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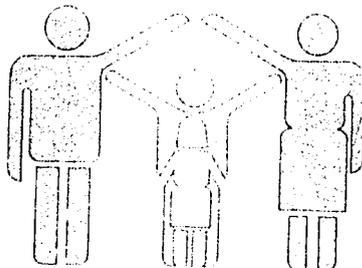
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Institute
for
International
Studies
in
Natural
Family
Planning

TECHNICAL PROGRESS REPORT

October 1, 1986 - March 31, 1987

Cooperative Agreement DPE-3040-A-00-5064-00
Georgetown University



PROGRESS REPORT

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LIST OF ABBREVIATIONS

AF	Action Familiale
AID	Agency for International Development (Washington)
ATLF	Asociacion de Trabajo Laico Familiar
BBT	Basal Body Temperature
CA	Cooperating Agency
CEIPLAN	Centro de Enseñanza e Investigacion de la Planeacion Natural de la Familia
CENPAFAL	Centro de Pastoral Familiar para America Latina
CENPLAFAM	Centro de Planejamento Natural de Familia
CEVIFA	Centro de Vida Familiar
CM/BBT	Cervical Mucus/Basal Body Temperature
CPAIMC	Centro de Pesquisas de Assistencia Integrada a Mulher e a Crianca
E-G	Estrone Glucuronide
ELISA	Enzyme Linked Immunosorbent Assays
FEMAP	Federacion Mexicana de Asociaciones Privadas de Planificacion Familiar, A.C.
FHI	Family Health International
FLACAM	Family Life Association of Cameroon
FLMZ	Family Life Movement of Zambia
FLPL	Family Life Promotion Center of Liberia
FPOP	Family Planning Organization of the Philippines
FRP	Follicle Regulatory Protein
FSH	Follicle Stimulating Hormone
IEC	Information, Education and Communication

IFFLP	International Federation for Family Life Promotion
JHU	Johns Hopkins University
LDC	Less Developed Country
LH	Lutinizing Hormone
MCH	Maternal and Child Health
NICH	National Institute for Child Health and Human Development
NIH	National Institutes of Health
NFP	Natural Family Planning
OR	Operations Research
FCS	Population Communication Services
PDG	Pregnanediol Glucuronide
PROVIFA	Movement Pour la Promotion de la Vie Familiale
RIA	Radioimmunoassay
USAID	United States Agency for International Development (Country Missions and representatives)
WHO	World Health Organization

I. Introduction and Executive Summary

This report describes the activities of the Institute for International Studies in Natural Family Planning under United States Agency for International Development (AID) Cooperative Agreement DPE-3040-A-00-5064-00 for the period 1 October 1986 through 31 March 1987. During the third reporting period under this agreement, the three institutions which form the Institute -- Georgetown University and its major subcontractors, the University of Pittsburgh Graduate School of Public Health and the Los Angeles Regional Family Planning Council -- continued to implement a broad program of work to achieve the Institute's goal of improving the knowledge, availability, acceptability, and effectiveness of natural family planning (NFP) in developing countries.

In biomedical research, the Institute's highest priority is in the area of new methods of monitoring the fertile period. Institute staff have met with pharmaceutical companies and academic researchers to encourage collaborative activities for the development and testing of a "dipstick" appropriate for home use to detect enzyme/hormone changes during the menstrual cycle in saliva or urine. This will provide women with an objective, accurate means to predict the beginning and identify the end of their cyclical fertile phase and should dramatically increase the number of women for whom NFP will be the method of choice. Three very promising proposals are being considered for funding, and negotiations are underway to conduct clinical trials for two potential home test kits. A study has been completed on a simple device to monitor the fertile phase through salivary enzyme fluctuations. In addition, the Institute is working with the University of Tennessee (in collaboration with two universities in Chile and an NFP program in Peru) to conduct a study on NFP use and pregnancy outcome, which addresses the issue of the possible negative effect of aged gametes. Assistance was provided to establish the three study sites, and the data management system was developed.

In collaboration with Family Health International (FHI), the Institute is studying the ability of breastfeeding women to use current NFP methods effectively. This study has been initiated in three sites (two with Institute support). A study of breastfeeding women's ability to use NFP during their first three postpartum menstrual cycles is underway with the Maryland - D.C. NFP Providers Association. For this effort, the Institute has tentatively identified a collaborating center in Kenya that has

close contact with experienced NFP users who are breastfeeding, and that is capable of following a rigorous research protocol that includes daily urine collection and storage. Their participation will be an important component of this on-going study. The significance of studies of breastfeeding women and NFP rests on the fact that a large number of women who are potential users of NFP need to learn the method during their transition period from breastfeeding to weaning to non-breastfeeding.

Discussions continued regarding a joint multi-country project with the World Health Organization (WHO) on breastfeeding practices and the postpartum return to fertility, and a study with a Latin American university on the effect of full nursing on fertility during the first six months postpartum.

In operation research, the Institute is developing a study with Action Familiale in Mauritius to test the efficiency and effectiveness of group or individual teaching in NFP, and another study to assess (prospectively) the characteristics of long-term NFP users and address the issue of the autonomous user of natural methods.

The Institute also is interested in the ability of multi-method programs to successfully provide NFP services. Currently, training and technical support are being provided to Centro de Pesquisas de Assistencia Integrada a Mulher e a Crianca (CPAIMC)/Brazil to enhance the successful implementation of their Pathfinder-funded NFP project; and a project is being developed with FPOP/Philippines to train their staff to provide NFP outreach and services, to be followed by a research project to assess program outcomes.

The Institute is studying the impact of breastfeeding promotion programs, particularly those which include an emphasis on breastfeeding practices which may contribute to child spacing. In addition to being consistent with the Agency's child survival efforts, this also appears to be of interest to a number of host country governments and MCH NGO's. Currently, the Institute is working with Federacion Mexicana de Asociaciones Privadas de Planificacion Familiar (FEMAP)/Mexico to conduct a study of breastfeeding promotion programs utilizing community health workers. Both training and educational materials developed with FEMAP will be adapted to the needs of other programs. The Institute is preparing a paper on breastfeeding in Africa (to be distributed by mid 1987), which will offer guidance to a number of program efforts.

During this reporting period, the Institute's Data Center has been established to assess and analyze existing data from NFP programs, to develop standards and promote consistency in data collection, and to provide technical assistance and consultation to less developed country (LDC) organizations. The Data Center is collaborating with other cooperating agencies to establish linkages for data sharing and cooperation with NFP providers in developing countries.

In social science research, the Institute's primary interest is in psychosocial factors affecting NFP use, including acceptance, ability to learn the method(s), continuation, and effective use. In this area, a project is being developed with Action Familiale/Mauritius to conduct a prospective study of autonomous users, and issues of psychosocial factors also are being addressed in our projects with the multi-method programs. With an archdiocesan NFP group in Ecuador, the Institute is designing focus group research on several topics of importance in this area. Another Institute paper on psychosocial issues in NFP will be distributed later this year.

In training, the Institute is developing an NFP Trainers Learning Package. This is a comprehensive package that guides an NFP trainer through the training process and will enhance the quality of NFP training programs. It includes guidelines for participant selection, a suggested training design, content, training methodology, audiovisual materials, and evaluation. Centro de Pastoral Familiar para America Latina (CENPAFAL)/Colombia is incorporating parts of it into their instructors training course, Family Planning Organization of the Philippines (FPOP) will incorporate it into their program, and it will be used in Ecuador for an instructor's update course. In addition, a Training of Trainers course in English is being planned for June, with courses in Spanish and French planned for FY'88. The curriculum for these courses is being developed in collaboration with the University of California Santa Cruz International Health Program. Instructor training programs are being conducted with organizations in Colombia, and are planned for Ecuador, Bolivia, the Philippines, the Ivory Coast and Brazil.

