are included in the calculations);

- Programmatic studies of family planning service delivery systems remained at less than one percent.

To summarize, between 1982 and 1984, there has been an overall decrease of 7 percent in funds spent on clinical trials of new contraceptive methods. This includes a significant drop of 11 percent for IUD research and a lesser drop of 3.5 percent for female sterilization. Simultaneously, there has been an increase of 5 percent allocated to systemics, which now receives the largest percentage of funds among various contraceptive technologies. The overall drop in the proportion of funds spent for contraceptive technology has been offset in part by an additional 5 percent in funds allocated to contraceptive safety (up to 12 percent from 7 percent).

Meanwhile, in the area of family health, funds spent on NFP have increased by 5 percent and now account for the same 11 percent proportion of the budget as does systemics research, while expenditures for MCM alone represent over 9 percent of the 1984 expenditures, only slightly less than expenditures on IUD, male sterilization and barrier methods research combined.

X.2 Special African Needs (see Appendix VII)

The importance of MCM expenditures in particular, and Reproductive Health studies in general, must be seen in the context of FP needs in Africa. The preponderance of FHI funds spent in Africa go to activities sponsored by the Reproductive Health Department and conversely Africa currently utilizes a larger proportion of the Reproductive Health Department budget than does any other region. AID's Africa Region, in fact, felt so strongly regarding the need for an increase in MCM activities that it earmarked $120,000 in 1984 Regional funds to supplement funds provided by the Office of Population (see Table X.1, footnotes 5 and 6). The funds are being spent on new studies which focus on different geographic areas and levels of care which in turn will be used to define African family planning needs (see V.6.2.1).

The Evaluation Team has concluded that FHI's expenditures in this area constitute a significant, long-term investment in the gradual introduction of FP into Africa and supports its continuation for the following reasons:

(i) Africa's women are more concerned with health issues and infertility than with FP.

Although high fertility is a critical problem for almost all African countries, MCH workers are seldom confronted with women who actively seek contraception. Instead, these workers face dramatic and tragic cases of serious and frequently fatal obstetric complications, infantile disease, cases of STD, or

infertility. Family planning can be introduced within the context of the problems but not in isolation. If organizations such as FHI attempt to study family planning research outside the confines of health issues, their work might be considered at best inappropriate and at worst insensitive; and

(ii) The information being developed through MCM will provide the basis for the introduction of family planning because:

(a) MCM data documents the need for FP. The description and quantification of maternal morbidity and mortality associated with various pregnancy outcomes and population-based reproductive health surveys can eventually be expanded to include work more directly focused on FP. This is especially likely because the maternity data documents serious health problems associated with unwanted pregnancies. In fact, a great deal of information with direct relevance to FP has already been collected through the MCM system. For instance, data reveals that a significant proportion of unmarried teenaged girls, especially those who are in school, are sexually active, but lack both knowledge about and access to modern FP methods. Unwanted pregnancies are common and are usually terminated by illegal abortions. Nevertheless, most women (including teens) want many children. Only women with six to eight surviving children want to cease childbearing. On the other hand, many women are interested in using modern contraceptives for spacing purposes if they are given information and access to a method in the immediate postpartum period. This kind of information is invaluable to set the stage for introduction of contraceptive use in Africa.

b) MCM data generates leadership support for FP. Historically, studies which showed that illegal abortion was a major cause of death and hospitalization for Latin American women have played an important role in the introduction of FP. There is evidence that similar changes will occur in Africa. For instance, as noted earlier, FHI's documentation of the extent of deaths, serious illness, and long (expensive) hospitalizations associated with illegal abortions in Zaire led to provision of FP information in the immediate postpartum period. Changes are also being considered in Mali as a result of a similar FHI study conducted there. A national advisory committee comprised of policy-level people from major women's organizations, the Ministry of Health and the Ministry of Education, has been formed in Zaire to recommend actions resulting from FHI's findings of a high incidence of illegal abortions (with concomitant death and serious morbidity) among unmarried teenage girls. The data developed through MCM is highly valued by African MCH leaders. Collaboration in this work between FHI and African providers and policy leaders should eventually be translatable into joint FP efforts.

X.3 Recommendations

(i) FHI's program mix is in general appropriate. The utilization of approximately 50 percent of the total budget for clinical trials and contraceptive safety is realistic. The new initiatives in the areas of reproductive health and natural family planning are appropriate the studies on breastfeeding however, which are currently focused on the efficacy of breastfeeding as a family

planning method, should be expanded to include the issues of transition from breastfeeding to other methods, the optimum time for that transition and the appropriate method to be adopted. IUD research funding should continue to decline since significantly improved products are unlikely to be developed. On the other hand, too little attention is being directed towards male methods of fertility regulation.

Clearly the emphasis needs to continue to be placed on new technology while maintaining appropriate country-specific initiatives in oral contraception, voluntary sterilization and new barrier technology -- reflecting both consumer demand and overall AID funding.

(ii) In Africa, FHI should be encouraged to explore new models of research on family health issues.

Models might include documentation of health problems associated with high parity and illegal abortions; clarification of the role of breastfeeding; and issues relating to STDs and infertility. Such studies should also identify and investigate the role played by indigenous fertility regulation methods and the reasons women fail to use available family planning services.

Such studies would provide useful information to MCH policy makers and lay the groundwork for successful introduction at a later date of FP programs.

(iii) FHI should continue to focus its non-family planning studies in countries with pro-family planning policies, USAID missions, and internal institutions interested in developing family planning services. Countries should be considered high priority because of their large size, rapid population growth, and high rates of maternal and infant mortality.

(iv) For non-family planning studies, FHI should be encouraged to explore the potential for receiving ancillary funding from health-designated funds from AID's Office of Health and/or Office of Nutrition.

The population-related activities of the Office of Health include Primary Health Care Centers, vaccines and oral rehydration while the Office of Nutrition has programs related to breastfeeding. The Office of Nutrition might be the more likely candidate for ancillary funding.

XI. SUMMARY OF RECOMMENDATIONS

The recommendations below represent, in the Team's judgment, the most important areas where FHI management should concentrate its attention. Many recommendations simply reflect concurrence with already occurring trends. In particular, the Team was very much in accord with FHI's overall strategy and goals, as reflected in recommendations 11 and 23. It also felt very comfortable with the procedures relating to priority-setting, research management, relationships with other organizations and dissemination of research findings.

If any area should take precedence, it would be the recommendations in regard to staffing. While cognizant of the difficulties of identifying and attracting the best candidates, the Team hopes that a suitable person will soon be hired for the post of Director of Quality Assurance (Recommendation 2). It is also concerned that the problem of field representation receive priority attention (Recommendations 7 and 8).

The only major departures from current practices are those contained in the recommendations regarding the Biostatistical Unit (Recommendation 5), the design of Phase II clinical trials (Recommendation 17) and the recommendations for conferences (i) with training institutions (Recommendation 18) and (ii) with leading researchers (Recommendation 22). The Team assumes the implementation of these recommendations would not disrupt the organization's generally smooth functioning and offers them only as means to achieve the goals FHI has already set for itself.

The recommendations below are listed in the order in which they appear in the Report.

Organization and Staff - Chapter IV

(1) As a means of attracting and retaining gifted clinicians, physican incentives should be explored with AID.

(2) Priority attention should be given to filling the top-level vacancies, including the Vice-President for Medical Affairs*, the Medical Director and the Director of Quality Assurance. First priority should go to the latter.

(3) An obstetric/gynecology specialist should be added to work with the clinical trials group.

(4) In hiring senior staff, FHI should attempt to maintain an appropriate mix at the top management level between medical and non-medical expertise so as to ensure a suitable balance between the perspectives of the provider and the needs of potential users.

(5) The work of the Biostatistical Unit should be better integrated with that of the Division for Quality Assurance.

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* Or the Vice-President for Research based upon the team's suggestions (see IV.4.1.[IV]).

(6) The TAC should be strengthened by the addition of a nurse-midwife and/or a second behavioral scientist.

(7) FHI should give high priority to seeking new ways to assure increased field participation, perhaps through individual country representatives or regional meetings.

(8) A field visit by external consultants or members of this evaluation Team is recommended, to suggest specific new models for field participation.

Decision-Making Process - Chapter VI

(9) FHI should continue to utilize both AID and its own senior staff, Board of Directors and Advisory Committees in setting research priorities.

(10) FHI should continue to be responsive to suggestions regarding specific projects generated by USAID missions.

(11) Although FHI's first priority should be to conduct large-scale clinical trials, it should continue to increase its capabilities to conduct trials from the pre-clinical phase through post-marketing surveillance, to permit a flexible response should opportunities arise for testing at any point in new product development.

(12) FHI should continue to give priority to projects offering the opportunity for cooperation with other research institutions or with industry.

Research Management - Chapter VII

(13) Continued formalization of monitoring and auditing procedures would ensure that discrepancies, omissions and errors in research activities are corrected.

(14) Preparation of a set of written clinical practices, including the formalized procedures in (11), would help provide an additional quality assurance instrument in research initiatives.

(15) The newly-initiated staff training in clinical practices should be continued, to reduce insofar as possible the need to hire additional staff for preparing submissions for FDA approval.

(16) New models for research in the social sciences need to be explored to address such issues as discrepancies in site-generated research data and contraceptive acceptability.

(17) Additional testing on the various components of acceptability should be incorporated within the Phase I and II clinical trial design.

Relationships With Other Organizations - Chapter VIII

(18) FHI should place priority on increased communication, perhaps on a regular basis, with representatives of international research and provider

agencies. Relationships with those that provide training activities should be formalized, perhaps through annual meetings under the auspices of AID's Training Division.

(19) Continued emphasis on linkages to academic institutions and private corporations adjacent to FHI's headquarters should remain a high priority.

Dissemination of Research Findings - Chapter IX

(20) Efforts to duplicate, translate and disseminate important papers on contraception from non-FHI sources should be expanded.

(21) Additional technical assistance should be provided in the rewriting and submission of papers.

(22) FHI-sponsored research conferences, perhaps regional in scope, should be expanded and held on a regular basis as a means influencing public policy.

Evolution into New Areas of Research - Chapter X

(23) FHI's program mix is in general appropriate. The new initiatives on reproductive health and natural family planning are to be commended although the breastfeeding studies should expanded to include the issue of transition to other methods. More attention should be directed towards male methods of fertility regulation.

(24) In Africa, FHI should be encouraged to continue to explore new models of research on family health issues.

(25) For non-family planning studies, FHI should be encouraged to explore receiving ancillary funding from AID's Office of Health and/or Office of Nutrition.

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SCOPE OF WORK

Appendix I

Appendix I

Scope of Work
In-depth Team Review

I. Project Title/Number

Family Health International (FHI), (Formerly, International Fertility Research Program, [IFRP]); 932-0537; Both Contract AID-DPE-0537-C-00-1028-00 and Grant AID/pha-G-1198.

II. Contractor/Agency

Family Health International
Research Triangle Park
North Carolina, 27709
(919) 549-0517

III. Purpose and Rationale for Team Evaluation

Periodic, in-depth, evaluation. The last evaluation of Family Health International (at that time IFRP) was done during the period, June 1981 - March 1982, through a team organized by the American Public Health Association. It was a major, intense, evaluation covering both FHI headquarter operations, organization, funding, and international operations. This interim evaluation is requested as both a followup to the recommendations of the 1982 evaluation, and because it is deemed beneficial to the ongoing project performance.

IV. Dates and Place of Evaluation

Third or Fourth Week of August 1984, Family Health International, Research Triangle Park, North Carolina

V. Composition of the Evaluation Team

A. A scientist from an agency involved in contraceptive development, who has a broad knowledge of the entire field of contraceptive development and the private sector.

Recommended Panel Member

Forest Greenslade, Ph. D.
Senior Consultant
International Programs
The Population Council

B. An obstetrician/gynecologist Clinician who is also familiar with contraceptive development and trials and with developing nation issues and field work.

Recommended Panel Member

Dick Derman, M. D.
Clinical Obstetrician-Gynecologist with faculty appointment at Cornell Medical School
Editor, Fertility Control, a soon to be issued text on contraception technology

C. An epidemiologist with orientation to reproductive health, and developing country family planning programs.

Recommended Panel Member

Judith Rooks, MS, MPH
President
American College of Midwives
2706 SW English Court
Portland, Oregon 79201
PHONE: (503) 243-2253

Jackie Gardner, Ph.D.
The Upjohn Company
Kalamazoo, Michigan
PHONE: (616) 323-6448

Nicholas Dodd, M.D.
Epidemiologist
United Nations Fund for Population Activities
PHONE: (212) 850-5782

D. A social scientist knowledgeable in contraceptive development with emphasis on acceptability studies in both developed and developing country populations.

Recommended Panel Member

Rochelle N. Shain, Ph. D.
Associate Professor
Department of Obstetrics and Gynecology
The University of Texas
Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, Texas 78274
PHONE: (512) 691-6181

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VI. Other Observers

Jim Shelton, M. D., ST/POP/R
Russel J. Thomsen, M. D., ST/POP/R
Maria Mamlouk, ST/POP/R
Other professionals from ST/POP/R

VII. Dates and Places of Evaluation

Family Health International, Research Triangle Park, North Carolina, one week of August, 1984.

VIII. Cost Analysis

To be determined by the National Science Foundation (NSF).

IX. Project Background

The International Fertility Research Program (IFRP) was established on 1 July 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 the ensuing years, FHI's scope of work has been broadened from "clinical trials" to include a wide variety of activities aimed at assessing and fostering contraceptive technology.

In 1977, the IFRP's proposal for renewal was reviewed by the Research Advisory Committee (RAC) of AID. Renewed funding was withheld pending further study by a RAC subcommittee. IFRP staffing and administrative changes were made on the basis of RAC recommendations. These changes were evaluated in a 1980 team report by the American Public Health Association (APHA). The last evaluation of IFRP was done in 1982 by an APHA team. It was an intensive review of IFRP organization, staffing, and research priorities. Evaluators also visited IFRP investigators in Asia, Africa, and Latin America.

In 1982, IFRP underwent an official name-change, becoming Family Health International. The new name signified the organization's increasing work in multiple facets of health. Hereafter, all references will be to Family Health International, FHI.

X. Problems and Issues to be Considered by the Evaluation Team

1. Assessment of current status of the various areas of fertility control technology research, including a review of all studies done since the last evaluation of 8-24-82:

a. Female sterilization
b. Male sterilization
c. Systemic oral contraception
d. Long term injectable contraception
e. Long term implant contraception
f. Barrier contraception
g. Natural family planning, birth spacing, breast feeding
h. Epidemiologic studies including contraceptive safety, cancer and contraceptive use, and contraception and sexually transmitted diseases

2 Assessment of the current status of grant activities, specifically since the last evaluation of 8-24-82:

a. National Fertility Research Programs (FRPs)
b. Technical assistance and training (particularly in the area of microcomputer technology
c. Studies of social aspects in family planning; "Needs Assessment," or "Programatic Studies"

3. Relationship of FHI with its field work and centers of research:

a. The quality and quantity of research undertaken or projects being carried out through collaborating investigators in developing and developed countries.
b. The quality and effectiveness of projects being carried out cooperatively with the several National Fertility Research Programs supported by FHI
c. The optimal number of collaborators which FHI should develop and maintain in both developing and developed countries

4. The effects of the June, 1983, working reorganization of Family Health International?(See FHI/Potts letter to Shelton dated 29 June 1983)

a. Has the reorganization affected contacts with field collaborators and FRP personnel?
b. How are overlapping functions and interests resolved under the current "departmental" format organization?

5. Assessment of publications produced or supported by FHI.

a. Does the quantity and quality of scientific articles produced by FHI staff seem appropriate, and are they published in the scientific literature in a timely fashion?

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b. Have FHI field workers or scientific staff adequately collaborated with developing nation collaborators in the preparation and submission of manuscripts for publication.

c. Does the periodical FHI newsletter, NETWORK, achieve quality of content and appropriate dissemination?

d. Has FHI work in monograph preparation seem appropriate, or should such effort be eliminated or upgraded?

e. What is the current FHI contribution to the editorial and scientific quality of the journal, THE INTERNATIONAL JOURNAL OF OBSTETRICS AND GYNECOLOGY, and at what level should such FHI cooperation be continued?

6. An assessment of FHI staffing:

a. Has FHI achieved a high (or adequate) quality of scientific staffing?

b. Has an appropriate mix of scientific to support staff been achieved?

c. Do FHI field staff have relevant qualifications for their respective areas of endeavor?

7. Assessing the process of FHI project approval:

a. What is the role of the Technical Advisory Committee (TAC) in FHI project approval and evaluation?

b. To what extent is independent advice sought if needed?

c. How are research studies/topics chosen, and how are they prioritized?

d. Is the process of project approval adequately efficient?

8. Relationship with AID and other organizations in application to the FDA for appropriate status of new drug applications:

a. What is the level of FHI expertise to obtain Investigational New Drug (IND) and New Drug Application (NDA) approval from the Food and Drug Administration (FDA)?

b. Are FHI relationships with private industry in obtaining INDs and NDAs reasonable and appropriate?

9. What is FHI's perception of its working relationship with AID and AID's contact level personnel?

XI. List of Documents to be Provided to the Evaluation Team

A. An Evaluation of the Goals, Objectives, and Activities of the International Fertility Research Program, dated 8-24-82.

B. Annual Report, 16 September 1982 - 15 September 1983, AID-DPE-0537-C-00-1028-00.

C. Annual Report, 30 September 1982 - 29 September 1983, Grant AID/pha-G-1198.

D. "Organization/Personnel" letter and accompanying listings from Malcolm Potts, M. D., of FHI to Jim Shelton, M. D., of AID, dated 29 June 1983.

E. Directions, 1983-1984. (An in-house publication of FHI setting out the goals and work program of the organization)

XII. Proposed Schedule of Events

Third or Fourth Week August 1984 - Site visit to Family Health International at Research Triangle Park, North Carolina.

Within 60 working days after the site visit the written report will be submitted to the requesting office.

RESEARCH STRATEGIES/WORKPLANS

Appendix II

RESEARCH STRATEGIES/WORKPLANS

FYs 1984/1985

FHI Family Health International • Research Triangle Park, NC 27709 USA

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(This document is designed for internal use as a research administrative tool.)

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CLINICAL TRIALS

he Division will ensure, by way of sound clinical/biomedical research, hat safe, effective and acceptable contraceptive agents, devices and ethods are made available to the developed and developing world. As pportunities arise, Clinical Trials will also become involved in the levelopment of other therapeutic agents which are essential to the improvement of maternal and child health in underdeveloped nations. A systematic, progressive strategy has been established in an effort to achieve the broad objective of product development:

I. Early or preliminary evaluation of new agents, devices and methods (Phase I-II).

II. Determination of the efficacy, acceptability and safety of new agents, devices and methodologies for purposes of regulatory approval and distribution internationally and domestically (Phases II-III).