In another important training area, the Institute is working with NFP programs to improve their outreach efforts and management systems. As is the case with fledgling family planning NGO's the world over, the efforts of small grassroots organizations are seriously hampered by a lack

of skill in outreach and management. This issue is being addressed in Mauritius, Liberia and Zambia through an institutional analysis to determine specific needs, a workshop [in collaboration with Johns Hopkins Population Communication Services (JHU/PCS)] on selected management and outreach issues, and technical assistance to further improve outreach and management. This approach will substantially increase the ability of NFP programs to provide quality services to a broader client population and to participate effectively in national population programs.

The Institute's outreach, education and communication strategy emphasizes promotion of NFP through educational research, mass-media and materials development, and training efforts. Materials development projects have been designed with two institutions in Mexico and one in Peru; and materials development is an important component of other Institute-supported activities in training and research. The Institute Resource Center has provided information services to individuals and organizations from twelve countries. A comprehensive glossary of NFP terms has been developed and is ready for final review and publication. This and other Institute publications, such as monographs and training packages, will be disseminated through the Resource Center as part of the Institute's outreach efforts.

II. Project Management

During this reporting period, the Institute continued to develop the management and administrative systems that are crucial for a project based in three separate institutions. The roles of the three institutions were more clearly defined, and a monthly reporting system was implemented.

A meeting of the Institute's Technical Advisory Group (TAG) was held at Georgetown University in November. At this meeting, numerous proposals and on-going projects were reviewed. The next TAG meeting is scheduled for May. Given the changing needs of the Institute, the role and composition of the TAG are being reviewed. It is anticipated that following the May meeting, the TAG will be re-structured to meet the Institute's current needs.

The Georgetown University Advisory Committee continues to coordinate the Institute's activities with other University programs, both national and international, and to provide policy guidance to the Institute.

During this reporting period, Rosalia Rodriguez-Garcia has joined the Institute staff as Director of Education and Communication. Her responsibilities include developing outreach/IEC and educational strategies and field projects, monitoring all Institute IEC activities, and coordinating between Georgetown University and the Los Angeles Family Regional Family Planning Council.

III. Research

A. Biomedical Research

During the third six month period, the Biomedical Research Division of the Institute has continued to provide both research development and support for intramural and extramural research interests in our five priority areas:

- o Develop new and improve existing methods of predicting ovulation and determining the fertile period;
- o Increase knowledge regarding the mechanism of breastfeeding as a method of childspacing and identify how specific breastfeeding practices affect fertility;
- o Assess the ability of current NFP and new natural methods to meet the needs of women of different reproductive states (e.g. breastfeeding/postpartum, perimenopausal, and different health statuses, e.g. with vaginal infection);
- o Determine the relationship between NFP practice and pregnancy outcome;
- o Define the duration of the fertile period, including further evaluation of the functional life span of the sperm and ovum in various reproductive states (follicular/luteal phase, lactation, etc).

Our work has been based on the strategies which were developed through literature reviews, discussions with the TAG, and meetings with other professionals in the field. In the last six months, biomedical scientists from the Institute staff have been engaged in extended discussions with pharmaceutical companies and notable scientists world wide. In addition to the research designed and conducted by the Institute staff, other proposals have been received and are at various points in the Institute review process. Two biomedical research projects are near completion, and four are ongoing. Several proposals are in the final review process and are expected to begin in the next six months.

The Institute's activities according to its established priorities are as follows:

1. Develop new and improve existing method for predicting ovulation and determining the fertile period.

State-of-the-Art Review of Ovulation Prediction

The Institute has completed a review paper which outlines the currently available techniques used to predict ovulation and determine the fertile period. This monograph reviews the symptothermal and ovulation method of determining the fertile period and summarizes the methodologies now available for monitoring the menstrual cycle in the most

obtainable body fluids, including urine, saliva and cervical mucus. In addition, novel research and clinical technologies being developed both in the United States and abroad are discussed. The Institute plans to publish this paper as a monograph by the end of FY'87.

Research Laboratory

The Institute's laboratory, located in the Department of OB/GYN at Georgetown University Medical Center, has continued to provide its services during this period. The laboratory is the primary site for the assays for two studies related to NFP in breastfeeding women, one in the area of ovulation prediction, and one related to mechanical breast pump stimulation in breastfeeding women. It also is designed as a reference laboratory that has begun the validation of new assays measuring urinary steroid conjugates with standard radioimmunoassays (RIAs) for estrone-glucuronide (E-G), pregnanediol-glucuronide (PDG), plasma prolactin levels, urinary LH and ultimately follicle stimulating hormone (FSH). Urinary steroid assays are normalized with urinary creatinine measurements by a modification of the Jaffe method incorporating microtiter plate technology to streamline this technique.

The Institute laboratory is near completion of the establishment of normative levels of these hormones and hormone metabolites in cycling women and/or breastfeeding women through the return of their ovarian function and fertility. The RIAs will also be used to validate new developments in ELISA, chemoluminescent, magnetic and inhibin-like peptide assays and new dip-stick technology that will be used to predict the fertile period and ovulation.

Collaborative Studies

The Institute has made considerable progress in establishing collaborative activities on the validation and monitoring of a variety of novel hormone assay systems and the establishment of new hormonal markers for detecting ovulation and defining the fertile period in both normally cycling and breastfeeding women. In this regard the Institute reference laboratory has received site visits from commercial companies both in the United States and abroad in preparation for collaborative projects which will contribute to the rapid development and availability of home tests for monitoring the fertile phase. These ventures will incorporate the resources of the Institute's Reference Laboratory and the expertise of both nationally and internationally recognized scientists currently working in the areas of fertility and reproductive endocrinology. This collaboration involves the use of ELISA technology for rapid and sensitive steroid and steroid conjugate measurements, chemoluminescent and other energy transfer assays which will

be useful in research laboratories as a cost effective means of performing these assays and ultimately reduce or eliminate the use of radioactive nuclides in hormone measurements. An international symposium is being planned by the Institute and the National Institutes of Health, Bethesda, Maryland, to address the research implication of these new non-radioactive methods in laboratory hormone analysis.

Extramural Proposals

Several proposals were presented to the TAG in November and are currently in the final stages by revision. These include the development of an at-home estrogen test, assessment of the proliferation of a follicular regulatory protein for ovulation prediction, a novel approach to a solid phase ELISA assay for urinary and salivary steroids, the production of novel second antibodies to steroid antibody complexes, and to generate new monoclonal antibodies to unique urinary steroid metabolites. In conjunction with these proposals, Institute biomedical staff are continuing to encourage the private sector to recognize the need for self-monitoring of ovarian function to be used in conjunction with other methods of natural family planning.

The Institute is nearing completion of its collaboration with Personal Diagnostics, Inc., in their development of a multiple, simultaneous, endocrine-responsive salivary enzyme testing kit that will be used to delineate the fertile period in both normally cycling and lactating women. During the past six months, women have been recruited and entered into the study. Salivary enzymes as well as urinary hormones measured in the reference lab are being correlated. The study is expected to be completed by May, 1987. (See section VII.)

The Institute is currently collaborating with investigators at the University of Southern California in measuring alterations of one of the inhibin-related peptides in urine during the normal menstrual cycle. These gonadal glycoproteins are emerging as the newest class of intra-ovarian molecules that modulate gonadal function including selection of the dominant follicle, lutenization, and possibly ovulation itself. Preliminary data from this collaboration has proved extremely promising, and additional work is currently ongoing. Results of these studies may provide important information to couples who need additional assistance or reassurance in using NFP, particularly during the learning phase, breastfeeding or premenopause.