III. Expansion of the clinical experience with previously approved/established agents, devices and methods to increase regulatory approval and/or distribution opportunities (Phases III-IV).

IV. Short and long term evaluation of the efficacy, safety and acceptability of established agents, devices and methods to answer new questions, increase distribution opportunities and adapt existing methods to new situations.

V. Development and improvement of research capabilities of new international investigators to enhance the quality of medical research and health care delivery in developing populations, and to form a base for continued expansion of the FHI network of qualified investigators.

VI. Collaboration with other FHI divisions as appropriate to optimize FHI's research efforts in family planning and health, and to provide for the development of new investigators and institutions.

VII. Expansion of opportunities for development of health care products in association with private and public agencies.

Projects or programs are being developed or are underway in all components of this overall strategy.

I. EARLY EVALUATON OF NEW AGENTS, DEVICES AND METHODS

1. Propranolol as a Spermicide:

Propranolol currently is being evaluated in post-coital tests in London; study completion is anticipated in 9/84. Additional post-coital studies will be initiated in Chile during 84. FHI will assist in the collection and analysis of data from an independent study which assesses the contraceptive efficacy of a propranolol vaginal tablet manufactured in

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Chile. A pharmacokinetic study is also underway in London and additional clinical pharmacology studies are anticipated.

2. IUD Studies:

In the Wing Sound II study (fitted IUDs), all subjects have been enrolled and data collection will continue through 9/84.

3. Male Sterilization Studies:

A percutaneous method of vasectomy using electocautery is under development. A male sterilization reversal registry will be developed.

4. Biodegradable NET:

Evaluation of PARFR-sponsored Phase II studies of norethindrone implants will be completed in July 84. Plans for Phase III trials are being considered.

II. DEVELOPMENT OF NEW AGENTS AND DEVICES FOR REGULATORY APPROVAL

1. 90-Day NET Microspheres:

This formulation of norethindrone holds the promise of an effective injectable contraceptive when administered once every three months. FHI has assisted with protocol preparation and design of data collection forms for the Phase II trials. These are on hold at present due to one pregnancy in the first cycle of use, but should begin again later in 1984. FHI will continue with study monitoring, and data collection and analysis for PARFR-funded Phase II trials. This study has top priority.

2. Once-a-month Injectables:

Plans have been developed for collaboration between WHO and FHI in studies of two formulations of progestogen plus estrogen once-a-month injectables. FHI will support trials in Chile, Peru, Guatemala and Italy beginning 7/84. FHI is also attempting to establish collaboration with investigators in China for studies of injectable contraceptives.

3. Nonsurgical Female Sterilization:

Extensive research is being conducted to develop a simple method of nonsurgical female sterilization that can be safely offered by paramedical personnel in large-scale programs. The most promising methods seem to be those involving chemicals that act as sclerosing agents designed to cause occlusion of the fallopian tubes.

- Trials under an FDA IND of prehysterectomy insertion of quinacrine pellets in the USA are being conducted
- An IND for use of tetracycline has been approved by the FDA
- Prehysterectomy insertion of tetracycline will be studied in the USA and abroad

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- A comparison of the placement of quinacrine and tetracycline in the Fallopian tubes under hysteroscopic vision is expected to begin in 9/84
- The long term follow-up of women who have participated in quinacrine pellet and MCA trials is continuing
- The Phenol-Mucilage technique of non-surgical female sterilization developed in China will be evaluated by physicians from Thailand with the potential of training for a Thai physician and data collection if appropriate

4. FEMTEST:

A cheap, simple-to-use device to test for tubal patency has been devised and will be evaluated and a protocol for testing is under development.

5. Vaginal Rings:

Comparative studies of the Population Council contraceptive vaginal ring and the low-dose oral contraceptive, Lo-Femenal, are planned for Peru, Yugoslavia and the U.S. Studies are currently on hold pending review of preclinical chemistry data.

III. EXPANSION OF CLINICAL EXPERIENCE WITH APPROVED AGENTS AND METHODS TO INCREASE REGULATORY APPROVAL AND DISTRIBUTION OPPORTUNITIES

1. NORPLANT[R] Implants:

This study, to be carried out in collaboration with the Population Council, will increase the clinical experience with the NORPLANT[R] system, a long-acting (5-year) implant system consisting of 6 Silastic capsules which contain levonorgestrel. (The product received marketing approval in Finland in 11/83.) These studies will be carried out in Bangladesh, Egypt, Nepal, Philippines and Sri Lanka. Investigator training and study initiation will begin in 8-9/84.

2. Surgical Female Sterilization:

Two types of studies via minilaparotomy began early in 84 - a comparison of the Filshie clip with the Secuclip (using a new disposable applicator) in interval patients, and a comparison of the Filshie clip with Pomeroy ligation in postpartum patients. The tubal ring must be substituted for the Secuclip in the first trial because the Secuclip is no longer being manufactured.

Future plans include a trial of the Filshie clip versus the tubal ring via laparoscopy, the evaluation of analgesics given for post-operative pain, and the creation of a registry for female sterilization reversals.

3. Ortho Vaginal Tablets

A vaginal tablet containing the new spermicide, menfegol, will be compared with the nonoxynol-9 tablet in domestic and international studies. Ortho

hopes to obtain FDA approval for the new formulation. Center selection will be complete in 5-6(84) and all studies initiated in 7-8(84).

IV. EVALUATION OF ESTABLISHED AGENTS, DEVICES AND METHODS TO ANSWER NEW QUESTIONS AND INCREASE DISTRIBUTION

1. Norinyl 1+35:

A clinical trial is designed to evaluate continuation rates and overall acceptability of Norinyl 1+35, a low dose OC, in comparison with Brevicon and Lo-Ovral, two other low-dose OCs, and Norinyl 1+50, a standard dose OC. By the end of fiscal 84, most of the 4800 expected caseload should be recruited. As of 4/84, Brevicon was replaced by Demulen at all sites in which studies had not already begun in response to AID's decision not to supply Brevicon in the future.

2. Progestogen-Only OCs:

This clinical trial is designed to assess acceptability of progestogen-only OCs in breastfeeding women. Twenty centers of 200 cases each, located primarily in Latin America and Africa, are expected with 12 committed as of 5/84. Admissions will begin in all centers by 12/84. An additional strategy to enroll 10,000 breast-feeding women through a variety of distribution programs has been approved by AID. Potential study countries include Brazil, Mexico, Morocco, Zaire and Thailand.

3. Retrospective Analysis of OC/Injectable Data:

Five centers are participating in this 1800-case clinical trial to compare continuation rates of DMPA and OC acceptors prior to 1981. About 50% of the data is expected by the end of 9/84.

4. Postpartum IUD Studies:

Follow-up data will be complete in early 84 from 3 remaining centers. One study in Mexico is using echosonography to determine IUD (Delta T and TCu) placement in the uterus. The study will be complete about 9/84.

5. Interval IUDs:

The emphasis will be on generic attempts to reduce infection and expulsion rates rather than on the design and performance of new devices. A long-term study of the influence of IUD strings on upper genital tract infections is expected to be virtually complete by 9/84.

Two studies comparing the TCu 380Ag to the Cu7 were completed early in 84. One study (Yugoslavia) will continue with a three-year follow-up phase in a comparison of the TCu 380Ag and the ML Cu375. Completion is expected 11/84.

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6. Fitted Diaphragms With and Without Spermicide:

An objective comparison of the contraceptive efficacy of a fitted diaphragm with andwithout the use of a spermicide has not been carried out previously. A pilot study is proposed for Britain and Australia.

7. Comparison of OCs with Iron and Without Iron:

The project, which will focus on safety and acceptability of the two available types of OCs, has been approved by AID. Center selection is underway with initiation expected 7-8/84.

V. EXPANSION OF OPPORTUNITIES FOR DEVELOPMENT OF CONTRACEPTIVE AND HEALTH CARE PRODUCTS IN ASSOCIATION WITH PRIVATE AND PUBLIC AGENCIES

A number of possibilities are under current consideration/development:

VI. CLINICAL TRIALS INVESTIGATOR DEVELOPMENT, FCO 2140

The identification and development of new investigators for clinical trials remains a high priority for the Division and the goal of establishing studies in 20 new centers has been set for 1984. Clinical Trials staff is a list of anticipated requirements for investigators for each ongoing and planned project/program has been prepared. The identification, enrollment, follow-up and evaluation of potential investigators via "Investigator Needs Studies" (FCO 2140) will be managed by Clinical Trials in close collaboration with Field Support and Training and Technology Development.

VII. COLLABORATION WITH OTHER FHI DIVISIONS

Clinical Trials collaborates with other FHI divisions in developing and carrying out projects and programs in family planning and health care delivery to meet the institution's goals. In particular, Clinical Trials works with Training and Technology Development in programs designed for the development of new international institutions and investigators.

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CONTRACEPTIVE SAFETY DIVISION

The Division identifies the benefits and risks associated with contraceptive use. This includes exploring hypothesized relationships between contraception and disease, the confirmation in developing countries of relationships that are already established in the developed countries, and the identification of special conditions (environmental or clinical) that affect the association between contraception and disease.

I. THE EXPLORATION OF HYPOTHESIZED RELATIONSHIPS BETWEEN CONTRACEPTION AND DISEASE

1. A follow-up of children approaching and past puberty who were exposed in utero to oral contraceptives and Depo-Provera will test the hypotheses that there is an increase in congenital anomalies and an effect on intellectual development associated with this exposure.

2. A case-control study of benign prostatic hyperplasia and/or prostatic cancer and vasectomy to test the hypothesis that vasectomy protects against prostatic disease has been initiated.

3. To test the hypothesis that sterilized women experience elevated rates of abdominal surgery, especially hysterectomy, the rates of abdominal surgery of women sterilized five years ago will be compared with the rates of a matched sample of women undergoing a therapeutic abortion in the same year.

II. CONFIRMATION IN DEVELOPING COUNTRIES OF ASSOCIATIONS BETWEEN CONTRACEPTION AND MORTALITY OR MORBIDITY

1. Two case-control studies of reproductive cancers and contraception are planned. Both of these are in Western Hemisphere countries; similar studies in Asia will be sought.

2. The relationship between vasectomy and cardiovascular disease is being examined in a cohort study in China and a case-control study in Korea.

3. A hospital discharge survey in Indonesia will identify the prevalence of conditions that may affect contraceptive safety.

III. IDENTIFICATION OF SPECIAL CONDITIONS THAT INFLUENCE THE BENEFITS AND RISKS OF CONTRACEPTION

1. The safety of various methods of contraception is being evaluated in women with specific chronic diseases. Studies are planned on women with rheumatic heart disease. The use of oral contraceptives by women with

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sickle cell disease has been documented in Ghana and will be explored further in Jamaica. Similar studies may be developed for women with hepatitis, diabetes and hypertension.

2. The safety of vasectomy when performed by paramedics is being evaluated in a large program in Indonesia.

3. The effect on incidence of PID of administration of a single dose of a long-acting antibiotic (doxycycline) at the time of IUD insertion is being evaluated.

4. An examination of the male contribution to infertility seeks to identify environmental factors which may increase male infertility.

IV. ANALYSIS

A model has been developed to assess the overall effect of oral contraception on the life expectancy of normal women. All known effects of oral contraception, both beneficial and negative, are incorporated into the model.

Analysis and presentation of the two RAMOS studies is continuing, as is presentation of data from Atlanta on Depo-Provera and other contraceptive methods.

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FIELD DEVELOPMENT AND TRAINING

(Note: As of June 15, 1984, the Field Support and Training and Technology Development Divisions were merged into a new Field Development and Training Division. Aspects of the strategy relating to other activities of the new Field Development and Training Division will be incorporated into the next revision.)

The Field Development and Training Division derives its basic strategy from overall FHI policy. It helps develop local skills and institutions for two main purposes: 1) to expand and improve FHI's international network of investigators, capable of collaborating with FHI on contract research with the highest degree of confidence and quality, and 2) to develop and support local institutions to competently carry out research which meets local needs and contributes positively to national decision making in the area of health and population policy.

The activities of the Division are divided into four major areas:
1. Institutional Development
2. Training in Research
3. Direct Transfer of Contraceptive Technology
4. Information Dissemination

I. INSTITUTION BUILDING

Through its institution building activities, FDT aims to create a number of research organizations throughout the developing world with the capability of conducting family planning research at a high level of technical competence. The heart of FHI's institution building program is its support of Family Health Research Centers (FHRCs). These are institutions which share with FHI a common interest in contraceptive method research, and with which we have comprehensive programs to strengthen their capabilities in this area. There are six of these institutions at present: BKS PENFIN (Badan Kerja Sama Penelitian Fertilitas Indonesia) in Indonesia: the Thai Fertility Research Association (TFRA); The Bangladesh Fertility Research Programme, or BFRP; The Egypt Fertility Care Society, or EFCS; The Sudan Fertility Control Association, or SFCA; and most recently, The Family Planning Association of Sri Lanka.

The nature of these organizations does and should vary with circumstances and opportunities. They may be networks of pre-existing centers, or programs grafted onto single existing organizations. Their association with the national government varies, but all operate at a national level and have the capability to influence national decisions. However, while the diversity of the group is a strength internationally, it does complicate the task of providing appropriate technical assistance.

FHRCs will be supported for long enough (up to 10 years) to become firmly established and fully competent, but not forever. "Technical and financial independence" means competence, both technically and administratively, to attract research support from people whose job it is to fund research, not build institutions. Other sources of support may include UN-WHO, national

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governments, other AID agencies, direct bilateral support, or private sources. It is also expected that FHI will support contract research with FHRCs indefinitely, to the extent that proposals are developed which meet the requirements of the individual FHI departments.

FDT supports the development of the FHRCs through several mechanisms, including:

- Cooperation in development of long-term plans and evaluation frameworks oriented towards a smooth transition to more contract-oriented management;
- Support for research, including financial support and assistance in design, execution, and report generation;
- In-country technical assistance, and training wherever appropriate, towards improvement of research capacity;
- Development of microcomputer capability.

In addition to supporting six comprehensive research programs, the Division supports other institutions on a more limited basis.

The common factor in this institutional assistance is its long-term implication. With some institutions, we hope to expand our current limited support into a more comprehensive program; in others, our aim is to meet a carefully specified need. In all cases, we are working with institutions which we expect to continue to collaborate with on contraceptive method research for the foreseeable future.

II. TRAINING IN RESEARCH

One of FDT's basic functions is to foster the development of research skills in FHI's traditional research areas. Apart from institution building, FDT does this in two basic ways: workshops in research methods, and training and transfer of microcomputer technology.

A. WORKSHOPS IN RESEARCH METHODS

Divisional priority is on workshops in clinical trials methods and epidemiologic methods, both because of FHI priorities in these areas and because strong training programs exist elsewhere for other research areas.

In Clinical Trials Methodology, FDT plans to develop a standard two-week training package, to be initially used in a workshop at FHI in Summer, 1985. This package should be usable for other audiences and settings, and we intend to sponsor additional workshops of this type in FY 1985 and 1986.

In Epidemiologic Methods , a package analogous to the one for clinical trials has already been developed for the training program in Durango, Mexico, in July 1984. We intend to fund at least one workshop of this type in FY 1985 (in addition to the second Durango workshop). We also hope to develop joint projects with other agencies, using the Durango FHI/UNFPA relationship as a model.

Workshops on other aspects of research methods will be considered on an ad hoc basis.

A more detailed substrategy for Training has been developed.

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B. MICROCOMPUTER TECHNOLOGY

A comprehensive and detailed strategy is being researched and developed by FDT at present. This will outline current status of the microcomputer transfer program, define goals and objectives, and set directions for future action.

The FHI program has involved and will continue to involve provision of hardware, software, and training. All three components are essential to this program serving a real and effective role in increasing local research capacity, efficiency, and independence.

The emphasis on microcomputer placements has been on FHRCs, but other collaborating institutions have also been targeted. These planned sites and numbers of microcomputers, along with the overall strategy, need to be reviewed carefully in the near future, in light of budget factors, industry developments, initial experience, AID guidance, and outstanding commitments or near-commitments. TI-352s have already been budgeted for FPA/Sri Lanka, BFRP, Durango, TFRA (replacement), and BKS PENFIN (replacement), Egypt and the Senegal. Plans to install microcomputers at several BKS PENFIN centers (to make Indonesia a "model country") are being held in abeyance, pending center by center utilization plans and further consultation with AID/Jakarta and AID/Washington.

In addition to these major programs, FDT provides training by sending investigators to conferences from time to time where this is considered valuable for their professional development.

III. DIRECT TRANSFER OF CONTRACEPTIVE TECHNOLOGY

Part of FHI's mandate involves the introduction of contraceptive technology into LDC's where that technology is new and appropriate. Part of FDT's strategy for this involves information dissemination, which will be discussed in Section IV. Other approaches involve projects to introduce specific new contraceptive technologies and support for individuals or organizations to develop authoritative status in international contaceptive technology. Our activity in these areas to date has been limited: we intend to develop new programs in the transfer of contraceptive technology during FY 1985.

Regarding projects introducing specific new technologies, these will largely involve such activities as workshops focused on the new technology, development of training and educational materials, provision of outside trainers for initial training, and occasionally introductory clinical trials. The current Turkish Postpartum IUD contract is of this type.

Another approach, still in the concept stage, which has raised considerable interest is to work with universities to help develop their role and effectiveness as national training centers for advanced family planning techniques. This is the approach being proposed (under development) for FHI involvement in Peru, and it would appear to be a useful one in many other countries as well.

IV. INFORMATION DISSEMINATION

FDT has two basic approaches to information dissemination, with a third under development. The department (1) sponsors our two regular publications activities, Network and subscrition support for the International Journal of Gynecology and Obstetrics; (2) supports ad hoc mailings, publications, and other information dissemination projects as needed; and (3) is developing a major new strategy for disseminating new developments in contraceptive technology and safety to physicians and media in selected major LDCs.

Network's mailing list has been reduced from about 5,000 down to 2,000. The marginal cost of producing and mailing additional copies of Network is low and the list will grow as need arises.

The number of IJGO subscriptions provided by FHI to overseas colleagues has been reduced, following a survey of all recipients. The purchase for 1984 is 500 subscriptions and this will be maintained.

Small ad hoc information dissemination projects have included distribution of selected publications, translations into French or Spanish with associated distribution, special mailings, and organization displays at selected professional meetings. We can sponsor publication of monographs, but have not yet done so.

FDT is also developing a strategy to enhance dissemination of research findings focusing on the message that contraception saves maternal and infant lives. This will involve regular mailings of a few key publications, distribution throughout appropriate medical circles, and dissemination to mass media, and will involve about a dozen countries.

NATURAL FAMILY PLANNING

The Division will:

A. Support research directed toward increasing the effectiveness of NFP methods and improving their delivery--for couples who prefer NFP methods.

B. Support research on the contraceptive effects of breast-feeding and how these effects can be enhanced.

C. Increase the ability of developing country institutions to conduct objective research on NFP methods and programs.

D. Increase awareness of facts about NFP methods and the contribution of breast-feeding to fertility control among family planning professionals and the general public through publications and professional meetings.

E. Establish Family Health International as an organization capable of doing high quality, useful, and objective research on NFP and working with a variety of NFP groups.

RESEARCH PRIORITIES IN NATURAL FAMILY PLANNING

I. BASIC RESEARCH

If women could more precisely predict the time of ovulation at least three to five days in advance, given that sperm live that long, NFP methods would be more effective and would require less abstinence.

The vaginal self-aspiration technique of Dr. Gebhard Schumacher is one promising approach. FHI has completed a study on the correlation of ovarian hormone changes and volume of vaginal secretions and is considering a larger trial. Other promising NFP devices may also be tested. Simplified or improved versions of modern NFP methods might also make a contribution to the effectiveness of NFP and will be explored.

II. PROGRAMMATIC RESEARCH IN NFP

To practice NFP methods satisfactorily usually requires a good educational program. Research is needed on: the effectiveness of NFP programs in helping couples plan their pregnancies; teaching approaches (group vs individual, couples vs women only); appropriateness of different types of instructors (volunteers? couples? married persons? physicians?) and recruitment approaches (house-to-house, through religious organizations, mass media); effectiveness of different NFP methods including the fertility awareness methods combined with barrier methods during fertile period; what kinds of couples are most satisfactory users of NFP methds; psychosocial aspects of using NFP methods; the role of men in NFP programs; and cost effectiveness of NFP methods and programs.

III. POPULATION SURVEYS ON USE OF NFP METHODS

Over the past decade, Family Health International has made a worldwide contribution to our knowledge of the effectiveness and safety of modern contraceptive methods in clinical settings. But equally interesting is the question of how effectively couples use the wide variety of known methods when they are not part of a clinical trial and may have had no contact with a clinic. This question is applicable to traditional and natural methods as well as "artificial" methods and combinations of methods.

A retrospective survey instrument has recently been developed by John E. Laing of The Population Council which collects information on pregnancy rates (and continuation) for all methods as well as no method. By controlling for the characteristics of users of different methods (for example, users of one method might be older), it is possible to estimate the contribution of each method to fertility control. Results from the Philippines using this survey approach have shown that oral

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contraceptives and rhythm (mostly calendar rhythm) have roughly equal use effectiveness in the general population.

Several countries (Sri Lanka, Bangladesh, Kenya and Peru) have expressed interest in having this kind of survey conducted and it is likely that others may be interested if they know it is available. It is a next logical step to the Contraceptive Prevalence Survey and can be expanded to collect information on why each method was selected or discontinued and on how the methods are being used. The NFP Department is beginning to develop a standard survey instrument, manuals and data processing programs for this research strategy.

IV. QUALITY OF NFP TEACHING

Presently no general certification procedure for NFP teachers, agreed upon by the major NFP groups, exists. In the past months the World Health Organization has completed a long-term project to standardize the content of NFP teaching. The next step is to bring public and private NFP groups together to prepare testing instruments (including a practicum) based on these WHO materials and on previous tests, and to try to establish what teachers should know and be able to teach. The resulting tests can be used to evalute teaching quality in NFP programs in the United States as well as internationally. They could also be used as a research instrument as part of a Knowledge, Attitude and Practice (KAP) survey of NFP providers and others such as physicians.

V. BREAST-FEEDING AS AN NFP METHOD

Breast-feeding makes a major contribution to child spacing in many developing countries. Breast-feeding can be considered a natural method of family planning since it delays ovulation as a part of a natural cycle.

We need to know more about what precipitates postpartum ovulation. FHI's Phase I "Return to Ovulation" studies are exploring the relationship of breast-feeding patterns to the timing of ovulation. A Phase II series will build on the findngs of Phase I and will explore whether it is possible to extend the anovulatory period by providing women support for breast-feeding and by giving them simple guidelines for enhancing the contraceptive effect of breast-feeding. Examples of guidelines might be: 1) maintain nighttime feedings; 2) delay supplementation to 6 months; 3) breast-feed on demand; 4) do not use a pacifier; and 5) after supplementation has been initiated, the baby should be encouraged to breast-feed before giving the supplements.

Another multicenter study is planned on the appropriateness of NFP methods (sympto-thermal, cervical mucus) for breast-feeding women. This has been a controversial issue. Some NFP programs assert that breast-feeding women have no trouble using NFP indicators to predict the first ovulation while others suggest that the erratic cycles of breast-feeding women make it difficult for them to use NFP methods.

A final area of research is on policies of hospitals and health personnel in developing countries toward the promotion of breast-feeding among delivering women. Most of the babies who are not breast-fed are delivered in hospitals and by physicians, suggesting that some hospitals may not be active in encouraging breast-feeding.

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REPRODUCTIVE HEALTH

The Division addresses issues relating to maternal and child health, the evaluation of health and family planning programs, and obstacles to the effective use of contraceptive methods. Studies are judged on scientific merit, the potential for affecting health and family planning programs, and on the availability of technical and administrative resources for carrying out the project.

I. MATERNAL AND CHILD HEALTH

Studies will be designed and implemented to obtain information to improve maternal and child health care. The emphasis will be to experiment with various methodologies for collecting data on neonatal, infant and maternal mortality and on causes of death; and to study the medical consequences of obstetric practices.

1. Neonatal and Infant Mortality:

In many developing countries, data on morbidity and mortality is limited or nonexistent. The development of programs to improve maternal and child health requires information on mortality levels and causes of death. Variations of the Reproductive Age Mortality Study (RAMOS) methodology will be used to obtain information on infant mortality. Three studies of neonatal and infant mortality will be implemented:

a. As part of a study on health care provided by traditional birth attendants, TBAs will locate infant deaths, and mothers will be interviewed concerning cause of death.

b. As part of a household-based sample survey, retrospective data on deaths to children aged 0-5 will be collected.

c. As part of a pregnancy epidemiology study in sub-Saharan Africa, a follow-up survey to obtain data on infant mortality will be undertaken. Methodology to obtain such data will be determined with the appropriate staff.

2. Maternal Mortality and Morbidity:

The purpose of these studies is to gain a better understanding of the patterns of morbidity and mortality associated with childbearing and to use this knowledge to maximize the effectiveness of limited existing health care resources.

Information on cause of death and rates of maternal mortality will be obtained for parts of the Sine Saloum region of Senegal. Reports on hospital deaths will be compared with information collected from surviving family members as a means of evaluating the utility of the latter in gathering cause of death data.

Studies on maternal morbidity will be limited. Possibilities include the examination of long-term medical consequences of female circumcision, particularly those associated with childbirth.

II. PROGRAM EVALUATION

1. Evaluation of Services Providing Obstetric Care:

The emphasis will be to undertake new maternity care monitoring projects, especially in Africa, to obtain information on home deliveries.

a. Pregnancy Monitoring Projects

The initiation of maternity care and pregnancy wastage studies in three or four countries of sub-Saharan Africa is planned. In addition, one or two other projects will be undertaken outside of this region. These studies will collect data on reproductive health, the patient referral process and the allocation of resources to provide care, contraceptive use and the need for improved services.

b. Traditional Birth Attendant Studies

The vast majority of births in the developing world take place at home. Very little information is available on care provided by traditional birth attendants, probably because of the difficulty of collecting such data. Several projects using different methodologies to obtain birth records will be carried out. Special attention will be paid to the adequacy of training and the appropriateness of referrals.

c. Obstetric Practices

Obstetric practices in developing countries are often different from those in the developed world. For example, women with previous cesarean sections are often delivered vaginally. In Africa, women with obstructed labor are sometimes delivered by symphysiotomy. An evaluation of such alternative practices can determine whether they provide the best outcome given limited resources or if alternative practices should be introduced. A prospective study of women with cesarean sections and symphysiotomies will compare long term morbidity of these two management approaches. Results will be useful in determining whether medical practitioners in Africa should be encouraged to substitute cesarean section for symphysiotomy.

2. Evaluation of Health and Family Planning Programs:

In many, if not most, developing countries, there is a substantial unmet demand for health and family planning services. The development and evaluation of programs to improve services requires data that will show what services are needed and how best to provide these services.

a. The Health of Women and Non-Medical Distribution Systems

Because of the paucity of medical services, many developing countries have initiated contraceptive distribution systems, often with little or no link to the existing medical infrastructure. Studies will be initiated to investigate such programs, and analysis of data from a completed study will continue.

Reproductive Health Surveys will assess the health status of women of childbearing age, examining health problems related to pregnancy, fecundity, and contraceptive use. Women exposed to high health risks during pregnancy and current users with method-specific contraindications and side effects will be identified to determine whether they would benefit from using alternative methods of contraception. The impact of side effects on subsequent contraceptive behavior will also be evaluated. The Reproductive Health Surveys will include household-based interviews of current users and non-users of family planning, followed by clinical examinations.

b. Maternal-Child Health/Family Planning Studies

Two surveys are planned to obtain information on both maternal and child health and family planning including use and source of family planning, use of primary care facilities, breastfeeding, and child mortality. Various aspects of these studies are covered in other sections.

c. Accessibility of Services

While clinical studies have been conducted by FHI to determine the best techniques for performing sterilization, the most appropriate IUD in a particular population, and the oral contraceptive with the least side effects, operational research needs to be done to find the most appropriate ways of providing services. Projects in the area of sterilization include:

- evaluation of new services designed to reduce the time and cost to women to obtain tubal ligation;
- determination of why many women who have been accepted for sterilization fail to follow through and get sterilized;
- evaluation of the impact of counseling during the prenatal period on the acceptance of sterilization;
- determination of long-term satisfaction of sterilization acceptors.

Where appropriate, projects to look at accessibility of oral contraceptives, IUDs, and other studies will be developed.

III. OBSTACLES TO FAMILY PLANNING

The use of family planning services is dependent on both the demand of potential users for methods and the willingness of suppliers to make methods available. Studies on users will focus on some often neglected groups--in particular, adolescents and males. Studies on providers may

include community-based distribution workers, physicians, pharmacists, and clinic personnel.

1. Adolescent Pregnancy Studies:

The increasing incidence of unwanted pregnancy among young and unmarried women has given rise to the need to examine the factors associated with sexual, contraceptive and reproductive behavior among adolescents. Particularly in sub-Saharan Africa, the already limited family planning service delivery programs have traditionally excluded this sector of the population. Physicians and other health care providers are now attempting to document the growing unmet need for contraceptive services among sexually active adolescents and to design counseling and distribution programs to reduce the number of pregnancies--and consequent abortions—to such individuals.

Studies in this area will be designed and implemented in response to specific requests from developing country researchers and will be limited to countries in which policy impact is likely. Adolescent sexuality studies are presently underway or in planning for Nigeria and Liberia, and being considered in several other countries in the region.

2. Providers of Family Planning:

Providers may affect the use of family planning in general, or affect the acceptability and continuation of particular methods. Areas in which projects are presently being developed to measure the role of service providers are physicians' and pharmacists' surveys and surveys of community-based distribution agents. Additional projects may be added as needs are identified.

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APPENDIX III

LIST OF INVESTIGATORS
BY COUNTRY

CENTER NO.	INVESTIGATOR	INSTITUTION	STUDY AREA OF INTEREST
EGYPT			
033	El-Essaily, I.	Cairo University Hospital Cairo, Egypt	IUD, FS
035	Kamal, I.	Kasr El-Aini Hospital Cairo, Egypt	IUD, FS
309	Hassan, E.	Mansoura University Dept. of Ob/Gyn Mansoura, Egypt	IUD, FS, FB
340	Etman, S.	Misr Spinning and Weaving Co. Hospital Mehalla-Kubra, Egypt	IUD, FS, SYS
351	Hefnawi, F.	Bab El-Sharia Hospital Cairo, Egypt	FS
353	El-Kady, A.A.	Boulak El-Dakrour Hospital Cairo, Egypt	FS
354	Al-Kholi	Tanta University Department of Ob/Gyn Tanta, Egypt	
356	Rahman, H.A.	El-Shatby Maternity Hospital Alexandria, Egypt	FS
358	Fathalla, M.F./ Shaaban, M.	Mabarrah Hospital Assiut, Egypt	SYS, IUD*, FS, FB
360	Mahran, M.	Ain Shams Medical School Cairo, Egypt	FB, FS, IUD
363	Toppozada, M.	El-Shatby Maternity Hospital Alexandria, Egypt	IUD
368	Youssef, H.	Family Planning Clinic Alexandria, Egypt	FB*
370	Nada, S.	Dept. of Ob/Gyn Ahmed Maher Hospital Cairo, Egypt	FS

TURKEY			
304	Kisnisci, H.	Hacettepe University Ankara, Turkey	IUD, FS
ISRAEL			
332	Goldman, J.	Hasharon Hospital Petah-Tikva, Israel	FB
LIBERIA			
416	Sherman, J.	St. Timothy Hospital Robertsport, Liberia	
418	Sherman, J. Woods, Emile	J.F. Kennedy Memorial Hospital Monrovia, Liberia	RH
NIGERIA			
	Otolorin, E.O.	Ibadan University Ibadan, Nigeria	CT, RH
040	Ojo, O.A./Ladipo	Department of Ob/Gyn University Teaching Hospital Zaria, Nigeria	FS, SYS
045	Marinho, A.O.	Catholic Hospital Ibadan, Nigeria	RH
436	Ayangade, O.	Department of Ob/Gyn University of Ife Ife-Ile, Nigeria	IUD, SYS
437	Omu, A.	University of Benin Dept. of Ob/Gyn	CT, RH, FS, FB
4000	Akuse, J.T.	Ahmadu Bello University Hospital Kaduna, Nigeria	CT
	Wright, E.A.	Jos University Teaching Hospital Jos, Nigeria	CT
GAMBIA			
4010	Dabo, Adama	GFPA Kanifing, Banjul, Gambia	CT, SYS
CAMEROON			
	Doh, A.	University of Yaounde Hospital Yaounde, Cameroon	

GHANA			
041	Ampofo, D.A.	Univ. of Ghana Medical School Accra, Ghana	RH, FS, FB
044	Klufio, Cecil	Univ. of Ghana Medical School Accra, Ghana	FB, CT
	Tagoe, Bruce	Univ. of Ghana Medical School Accra, Ghana	
045	Gunney, E.	Univ. of Ghana Medical School Accra, Ghana	CT, FB
IVORY COAST			
150	Sangaret, M.	CHU de Cocody Abidjan, Cote d'Ivoire	RH
151	Diarra, S.	CHU de Treichville Abidjan, Cote d'Ivoire	RH
SUDAN			
046-049 401-413	Rushwan, H.	Multicenters Khartoum, Sudan	IUD, SYS, FS
SIERRA LEONE			
415	Jarret, D.	Princess Christian Maternity Hosp. Freetown, Sierra Leone	FS
RWANDA			
422	Broquet, J.	Maternity de Nyundo Gisenyi, Rwanda	RH
ZAIRE			
425	Miatudilla, Dr.	Clinique de Bukavu, CNND Kinshasa, Zaire	RH
430	Nelson, G.	Hospital C.E.U.M. Karawa, Zaire	RH, IUD, FS
	Duale, Samba	Hospital C.E.U.M. Karawa, Zaire	
431	Otshudi, Dr.	Mama Yemo Hospital Kinshasa, Zaire	RH
432	Nguma, M.	Cliniques Universitaires	OC
MALI			
440	Sangare, M.	Clinique Hamdallaye Bamako, Mali	SYS

441	Tounkara, A.	Association Malienne de la Promotion et la Protection de la Famille Bamako, Mali	CT, FDT
442	Traore, L.	Hospital Du point G Bamako, Mali	RH
	Doucoure, A.	PMI Centrale Bamako, Mali	CT
	Barry, L.	MOH Division de Sante Familiale Bamako, Mali	CT, RH
	Toure, A.	Hopital Regional Kayes, Mali	CT
KENYA			
450	Mati, J.K.	University of Nairobi Nairobi, Kenya	CS
	Sinei, A.		CS
451	Githiari, J.N.	Provincial General Hospital Nyeri Nyeri, Kenya	CT, FS
TUNISIA			
469	Tallouch	ONPFP, Sousse FP Clinic Tunisia	
476	Hayder, M.	Hopital Regional de Sousse Sousse, Tunisia	
479	Ben Amor, S.	Maternite de l'Hopital Habib Thameur Tunis, Tunisia	
SENEGAL			
	Thiam, M.K.	ASBEF Dakar, Senegal	
480	Lauroy, Dr.	Centre Hospitalier Municipal Abass N'Dao Dakar, Senegal	RH
482	Correa, P.	Hopital le Dantec Dakar, Senegal	RH
483	Ndiaye, Dr.	PMI de Medina	SYS
	Mme. A. Niang/ Loume, M.	Hopital Regional Sine Saloum, Senegal	RH
	M'Bodje, M./ Diop, M.	National Census Bureau Dakar, Senegal	FDT

TANZANIA			
492	Chanji, A.G.	Bugando Hospital Mwanza, Tanzania	SYS, CT
PHILIPPINES			
060	Oblepias, V.R.	Mary Johnston Hospital Manila, Philippines	FS
061	Alfonso, L.A.	Southwestern Univ. Medical School Cebu City, Philippines	Norplant, IUD, MS
066	Dacalos, E.	Sacred Heart Hospital Southwestern University Cebu City, Philippines	FS, SYS
067	"	Cebu Medical Center Cebu City, Philippines	FS
600	Apelo, R.A.	Jose Fabella Memorial Hospital Manila, Philippines	IUD*, FS*, Norplant, FS (MCA)
SINGAPORE			
798	Ratnam, S.S.	Kandang-Kerbau Hospital Singapore	FS, Norplant
7000	Vengadasalam, D.	Alexandra Hospital Singapore	Norplant
KOREA			
	Park Chan-Moo Ko		MS
7010	Sung-Bong Hong	Korea Univ. College of Medicine Seoul, Korea	FS (MCA)
NEPAL			
	Chhetri, Mahendra		
079	Malla, P.	Maternity Hospital Kathmandu, Nepal	FS
	Bhaidya, Kokila		

INDONESIA

074	G., Wiknojosastro	General Hospital University of Indonesia Djakarta, Indonesia	FS, IUD, NFP
739	Sulaiman, S./ Agoestina, T.	Hasan Sadikin Hospital Padjadjaran Univ. Scho. of Medicine Bandung, Indonesia	FDT (FHRC) IUD, FS, SYS
764	Wowor, G.E.	Medical School Univ. of Sam Ratulangi Manado, Indonesia	IUD
768	Syahrial, H.A.R.	Faculty of Medicine University of Andalas Padang, Indonesia	IUF, OC
769	Harjono, M.	School of Medicine University of Airlangga Malang, Indonesia	FS, IUD, OC
794	Ariawan, S.	Dr. Kariadi Hospital Semarang, Indonesia	IUD, FS, OC
979	Manuaba, I.B.G.	Medical School University of Udayana Denpasar, Bali, Indonesia	IUD, OC, FS
777	Biran, S.A.	Raden Saleh Clinic Djakarta, Indonesia	

THAILAND

075	Suporn, K.	FP Research Unit Siriraj Hospital, Mahidol Univ. Bangkok, Thailand	FS*, SYS
103-104 106-109, 611	TFRA	Multicenters	
113	Togkunsamut, S. (TFRA)	Phuthaisong Distric Hospital Phuthaisong, Thailand	
679	Chuntrasri, B.	Pramongkutklao Thai Army Hosp. Bangkok, Thailand	NFP
686, 689 694, 695	TFRA	Multicenters	
709	Mongkol, S.	Provincial Hospital Udorn Thani, Thailand	FS, SYS
740	Kamheang, C.	Ramathibodi Hospital Mahidol University Bangkok, Thailand	FS

THAILAND (Cont.)