2. Increase knowledge regarding the mechanism of breastfeeding as a method of child spacing and identify how specific breastfeeding practices

affect fertility.

Establishing Hormone Profiles

The funded proposal with Johns Hopkins University, on the study of "Predictors of Ovulation during Lactation in Manila, Philippines" (see Section VII) is in its final phase. It is hoped that consistent, specific hormonal profiles provided by this study will correlate with specific breastfeeding practices of the women enrolled, i.e. that efficacy of lactation as a method of family planning may be dependent on the patterns of breastfeeding or infant supplemental feeding. (See Section VII)

Identifying Patterns of Lactation and Amenorrhea

At the November TAG meeting, a joint proposal between the Institute and the World Health Organization (WHO) was presented. This study will examine the role of population dependent variables in determining the return to menses and seek to explain differences between populations that numerous investigations have previously noted. Hopefully it will allow us to draw conclusions related to breastfeeding practices and fertility which are applicable to all groups of women regardless of geographic location and socioeconomic status. This pilot study was met with unanimous support by the TAG. The initial phase of the study in six developing countries is currently underway. The Institute is collaborating with WHO on protocol revisions and the implementation of field studies. In the next six months the Institute anticipates selecting two developing countries in which to support the full study.

Breastfeeding Subgroups

A third approach relates to the ability of lactation to serve special groups of women as an appropriate method of childspacing. Two groups of women in particular are known to have difficulty with lactation and could be well served by increasing knowledge of the role of manual expression and breast pumping in maintaining milk supply and delaying the post-partum return of fertility. The first are women who deliver prematurely or deliver a term infant requiring extensive hospitalization and are unable to initiate a supply of breast milk by breast pumping. These women have difficulty maintaining the supply until their infants are well enough to nurse at the breast. Secondly, many women successfully initiate lactation but by choice or necessity return to work and become "part time breastfeeders." They too have problems maintaining a sufficient supply of milk and frequently choose to provide essential supplements to their babies and/or to substitute other feeds entirely. Both of these groups have a rapid return of ovulation in the post

partum period and fail to gain from the potential benefits afforded by lactation.

To begin to answer questions related to milk production and fertility status of women who fall into one of these groups, the Institute staff has assisted in the development of a protocol with the Capital Area Milk Bank (based at Georgetown University). A final protocol was developed and approved for funding in the volumes of milk and prolactin responses obtained March, 1987. This study will attempt to assess how they relate to various milk let-down techniques, including manual expression as well as a variety of mechanical pumps.

Protective Effect of Full Breastfeeding

Institute staff and consultants have worked with investigators from Catholic University in Chile to revise a proposal which has been presented at the past two TAG meetings. The proposal is designed to study 500 fully lactating women who are using no other form of contraception for the first six months post partum. At the end of six months the women participating in the study would be offered instruction in natural methods of family planning. Conception rates during the first six months of lactation as well as NFP acceptance and continuance rate would be studied. A final proposal is expected by mid 1987.

The Institute has also evaluated two proposals to review several computer tapes on file at Johns Hopkins University that contain data on signs and symptoms of NFP in lactating women. These data sets contain complete NFP charts in lactating women and will allow extensive evaluation of the NFP signs and symptoms which are predictive of fertility. These analyses may yield useful data about the return to fertility among cultural groups with very different breastfeeding patterns.

Finally, during this reporting period, a study to determine the underlying physiologic mechanisms responsible for lactation induced infertility has begun in collaboration with NIH researchers. While Institute staff have been responsible for developing the study protocol, the NIH has agreed to support a majority of the costs of this study. It is hoped that information regarding the neuroendocrine mechanisms involved in the control of lactation induced infertility may be applied to the natural regulation of a woman's fertility.

3. Assess the ability of current NFP and new natural methods to meet the needs of women of different reproductive states and health statuses.

NFP for Breastfeeding Women

During the past twelve months, funding was provided to the NFP and Breastfeeding Division of Family Health International (FHI) for a multicenter study of the applicability of the symptothermal method to the needs of breastfeeding women. The Institute's Reference Laboratory has recently received split early morning urine specimens which will allow the lab to validate Dr. James Brown's (Melbourne, Australia) simplified ELISA methods. The Institute continues to fund the field costs for Melbourne, Australia and Birmingham, England as well as laboratory assays in Australia (see Section VII).

In addition, the Maryland and D.C. NFP Providers Association in conjunction with Institute staff has initiated a study of NFP in breastfeeding women after the cessation of amenorrhea. This study addresses the concern that the period of time surrounding the return to menses in lactating women using NFP represents a potentially difficult one where the method failure rates are increased and abstinence times can be discouragingly long. The proposal hopes to determine which signs and symptoms are most reliable in predicting and confirming ovulatory activity. While the project has begun in a United States based NFP program, LDC NFP sites are reviewing the protocol and are pursuing the possibility of carrying out a "twin" study with a common design. Most recently, a group of scientists from Kenya have expressed a strong interest as a possible site for such a study. This will be pursued in the coming months.

NFP and Vaginal Infections

The Institute has received a number of inquiries from LDC NFP providers and researchers regarding the possibility of a study of the implications of vaginal infection for NFP use. A review of the literature in this area revealed a paucity of hard data. However, given reports (in response to a survey of several physicians from LDCs) of vaginal infection rates of 50-60%, this clearly is an issue which needs to be addressed.

The November TAG reviewed a proposal from Chilean investigators on this topic. Based on a number of concerns raised by the TAG, Institute biomedical staff have completely revised the protocol and plan to present it for re-review at the May, TAG meeting.

NFP and Perimenopause

Additional information is needed to assist perimenopausal women, who represent a particularly high risk group when pregnancy occurs, to continue or initiate use of NFP. During the last six months, we have been unable to find developing country investigators with access to adequate numbers of perimenopausal women using NFP to perform a meaningful study.

At this point the Institute staff are monitoring a WHO funded study looking at detailed hormonal and ultra sound data in perimenopausal women in England and contining to look for a developing country site in which a follow-on study could be conducted.

4. Determine the relationship between NFP practice and pregnancy outcome.

Since one of the major concerns in the are of NFP is the possibility that the practice of NFP increases the risks of adverse pregnancy outcomes, the Institute has completed negotiations and funding of investigators, at the University of Tennessee and the Johns Hopkins University, with a major part of the field work being carried out at two sites in Chile (Catholic University and the National University) and one in Peru . An Institute staff member as well as an investigator from the University of Tennessee have recently returned from a site visit to these institutions. (See Section VII.)

5. Define the duration of the fertile period, including further evaluation of the functional life span of the sperm and ovum in various reproductive states.

The definition of the "fertile period" takes into account assumptions of the fertilizable status of each gamete and the use of various algorithms to determine the "safe" and "unsafe" periods. According to the current NFP rules, the presence of any fertile type mucus generally requires abstinence regardless of the anticipated day of ovulation based previous cycle history. This is in part due to lack of knowledge concerning the functional survival time of sperm in the female reproductive tract.

A protocol to study sperm function and survival in human cervical mucus was presented at the November TAG meeting. This was developed by Institute staff and University of California (Davis) investigators. Several methodologic concerns were raised and have been addressed in a revised protocol. The protocol has been reviewed, and the Institute anticipaes funding this important aspect of reproductive physiology in the near future.