741	Charanpat, I. Sumana, C. Reinprayoon, D.	Chulalongkorn Hos. & Med. School Chulalongkorn University Bangkok, Thailand	FS, FB
748	McDaniel, E.	McCormich Hospital Chiang Mai, Thailand	

MALAYSIA

747	Hamid, A	General Hospital Malaysia	FS
770	"	NFPB Clinic Kelantan, Malaysia	
795	Mehra, B.	Maternity Hospital Kuala Lumpur, Malaysia	FS

SRI LANKA

700	Chinnatamby, S.	FP Association Research Unit Colombo, Sri Lanka	Norplant
703	Basnayake	FP Association Puttalam, Sri Lanka	Norplant FS, SYS
749	Abeywickrame, D.	FP Association Colombo, Sri Lanka	
	Hopugalle, D.	Community Development Service	RH, FS, MS

BANGLADESH

161	Sultana Jahan	Khulna Sadar Hospital Khulna, Bangladesh	IUD
164	Rahman, M.A.	Maternity and Child Welfare Center Tangail, Bangladesh	
165	Shamsuddin, L.	Bogra Sadar Hospital Bogra, Bangladesh	
701	Bhuiyan S. (BFRP) (1)	MCH Model Clinic Chittagong, Bangladesh	FS
704	Begum, S.F.	Dacca Medical College & Hospital Dacca, Bangladesh	Norplant, IUD FB, FS
705	Jabeen, S. (BFRP)	Sir Salimullah Medical College Mitford Hospital Dacca, Bangladesh	Norplant IUD, FS, SYS

BANGLADESH (Cont.)			
715	Barua, A.	Sylhet Medical College Sylhet, Bangladesh	
718	Chowdhury, T.A.	Institute of Postgraduate Medicine	FS, Norplant
721	Rahman, S.	Model Outpatient Clinic Dacca, Bangladesh	IUD, FB, FS, MS, SYS, Norplant
724	Rahman, A	BAVS Camp Cases Dacca, Bangladesh	FS, MS
728	Bhuiyan, S.N.	Bhuiyan's Clinic Chittagong, Bangladesh	IUD, FS
730	Rahman Kahn, A.	Thana Health Complex Kalihati, Tangail Dacca, Bangladesh	FS, MS
744	Malakar, M.	Dacca, Bangladesh	
786	Bhuiyan, A.B.	Rangpur Medical College Hospital Rangpur, Bangladesh	IUD, FB
TAIWAN			
781	Chen, F.M.	Air Force General Hospital Taipei, Taiwan	IUD, FS*
	Yan, Jaw-Shong/ Hsu, Joshn	Tri-Service General Hospital	
PANAMA			
081	Moreno, J.	Hospital Santo Tomas Panama City, Panama	CT, IUD*, SYS
832	Lasso de la Vega	Complejo Hosp. Metropolitano Panama City, Panama	CT, FS* IUD
083	Contreras, J.	Hospital Jose Domingo de Obaldia	CT, IUD*, FS
BOLIVIA			
8023		Hospital Metodista La Paz, Bolivia	RH
8024		Hospital de Clinicas La Paz, Bolivia	RH

BOLIVIA (Cont.)

8025		Maternidad German Urquidi Cochabamba, Bolivia	RH
8026		Hospital General No. 2 CNSS Cochabamba, Bolivia	RH
8027		Maternidad Percy Boland Santa Cruz, Bolivia	RH
8028		Hospital San Juan de Dios, CNS Santa Cruz, Bolivia	RH
8029		Hospital de CNSS Sucre, Bolivia	RH
8031		Hospital Ob/Gyn No. 4 CNSS Instituto Gineco-Obstetrico Oruro, Bolivia	RH
8032		27 de Mayo Sucre, Bolivia	RH
8033		Hospital Militar La Paz, Bolivia	RH
8034		Hospital General Obrero No.1 CNSS La Paz, Bolivia	RH

CHILE

086	Tacla, X.	Hospital Barros Luco University of Chile Santiago, Chile	CT, IUD
088	Zipper, J.	Hospital Sotero del Rio Santiago, Chile	CT, IUD*, FB
850	Guzman-Serani, R.	Universidad of Valdivia Valdivia, Chile	CT, IUD, FS (MCA and non-surgical FS)

EL SALVADOR

821	Argueta, G.	Asociacion Demografica Salvadorena San Salvador, El Salvador	FS*, MS*, OC IUD, CT

COSTA RICA

831	Aranda, C.	Hospital Mexico ICSS San Jose, Costa Rica	CT, IUD*, FS*, OC

PERU			
101	Acosta, M.	Maternidad de Lima Lima, Peru	CT, IUD
102	Guzman, C.	Centro Medico Carmen de la Legua Lima, Peru	CT, IUD
110	Romero, F.	Hospital San Juan de Dios Lima, Peru	CT, IUD
836	Nagahata, J.	Hospital San Juan de Dios Lima, Peru	CT, IUD, FS*
VENEZUELA			
100	Zighelboim, I.	Hospital Concepcion Palacios Caracas, Venezuela	CT, IUD, FS, (MCA)
GUATEMALA			
841	Santiso, R.	APROFAM Guatemala City, Guatemala	CT, IUD, FS, MS, OC
MEXICO			
825	Rivera, R.	Inst. Investigacion Cientifica Durango, Mexico	IUD*, FS, SYS, CT, FDT, Implant
084	Betancourt, J.D.	Villahermosa, Tabasco, Mexico	CT, SYS (POCs)
840	Serratos, M.	Ciudad Juarez, Chihuahua, Mexico	CT, SYS (POCs)
869	Cetina, T.	C.I.R. Hideyo Noguchi Merida, Mexico	CT, IUD, SYS
892	Ortiz Mariscal, D.	ESPLANIFAM Nuevo Leon, Mexico	CT, IUD, FS
BRAZIL			
843	Galba, A.	Maternidad Lago Redondo Aguirraz, Fortaleza, Brazil	RH, CT, SYS
858	De Castro, M.	Pro-Pater Sao Paulo, Brazil	CT, RH, FS, MS*
865	Bossemeyer, R.	Santa Maria Institute of Reproductive Health Santa Maria, Brazil	CT, IUD, FS*
8003	Albuquerque, L.A.	Materno Infantil de Rio Claro Rio Claro, Brazil	CT, SYS, IUD

BRAZIL (Cont.)

8020	Aguinaga, H.	CPAIMC Rio de Janeiro, Brazil	CT, RH, FDT, FS

ARGENTINA

871	Moggia, A.	Hospital Bernal Buenos Aires, Argentina	CT, SYS

HONDURAS

890	Nunez, J.	ASHONPLAFA Tegucigalpa, Honduras,	RH, CT, FS, FB, SYS, IUD

SPAIN			
230	Bonilla, F.M.	Hospital Universitario Clinico Valencia, Spain	IUD
NETHERLANDS			
266	Van Lith, D./ Van Schie	Centre for Human Reproduction Leiden, Netherlands (Holland)	FS
BELGIUM			
277	Thiery, M.	University of Ghent Ghent, Belgium	IUD*
SWEDEN			
276	Joelsson, I.	Umea University Hospital Umea, Sweden	FB
YUGOSLAVIA			
020	Andolsek, L.	FP Institute Ljubljana, Yugoslavia	IUD*, FB, SYS
021	Antonnovski, L.	Ginekilosko-Akuserska Klinika Skopje, Yugoslavia	FB
022	Randic, L.	Ginekiloska Klinika Medicinskog Fakultat Rijeka, Yugoslavia	IUD*
023	Borko, E.	Maribor General Hospital Slovenja, Yugoslavia	FB*, SYS, FS
024	Behlilovic, B.	Dom Zdravlja, Stari Grad Belgrade, Yugoslavia	IUD, SYS, FB
HUNGARY			
026	Lampe, L.	Noi Klinika Debrecen, Hungary	SYS, IUD
221	Sas, M.	Univ. Medical School of Szeged Szeged, Hungary	SYS, IUD
AUSTRALIA			
283	Sidhu, M.S.	General Hospital Townsivlle, Australia	IUD

CANADA

272	Lefebvre, J.	Notre Dame Hospital FP Clinic Montreal, Quebec, Canada	FB, SYS

ENGLAND

015	Fairweather, D.	University of London London, England	FS
016	Beard, R.W.	St. Mary's Hospital London, England	FS
018	Thomas, M.	Hampshire Area Health Authority Winchester, England	IUD
217	Filshie, M.	University Hospital Nittingham, England	FS*
218	Snowden, R.	FP Research Unit University of Exeter Exeter, England	IUD
295	Laverly, K.	Marie Stopes Clinic London, England	FB, MS*
296	Craft, I.	Royal Free Hospital London, England	FS
298	Guillebaud, J.	Margaret Pyke Center London, England	FB*, SYS

FRANCE

297	Audebert, A.	Society Civile Professionnel Medecins France	FS, IUD
299	Cohen, J.	Clinique Marignan Paris, France	IUD

GERMANY

250	Tauber, P.	Essen University Clinics Essen, West Germany	IUD

AUSTRIA

260	Rocksenschaub, A.	Tgnaz Semmelweis Frauenklinik Vienna, Austria	FS

ITALY

264	Flamigni, C.	University di Bologna Italy	IUD
273	Benagiano, G.	University of Rome Rome, Italy	SYS*

UNITED STATES

010	Tatum, H.	Emory University Atlanta, Georgia	SYS
209	North, B.	Healthworks, Inc. Laguna Beach, California	FB*
210	Fotier, L.	Planned Parenthood Clinic Los Angeles, California	FB*, FS, MS
211	Stewart, G.K.	Planned Parenthood Assoc. of Sacramento Sacramento, California	FB*, SYS
213	Gilbert, H.	Central Iowa Family Planning Marshalltown, Iowa	FB, NFP
214	Goldberger, N.	Akron Women's Clinic Akron, Ohio	FB, SYS
215	Dunn, C.	Toledo Medical Services, Inc. Toledo, Ohio	FB
216	Daystar, P.	Womenside Healthcare Denver, Colorado	FB*, NFP
220	Ruoff, G.	Westside Family Medical Center Kalamazoo, Michigan	FB*, SYS
222	Foreman, H.	Center for Population Studies University of Minnesota Minneapolis, Minnesota	FB*, SYS, IUD
223	Schultz, M.	Planned Parenthood of Minnesota St. Paul, Minnesota	FB*, SYS
225	Poindexter, A.	Baylor College of Medicine Texas Medical Center Houston, Texas	FB*, SYS
226	Soderstrom, R.	Clinical Pharmacology Unit of the Mason Clinic Seattle, Washington	FB*, IUD, SYS
227	Tereszkiewicz, L.	Planned Parenthood Alameda San Francisco, California	FB*
228	Beck, A.	University of Alabama Birmingham, Alabama	SYS*
	Utian, Wulf H.	Mt. Sinai Medical Center University Circle Cleveland, Ohio	FS

UNITED STATES (Cont.)

	Katz, D.	Pittsburg, PA	FS
	Denniston, G.	Population Dynamics Seattle, Washington	IUD
907	Berger, G.	Center for Reproductive Health Chapel Hill, North Carolina	FB*, FS
911	Davis, J.	New York Medical College New York, New York	FS*, MS
919	Stumpf, P.	Hershey Medical Center Hershey, Pennsylvania	IUD, FB, SYS
944	Wennberg, E.	Vermont Women's Health Center Burlington, Vermont	
951	Schmidt, S.S.	Drs. Schmidt & Mooslin, Inc. Eurecka, California	MS
952	Saxena, Dr.	Cornell Medical College New York, New York	MS, SYS
957	Bernstein, G.	Univ. Of Southern California Medical School Los Angeles, California	MS
961	Asch, R.	Univ. of Texas, San Antonio Medical School San Antonio, Texas	IUD, FS, SYS
968		California Hosp. Medical Center Los Angeles, California	
969	Crocker, C.	Howard University Hospital Washington, D.C	
970		PRETERM Washington, D.C.	
971	Davidson, O.	University of Miami Miami, Florida	
973	Kerenyi, T.	Mr. Sinai Medical Center New York, New York	FB
974	Holly, R.	Planned Parenthood Association of Wisconsin Milwaukee, Wisconsin	FB
975	Hasson, H.	Private Clinic Chicago, Illinois	IUD

CONTRACEPTIVE SAFETY DIVISION APPENDIX IV

FCO	PROJECT	COUNTRY	INVESTIGATOR	FHI MONITOR
ONGOING				
0197	Occupational influences on reproduction	USA	Rosenberg	Rosenberg/Feldblu
0672	Case control study of atherosclerosis	Korea	Ko	Chi
3201	Sickle Cell Anemia and OCs	Jamaica	de Ceulaer	Fortney/Bonhomme
3201	KAP study of women with SCA	Ghana	Klufio	Fortney/Bonhomme
3202	Case control study of Cervical Cancer	Jamaica	Cancer Soc.	Fortney/Bonhomme
3203	Analysis of Depo Provera	Indonesia	Agoestina	Feldblum
3204	RAMOS (complete)	Indonesia	Susanti	Fortney/Rogers
3228	Depo Provera exposure at Grady Hospital	USA	--	Higgins
3205	RAMOS	Egypt	Gadalla	Fortney/Rogers
3206	Smoking & Reproductive Health	USA	Rosenberg	Rosenberg/Keel
3207	Attitudes of physicians & midwives/OC use	Indonesia	BKKBN	Fortney
3208	Case control study of prostatic disease	USA	Kaiser Perm	Rosenberg
3209	Contraception and STDs	USA	Rosenberg	Rosenberg/Feldblu
3210	Spermicides and STDs	Bangkok	Wiwat	Rosenberg/Feldbl
3212	Children exposed in utero to MPA	Israel	Harlap	Rosenberg
3200	LT cardiovascular consequences of vasectomy	China	WHO	Rosenberg
3213	Hospital discharge survey	Indonesia	BKKBN	Fortney
3214	Vasectomy by paramedics	Indonesia	Guno	Fortney/Rogers
3216	Risk/benefit of OCs	--	Fortney	Fortney
3217	Case control study of reproductive cancer	Costa Rica	Rosero	Fortney
3218	Doxycycline and PID in IUD users	Kenya	Sinei	Teeter
3219	Follow-up of long-term IUD users	Yugoslavia	Kozuh	Teeter
3220	Male influence on spontaneous abortion	Finland	Hemminki	Rosenberg
3221	In utero Depo exposure	Thailand	Gray	Rosenberg
3224	Sterilization as a risk factor for hysterectomy	Mexico	Garza	Rosenberg
3223	Folate and cervical dysplasia	Mexico	Acosta	Grubb
3225	Vitamins & neural tube defects	China		Rosenberg
3226	OCs and birth defects			Rosenberg
3227	OCs and Schistosomiasis			Grubb
MISCELLANEOUS				
0016	Home department	--	--	Rosenberg
07	Epidemiologic Workshop	Mexico	Rivera	Higgins
00	Contract development	--	--	Rosenberg
.15	IUD Papers	--	--	Chi
3211	Hysterectomy following sterilization	Singapore		Rosenberg
3222	RHD and contraception	Egypt	--	Rosenberg/Grubb
0992	Grant and Development	--	--	Rosenberg

REPRODUCTIVE HEALTH
PROJECT STATUS LIST
OCTOBER, 1984

I. ONGOING PROJECTS

FCO	TITLE	MANAGER	STATUS
0765	GHANA PREGNANCY EPIDEMIOLOGY	LAMPTEY	ANALYSIS PLANNED
0782	ZAIRE PREGNANCY EPIDEMIOLOGY	NICHOLS	REPORT BEING PREPARED
1051	EGYPT DAYA TRAINING PROJECT	SMITH	DATA COLLECTION IN PROGRESS
1071	SENEGAL CLINIC-BASED F.P ACCEPTORS	NICHOLS	REPORT COMPLETE
1117	OBSTETRIC CARE IN AFRICA (MONOGRAPH)	JANOWITZ	BEGIN TYPESET
1142	PARTEIRAS IN NORTHEAST BRAZIL	BAILEY	DATA COLLECTION IN PROGRESS
1188	BOLIVIA PREGNANCY EPIDEMIOLOGY	BAILEY	ANALYSIS UNDERWAY
1235	EGYPT FEMALE CIRCUMCISION	KAFAFI	DATA COLLECTION IN PROGRESS
1264	SENEGAL SUPPORT TO ORSTROM	BURTON	FUNDING ONLY
1269	LIBERIA ADOLESCENT SEXUALITY SURVEY	NICHOLS	DATA COLLECTION COMPLETE
1272	SENEGAL MATERNAL MORTALITY	BURTON	DATA COLLECTION IN PROGRESS
1278	IVORY COAST PREGNANCY MONITORING	LEWIS	DATA COLLECTION IN PROGRESS
1279	ZAIRE PREGNANCY CARE MONITORING	SMITH	DATA COLLECTION IN PROGRESS
1280	AFRICA BUREAU MCM (PROJECT DEVELOPMENT)	BURTON	PROJECT DEVELOPMENT
1281	HAITI MATERNITY CARE MONITORING	JESENCKY	FIELD WORK TO START IN NOVEMBER
1305	MATERNITY CARE MONITORING (IN-HOUSE)	SMITH	CONTINUOUS
3301	MEXICO MATAMOROS SECONDARY ANALYSIS	MILLER	REPORT PREPARED: PAPERS IN PROGRESS