6. Plans For The Next Six Months

The Biomedical Division expects to follow very closely the project activities listed above and implement new proposals in the Institute's priority research areas. The plans for the next six months include:

- o Complete the salivary enzyme project in conjunction with Personnel Diagnostics, Inc., including laboratory hormone assays and correlation with salivary enzyme

activities during the normal menstrual cycle. The Biomedical Division will continue to collaborate with Personal Diagnostics, Inc. in the field of ovulation detection;

- o Monitor and review the final results of the study on "Predictors of Ovulation During Lactation in Manila";
- o Monitor the FHI multicenter breastfeeding and natural family planning study;
- o Monitor the University of Tennessee NFP and Fetal Outcome Study;
- o Monitor the NFP Providers" Breastfeeding and NFP Return of Menses study;
- o Monitor the progress of the Capitol Area/Georgetown University Milk Bank study on prolactin levels and milk production using mechanical and manual breastpumping;
- o Perform urinary steroid hormone assays in the Reference Laboratory for the FHI multicenter project, the NFP Providers project, and, the Georgetown milk bank study.
- o Pursue collaboration with Boots-Celltech, Inc, (Slough, Eng.) in testing and validating their novel "dual analyte" ELISA assay for estrone-glucuronide to pregnanediol ratios in urine;
- o Pursue collaboration with Hygiea, Inc. (Boston, Ma.) in testing new laboratory and at-home technology for the measurement of urinary hormones;
- o Assist and encourage other high tech/biotech companies (e.g. Advanced Care Products, Ortho.) to bring to market as expeditiously as possible a product (or products) compatible with natural methods of fertility regulation;
- o Continue to offer the expertise of the reference laboratory to both the private and government sectors in evaluating ovarian function in health and disease.

We anticipate funding several projects in the area of ovulation prediction and sperm function and survival. In addition we plan to continue to explore the feasibility of performing several studies in developing countries using prepared protocols.

In addition, the Biomedical Division with the National Institute for Child Health & Human Development (NICHD), NIH, to conduct an International Symposium on the use of non-radioactive techniques and methodologies in Endocrine research. This will be a

state-of-the-art forum to stimulate and promote the use of new non-radiometric techniques in the measurement of steroid and peptide hormones. The agenda and meeting date/place will be announced in early summer, 1987.

B. Social Science Research

Priorities

During the past six months, a strategy has been developed which emphasizes efficient management of resources and project implementation. Several of the Institute's original priorities have been restated to reflect a revised focus of attention. A major potential role for the Institute has been identified in the area of data collection, data analysis, and general research support functions. The Institute's activities in this area have been clarified under the administrative heading of "NFP and Breastfeeding Data Center." Formation of the Data Center does not reflect actual creation of a new entity within the Institute, but indicates an attempt at coordinating administratively a variety of analytical, project development, and technical assistance functions directly related to data collection and management. Activities such as the CMBBT (and other NFP methods) analyses, secondary analysis of survey data, client data system development, collaboration with Institute biomedical projects, follow-up with participants in Institute-sponsored training programs, and on-site technical assistance to LDC organizations are part of the Data Center functions. Appropriate staff are used on an ad hoc basis to complete required activities and to produce periodic reports based on data compiled and analyzed. An aggressive policy of offering technical assistance to LDC organizations is being undertaken with the goal of improving data collection in the field, gaining access to usable data, and laying groundwork for field based research efforts. The following are the general social science research priorities:

- o Identify and study a variety of psychosocial and demographic factors related to NFP acceptance, continuation and patterns of method use.
- o Explore attitudes toward NFP and potential demand for services; identify and test mechanisms for changing attitudes and increasing knowledge through promotion and education.
- o Explore the relationship of breastfeeding to child spacing and child survival.

- o Describe the cross-national prevalence of NFP use by socioeconomic, demographic, and cultural subgroups.
- o Study the use-effectiveness of existing and new NFP methods under a variety of conditions.
- 1. Identify and study a variety of psychosocial and demographic factors related to NFP acceptance, continuation and patterns of method use.

a. Prospective NFP User Study (Action Familiale/Mauritius)

The general protocol for this project has been designed, and was approved by the Institute Technical Advisory Group in November 1986. This project, along with three others, has been integrated into the Institute's coordinated three year plan of support for Action Familiale. The three year plan includes social science, operations research, and IEC projects, all of which together:

- 1) address needs of Action Familiale;
- 2) have applicability for other NFP programs in Africa; and
- 3) increase the capability of Action Familiale to provide technical assistance, consultation and training to other NFP programs in the region.

The total three year plan has been revised several times based on internal review and comments from USAID. The Managing Secretary from Action Familiale was in the U.S. in late November 1986 during which time a revised version of the plan was prepared. A detailed budget to accompany the document has been subsequently requested from AF. To facilitate the initial technical assistance component of this strategy, a planning session was held with representatives from IFFLP, the Institute, USAID, Development Group and the AF Managing Secretary regarding development and implementation of a management workshop for the NFP program in Mauritius, Zambia, and Liberia.

- b. User Follow-Up Study (FLACAM/Cameroon)
This project is being developed as a result of meetings held between Institute staff and representatives of FLACAM during a visit to Washington in February 1987. The project is encouraging since the Family Life Association of Cameroon (FLACAM) appears interested in conducting a thorough appraisal of its NFP program, and its leaders are intent upon establishing coordination of their efforts with the government health care delivery system. This proposed study would involved an initial phase of technical assistance to FLACAM followed by a needs assessment survey of a sample of FLACAM's client population. The goal of this effort is two-fold: to improve the FLACAM program, making it more responsive to NFP users, and to report the results of this study (including proposed program adjustments) to the government of Cameroon for acceptance and approval. At the end of March a project proposal was submitted to AID-Washington for discussion.
- c. Psychosocial Issues Paper
The Institute monograph titled "Psychosocial Aspects of Periodic Abstinence" has proceeded through the Institute's internal review process and has undergone major revisions. This document, designed to be used by researchers as well as program managers, will undergo external review by selected experts, and will be published as a formal Institute monograph shortly thereafter.
- d. Multi-Country Study (Australia)
At the November TAG meeting, a proposal from the Health Economics and Technology Assessment Corporation in Australia was presented to conduct a comprehensive six-country study of the characteristics of successful and unsuccessful users of NFP methods. The TAG made several recommendations to narrow the scope of the study. The new proposal will be reviewed again at the May TAG meeting. If the review is positive, the pilot study (probably in the Philippines) could begin within the next few months.

2. Explore attitudes toward NFP and potential demand for services; identify and test mechanisms for changing attitudes and increasing knowledge through promotion and education.
 - a. Demand for NFP Services (Cuenca, Ecuador)

This planned project with the Cuenca NFP program has been redesigned for easier implementation following the most recent planning visit to Ecuador by Institute staff. Pending AID review and subsequent revisions, the project is ready for implementation. Phase 1 will involve a series of focus groups designed to gather information upon which to base an outreach and promotion strategy. The Institute has tentatively arranged with an Ecuadorian research organization to begin the focus groups once project approval has been received from AID-Washington. It is anticipated that this method for assessing attitudes toward NFP and designing outreach will potentially be useful for other NFP programs, particularly those in the Andean region. Following the focus group phase, the outreach and promotion strategy will be implemented and assessed.
 - b. Attitudes Toward NFP/Brazil (CPAIMEC Project)

With CPAIMEC/Brazil, the Pathfinder Fund is supporting an NFP service delivery project with a research component. The research component involves conducting focus groups in the areas of Rio de Janeiro where CPAIMEC plans to provide NFP services, for the purpose of determining the potential acceptability of NFP in those communities and the most appropriate means of providing information about NFP. It also involves a system of client follow-up to provide information about the numbers and characteristics of acceptors and continuing/discontinuing users. The Institute is providing technical assistance to this research. During this reporting period, the Institute has worked with CPAIMEC staff on the focus group discussion guide and data analysis, staff training, the design of the follow-up forms, and the development of

client education/motivation materials. In the project's first eight months, the development phase is essentially complete: the focus groups have been conducted, the staff have been hired and trained, the target communities have been selected, community leaders have been contacted, outreach activities have been initiated, appropriate administrative systems have been implemented, and NFP instruction has been provided to 27 couples. The Institute will continue to provide technical assistance to the project.

3. Explore the relationship of breastfeeding to child spacing and child survival.

a. Study of Breastfeeding Trends (AMIDEM, Mexico)

This proposed study has been revised by the Academia Mexicana de Investigacion en Demografia Medica (AMIDEM) and approved by Institute staff. During a recent visit to Mexico, Institute staff met with the Academia to discuss details of project implementation. Some preliminary activity has already occurred and full implementation will begin upon final approval by AID-Washington. The results of this study will be actively disseminated in Mexico. The Institute has also sponsored the FEMAP breastfeeding promotion project in Mexico. The results of these two projects could significantly influence the breastfeeding policies within the Mexican health care delivery system.

b. Breastfeeding Promotion (FEMAP/Mexico)

Implementation of this project is presently underway. Although this is primarily an operations research study of the impact of a promotion program, a variety of psychosocial factors and other social science issues will be examined as well. The data collection forms being designed will reflect this emphasis.

c. Breastfeeding Research Paper (Sub-Saharan Africa)

This manuscript is designed to present an

overview of information about the contraceptive effect of breastfeeding in sub-Saharan Africa. The document is primarily directed to researchers in the field of nutrition, family planning, and reproductive physiology with the goal of helping to establish an appropriate research agenda in the field. Health care policy makers in developing countries can also benefit from this monograph. The monograph reviews relevant literature and identifies gaps in knowledge in the following topic areas: contraceptive effect of breastfeeding, trends in prevalence and duration of breastfeeding, and the effect of breastfeeding on child spacing. Additionally, current interventions and breastfeeding policies in Africa are summarized, and research and policy strategies are recommended.

Internal review of this monograph is complete; external review by at least three experts will occur during April-May. The document will be presented to the TAG in May with final revisions occurring by June. Formal dissemination of the published document is projected for August.

4. Describe the cross-national prevalence of NFP use by socioeconomic, demographic, and cultural groups.
 - a. NFP and Periodic Abstinence Patterns (Carolina Population Center/Philippines)

This project, outlined in the last Progress Report, received an extensive review by Institute staff, TAG, AID-Washington and ultimately by USAID-Manila. Approvals at all levels have been received, and the investigators await processing of the agreement by AID-Washington Contracts Office prior to full scale implementation. Institute staff enthusiastically await preliminary results of this analysis which may be relevant to two other NFP studies planned for implementation in Philippines during the next several months. All of these projects should help in giving direction to NFP policy within overall

Philippine national family planning strategy.

b. Data Analyses of National/International Surveys

Activities of this type have been centralized and will be coordinated under the aegis of the Institute Data Center. Data tapes from previous Contraceptive Prevalence Surveys (CPS) and World Fertility Surveys (WFS) have been converted and analyses are underway subsequent to producing a series of reports.

Data from recently completed Demographic and Health Surveys (DHS) projects in El Salvador and Peru has not yet been made available to the Institute. It is anticipated, however, that the Institute will play a major role in the analysis of these data, hopefully working directly with investigators in developing countries.

5. Study the use-effectiveness of existing and new NFP methods under a variety of conditions.

In the design of a number of projects, practical use effectiveness of NFP methods is an important focus for the Institute.

Use effectiveness will be calculated as part of the prospective user study in Mauritius. Most of the client data systems which the Institute is designing and promoting will generate reasonable use-effectiveness data. In the case of the Xavier University project in the Philippines, a revised NFP teaching method is to be tested, with use-effectiveness as a major outcome measure. Also, use effectiveness is a key indicator of the impact of the FPOP NFP intervention.

As part of its role as an NFP data center, the Institute is attempting to promote some degree of standardization and precision to the way programs assess the concept of use-effectiveness. It is important to work with those NFP providers which are willing to realistically address this important issue; and to avoid the controversy surrounding the post hoc classification of pregnancies. Evaluating modifications of NFP

methods, and pilot testing innovative service delivery models requires an assessment of use-effectiveness as part of the total strategy.

An expert meeting is planned to discuss use-effectiveness in NFP, and to establish guidelines and data collection models for addressing this issue in actual program situations. This meeting would be coordinated by the Institute Data Center and will include Institute staff, and other appropriate researchers in family planning. The proceedings and recommendations from this meeting would be formalized and disseminated to the NFP and general family planning community.

a. Testing Simplified NFP Teaching Method
(Xavier University/Philippines)

This proposed study has been under discussion by the Institute for some time. Staff discussed the study with representatives of Xavier University at the IFFLP conference in Ottawa in July. During a trip to the Philippines in October 1986, discussions continued regarding details of the training requirements for this type of study. Basically, the proposal calls for the implementation and evaluation of a simplified program for teaching the mucus method; an approach with a relatively brief teaching phase that would be feasible for use with illiterate women in remote areas. The project essentially involves two phases: the development of the training/service delivery design, and the actual evaluation phase. A major measure of outcome will be the use-effectiveness rates for this method; however, a number of other important variables, i.e. cost, acceptance rates, continuation rates, efficiency of service delivery will also be analyzed in this study. It is a particularly important study for the Philippines where periodic abstinence use is high but acceptance of "modern" NFP methods seems limited. It could result in a model which would significantly improve the effectiveness of periodic abstinence methods in a portion of the population not likely to be reached by the typical NFP service delivery system.

A review of the research design has been conducted by Institute staff and responses from Xavier University appear to adequately address most of the key issues. Some

additional technical assistance from the Institute is anticipated in the form of a trip to Mindanao in late summer to finalize the research design.

6. Plans for the Next Six Months

We anticipate shortly the approval of the prospective user study in Mauritius followed by issuing of a formal sub-agreement. A site visit is planned to finalize the protocol and assist in any training and/or preparatory activities which may be required. Preliminary enrollment data should be forthcoming which will be monitored and reviewed for any potential problems.

Following AID review and modification of the Cuenca, Ecuador project, sub-agreements will be prepared for immediate implementation. Focus groups should be underway in July with the new outreach design anticipated early in the next fiscal year.

The Institute anticipates a request from the Lesotho Family Planning Association to assist in the planning of an NFP component as part of their national family planning services. This activity will involve considerable technical assistance and consultation, including the design of a basic client monitoring/record keeping system. The development of a study to assess potential demand and target outreach will be a major priority in this initial phase. Up to three weeks on-site in Lesotho is anticipated based on the Lesotho planning document.

Following final approval, the AMIDEM project in Mexico will require minimal monitoring. No preliminary results are anticipated during the next six months.

No major results are anticipated during the next six months from Carolina Population Center longitudinal study in Philippines.

Both the breastfeeding and psychosocial monographs will be finalized, printed and disseminated. The former should be available around August 1, with the latter forthcoming approximately one month later.

Multi-country reports will be forthcoming on periodic abstinence patterns based on secondary analysis of existing WFS and CPS data. In addition, an agreement for joint analysis of periodic abstinence data from 1986 Demographic and Health Survey in Peru should be completed and preliminary analysis should be underway. In all cases, the forthcoming reports will be disseminated by the Institute, and aggressive efforts will be made to secure acceptance of papers in appropriate journals and other publications.

A visit to Xavier University is planned for July 1987 to finalize their proposal. Prior to the end of the present fiscal year a sub-agreement will be signed, and the preliminary materials development/training phase will be underway.