I. ONGOING PROJECTS - CONTINUED

[illegible]	TITLE	MANAGER	STATUS
3303	HONDURAS ASHONPLAFA SECONDARY ANALYSIS	JANOWITZ	REPORT PREPARED; PAPERS IN PROGRESS
3304	BRAZIL SECONDARY ANALYSIS OF SURVEYS	JANOWITZ	PAPERS AVAILABLE
3305	BRAZIL PHYSICIANS' ATTITUDE SURVEY	BAILEY	ANALYSIS UNDERWAY
3306	NIGERIA SECONDARY ANALYSIS OF SURVEY	NICHOLS	REPORTS COMPLETE; PAPERS IN PROGRESS
3308	HONDURAS ACCESS TO STERILIZATION	JANOWITZ	DATA COLLECTION IN PROGRESS
3309	NIGERIA FEMALE STERILIZATION COUNSELING	COVINGTON	PILOT STUDY COMPLETE; DATA COLLECTION IN PROGRESS
3310	SRI LANKA TUBAL LIGATION FOLLOW UP	COVINGTON	FIELD WORK TO START IN NOVEMBER
3311	INDIA BIRTH SPACING (JHU-NAHRWAL DATA)	JANOWITZ	FUNDING ONLY
3312	TECHNICAL ASSISTANCE TO CPAIMC	JANOWITZ	FIRST DRAFT COMPLETE
3313	HONDURAS DEPO-PROVERA FOLLOW UP	JANOWITZ	ANALYSIS UNDERWAY
3314	NIGERIA PHYSICIANS'ATTITUDE SURVEY	COVINGTON	DATA COLLECTION IN PROGRESS
3315	HONDURAS MCH/FP NATIONAL SURVEY	JANOWITZ	DATA COLLECTION IN PROGRESS
3316	GHANA MALE ATTITUDES SURVEY	LAMPTEY	ANALYSIS PLANNED
3317	MEXICO CBD EVALUATION SURVEY	WELSH	DATA COLLECTION COMPLETE

II. PLANNED PROJECTS - UNDER DEVELOPMENT

FCO	TITLE	STATUS
1238	EGYPT MATERNAL MORTALITY	SUBGRANT SENT TO AID
1315	THAILAND FOLLOW UP OF INFANTS IN SUKOTHAI	SUBGRANT BEING PREPARED
2***	HONDURAS ASHONPLAFA CRS OC PROJECT	UNDER DEVELOPMENT
2***	BRAZIL FOCUS GROUPS ON STERILIZATION	CONCEPT APPROVED BY SCIENTIFIC COMMITTEE
2***	THAILAND TRAINING FOR NURSE-MIDWIVES IN STERILIZATION	CONCEPT APPROVED BY SCIENTIFIC COMMITTEE/CT
3307	THAILAND INFANT MORTALITY/BREASTFEEDING	APPROVED BY AID/W
3301	NEPAL CONTRACEPTIVE RETAIL SALES STUDY	SUBCONTRACT BEING PREPARED
3318	MEXICO KAP SURVEY OF YOUNG ADULTS	SUBCONTRACT BEING PREPARED

III. CLOSED, COMPLETE, TABLED AND NOT APPROVED PROJECTS

FCO	TITLE	STATUS
1181	CHILDBIRTH IN DEVELOPING COUNTRIES	COMPLETE/CLOSED
1237	PREGNANCY EPIDEMIOLOGY AT AIN SHAMS HOSPITAL	NOT APPROVED/AID
1265	HONDURAS PREGNANCY EPIDEMIOLOGY	CANCELLED
1266	ZARIA CONTRACEPTIVE SURVEY	CANCELLED IN-HOUSE
1267	MALI TECHNICAL ASSISTANCE MCH/FP	COMPLETE
1268	ZAIRE SYMPHISIOTOMY	CLOSED
2235	EGYPT REPRODUCTIVE HEALTH SURVEY	TABLED
2238	BRAZIL SURVEY OF MEN	CANCELLED IN-HOUSE
2253	SRI LANKA PRICE ELASTICITY OF DEPO-PROVERA	CANCELLED
2254	EGYPT PHYSICIANS' ATTITUDE SURVEY	CANCELLED

NFP/BREASTFEEDING PROJECT LOG
August, 1984

Log #	TITLE	P.I.	FCO/Status
	I. COMPLETED PROJECTS (8)		
*2.	Mexico: Longitudinal Study of BF and Return to Ovulation, Phase I	Rivera	Completed 1983
4.	USA: Self Aspiration of Vaginal Fluid for Ovulation Timing	Schumacher	Completed 7/84
*5.	Hospital Practices on Promotion of BF in Five Countries	Janowitz	Completed 5/84
*8.	Hong Kong: Support for IFFLP Monograph	Lanctot/ Gould	Completed 7/84
9.	Chile: Training for Argentine Physician	Rinaudo	Completed 3/84
10.	Philippines: Longitudinal BF Study in Laguna	Lipton	Completed 8/85
14.	Egypt: Workshop on BF Research	Younis	Completed 5/84
*45.	Kenya: NFP Assessment Site Visit	Thapa/ Gross	Completed 7/84
22.	USA: NFP Training Course in N.C.	Conroy	Completed 9/84

* Paper or Monograph Completed

Key: NFP - Natural Family Planning
BF - Breastfeeding

Type of Project

1. Basic Research
2. Programmatic Research
3. Population Surveys on NFP Methods
4. Quality of NFP Teaching
5. Breastfeeding as NFP Method
6. Dissemination (workshop, conference or publication)

II. DISAPPROVED, TABLED, OR TRANSFERRED (12)

TITLE	Action Taken
34. Mexico: Evaluation of Effectiveness of Billings Method (Roca)	Disapproved No NFP expertise
39. UK: BF Perceptions (Snowden)	Disapproved
27. USA: RTSA NFP Training Course (Hunter) (Funded by AID through Training Division)	Training activity
28. UK: Physician NFP Attitude Study in US/UK (Snowden)	Disapproved: Not relevant to Develop. Country
42. Brazil: Role of Men Workshop (Noronha)	Tabled by Sci. Committee
49. USA: Marketing of Breastfeeding (Davies)	Transferred to Reprod. Health
54. Australia: Effect of Mini-pill on Milk Yield (Short/Hartmann)	Transferred to Clin. Tr.
19. Mexico: Validation of Ovulometer (Rivera)	Closed-funding from inventor not received
33. Cameroons: NFP Survey (Rens)	No proposal received
38. Thailand: Breastfeeding and Infant Mortality in N.E. Thailand (Peerasit)	Transferred to Reprod. Health
56. Mexico: Training in Billings (Fuentes) (Service program funding requested)	Referred to AID Office of Popul. for funding
13. Egypt: BF and Health Care Providers Study (Shawky)	Investigator not able to do study (FCO2245)
43. USA: Human Life Center - Fertility Awareness and Choice of FP Method	Proper setting still needed
57: Australia: Field Trial of Filter Spot Blood Prolacting in BF Women	Pending Expert Meeting
63: Egypt & Md: Development of NFP Concept Cards	Disapproved by Sci.C.

APPENDIX VII

FHI
ACTIVE STUDIES IN AFRICA
FUNDED BY USAID

DEPARTMENT	TYPES OF ACTIVITIES	INVOLVED COUNTRIES	BUDGET
Clinical Trials			
	Acceptability of Progestogen-only pills	Cameroon Egypt Mali Nigeria Senegal Sudan	55,100
	Comparison of OVT Menfegol vs OVT Nonoxynol (approval pending)	Egypt Ghana Nigeria	25,135
	Comparison of Barrier Methods - foam, spermicides or vaginal tablets	Egypt	26,425
	Comparison of Oral Contraceptives	Egypt Mali Nigeria	39,260
	Comparison of IUD's	Egypt Mali Nigeria	12,265
	Surveillance of Female Sterilization	Kenya	2,060
	Comparative Retrospective Study of Injectables and OC's	Gambia Egypt	7,800
	NORPLANT® Coordinating Meeting	Egypt	5,000
	Total of 30 Studies		$173,045
Reproductive Health			
	Pregnancy Surveillance Study	Ivory Coast Zaire Senegal	421,240
	Maternity Care Monitoring	Rwanda Nigeria Egypt Liberia Zaire	15,000
	MCH Evaluation	Mali	11,858

DEPARTMENT	TYPES OF ACTIVITIES	INVOLVED COUNTRIES	BUDGET
Reproductive Health (continued)			
	Adolescent Sexuality	Liberia	49,555
	Counseling Concerning Female Sterilization	Nigeria	14,755
	Extent and Attitude Towards Female Circumcision	Egypt	65,000
	Physicians' Attitude Towards Family Planning	Nigeria	16,830
	Male Attitudes Towards Family Planning	Ghana	2,504
	Secondary Data Analysis, Maternal Morbidity and Mortality, Contraceptive Prevalence Surveys	Nigeria	16,819
	Support to ORSTOM - Maternal Mortality	Senegal	21,196
	Total of 19 Studies		$634,757
Natural Family Planning			
	Effectiveness of Natural Family Planning	Egypt	5,000
	Breastfeeding Surveys	Egypt	81,129
	Total of 2 Studies		$86,129
Contraceptive Safety			
	Evaluation of the Effectiveness of Antibiotics in Preventing PID	Kenya	15,960
	RAMOS (Reproductive Age Mortality Study)	Egypt	217,560
	Total of 2 Studies		$233,520

PRINCIPAL COUNTRIES IN AFRICA CONDUCTING FHI ACTIVITIES

COUNTRY	NUMBER OF STUDIES	MAJOR PROJECTS	BUDGET IN-HOUSE/ FIELD/TOTAL
Egypt	25 approved on-going studies	EFCS Core Support Physician/Pharmacist Training Bulletin Longitudinal Breast-Feeding Study Extent & Attitude Towards Female Circumcision RAMOS	490,019 1,042,832 1,532,851
Nigeria	10 approved on-going studies	Maternity Care Monitoring Physician's Attitude Survey Female Sterilization Counseling Comparison of Oral Contraceptives	------ 75,224 75,224
Senegal	6 approved on-going studies	Maternal Mortality Study in Sine Saloum Microcomputer Technology Transfer Financial Support to ORSTOM (Maternal Mortality)	133,576 60,457 194,033

DEPARTMENT	TYPES OF ACTIVITIES	INVOLVED COUNTRIES	BUDGET
Field Development & Training			
	Core Support for Family Health Research Centers	Sudan Egypt	812,061
	Microcomputer Technology Transfer	Egypt Senegal	94,255
	Workshops: Contraceptive Technology, Clinical Trials, Breastfeeding	Egypt Senegal	130,109
	Physician/Pharmacist Training Bulletin	Egypt	184,780
	Ultrasound Technology in Family Planning Clinics	Egypt	42,000
	Technical Assistance to Family Planning Research	Mali	40,968
	Total of 10 Activities		$1,304,173
		TOTAL	$2,431,624

APPENDIX VIII

RATINGS: 0 = no capability
1 = beginning/marginal
2 = intermediate
3 = fully developed capability
9 = unknown or unable to evaluate

PROGRAM: BKS PENFIN
DATE: NOVEMBER 1983

FHRC MASTER PLAN SUMMARY

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
A. Planning and Coordination				Joint planning; promote BKS PENFIN/BKKBN/AID/FHI dialogue continued support of BKS PENFIN advisory committee and general investigator meetings which discuss these matters. Encourage BKS PENFIN to delegate mangerial responsibility to program officer and work closely with that person.
1. Clarity of goals/objectives	2	2+	2+	
2. Functional mechanisms				
a. Definition of research needs	2	2+	2+	
b. Program management	1	2	2	
c. Technology introduction	2	2	2	
d. Policy formulation	1+	2	2	
B. Research Capacity				
1. Investigator Network				
a. Network in place	3	3	3	Evaluate performance and experience in current decentralized clinical trials. Respond to problems identified.
b. Able to develop new centers	2-	2+	3	
c. Expansion outside major cities	2-	2+	3	
2. Study Implementation				
a. Data collection	2	2+	3	Give support and assistance to Program Officer, Assistance, site visits by FHRC coordinator.
b. Study logistics	3-	3	3	
c. Monitoring	2	2+	2+	

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
d. Quality assurance	2	2+	3	Give support and assistance to Program Officer, Assistance, site visits by FHRC coordinator.
e. Problem solving	2	2+	2+	
f. Voluntary consent	2	2+	3	
g. Efficiency	1	1+	2	
h. Evaluation - feedback	9	2	2	
3. Data Processing and Analysis				
a. Data editing	2	2+	3	FHI Research Analyst to visit and provide technical training, followed by continued "counterpart" relationship to review work and provide assistance. Computer programmer training at FHI and site visits by FHI specialists. Add Info Coordinator to BKS PENFIN staff.
b. Data entry	2	2+	3	
c. Generation of standard tables	2	2+	3	
d. Interpretation of standard tables	1	1+	2	
e. Writing of consultant reports	1	1+	2+	
f. Additional analysis	1	1+	2	
g. Writing of research papers	2-	2	2	
h. Adaptation of new software	2	2+	2+	
i. Production of new software	2	2+	2+	
C. Training				
1. Ability to train new staff	2	2	2+	Promote development of program officer position
2. Training of investigators				Clinical research workshops and program review meetings
a. Routine data collection techniques	2	2+	2+	Annual investigators meeting
b. Research methods/design				Additional biostatistic training by FHI

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
c. Data interpretation/analysis				Give support and assistance to Program Officer, Assistance, site visits by FHRC coordinator.
3. Clinical training/New technology	2	2+	2+	
D. Policy Impact/Dissemination of Research				
1. Feedback mechanisms	2	2+	2+	Continue and strengthen newsletter - add info coordinator to staff. Increased FHI support for these activities.
2. Dissemination to providers	2	2+	2+	
3. Linkage with policy makers	2-	2	2+	
4. Local publications	1	1+	2	
5. Dissemination conferences	2	2+	2+	
6. Participation in international fora	1	2	2	
7. Linkage with potential clients	2	2+	2+	
E. Administrative				
1. Basic accounting system	1+	2	2+	Technical assistance by FHI Coordinator and possible consultant from local accounting firm.
2. Knowledge of country requirements				
a. Taxes	9	2+	3	
b. Insurance	9	2+	3	
c. Employee benefits	9	2+	3	
d. Salary restrictions	9	2+	3	
e. Customs	9	2+	3	
f. Drug regulations	9	2+	3	

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
g. Foreign exchange	9	2+	3	Technical assistance by FHI Coordinator and possible consultant from local accounting firm.
h. Research regulating agencies	9	2+	3	
3. Administration FHI Budgets	2	2+	3	
4. Record keeping	9	2+	2+	
5. Personnel				
a. Decision making	1	1+	2	Technical assistance by FHI Coordinator and possible consultant from local accounting firm.
b. Staff recruitment	1	1+	2	
c. Job descriptions	1	2	2	
d. Salary scale	9	2	2	
e. Lines of authority	2	2+	2+	
6. Budgeting	2	2+	2+	
7. Monitoring of finances	2	2+	3	
8. Self-evaluation	9	2	2+	
9. Responsiveness to outside evaluation	1	2	2+	
10. Cost-sharing capability	0	1	2	

0 = no capability
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2 = intermediate
3 = fully developed capability
9 = unknown or unable to evaluate

PROGRAM: TFRA

DATE: SEPTEMBER 1983

FHRC MASTER PLAN SUMMARY

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
A. Planning and Coordination				
1. Clarity of goals/objectives	1	2	2	More attention internally to this need - Participate and exert leadership in national planning forum
2. Functional mechanisms				
a. Definition of research needs	1	2	2	Continue normal support for TFRA advisory committee, meetings, etc.
b. Program management	2	2+	3	
c. Technology introduction	2	2+	2+	
d. Policy formulation	2	2+	2+	
B. Research Capacity				
1. Investigator Network				
a. Network in place	2	2+	2+	Continued development by experience
b. Able to develop new centers	1	2	2+	
c. Expansion outside major cities	2	2+	3	
2. Study Implementation				
a. Data collection	2	2+	3	Closer FHI monitoring, promoting these skills
b. Study logistics	2	2+	3	
c. Monitoring	1+	2	2+	

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
d. Quality assurance	1+	2	2+	
e. Problem solving	1+	2	2+	As above
f. Voluntary consent	2	2+	3	
g. Efficiency	1+	2	2	
h. Evaluation - feedback	9	2	2	
3. Data Processing and Analysis				
a. Data editing	2+	3	3	Computer programmer training at FHI and locally. FHI Research Analyst site visits and continued "counterpart" relationship to assist and review CPs etc.
b. Data entry	2+	3	3	
c. Generation of standard tables	2	2+	3	
d. Interpretation of standard tables	1	2	2+	
e. Writing of consultant reports	1	2	2+	
f. Additional analysis	1	2	2	
g. Writing of research papers	1	2	2	
h. Adaptation of new software	1	1+	2	
i. Production of new software	1	1+	2	
C. Training				
1. Ability to train new staff	2+	2+	3	Increased core salary support of needed and justified by workload. More training seminars and workshops.
2. Training of investigators				
a. Routine data collection techniques	1	2	2	
b. Research methods/design	1	2	2	

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
c. Data interpretation/analysis	1	2	2	
3. Clinical training/New technology	9	2	2	
D. Policy Impact/Dissemination of Research				
1. Feedback mechanisms	1	2	2+	Continue and strengthen Newletter. Play leading role in setting NFPP research directions. Develop ability to write CP's and papers, disseminate same at local forums
2. Dissemination to providers	1	2	2+	
3. Linkage with policy makers	2	2+	2+	
4. Local publications	1	2	2	
5. Dissemination conferences	2	2+	2+	
6. Participation in international fora	1+	2	2+	
7. Linkage with potential clients	1-	1+	2	
E. Administrative				
1. Basic accounting system	2	2+	3	
2. Knowledge of country requirements				
a. Taxes				
b. Insurance				
c. Employee benefits	3	3	3	
d. Salary restrictions				
e. Customs				
f. Drug regulations				

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
g. Foreign exchange	3	3	3	
h. Research regulating agencies				
3. Administration FHI Budgets	3	3	3	
4. Record keeping	3	3	3	
5. Personnel				
a. Decision making				
b. Staff recruitment	2	2+	3	FHI Coordinator to work with program officer to review and improve staffing; increased FHI support if necessary
c. Job descriptions				
d. Salary scale				
e. Lines of authority				
6. Budgeting	1	2	2+	
7. Monitoring of finances	2	2+	2+	
8. Self-evaluation	9	2	2	
9. Responsiveness to outside evaluation	2	2+	3	
10. Cost-sharing capability	9	2	2	

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1 = beginning/marginal
2 = intermediate
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9 = unknown or unable to evaluate