C. Operations Research

The priorities for operations research have been expanded to reflect the Institute's Data Center activities. The priorities now include:

- o Identify the impact of structural and operational factors on management, service delivery and cost-effectiveness of NFP and breastfeeding programs.
- o Assess and evaluate NFP delivery systems teaching/ training activities, and breastfeeding promotion programs.
- o Assess the accuracy, effectiveness and appropriateness of NFP client data systems and NFP record keeping/charting procedures; develop standardized models for developing countries; disseminate and promote implementation of these systems.

Following is an update of project activity during the last six month reporting period under each priority area.

1. Identify the impact of structural and operational factors on management, service delivery and cost-effectiveness of NFP and breastfeeding programs.

a. Client Data Systems (Action Familiale/Mauritius)

This project was approved and a sub-agreement developed with Action Familiale. They have continued the implementation and refinement of their data system. (See Technical Report, Section VII.)

b. Pilot Test Group Teaching of NFP (Action Familiale/Mauritius)

This proposed project has been included in pre-proposal format in the Institute three year plan for Action Familiale. Detailed development of the proposal will not occur, however, until the total Action Familiale plan is approved and the autonomous user study is under way.

c. NFP Service in Multi-Method Clinic (FPOP/Philippines)

A proposal was received from the Family Planning Organization of the Philippines (FPOP) to study the introduction of NFP (Ovulation method) services in 6 FPOP chapter clinics. This three year study proposes to test two distinct methods of NFP services delivery (one with follow-up and one without follow-up). The project will involve preparation and training in the first phase, followed by implementation of the service and measurement of the effects and impact vis a vis clients, staff, and the organization.

This proposal has been reviewed by Institute staff and several questions were raised. A separate proposal for the initial training phase is being designed by Institute staff.

The research design to study the effect of the intervention will be finalized during a site visit to the Philippines planned for July 1987.

2. Assess and evaluate the NFP delivery systems teaching/training activities, and breastfeeding promotion programs.

a. Implement and Evaluate Breastfeeding Promotion (FEMAP/Mexico)

The FEMAP project has been finalized following a long review and refinement process. The sub-agreement for the IEC and Training phase of the project was approved and activities are underway. In March an Institute staff visit to FEMAP was made to finalize the service delivery and evaluation research strategy. All components of the project have been approved and the project is now moving forward on schedule. Final revisions were made to the research protocol and these modifications were accepted by FEMAP staff. A design and schedule for the formative component of the evaluation was also agreed upon. Coordination of the scheduling of training, IEC and research activities has been completed, and project staff recruitment is underway. Each of the program sites is ready to proceed with involvement in the project. Educational and promotional materials have been reviewed and additional materials development is underway. The training of supervisors will be completed by Institute staff in May-June 1987, followed by instructor training and enrollment of clients into the study.

b. WHO Breastfeeding Research Action Program

The Institute has continued discussions with the Maternal and Child Health Division of WHO regarding a project to describe breastfeeding and lactational amenorrhea patterns in selected countries, identify key patterns, and conduct and evaluate specific interventions designed to promote better amenorrhea. At this point, the Institute has advised WHO that our support of this activity will need to be delayed, pending the outcome of other WHO/Institute collaboration (see Section III.A.2 and IV.B.3).

c. Multi-Method Programs and NFP

With CPAIMC/Brazil (see Section III.B.2), the Institute is preparing a report to document all aspects of program development and implementation and to make recommendations for the provision of NFP

services through multi-method programs based on the CPAIMC experience. The outline of this report has been developed, and the documentation of the development phase has been completed.

3. Assess the accuracy, effectiveness and appropriateness of NFP client data systems and NFP record keeping/charting procedures; develop standardized models for developing countries; disseminate and promote implementation of these systems.

The Institute has embarked upon a strategy to collaborate with LDC groups and other cooperating agencies to address the issue of of NFP data collection, management and analysis. The goal is not only to gather and analyze available data on NFP, but to promote the development of an environment which will facilitate the creation of new sources of valid and reliable data.

The Institute is available to offer a broad range of technical assistance and consultation to organizations which deliver NFP services, or need information on NFP with which to make policy decisions. The Institute is developing formal linkages with NFP programs which could provide data to the Institute in exchange for data analysis, reporting and technical assistance services. Data of interest range from physiological readings (i.e. temperature and mucus charts, assays, etc.) to basic agency client record keeping, and business management functions (bookkeeping procedures, etc.). The Institute shall also sponsor and participate in workshops and conferences which will promote systematic and standardized data collection, and mutual sharing of information and expertise. To address this goal, the Data Center has scheduled an expert meeting for early May to discuss data collection needs in NFP and to develop data collection models (including forms) to be pilot tested in various LDC settings. A summary of the proceedings and recommendations will be forthcoming. A summary of the proceedings and recommendations will be forthcoming. In addition, the Institute is to co-sponsor a data management seminar for Asia NFP programs in July which will provide training, promote improved

systematic data collection, and create a network for data and information sharing. These activities will generate a series of reports and publications as well as a continuing agenda of technical assistance and educational functions. A variety of operations research projects (many involving pilot testing and evaluation of client data systems) will emerge as strong linkages are established with various LDC organizations.

4. Plans for the Next Six Months

During the next reporting period, interim results will become available from the Action Familiale system project. Computer generated output will be reviewed by Institute Data Center staff and any necessary consultation will be provided. Appropriate adjustments to the client record forms and to data management procedures will be undertaken. Available client data will be transmitted to, compiled and stored at the Institute data center as well.

The design for the pilot test of Action Familiale's group teaching program will be finalized and approved. Institute staff will work with Action Familiale to design the training model for instructors and the teaching model to be implemented. A site visit to Mauritius will be required during this phase. Implementation of the initial training of group instructors phase will begin early in the next fiscal year with the actual group teaching of clients beginning shortly thereafter.

The FEMAP breastfeeding project will become fully operational during the next few months. Activities of Institute staff from Pittsburgh, LARFPC and Georgetown will be coordinated to facilitate necessary FEMAP staff training, materials development and service delivery/data collection.

The FPOP, Philippines test of NFP services in multi-method family planning clinics should be developed and approved in 2 phases. The training phase for FPOP staff will get underway first. The specific protocol should be finalized following an Institute staff visit to the Philippines in July. The final protocol for the

implementation and evaluation phase will be completed following a subsequent visit by Institute research personnel.

Although additional operations research activities have not been clearly defined at this time, there remains considerable potential for 1) pilot testing a service delivery model in Lesotho; 2) evaluating outreach/promotion strategy in Ecuador (second phase of Cuenca study); 3) testing NFP program interventions as second phase of Cameroon (FLACAM) activity; 4) testing effectiveness of outreach/promotion program with Action Familiale, Mauritius; and 5) pilot testing client data systems in several possible settings.

IV. Training, Education and Communication

The emphasis of the Education/Communication and Training Divisions' activities during this reporting period has been twofold: (1) the development and implementation of field projects in collaboration with third country institutions; and (2) the development of professional papers, educational and training materials, and training programs to serve various target populations. These activities reflect the priorities identified by the Institute as follows:

- o Improve the quality and availability of NFP instructors and breastfeeding training programs and training materials;
- o Enhance the availability of quality educational materials on NFP and breastfeeding;
- o Increase the acceptability of NFP and breastfeeding to policy makers, health care and family planning professionals and clients;
- o Maximize the appropriateness and effectiveness of NFP and breastfeeding educational and outreach programs; and
- o Improve management and outreach capability of NFP service provider groups.