PROGRAM: FPA/SL
DATE: NOVEMBER 1983

FHRC MASTER PLAN SUMMARY

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
A. Planning and Coordination				
1. Clarity of goals/objectives	1	3	3	Discussions during monitor's visit, followed by FPA action
2. Functional mechanisms				
a. Definition of research needs	1	2	3	Discussions during monitor's visit; discussions between FPA and relevant agencies
b. Program management	2	3	3	Organization of research management by FPA
c. Technology introduction	1	2	2	Development of internal FPA mechanism, establishment of link with GOSL
d. Policy formulation	2	3	3	Explicit development of research policy formulation mechanism by FPA
B. Research Capacity				
1. Investigator Network				
a. Network in place	1	1.5	2	Initiation of discussions between FPA and potential centers; initiation of first clinical trials in such centers, involving a broad geographic network.
b. Able to develop new centers	1	1.5	2	
c. Expansion outside major cities	1	1.5	2	
2. Study Implementation				
a. Data collection	2	3	3	Review by monitor of systems needs; Implementation by FPA
b. Study logistics	2	3	3	
c. Monitoring	3	3	3	None

FPA/SL-1

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
d. Quality assurance	1	1.5	2	Continued monitoring
e. Problem solving	2	2	2.5	Gradual development of Assistant Director
f. Voluntary consent	2	3	3	Establishment and implementation of clear FPA policy consistent with FHI
g. Efficiency	3	3	3	None
h. Evaluation - feedback	2	3	3	Improvement of feedback systems with FHI advice
3. Data Processing and Analysis				
a. Data editing	2	2.5	3	Establishment and implementation of routine editing procedures.
b. Data entry	1	2	3	Training of staff, with microcomputer experience; presence of FHI research staff
c. Generation of standard tables	0	1	2	
d. Interpretation of standard tables	1	2	3	Experience plus assistance from FHI monitor, research staff
e. Writing of consultant reports	0	1	2	"
f. Additional analysis	0	1	2	"
g. Writing of research papers	1	1.5	2	Experience, FHI monitor's editing and technical advice
h. Adaptation of new software	0	0.5	1	
i. Production of new software	0	0.5	1	Training of FPA programmer in country, at FHI
C. Training				
1. Ability to train new staff	1	1.5	2	Improvement of in-house expertise; establishment of links with training institutions
2. Training of investigators				
• a. Routine data collection techniques	2/0	2.5/1	3/1	Improvement due to staff experience/ feedback to investigators
• b. Research methods/design	1/0	1.5/0	2/1	Training of senior staff in Asia/Pacific region; [illegible]

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
c. Data interpretation/analysis	1/0	1.5/0	2/0.5	Training /experience of staff/basic intro, possible workshop
3. Clinical training/New technology	2	2.5	2.5	Participation of Clinical Director in FHI training, conferences, etc.
D. Policy Impact/Dissemination of Research				
1. Feedback mechanisms	0	1	2	Initial development w/monitor's advice; experience
2. Dissemination to providers	1	2	3	Establishment of journal; possible workshops/conference
3. Linkage with policy makers	2	2.5	3	Improvement of institutional relations and functional mechanisms
4. Local publications	1	2.5	3	Establishment and improvement of journal improvement of press links
5. Dissemination conferences	2	2	2	Continuation of present FPA policies, activities
6. Participation in international fora	1	2	2	Budget for travel
7. Linkage with potential clients	2	2.5	3	Linkages exist, should strengthen due to institutionalization of research capacity.
E. Administrative				
1. Basic accounting system	3	3	3	
2. Knowledge of country requirements				
a. Taxes	3	3	3	
b. Insurance	3	3	3	
c. Employee benefits	3	3	3	
d. Salary restrictions	3	3	3	None
e. Customs	3	3	3	
f. Drug regulations	3	3	3	

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
g. Foreign exchange	3	3	3	
h. Research regulating agencies	3	3	3	None
3. Administration FHI Budgets	3	3	3	
4. Record keeping	2	3	3	Establishment of improved procedures
5. Personnel				
a. Decision making	2	3	3	Daya will take care of it
b. Staff recruitment	2	2	2.5	Slow improvement of reputation; experience
c. Job descriptions	2	3	3	Procedures, experience
d. Salary scale	2	3	3	Budget
e. Lines of authority	3	3	3	None
6. Budgeting	2	3	3	Adaptation of current procedures to research
7. Monitoring of finances	2	3	3	
8. Self-evaluation	1	2	2	Attention to problem; possible establishment of volunteer RAC
9. Responsiveness to outside evaluation	1	2	3	Experience with institutionalized research evaluation
10. Cost-sharing capability	2	2	3(?)	Possible assistance from FHI administration

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2 = intermediate
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9 = unknown or unable to evaluate

PROGRAM: EFCS
DATE: NOVEMBER 1983

FHRC MASTER PLAN SUMMARY

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
A. Planning and Coordination				
1. Clarity of goals/objectives	1	2	3	Continue function of Research Coordinator, Committee, Executive Committee and monitor activities of study area subcommittees
2. Functional mechanisms				
a. Definition of research needs	2	2	3	
b. Program management	1	2	3	
c. Technology introduction	0	1	2	
d. Policy formulation	2	2	3	
B. Research Capacity				
1. Investigator Network				
a. Network in place	1	2	2	Annual Investigators Meetings
b. Able to develop new centers	1	2	3	- Study Area subcommittees
c. Expansion outside major cities	1	2	2	- Clinical Research and Cont-Tech Workshops - Utilize Consultants
2. Study Implementation				
a. Data collection	1	2	3	
b. Study logistics	0	2	3	Data Collection Coordinator - regular site visits,
c. Monitoring				

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Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
d. Quality assurance	1	2	3	for QA, VC & DQ records for FHI monitoring -
e. Problem solving	0	2	2	Discuss problems with investigators during site visits
f. Voluntary consent	1	2	2	
g. Efficiency	0	1	2	
h. Evaluation - feedback	1	1	2	
3. Data Processing and Analysis				
a. Data editing	1	2	3	- Schedule FUP by TI crew*
b. Data entry	0	2	3	- Discuss during Clinical Research Workshop
c. Generation of standard tables	0	2	3	- Review output as part of site visits - * including Biostatistics review by FHI Bios staff member
d. Interpretation of standard tables	1	2	3	
e. Writing of consultant reports	0	1	2	
f. Additional analysis	0	1	2	
g. Writing of research papers	2	2	3	
h. Adaptation of new software	0	1	2	
i. Production of new software	0	1	2	
C. Training				
1. Ability to train new staff	2	2	3	- Clinical Research Workshops
2. Training of investigators				
a. Routine data collection techniques	1	2	3	- Annual Meeting of Investigators
b. Research methods/design	0	1	2	- Bios. review course

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
c. Data interpretation/analysis	0	1	2	Physician training visit by FHI MD
3. Clinical training/New technology	2	2	3	
D. Policy Impact/Dissemination of Research				
1. Feedback mechanisms	1	2	3	- Physician's Bulletin
2. Dissemination to providers	2	2	3	- Pharmacists Bulletin
3. Linkage with policy makers	2	2	3	- Nurse/MW Bulletin
4. Local publications	1	2	3	- Strengthen OB/Gyn Journal
5. Dissemination conferences	2	2	3	- Invite to FHI Annual Investigators Meeting
6. Participation in international fora	2	2	2	
7. Linkage with potential clients	1	2	2	
E. Administrative				
1. Basic accounting system	1	2	2	- Send FHI-sponsored accountant to review procedures, institute appropriate acct. system for sharing OH expenses
2. Knowledge of country requirements				
a. Taxes	2	2	3	
b. Insurance	2	2	3	
c. Employee benefits	2	2	3	
d. Salary restrictions	2	2	3	- review during site visit
e. Customs	3	3	3	
f. Drug regulations	2	2	3	

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
g. Foreign exchange	2	3	3	
h. Research regulating agencies	2	3	3	
3. Administration FHI Budgets	1	2	3	- See E.1 above
4. Record keeping	2	2	3	
5. Personnel				
a. Decision making	2	2	3	(Provide copies of FHI policies and procedures
b. Staff recruitment	1	2	2	
c. Job descriptions	1	2	2	
d. Salary scale	1	2	2	
e. Lines of authority	1	2	3	
6. Budgeting	1	2	3	- See E.1 above
7. Monitoring of finances	1	2	3	- See E.1 above
8. Self-evaluation	1	2	2	-Have EFCS complete this master plan summary
9. Responsiveness to outside evaluation	1	2	3	
10. Cost-sharing capability	1	2	3	- Continue IPAVS cooperation

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PROGRAM: SFCA
DATE: NOVEMBER 1983

FHRC MASTER PLAN SUMMARY

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
A. Planning and Coordination				
1. Clarity of goals/objectives	1	2	2	Joint planning process, improved SFCA secretariat
2. Functional mechanisms				
a. Definition of research needs	1	1.5	2	Gradual consensus by SFCA Board, towards next subgrant
b. Program management	1	1.5	2	Hiring of Executive Director, gradual refining of relationships
c. Technology introduction	1.5	2	2	Extension to regional affiliate system
d. Policy formulation	2	2	2	Improved secretariat may lead to more efficient discussion
B. Research Capacity				
1. Investigator Network				
a. Network in place	1.5	1.5	2	Improved core research staff->better defined network,
b. Able to develop new centers	1	1.5	1.5	better capacity of membership
c. Expansion outside major cities	1	1.5	2	Establishment of regional affiliate system
2. Study Implementation				
a. Data collection	1	1.5	2	Experience, improved FHI support
b. Study logistics	1	2	2.5	Improved secretariat, FHI monitoring
c. Monitoring	1	2	2	Stronger supervision of DCC, better FHI monitoring

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
d. Quality assurance	1	2	2	Improved performance of DCC
e. Problem solving	1	2	2.5	Better management
f. Voluntary consent	n.a.	1	1	Only one study requires informed consent PHSC in Sudan?
g. Efficiency	1	1.5	2	Improved secretariat, limited by communications and implementation constraints
h. Evaluation - feedback	1	1.5	2	Better DCC-ED-Board feedback procedures
3. Data Processing and Analysis				
a. Data editing	1.5	2	2.5	Improved performance of DCC
b. Data entry	0	1	2	Linkage with local facilities yr. 1; microcomputer yr.2?
c. Generation of standard tables	0	0	1	Microcomputer?
d. Interpretation of standard tables	1	1	1.5	Few standard tables to be generated
e. Writing of consultant reports	1	1.5	2	Experience, FHI in country technical support
f. Additional analysis	1	1.5	2	
g. Writing of research papers	1	1.5	2	
h. Adaptation of new software	0	0	1	Microcomputer?
i. Production of new software	0	0	0	
C. Training				
1. Ability to train new staff	1	1.5	2	Improved utilization of local consultants
2. Training of investigators				
a. Routine data collection techniques	1.5	2	2.5	Proposed training workshops, experience, FHI technical support
b. Research methods/design	1	1.5	1.5	

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
c. Data interpretation/analysis	1	1.5	1.5	Training workshops, experience, FHI support
3. Clinical training/New technology	1	1	1	No plans in this area: should consider improved information dissemination systems.
D. Policy Impact/Dissemination of Research				
1. Feedback mechanisms	2	2.5	2.5	Photocopy machine, generally richer information dissemination
2. Dissemination to providers	1.5	1.5	1.5	Currently through membership, contacts; no planned change.
3. Linkage with policy makers	2	2	2	
4. Local publications	n.a.	n.a.	n.a.	No such journals
5. Dissemination conferences	2	2	2	No plans
6. Participation in international fora	2	2	2	No plans
7. Linkage with potential clients	1	1.5	2	Improved secretariat, overall performance
E. Administrative				
1. Basic accounting system	2	2	2	None; ultimate need for merged systems to handle multiple funding sources.
2. Knowledge of country requirements				
a. Taxes	3	3	3	
b. Insurance	3	3	3	
c. Employee benefits	3	3	3	No change needed
d. Salary restrictions	3	3	3	
e. Customs	9			
f. Drug regulations	9			

Activity	Rating 7/83	Targets 9/84	Targets 9/85	Proposed Actions
g. Foreign exchange	3	3	3	
h. Research regulating agencies	9			
3. Administration FHI Budgets	2	2.5	2.5	Better articulation of investigator support procedures
4. Record keeping	1.5	2	2.5	Improved secretariat, FHI monitoring
5. Personnel				
a. Decision making	1	1.5	2	Improved secretariat, FHI monitoring
b. Staff recruitment	1	1.5	2	
c. Job descriptions	0	2	2	
d. Salary scale	2	2	2	
e. Lines of authority	1	1.5	2	
6. Budgeting	1.5	2	2.5	Needs clearer substantive planning process; improved secretariat.
7. Monitoring of finances	2	2	2	No plans
8. Self-evaluation	9			
9. Responsiveness to outside evaluation	1	1.5	2	Improved long-range funding, planning position
10. Cost-sharing capability	2	2	2	No plans. More elaborate system will ultimately be needed.

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PROGRAM: BFRP

DATE: NOVEMBER 1983

[illegible]
1 = beginning minimal
2 = intermediate
3 = fully developed capability
9 = unknown or unable to evaluate

FHRC MASTER PLAN SUMMARY

Activity	Rating 9/83	Targets 9/84	Targets 9/85	Proposed Actions
A. Planning and Coordination				
1. Clarity of goals/objectives	2	2	3	Consultants, FHI provision of technical assistance, on-site monitoring
2. Functional mechanisms	2	2	3	
a. Definition of research needs	2	3	3	
b. Program management	1	2	2	
c. Technology introduction	2	2	2	
d. Policy formulation	1	1	2	
B. Research Capacity				
1. Investigator Network				
a. Network in place	2	2	3	
b. Able to develop new centers	2	3	2	
c. Expansion outside major cities	2	2	3	
2. Study Implementation				
a. Data collection	3	3	3	Schedules of site visits, project monitoring
b. Study logi[illegible]ts	2	2	3	
c. Monitoring	2	2	2	

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Activity	Rating 9/83	Targets 9/84	Targets 9/85	Proposed Actions
d. Quality assurance	2	2	3	
e. Problem solving	2	2	3	
f. Voluntary consent	3	3	3	
g. Efficiency	1	2	2	
h. Evaluation - feedback	1	1	2	
3. Data Processing and Analysis				
a. Data editing	2	2	3	
b. Data entry	0	1	2	
c. Generation of standard tables	0	1	2	
d. Interpretation of standard tables	1	2	2	
e. Writing of consultant reports	0	1	2	Microcomputer installation and training 84-85.
f. Additional analysis	0	1	2	
g. Writing of research papers	1	1	2	
h. Adaptation of new software	0	1	2	
i. Production of new software	0	1	1	
C. Training				
1. Ability to train new staff	1	1	2	
2. Training of investigators				
a. Routine data collection techniques	2	2	3	
b. Research methods/design	1	1	2	

Activity	Rating 9/83	Targets 9/84	Targets 9/85	Proposed Actions
c. Data interpretation/analysis	1	1	2	
3. Clinical training/New technology	0	1	2	
D. Policy Impact/Dissemination of Research				
1. Feedback mechanisms	1	1	2	FHI technical assistance; development of policy guidelines, government liaison. Shafiqur/Ferdaus important in thin role.
2. Dissemination to providers	1	2	2	
3. Linkage with policy makers	1	2	2	
4. Local publications	1	1	2	
5. Dissemination conferences	2	2	2	
6. Participation in international fora	1	2	2	
7. Linkage with potential clients	1	2	2	
E. Administrative				
1. Basic accounting system	2	2	2	
2. Knowledge of country requirements				
a. Taxes	1	2	3	Financial management consultant, administrative policies.
b. Insurance		2	3	
c. Employee benefits	Overall 9	2	3	
d. Salary restrictions		2	3	
e. Customs		2	3	
f. Drug regulations		2	3	

Activity	Rating 9/83	Targets 9/84	Targets 9/85	Proposed Actions
g. Foreign exchange	9	2	2	
h. Research regulating agencies	9	2	3	
3. Administration FHI Budgets	3	3	3	
4. Record keeping	2	3	3	
5. Personnel				
a. Decision making	2	3	3	
b. Staff recruitment	2	2	3	
c. Job descriptions	1	2	3	
d. Salary scale	2	2	3	
e. Lines of authority	1	2	2	
6. Budgeting	2	2	2	
7. Monitoring of finances	2	2	2	
8. Self-evaluation	1	2	2	
9. Responsiveness to outside evaluation	1	2	2	
10. Cost-sharing capability	1	2	2	

FRAMEWORK FOR POSSIBLE RESEARCH OVER FIVE YEARS

PROJECT TITLE	HYPOTHESIS	METHOD	START-UP AND NEEDS	FOLLOW UP/ YEARS	NUMBERS	ORGANIZATIONS INTERESTED	PRIORITY INTEREST
1. Progesterone-only OC (minipill) in breast-feeding women	Effects on: (a) Milk volume (b) Constituents/quality of milk (c) Acceptability and effectiveness as method of contraception (d) Neonate and infant: e.g. weight, diarrhea (e) Mother: e.g. thrombosis, menstruation	Straight or Comparative, with two brands and/or IUD	3 months 6 months Protocol ↓ Agreement ↓ Supplies + Contact for milk analysis with lab Training - BKS PENFIN	Each 3 months for 2 years	300 straight 200 each group Comparative	F.H.I. → BKS PENFIN → Min. Health → (MCH Subdirectorate)	High Medium Medium to low
2. Quinacrine insertion for sterilization	(a) Safe and effective means of tubal-occlusion-faster, easier than tubal ligation (b) Clinic outpatient procedure	Straight	3 months ↓ Protocol ↓ Agreement ↓ Supplies and training Data analysis	Each 3 months for 2-5 years	500+	F.H.I. → BKS PENFIN →	High High
3. Norplant Long term follow up	(a) Acceptability (b) Menstrual pattern changes (c) Use of fewer implants (d) Different configurations: e.g. Micro spheres (e) Removal problems and identification after implant (f) Effectiveness over 5 years (g) New method of insertion	Straight and Comparative of Norplant I versus II* *I=6 implants II=2 implants	3 months Need stable population Training as needed Protocol ↓ Agreement ↓ Supplies and training Data analysis	5 years	500+	F.H.I. → BKKBN → (safety) Min. of Health → BKS PENFIN →	High High High High

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FRAMEWORK FOR POSSIBLE RESEARCH OVER FIVE YEARS

PROJECT TITLE	HYPOTHESIS	METHOD	START-UP AND NEEDS	FOLLOW UP/ YEARS	NUMBERS	ORGANIZATIONS INTERESTED	PRIORITY INTEREST
5. OCs with and without iron	Iron in OC pack may reduce acceptance due to GI disturbances 60% women have Hb ↓ 10 Gms	Comparative 28 day OCs, last 7 pills with iron, or 21 day OCs	Immediate ↓ Protocol ready (FHI) ↓ Agreement ↓ Supplies ↓ Data analysis	1 year	100 each group	F.H.I. ⟶ BKS PENFIN ⟶	Medium Medium
6. Diet and breast feeding	Low protein, High CH, High fat, or Multiples Affects quality and quantity of breast milk	Comparative Diet histories and assessment Breast milk and infant feeding assessment (Wt. gain), etc.	Comparative 3 months Dieticians Protocol for illiterates and literates Agreement Data analysis	2-5 years	Large numbers Minimum 300 each group	Min. Health ⟶ BKKBN ⟶ F.H.I. ⟶	High (particularly) re: village population High (particularly) re: village population Moderate to low
6. High risk profile for trophoblastic disease	Identify high risk women ↓ Earlier intervention Reduce (?) risk of choriocarcinoma	Straight Retrospective Current prospective	Immediate Protocol ↓ Agreement ↓ Analysis	2 years	500 retrospective + Current	BKS PENFIN ⟶ F.H.I. ⟶	High High * * Would be considered only if private funding could be raised by FHI

FRAMEWORK FOR POSSIBLE RESEARCH OVER FIVE YEARS

PROJECT TITLE	HYPOTHESIS	METHOD	START-UP AND NEEDS	FOLLOW UP/ YEARS	NUMBERS	ORGANIZATIONS INTERESTED	PRIORITY INTEREST
7. MCH profile for early detection of high risk pregnancy (Continuation of previous work on MCH)	(a) Need to identify high-risk pregnancies particularly in villages (b) Develop protocol for use by field workers	(a) Straight Outcome analysis by computer (b) Develop profile	Analysis of available MCH data Develop profile Develop simple data forms Train health workers in villages Develop training Develop transfer systems Set up consultation mechanism Protocols ↓ Agreement	5 years Place computers, software in regional centers Training: (a) Field workers (b) computer personnel in regions (c) re: data transfer systems	5,000+	F.H.I. ⟶ BKS PENPIN ⟶ BKKBN ⟶ Min. of Health ⟶ UNFPA ⟶ * UNFPA has funded an MCH data collection project at regency hospital level; continued funding for last phase disapproved (see text of this report)	High-Medium High High High Unknown*
8. Radio-immunoassay standardization why	Need for standardization, and training lab personnel for Indonesian populations Prolactin, FSH, LH, Hcg, etc.	Train personnal and set up standards	Immediate Consultants, Supplies, Training in U.S.	Continuous	—	F.H.I. ⟶ BKS PENPIN ⟶ Min. of Health ⟶	Supportive* High High * FHI willing to serve as an intermediary to locate assistance from other sources.
9. New drug delivery systems e.g. injectables (microcapsules)	Apply new delivery systems to hormonal construction as they arise, e.g. Insulin, nitrates	Straight then Comparative	New systems, Modified or invented	—	—	F.H.I. BKS PENPIN Min. of Health BKKBN	Medium to Low

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FRAMEWORK FOR POSSIBLE RESEARCH OVER FIVE YEARS

PROJECT TITLE	HYPOTHESIS	METHOD	START-UP AND NEEDS	FOLLOW UP/ YEARS	NUMBERS	ORGANIZATIONS INTERESTED	PRIORITY INTEREST
10. Determinants of contraceptive choice in Indonesia	Why do women choose or reject a particular contraceptive method in Indonesia?	Straight Survey of clients	Immediate Protocol, simple	1 year	300	F.H.I. → BKS PENFIN → BKKBN →	Medium High High
11. Pregnancy diet and outcome, particularly in village	High risk factors in Indonesia (a) Premature labor (b) Stillbirths (c) Infant & neonatal mortality and morbidity (d) Trophoblastic disease	Use trained dietitians, or train Develop protocol Follow outcomes	3 months+ Identify and further train dietitians Develop protocols ↓ Agreement Data storage and analysis on regional microcomputers	5 years	10,000-50,000	BKS PENFIN → Min. Health → BKKBN → F.H.I. →	High High High Medium
12. Ultrasonic fetal growth mensuration in Indonesia (MCH-related)	Significant discrepancy noted in fetal growth estimates when using U.S. mensuration data (BPD, thorax, abdomen	Computer analysis of data. Development of formula for Indonesia Wt. born < determinations	Immediate + more training for BKS PENFIN specialist	2-5 years	1,000	BKS PENFIN → F.H.I. →	High Medium
13. Best contraceptive technique to use in delaying first pregnancy	Early marriage and Government + President urging delay 1st pregnancy to control family size	Comparative study OC, Vaginal ring, injectable implant, other	As soon as possible Protocol ↓ Agreement ↓ Supplies Sociologist, Demographers, field workers Conference & training	2 years	Newly weds, as many as possible	President Min. Health BKKBN BKS PINFIN F.H.I.	High Top Priority

NOTE: ...e evaluation team perceived no immediate interest in participation in drug trials except insofar as these bear a direct relationship to Indonesian health and family planning concerns.

FHRC SUMMARY SHEET

Appendix IX

INSTITUTION	PRIORITY RESEARCH	MOST IMPORTANT ACHIEVEMENT	HOW TO USE FINDINGS TO INFLUENCE NATIONAL DECISION-MAKING	ADDITIONAL INPUTS NEEDED BY FHRC	MISSING ACTIVITIES AT FHRC	OPTIMUM LONG TERM RELATIONSHIP WITH GOVERNMENT	SOURCES OF I SUPPORT
BKS PENFIN Indonesia	1. MCH 2. CCM	Recognition by gov't and collaborating centers for its role in research	Need to translate findings into usable terms	More skills in epidemiology, statistics, and evaluation of data	Studies in family health: prenatal care, breastfeeding, immunizations	To be seen as a tool of the government to study questions in family health	Generate own funds but al need outside support
Bangladesh Fertility Research Programme	1. Service research: - oral rehydration, immunizations, TBAs, growth monitoring, service levels 2. Clinical trials and survey research: - contraceptive safety, NFP - herbal medicines, motivation research	1. established research network 2. recruiting investigators 3. introducing new f.p. methods 4. disseminating findings 5. Giving info to govt	1. Organize workshops/seminars 2. Publication dissemination 3. Formulate specific recommendations 4. Form consensus with other organizations	1. Development of research training unit 2. Education abroad 3. Funds 4. Continued collaboration w/ FHI 5. Material support	1. Service research 2. Certificate course on research	1. Regular supply of info to govt 2. Govt membership on committees 3. Establishing easy project clearance mechanisms 4. Working with govt Field Offices when possible 5. Participate in govt forums	WHO UNDP Ford Foundat Government's Year Plan
Egyptian Fertility Control Association	1. Child morbidity and mortality 2. Safe and acceptable contraceptives	Building consensus on family health and family planning	1. Publishing and presenting findings 2. Involve leaders in deciding research priorities	Involvement of more health institutions in research	More communication and exchange with medical profession	EFCS to become research wing of National Family Planning Program	Limited govt or support
Family Planning Association of Sri Lanka	1. MCH/CCM 2. Acceptance of service delivery systems 3. Acceptance of new contraceptive technology 4. Long term effects of sterilizations	Public acceptance of need for family planning	1. Discuss findings at seminars attended by opinion leaders 2. Publish journal 3. Sponsor regular seminars	1. Staff Training 2. Add qualified new staff	More data needed on currently used methods of family planning	Become government's key research organization	IPPF and FHI
Sudan Fertility Control Association	1. Delivery of contraceptive methods 2. Delivery of MCH services 3. KAP in rural areas	Spawned interest in fertility care and management among professionals throughout country	1. Hold seminars and workshops 2. Send results to institutions and ministries	1. Strengthening administrative support 2. Microcomputer for data analysis		Collaboration in setting up model family planning service with both service and research	WHO and UNICEF
Thailand Fertility Research Association	1. MCH service delivery 2. Improve data collection, service statistics, follow-up, and motivational strategy	Research capability and collaboration among rural health and medical institutions	Findings have been used by NFPP	1. Training in research techniques and analysis 2. Microcomputer hardware and software	Nothing missing at present	Research coordinating body for National Family Planning Program (NFPP)	1. Developing self-relian through man power devel ment 2. Bilateral multilatera assistance, as well as private fun ing

APPENDIX IX

BKS PENFIN

Appendix X(a)

May, 1984

DRAFT - For Discussion

BKS PENFIN

Five Year Plan

(1984-88)

I. Goals and Objectives

A. Goals

1. To establish the BKS PENFIN as a self-sustaining independent center for family planning research in Indonesia, comprised of a multi-center network, in service to the natonal family planning program and capable of carrying out contract research for national and foreign agencies.

2. To provide the Government and people of Indonesia appropriate and useful information regarding the effectiveness, safety and acceptability of various contraceptive methods and regarding the risks and benefits of contraception and childbirth in Indonesia.

3. To contribute to the skills and capacity of individual investigators and institutions in Indonesia, especially within the BKS PENFIN network, to carry o high quality family planning research, including study velopment, planning, implementation, data processing, an lysis, and dissemination of information.

B. Objectives

1. To utilize FHI core support and other available resources to develop the BKS PENFIN's capacity to manage and implement high quality research, including in the first instance clinical trials at internationally recognized standards by 1988, through:

   - effective leadership and supervision of secretariat officers and staff

   - program of in-service training with FHI assistance

   - development of staff resources, including hiring of senior program officer and informatin coordinator to provide administrative direction and data analysis support.

2. To consult closely with the BKKBN and other relevant national and other family planning and health agencies to define research priorities and solicit funding support for specific studies.

3. To develop institutional skills and capacity to write research proposals to various potential funding agencies and to account adequately for all BKS PENFIN income and expenditure to the satisfaction of donor and funding agencies.

4. To undertake in collaboration with FHI or other funding agencies as appropriate a number of new studies during the period 1985-88 (following completion of the BKKBN biomedical research program in 1984) based on the attached framework of possible research, with the following prioritization (subject to future revision and changes):

   1) Project 7: MCM Profile
   2) Project 4: OCs with and without Iron
   3) Project 3: NORPLANT Follow-up
   4) Project 6: High Risk Profile for Trophoblastic Disease
   5) Project 8: Radio-Immunoassay Standardization
   6) Project 12: Ultrasonic Fetal Growth Menstruation
   7) Project 13: Best Contraceptive Technique to Delay First Pregnancy

5. To undertake, with appropriate training and technical assistance from FHI, one major multi-center case control epidemiological study, probably regarding long term sequelae of oral contraception in Indonesia.

III. PROJECTS APPROVED BY FHI SCIENTIFIC COMMITTEE AND PENDING FURTHER ACTION

Log #	TITLE	P.I.	FCO/ Status	Type of Project
	A. NFP PROJECTS			
21.	USA: Qualifications for NFP Providers	Kass-Annese	3420	4
23.	Haiti: Technical Assist. to NFP Projects in Haiti	Alarie/ Lanctot	3416 Local consult. being engaged	2
17.	India: Evaluation of Tamil Nadu NFP Program	Bernard	3417 Pend. fund.	2
25.	Kenya: Knowledge and Prevalence of NFP in Kenya	Nyanyi	3443 In develop.	3
29.	Multi-center NFP Study: Appropriateness of NFP for Breastfeeding Women			
	Egypt: Hassan — Protocol under development		3430	1
	USA: Labbok — Protocol under development		3431	1
	Australia: Gross — Protocol under development		3433	1
	Canada: Parenteau-Carreau — Protocol under develop.		3434	1
35.	Bangladesh: Tech Assist. to Caritas NFP Project	G. Ahmed	2248/3412 On hold pend. site visit.	2
47.	India: Family in Tech. Soc. Workshop	C. Bernard	3400 Approv. two speakers	6
50.	Egypt: RIA of Progesterone in Saliva (Info. needed from WHO - Peter Hall)	Sayed	3422 Sent to Peter Hall	1
55.	USA: Secondary Analysis of NFP Data (Chile & H. Klaus)	Labbok/ Klaus	3419 Prop. 10/84	1
66.	Thailand: Use Effectiveness of FP Methods in Southern Thailand	Thapa	3426 In Development	2
36.	Mexico: Billings Method Site Visit and Evaluation	Fuentes/ Potts	3415/3439	2
65.	India: Consultant Services for NFP Project with CREST in Bangalore	Thormann	3421 (See # 58)	4

59.	Philippines: NFP Continuers and Drop-out Study	Dowling/ Williamson	3440 Await site visit	2
61.	Egypt: Follow-up of OM Users - Phase I	Shea/ Langsten	3424 Develop. by Consultant	6
	Latin America NFP Meeting	Welsh	3436	6
	Nepal: Technical Assistance	Schubarth	3442	4
	USA: Vaginal Aspirator - Phase II	Schumacher/ Kennedy	3441	1

B. BREASTFEEDING PROJECTS

30. Multi-center study: Experiment to Increase Effectiveness of Breastfeeding as a Family Planning Method (Consultant preparing protocol: Dr. Meg McCann)

Philippines:	BF and Return to Ovulation-Phase II (Puertollano/ Valenzuela) - URBAN	Protocol under develop.	3427	5
Philippines:	Frequency of Suckling Study (Savina) - RURAL	Protocol under develop.	3428	5
Egypt:	Lactational Infertility among Night and Non-night Feeders (Sayed)	Protocol under develop.	3429	5

48.	Mauritius: Workshop in Infant and Child Feeding Patterns (WHO)	Carballo	3413 Info. requested	6
60.	Mexico: BF Research Conference	Rivera/ Kennedy/ Marcia Potts	3418 Under Develop.	6
62.	Niger: BF, Birthing and Child Spacing Practices among Nomadic Tuaregs	Hogle/ JoAnn Lewis	3435 Under Develop.	5
67.	USA: Breastfeeding Intensity Device	Wheeler/	3400	
	Africa or Latin America: BF Phase II Urban	Kennedy	3432	5

IV. ON-GOING PROJECTS

Log #	TITLE	PI/FHI Monitor	FCO/ Status	Type of Project
	A. BREASTFEEDING PROJECTS			
1.	Thailand: Longitudinal Study of BF and Return to Ovulation Phase I	Boonsri/ Robbins/ Kennedy	2162/3401	5
3.	Egypt: Longitudinal Study of BF and Return to Ovulation Phase I	Shaaban/ Kennedy	2164/3402	5
18.	Mexico: Longitudinal Study of BF and Return to Ovulation Phase II	Rivera/ Kennedy	2243/3403	5
44.	Pakistan: Return to Ovulation Phase I	Talat Khan/ Kennedy	2247/3404	5
7.	Philippines: BF Seminar and Special Issue of Journal of Biosocial Science	Thapa	2184/3405 sent to Journal 7/84	6
	B. NFP PROJECTS			
6.	Peru: NFP Evaluation	A. McKay/ Kennedy	2172/3406	5
11.	Bangladesh: "Safe Period" Study (Use Effectiveness Survey)	S. [illegible]-hman/ Th.	1203 Being Redesigned	3
12.	Egypt: Effectiveness of NFP in Urban Egypt Phase I	Mah[illegible]an/ Kennedy	2244/3407	2
15.	Sri Lanka: Traditional Contraceptive Survey (Dept. of Census and Statistics)	Fernando/ A. Evans/Thapa	2241/3408	2
16.	Sri Lanka: Use of Traditional and NFP Methods (Family Planning Association)	de Silva/ Thapa	2242/3409	3
20.	USA: Effectiveness of TODAY Sponge with and without Fertility Awareness	Kass-Annese/ K. Forrest/ Kennedy	2240/3410	1
46.	USA: NFP Review Paper (DDD)	Sullivan/ C. Hermann/ Williamson	2204/3414	6

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36. Mexico: Evaluation of Billings Method Site visit	Guzman/ Fuentes/ H. McKay	2204/3415 Scheduled for 9/84	2
58. India: NFP Among a Tribal Population in Vijayawada	Thormann/ Williamson	2204/3421 On Consult. basis	2
24. UK: NFP Attitudes of Physicians in Five Countries	Snowden/ Severy	3411	3
53. USA: Expert Meeting on Measuring Hormone Levels and Predicting Ovulation	Kennedy/ Campbell	3425	6
31. Indonesia: BF and Hospital Practices	Wiknjosastro/ Thapa	3413	5

THAILAND FERTILITY RESEARCH ASSOCIATION (TFRA)
FIVE YEAR PLAN
(1984 - 1988)

1. Background

The Government of Thailand first declared a Population Policy in 1970, and TFRA was established in 1979 in order to carry out family planning (FP) research and serve as a national center for family planning research in Thailand. TFRA is an independent, non-profit private organization which enlists capable researchers in private and public sectors to assist the work of the National Family Planning Program (NFPP) of Thailand. In developing this 5 year plan, several factors which follow have been taken into consideration:

(1) NFPP's plan in the 5th and the 6th National Socio-economic Development Plans of Thailand (1982-86, 1987-91). The national population target in the 5th Plan (1982-86) was to lower the growth rate from 2.0% (1982) to 1.5% by the end of 1986. It was expected that there would be about 4.2 million new FP acceptors. In the 6th Plan (1987-91), the national target by the end of 1991 is the growth rate of 1.0%. Over 4 million new FP acceptors will have to be recruited.

(2) Trends of new FP acceptors using various contraceptive methods. Decreases were detected in oral contraception and vasectomy while increases were seen in DMPA injectable contraception and IUDs. Female sterilization and condom use remained generally stable.

(3) Outcome of FP meeting in Chiengmai, in 1983.

(4) Outcome of FP meeting at the ministry of Public Health among the FP expert working group on research topics for 1984, in October 1983.

(5) Guideline of FHI's framework for development and evaluation.

(6) Evaluation of assistance by Family Health International (FHI) to TFRA, conducted in September 1983 by Dr. Pouru Bhiwandiwala and Ms. Sharon Epstein.

2. Goals and Objectives

2.1 Goals

(1) To establish TFRA as a national center for family planning research in Thailand.

(2) To provide NFPP, private FP associations, other FP-related governmental agencies and the Thai people with appropriate and useful information concerning the effectiveness, safety and acceptability of various contraceptive methods, and people's behavior and attitudes on their usage.

(3) To exchange FP information obtained from these research studies with other foreign FP agencies and the national family planning agencies of various countries in Asia and other continents.

2.2 Objectives

(1) To support TFRA so that it can serve as a research coordination group as well as an advisory body to NFPP.

(2) To conduct field trials of new contraceptives in terms of safety, acceptability and effectiveness and make recommendations to the NFPP concerning their usage.

(3) To conduct nation-wide survey research on maternal reproductive parameters and basic data on their children to identify regional problems in MCH care so that MCH services can be improved and provided accordingly nation-wide.

(4) To conduct some social and behavioral science research relevant to the clinical field trials carried out by TFRA or others.

(5) To disseminate the results of program activities through publication and various research papers within the country as well as to foreign countries, especially in Asia.

(6) To strengthen research and analysis skills among investigators in the TFRA network by means of conferences, study tours, seminars, or short courses in Thailand and elsewhere.

(7) To strengthen the utilization of a micro-computer in TFRA data processing and analysis for promoting the rapid feedback of research results to network investigators.