To meet these identified priorities, the Education/Communication and Training Divisions have undertaken the development and/or implementation of training, educational and outreach strategies through Institute-based and field-based efforts.

A. Improve the quality of NFP instructors and breastfeeding training programs and training materials.

1. NFP Trainers Learning Package

In an effort to meet the needs of developing country NFP organizations to provide comprehensive training programs which can result in well-trained NFP instructors, the Institute is developing an NFP Trainers Learning Package. This package includes information about the development, implementation and evaluation of NFP Instructors Training Programs, and a detailed

training design describing a two week NFP instructors training program, training outlines, lecture notes and training activities. It includes samples of visual aids, an NFP and training bibliography, and an NFP glossary. Samples of fold-up posters of reproductive anatomy and physiology fertility signs and other major concepts of NFP are included as well.

The introduction and instructions for use of the manual, format, training design, introductions for each section of the manual, lecture notes, activities and evaluation tools are being prepared for internal review scheduled in April and May. It is anticipated that the Learning Package will be ready for external field review by June and that it will be available for limited distribution and field testing by the end of the next reporting period.

2. Training of Trainers Course for English Speaking Participants

The majority of the NFP Instructors Training Programs offered in LDCs are conducted by experienced NFP instructors. These instructors often have minimal or no prior training experience or knowledge of the training process. Though some of these programs are successful, increasing the level of expertise of these instructors to impact on their programs' effectiveness is extremely important. During this reporting period, Institute staff have collaborated with the International Health Program at the University of California/Santa Cruz to develop a three-week program of didactic and experiential learning designed to enhance the training skills of NFP trainers. Principles of training and curriculum development for NFP Instructors Training Programs will serve as the foundation for this program. It will also include topics ranging from adult learning theory to facilitation of group processes and evaluation of training programs.

A major outcome of the training program will be the initial preparation of a maximum of twenty participants from selected LDCs to function as trainers of NFP instructors. This is an important step in furthering the growth of NFP

services as well as supporting the need for cost effective programs and well prepared NFP instructors.

Upon completion of the training program, selected participants will be assisted by the Training Division in developing proposals to implement a NFP Instructor's Training Program in their countries. These proposals will be submitted to the Institute for review, and selected proposals will be funded. Upon completion of this process, the Training Division will evaluate the trainers during these in-country training programs and provide technical assistance as needed. The Training Division will also conduct evaluations and provide technical assistance to selected participants whose organizations are able to offer the training programs without the financial assistance of the Institute.

The Training of Trainer's Program will be offered in July 1987 in Santa Cruz, California, in English, in cooperation with the International Health Program. The Spanish program is planned for early 1988, and the French program will be offered in late 1988. Brochures announcing the program have been sent to NFP providers, AID Missions and Ministries of Health in LDCs. Participants will be selected to attend the English program by the end of May.

Another important aspect of the Training of Trainers Programs is that the participants will be provided with the simplified client and program data forms being developed by the Institute. They will be instructed in the use of these forms and asked to provide data to the Institute's Data Center (see Section III.B.3). This will contribute not only to the management of the NFP instructors training program developed and provided by these TOT participants, but it also will contribute to information about the numbers and characteristics of NFP teachers and users.

3. NFP Instructors Training Programs

The Institute is committed to increasing the availability of NFP services by supporting a limited number of instructor training programs. The programs may increase the number of

qualified instructors in a given geographical location, or increase the level of knowledge and skills of instructors which already exist. Institutions and organizations are provided funding for these efforts if they are able to demonstrate expertise in the area of NFP Instructor's Training. Documentation of the need for supporting these training efforts is also a major determining factor in funding decisions. It is anticipated that after the Training of Trainers courses are conducted, the Institute's primary support in this area will focus on those programs that have trainers who were TOT participants.

CENPAFAL/Colombia Motivation Seminars and Instructor's Training

Centro de Pastoral Familiar de America Latina (CENPAFAL) is a non-profit organization in Bogota, Colombia which has conducted NFP Instructor's Training Programs for the past several years. Through funding by the Institute, CENPAFAL is currently offering motivational seminars for health care professionals and NFP Instructor's Training Programs for staff of government and private organizations.

Twenty-four motivational seminars have been offered to 537 participants, in addition to one Instructor's Training Program for 27 NFP instructors. These seminars provide an overview of NFP and provide a mechanism for dispelling myths about NFP. They also serve to increase support for NFP and are a means to recruit potential NFP instructors throughout Bogota. The Institute has provided technical assistance both through an on-site visit and through review of materials and curriculum sent by CENPAFAL. CENPAFAL has developed a pamphlet about NFP and materials for their instructor's training. These materials have been reviewed by the Training Division and will be made available to other programs in Latin America.

CEVIFA/Bolivia Instructor's Continuing Education Program

The Centro de Vida Familiar (CEVIFA) is a

church funded organization with chapters throughout Bolivia. Each of these chapters currently has NFP instructors who have received varying types of NFP instructor's training. Because of the lack of consistency of the training, and deficiencies in their training which the trainers themselves have identified, they have expressed the need for continuing education programs. The Institute has provided technical assistance to CEVIFA to develop a training project to provide NFP information to 14-18 instructors from six CEVIFA chapters. This project is in the final stages of development, and it is scheduled to begin in June.

By being able to provide instructors with new information, a review of standardized content, and an opportunity to share problems and concerns, the quality of CEVIFA's instruction will be enhanced.

FPOP/Philippines Instructor's Training Program

The Family Planning Organization of the Philippines (FPOP) is a multimethod family planning program with chapters in various areas of the Philippines. FPOP recognizes the need to provide NFP services in the communities it serves and has submitted a proposal to the Institute to support this service. The proposal describes several activities; the development and implementation of an NFP instructors Training Program for staff of six of its chapters; development of NFP materials for staff and NFP users; development of instruments to be used in establishing a baseline data of knowledge and attitudes about all methods of family planning, including NFP; and a use effectiveness study of NFP as offered through six of their chapters.

During the next reporting period, the Institute plans to support the training and materials development components of this project and to provide further assistance to FPOP in designing the study (see Section III.C.1).

Through this project, the effectiveness of NFP and other family planning methods will be determined. The potential for integration of NFP into a multimethod family planning program will be assessed as well. In addition, valuable information about mechanisms for recruitment of potential users, as well as effectiveness of NFP among the population to be served, will be obtained. This information could assist family planning and NFP providers in developing a strategy for expanding NFP services and training throughout the Philippines.

Xavier University/Philippines Modified Mucus Method Instructors Training Program

The Mindanao Center for Population Studies, Xavier University, has developed a project to offer a modified calendar rhythm and mucus method of NFP to couples in the rural and urban areas of Mindanao. Because the calendar rhythm method is often poorly followed by this population, the added use of the mucus indicator could increase the acceptability and effectiveness of the currently used approach to periodic abstinence. The objective of this project is to develop simple instructions for potential users, which require a minimal amount of instruction and follow-up by the instructors. After the users have received their instruction, follow-up to determine the acceptability and use effectiveness of the method would be conducted. Additional assistance to clarify specific research issues is being provided by the Operations and Social Science Research Division. The Institute has provided technical assistance to Xavier University to further refine the simplified method and to develop the training and education materials needed for the study.

An extremely important outcome of this study will be the assessment of a potentially simple and cost effective form of NFP that could be utilized throughout the Philippines and in other countries. (See Section III.B.5.)