3. Five Year Plan for TFRA Activities

Training

1. A Research Design Course for investigators in the TFRA network (as well as other personnel concerned) to develop a greater research orientation and strengthen their knowledge and capabilities in research methodology.

2. Clinical Research Methodology "training of trainers" for research course instructors from TFRA or WHO CCR, in order to teach the course to other people.

3. Medical and Surgical Techniques and Skills required in the implementation of clinical research.

4. Form Filling and General Project Administration for project staff.

5. Computer technology, including use of TI-352 microcomputer, to be provided by FHI as replacement for the TI-1 unit.

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Clinical Research

1. A maximum of five new studies annually (see attachment I for suggested FP research topics).

2. A Committee of about three members to screen submitted research proposals and make recommendations for TFRA action.

3. Data Collection

4. Data Processing using the available computer and its software.

5. Data Analysis and Consultant Reports.

Dissemination

1. Newsletter (quarterly).

2. Inventory and abstracts of biomedical research in FP/MCH (finished and on-going) in Thailand (bi-annually).

3. TFRA research findings (periodically).

4. Meeting Proceedings (periodically).

5. Others.

Conference & Meeting & Seminar

1. Annual National Seminar to define needs for new and additional fertility research studies among key investigators and other potential experts from various agencies (to be attended by key investigators and policy makers).

2. International or Regional Conferences: At least two persons per year from the TFRA network of investigators to attend recognized international or regional conferences on fertility.

3. Investigators' Meeting for current and potential investigators to present their papers and exchange their views as well as learning the new events beneficial to the Thai setting.

General Administration

1. Advisory Committee Meeting (bimonthly).

2. Protection of Human Subjects Committee (semi-annually).

3. Research Screening Committee (semi-annually).

4. Financial Report (monthly).

5. Progress Report (quarterly).

6. Final Report of the Subgrant.

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7. Routine management, accounting, travel, customs, communications, meetings, etc.

Manpower

1. One full time associate research analyst is needed to be in charge of data analysis and preparing consultant reports, requiring a master's degree graduate with background in FP/MCH and computer skills, with excellent command of English.

2. One full time information officer to be in charge of the dissemination activities listed in item III.

The Royal Thai Government (through the MOPH) will provide office space and equipment, staff time, vehicles and some contraceptives and medical supplies.

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ATTACHMENT I

Suggested Family Planning Research Topics

1. Training

   1.1 Training Program For Female Sterilization.

2. Services

   2.1 Program Provided Sterilization For Intended Users.

   2.2 Accessibility and Availability of Male and Female Sterilization in the Rural Area.

   2.3 User and Non-User of Family Planning among the Special Target Groups of National Five Year Plan (Slum, Muslim, Hilltribe, Poverty Stricken Area).

   2.4 Study of the Reason of Non-use Family Planning.

   2.5 Operational Research on Expanding and Distribution of Family Planning Services to the Eligible Non-users.

   2.6 Study of the Mobile IUD Campaign in terms of Operation, Provider, Acceptor and Cost.

   2.7 Comparative Study of the Psychological Sequellae of Women Receiving a Post-Abortion, Post-partum and Interval Sterilization.

   2.8 Study of Potential Program Interventions to Reduce Adolescent Fertility.

   2.9 Study of Utilization of TBAs to Distribute Oral Contraceptives.

3. Information Education and Communication

   3.1 Effect of IE&C on Family Planning Acceptance.

   3.2 Study of Role of Women in Promoting MCH/FP in the Community.

4. Demographic

   4.1 Surveillance of Morbidity and Mortality of Infants at Village Level.

   4.2 Child Mortality Perception As a Determinant of Fertility Behavior.

   4.3 Effects of Reducing Infant Mortality and Morbidity on Family Planning Acceptance.

   4.4 The Impact of the Different Family Planning Methods on Fertility.

4.5 The Effect of the Decline of Breastfeeding on Fertility.

5. Policy

5.1 Changing Values of and Attitude Towards Birth Control with Special Emphasis on the "Hard-core" Population.

5.2 The Role of Official Leaders in Family Planning.

5.3 Policy and Program Necessary to Achieve 1% Population Growth.

5.4 Study of the Use of Research Results by Senior Program Managers.

6. Evaluation

6.1 Demographic and Health Impact of "Risk Approach" in Family Planning Services.

6.2 Follow-up Study of Injectable Contraceptives Provided by Auxiliary Midwives.

February 1984

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FIVE-YEAR PLAN FOR THE FAMILY PLANNING ASSOCIATION OF SRI LANKA FHRC

I. GOALS AND OBJECTIVES

A. Goals

1. To establish the SL/FPA as a national center for family planning research in Sri Lanka

2. To provide the Government and people of Sri Lanka with appropriate and useful information regarding the effectiveness, safety, and acceptability of various contraceptive methods.

B. Objectives

1. To increase the range and quality of research undertaken by the FPA/SL

   a. To be able to design and analyze clinical trials at internationally recognized standards by 1988.

   b. To be able to design and analyze complex sample surveys at internationally recognized standards by 1988.

   c. To create a data base, from historical FPA clinical data and other sources, suitable for retrospective biomedical and epidemiologic analysis by 1986.

   d. To develop solid basic epidemiologic expertise by 1988.

   e. To develop the capacity to analyze all data from FPA studies by computer by 1986, and to become a service center for computer analysis by 1988.

2. To increase the budget for research at the FPA in both size and variety of sources

   a. By 1988, to increase the research budget in 1983 dollars.

   b. To maintain a steady level of FHRC subgrant support at about $50,000 per year by 1988.

   c. To increase FHI contract research support to approximately $50,000 per year by 1988.

   d. To develop at least two new sources of contract research support by 1988.

3. To widen the research network of the FPA.

   a. To increase the number of participating clinical trials centers to at least 10 by 1986.

b. To establish a sample of Rural Health Services Programme villages as a permanent base of rural family planning research by 1986.

4. To increase the impact of the FPA on national family planning policy

a. To create a family health journal in 1984, and to have that journal fully established as a national journal with a solid scientific reputation by 1987.

b. To establish a series of mechanisms to determine and respond to national research needs in 1984.

c. To maintain and improve its status as a research resource for the Government.

d. To develop a variety of information dissemination mechanisms appropriate to ensure proper utilization of research findings.

II. IMPLEMENTATION STRATEGIES

A. Increasing range and quality of research

1. Clinical Trials. The FPA should have at least 3 clinical trials underway at all times. The Director of Clinical Services needs additional statistical training, involving workshops and seminars where appropriate, and continuous training by FHI through staff visits and correspondence. The medical statistician should obtain basic training in clinical trials methodology. Clinical trials software should be used at the FPA as soon as possible. FHI should systematically edit and criticize FPA research papers.

2. Survey Research. There should be a continuous process of upgrading the technical aspects of FPA surveys, especially in analysis. Training should be sought to fill any gaps in the technical capabilities of the Assistant Director of Evaluation and Research. Two additional assistants should be trained in survey research methodology.

3. Data Base. Plans to computerize the FPA records, both retrospectively and prospectively, should be inplemented. Also, centers contributing to the network should be assisted in developing strong record systems, and these and other sources should be used to augment the FPA's data base. FHI consultation should be sought early in this process.

4. Epidemiologic Expertise. Basic epidemiologic training should be obtained for at least one member of the FPA staff. National consultants should be identified and utilized.

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5. Computer Skills. The TI microcomputer should be installed as soon as possible. Computer skills should be improved gradually until at least 2 staff members have strong programming skills and all other analysts should be trained in software use. FHI research analysts should spend about one month per year at the FPA helping to analyze data and train analysts.

B. Financial Status

1. As its staff capacity increases, the FPA should agressively seek increased research support from existing and new sources.

2. TTD will facilitate linkages between the FPA and the other four FHI departments, developing contract research as much as possible within the FPA's competence and capacity.

3. As the FPA improves its abilities and reputation in a particular area, TTD and the FPA will look for contract possibilities in that area, and concomitantly reduce grant support.

4. TTD will assist the FPA in obtaining the widest possible international dissemination of its research papers and findings.

C. Research Network

1. The FPA will recruit collaborating investigators both in Colombo and elsewhere, among physicians with appropriate case loads and interests.

2. A small amount of money will be set aside each year for "investigator needs" studies to be done by investigators outside the FPA.

3. The FPA will set up training programs for investigators.

4. Investigator meetings and workshops will be sponsored as appropriate to stimulate interest.

5. A sample of Village Family Health Program villages will be selected to participate in a rural data base. Services for those villages will be maintained on a long-term basis, with some rotation of villages in and out of the sample. Basic data will be collected along current lines, but will be strengthened and computerized. Members of appropriate District Councils will be trained and involved in management and communications.

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D. Influence on Policy

1. The Family Health Journal will be initiated in 1984, with a full-time editor and a volunteer editorial board. At first, the subject matter will be family health in a broad sense, and will not require rigorous research standards. Over time, the focus will narrow and the quality will increase. Throughout, the journal will include non-technical information, both national and international, of importance to family planning professionals in Sri Lanka.

2. The FPA will work to have established in the Government a research advisory group.

3. The Executive Director and the Director of Evalution and Research will review each study to determine the appropriate dissemination strategy.

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APPENDIX XI

TRAINING ACTIVITIES SUPPORTED - FY '82, 83, 84

Completed and Ongoing

1. Travel support for FP/MCH Research Trainees from Latin American countries to the Corporacion Centro Regional de Poblacion in Bogota, Colombia

2. Mexico: Family Planning Educational Modules for Medical Schools

3. Mexico: Training in Contraceptive Technology in Social Sciences

4. Ecuador: Seminar on Advances in Human Reproduction and Contraception

5. Mexico: Translation of Manual for Vasectomy Counseling

6. Ecuador: Support for Lecturers to a Seminar on Population

7. Brazil: Travel Support for Vasectomy Trainees

8. Egypt: Training Materials in Contraceptive Technology for Pharmacists and Physicians

9. Egypt: Maternity Care Monitoring Workshop

10. Panama: Symposium on Contraceptive Research

11. Senegal: Contraceptive Technology Seminar

12. Egypt: Clinical Trials Research Workshop

13. Noyes Foundation Clinical Trials Workshops (2)

14. Honduras: Research Methods Seminar

15. Training for Computer Programmers from FHRC's

16. Haiti: Seminar on Voluntary Sterilization

17. Gambia: Applied Research Methods Workshop

18. Mexico: Reproductive Biology Seminar

19. Mexico: Epidemiology Training

20. Mexico: Medical Demography Seminar

21. Egypt: Pharmacist/MD Training Materials

Planned and In-Development

1. Mexico: Evaluation of FP Training for Nurses
2. Mexico: Evaluation of Training in Voluntary Sterilization
3. Philippines: Contraceptive Technology Workshop
4. Sri Lanka: Seminar for Traditional Healers in FP
5. Brazil: Translation of Vasectomy Manual
6. Peru: Advanced Contraceptive Methods Research Training

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CONSULTANT ROSTER
PROGRAM EVALUATION DEPARTMENT
October 1984

Appendix XII(a)

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CONSULTANT ROSTER
PROGRAM EVALUATION DEPARTMENT
OCTOBER 1984

1. Dr. Kenneth Campbell, organizing Expert Meeting in Measurement of Hormonal Levels

2. Dr. Aphichat Chamratrithirong, Thai Projects (1985)

3. Dr. Armando Cifuentes, Peru NFP Project

4. Dr. Ann Evans, Sri Lanka Census Department Traditional Contraceptives Study

5. Dr. Karen Foreit, Honduras MCHIFP Services (start January 1, 1985)

6. Dr. Katherine Forrest, Consultant to Sponge Study in Los Angeles

7. Dr. Bejar Fuentes, Mexico. NFP Consultant, Mexico site visit

8. Mrs. Barbara Gross, Consultant to Kenya site visit, BF and NFP multi-center study

9. Dr. John Hedderson, University of Texas, consultant to Mexico FEMAP project

10. Dr. Jaroslav Hulka, Female Circumcision Project, Egypt

11. Dr. Valerie Hull, Indonesia Hospital Practices Toward Breastfeeding Study

12. Dr. John Knodel, Thailand projects (1985)

13. Sister Francesca Kearns, Peru NFP Project

14. Dr. Claude A. Lanctot, Haiti NFP activities

15. Dr. Ray Langsten, Egypt NFP and Breastfeeding Projects

16. Dr. Michele Lioy, Mali, Senegal, Ivory Coast (1984)

17. Dr. Meg McCann, Breastfeeding Projects

18. Dr. Arlene McKay, Peru NFP Project Evaluation

19. Dr. Harrison McKay, Mexico's Site Visit (evaluation of Billings clinics)

20. Ms. Elisa Munoz, NFP Consultant, Mexico site visit

21. Dr. Peerasit Kamhuansilpa (1985)

22. Mrs. Marcia Jaffe Potts, Consultant for projects in Spanish-speaking countries

23. Mrs. Maria Claudia de Ramirez, Peru NFP Project

24. Dr. Larry Severy, Study on Attitudes and Knowledge of Physicians toward NFP, FP and BF

25. Dr. Mary Thormann, Study of NFP among a tribal population in India

26. Ms. Mary F. Vandenbroucke, Mexico FP site visit

FY 84 FHI CONSULTANTS

NAME	PROFESSION	AFFLIATION
CAMPBELL, William	Attorney	Institute of Government, UNC, Chapel Hill, NC
CIFUENTES, Armando	MD, Epidemiology Director	Family Action Program, Cali Colombia
De RAMIREZ, Maria Claudia	Psychologist	Private Practice, Cali, Colombia
DENNIS, Betty	Assistant Professor	School of Pharmacy, UNC, Chapel Hill, NC
EDELMAN, David	PhD, Biostatistics President	Medical Research Consultants Chapel Hill, NC
EPSTEIN, Sharon	MPH, Maternal/Child Health, Consultant	UNFPA, New York, NY
EVANS, Ann	ScD, Population Dynamics Assoc. Health Specialist	Westinghouse Electric Corp. Columbia, MD
FORREST, Katherine	MD, MPH Medical Director	Planned Parenthood of Santa Clara County, California
FORTIER, Lise	MD, OB/GYN Clinical Professor	School of Medicine, Univ. of Southern California
GLENN, Dorothy	MD, OB/GYN Clinical Consultant	JHPIEGO, UNFPA and the World Bank
GOULD, Elizabeth	Writer/Editor	East-West Population Institute Honolulu, Hawaii
GRAY, Mary Jane	MD, Director of Gynecological Services	Student Health Servics, UNC Chapel Hill, NC
GROSS, Barbara	Research Associate	Westmead Centre, Westmead Australia
HAFEZ, Mohamed	MD, MPH Program Officer	Egyptian Fertility Care Society, Cairo, Egypt
HERNANDEZ, Gloria	Nurse	University of Juarez, Durango Mexico
HOFFMAN, Jerome	MD, Associate Clinical Professor	Baylor College of Medicine Houston, Texas
HOGLE, Janice	PhD, Medical Anthropology Clinical Instructor	Univ. of New Mexico School of Medicine, Albuquerque, NM

KASS-ANNESE, Barbara	Nurse Project Coordinator	Los Angeles Regional Family Planning Council, Los Angeles CA
KEARNS, Francesca	Nurse Executive Director	World Organization of Ovulation Method, Guatemala
KING, Theodore	MD, OB/GYN President	Johns Hopkins Program for Int. Education in OB/GYN, MD
LANCTOT, Claude	MD, OB/GYN Executive Director	Int. Federation for Family Life Promotion, Washington, DC
LAUFE, Leonard	MD, OB/GYN Professor	Univ. of Texas Health Sciences Center, San Antonio, TX
LONDON, Steve	MD, OB/GYN Associate Professor	Duke University Medical Center Durham, NC
MCCANN, Margaret	Writer/Consultant	Johns Hopkins University, Baltimore, MD
MCKAY, Arlent	PhD, Psychology	Institute for Social Research Ann Arbor, MI
MONTEIRO, Lois	PhD, Sociology Associate Professor	Brown University Providence, RI
NICHTER, Mimi	Research Intern	East-West Communications Institute, Honolulu, Hawaii
OMRAN, Abdel	MD, OB/GYN-Epidemiology	Dept. of Epidemiology UNC, Chapel Hill, NC
OMRAN, Kay	MD, Epidemiology	Johnson City Medical Center Johnson City, TN
PARENTEAU-CARREAU, Suzanne	MD, Medical Director	SERENA-CANADA Quebec, Canada
PHILLIBER, Susan	PhD, Sociology, Director of Adolescent Soc. Science	Center for Poulation and Family Health, Columbia Univ. NY
PHILLIPS, Steven	MD, Director of Environmental Health	EXXON Corp. East Millstone, NJ
POLLACK, Marjorie	MD, Epidemiology	Private Consultanting Practice Atlanta, GA
POTTS, Marcia	Health Education Consultant	Formerly FHI Staff member RTP, NC
PRICE, Robert	Attorney	Jordan, Brown, Price & Wall Raleigh, NC

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REED, John Jr.	PhD, Sociology Associate Professor	University of North Carolina Chapel Hill, NC
RIVERA, Roberto	MD, Director	Institute de Investigacion Cientifica, Durango, Mexico
ROSENFIELD, Allan	MD, OB/GYN Director	Center for Population and Family Health, Columbia Univ. NY
SACHS, Benjamin	MD, OB/GYN-Perinatology Director of Obstetrics	Beth Israel Hospital Boston, MA
SCHUMACHER, Gebhard	MD, OB/GYN	Dept. of OB/GYN, Pritzker School of Medicine, Univ. of Chicago, IL
SEEDS, John	MD, OB/GYN Assistant Professor	Dept. of OB/GYN & Radiology School of Medicine, UNC, Chapel Hill, NC
SPEIDEL, Joseph	MD, Vice President	Population Crisis Committee, Washington, DC
TOUMI, Liliane	MD, OB/GYN Consultant	JHPIEGO, Population Council, INTRAH
WINGATE, Martin	MD, Professor and Assistant Dean	State Univ. of New York, Buffalo, NY
WRIGHT, Nicholas	PhD, Sociology Research Associate	Center for Population and Family Health, Columbia Univ. NY
ZIPPER, Jaime	MD, Parasitology/Physiology Professor	Reproduction Laboratory University of Chile, Santiago, Chile
FUENTES, Luis	PhD, Urban & Regional Planning	Free Lance Researcher/Consultant Colima, Mexico
DeMUNOZ, Elisa	Registered Nurse Principal Associate	Los Angeles Regional Family Planning, Los Angeles, California
VANDENBROUCKE, Mary	Registered Nurse Nursing Supervisor	Research and Education Institute Torrance, California
CALDERON, Miguel	Survey Coordinator	Management Sciences for Health Tegucigalpa, Honduras