Natural Family Planning Continuing Education Program for Instructors/Ecuador

The three natural family planning programs in Ecuador that are receiving support from the USAID bilateral project (Cuenca, Guayaquil, and Esmeraldas) have expressed the need for a continuing education program for their instructors. This program will serve to update their instructors and increase their level of knowledge and skills. It also will assist the three programs to develop a standard approach to NFP instruction. A needs assessment was conducted by the Institute through a questionnaire sent to the three programs and their instructors. The results of the needs assessment will enable the Institute to develop a program that will meet the needs of the instructors. These results should be received and reviewed by the end of April. A host organization which will be responsible for logistics of the training program will be identified by the end of April as well. This host organization will also function as the liaison between the Institute and participants during the pre-planning stages of the training program.

Approximately fifteen participants from the three Ecuadorean programs will be selected to attend this program. In addition, a limited number of NFP instructors (preferably those with some responsibility for training other instructors) from Bolivia, Colombia, El Salvador and Peru will be invited to attend.

CENPLAFAM/Brazil

During this reporting period, an Institute consultant provided technical assistance to CENPLAFAM to develop a project for refresher training of CENPLAFAM instructors in three Brazilian cities. CENPLAFAM, the major NFP provider in Brazil, is conducting an active outreach program to recruit more users, and it also is developing a strong relationship with the new government population program. The instructor training included in the Institute sponsored project will strengthen CENPLAFAM's ability to provide services to a

broad spectrum of potential users and increase its capability to participate in the national population program. The training project is expected to begin in July of this year.

4. Breastfeeding Training Program/FEMAP

Federacion Mexicana de Asociaciones Privadas de Planificacion Familiar, A.C. (FEMAP) provides maternal-child health and family planning in several states in Mexico. The Institute has developed a comprehensive project with FEMAP to promote breastfeeding in selected communities and to assess the impact of the breastfeeding promotion program in breastfeeding practices. This project includes the preparation of a breastfeeding training program for its supervisors and trainers; development of breastfeeding materials for use in client education; and promotion of breastfeeding on different levels, with subsequent analysis of the success of these efforts.

During this reporting period, the Training Division has been responsible for assisting FEMAP with the development of training materials and for conducting and evaluating the Breastfeeding Training Program for the supervisors and educators. This program will be offered in two phases during May and June, with the follow-up evaluation and technical assistance conducted during August and December. The Training Division is also involved in assisting with the review of IEC materials developed by FEMAP. FEMAP is currently developing these materials which will be an integral part of the training and promotion programs.

B. Enhance the availability of quality educational materials on NFP and breastfeeding.

1. Resource Center

A major undertaking of the Education/Communication Division during the last six months has been the establishment of the Resource Center as a functional unit of the Institute. The Resource Center is a growing collection of a variety of materials ranging from scientific

papers in various languages to client education brochures and involves all materials that were part of the Human Life Foundation Library. The Resource Center has received a number of requests from developing countries and other US institutions and individuals and is used as a source of reference for NFP and breastfeeding. The "packet responses" on NFP effectiveness and client education and on breastfeeding have been particularly useful in responding to their requests.

2. Publications

The Resource Center also is the unit from which publications from the Institute and Institute-supported groups will be disseminated. The following Institute publications are currently being developed:

- o Glossary of NFP Terms, with comprehensive definitions of selected NFP terms which will be published in mid-1987;
- o NFP and Breastfeeding Information Package, including booklets on NFP and breastfeeding for dissemination by the end of this fiscal year.
- o NFP Trainers Learning Package, designed as a resource for trainers of NFP instructors, which will be ready for limited distribution by September '87; and
- o Monographs:
 - Psychosocial Aspects of Periodic Abstinence
 - Current State of Knowledge About the Contraceptive Effect of Breastfeeding in Africa and Lacunae in Existing Research
 - The Prediction of Ovulation and Prognostication of the Fertile Period

The Institute is also working with the IFFLP to publish a special edition of the International Journal of Fertility containing approximately twenty of the scientific papers presented at the

Fourth International Congress on Natural Family Planning in Ottawa in July, 1986.

In collaboration with WHO, FHI and IPPF, the Institute has continued to work on a booklet for breastfeeding as a method of childspacing. Institute staff prepared the third revision of the booklet, which was reviewed by the WHO HRP natural methods task force during their March meeting. Additional revisions were made, and it is anticipated that the booklet will be published by September of this year.

- C. Increase the acceptability of NFP and breastfeeding to policy makers, health care and family planning providers, and clients.

During this reporting period, the Institute has drafted information packages on NFP and breastfeeding that would be appropriate for general distribution to policy makers and health care professionals in developing countries. Preliminary discussions have taken place with the Population Reference Bureau's IMPACT project to develop these packages further in an appropriate format, and with the additional content needed, to make them acceptable and interesting to the target audience. Further developing is expected during the next reporting period.

The Institute also is available to provide technical assistance and funding to developing country institutions to prepare documents and publish studies in natural family planning and breastfeeding that were conducted without Institute support. Two institutions are currently receiving Institute assistance in this area. The Academia Mexicana de Demografia Medica (Mexico) has submitted a draft of a monograph on Patterns and Determinants of Breastfeeding and Contraceptive Use in Mexico for review and consideration by the Institute. Staff and other reviewers have prepared comments on the monograph, and the Institute's IEC Director will work further with the Academia during a planned trip to Mexico early in the next reporting period. This monograph will be used by the Academia to develop breastfeeding and family policy and also will be distributed to researchers and planners in other countries in the region to focus attention on issues related to declines in breastfeeding. In addition, an Institute consultant is assisting CPAIMC/Brazil with preparing a

document describing CPAIMC's experience in planning and implementing an NFP service as part of a multi-method family planning program (see Section III.B.2). This document will provide information to other family planning organizations on the steps and strategies required to integrate NFP into a broader service delivery system.

D. Maximize the appropriateness and effectiveness of NFP and breastfeeding educational and outreach programs.

The role of nurses and nurse midwives in the health care delivery system of many developing countries suggests that they are an important focus of education and information about NFP and breastfeeding. The Institute is currently preparing a survey on schools of nursing and nurse midwifery in selected Latin American countries to assess the NFP and breastfeeding material included in their professional education curricula and to determine their interest in participating in a round table/workshop to share information and plan strategies for increasing and enhancing the education of their faculty and students in these areas. Javeriana University in Colombia has expressed an interest in being the host for this activity. Depending on the outcome of the survey, the round table is tentatively scheduled for early 1988.

The Javeriana University Nursing School also has further discussed with the Institute a project to survey all Colombian nursing schools regarding their faculty's current knowledge of and attitudes toward NFP and their including of NFP in the curriculum. Following this initial survey, Javeriana would provide a series of seminars and workshops for faculty from selected Colombian nursing schools and determine the impact of these activities on knowledge, attitudes, and curriculum content. The Institute is interested in collaborating with Javeriana on this project and expects to receive a full proposal within the next few weeks.

Another Institute strategy for increasing the appropriateness and effectiveness of NFP educational and outreach programs is to support these activities in developing country institutions. Following are five programs with which the Institute is currently developing projects that are expected to be funded during the next reporting period.

PROVIFA/Ivory Coast. Movement Pour la Promotion de la Vie Familiale (PROVIFA) has submitted a preliminary proposal to the Institute to provide training to educators in selected women's training centers around the country ("Foyers Feminins"), and to assist the faculty in educating the young women who attend these centers in fertility awareness and natural family planning. This is potentially an interesting and important project because of the numbers of women who could be reached through this means. An Institute staff member will visit PROVIFA in April to finalize this project.

CEIPLAN/Mexico. Centro de Ensenanza e Investigacion de la Planeacion Natural de la Familia (CEIPLAN) has requested Institute assistance and support in re-designing its training and IEC materials to make them more appropriate to a wider audience and more acceptable for a program on which CEIPLAN is collaborating with the Academia Mexicana de Demografia Medica. An Institute staff member provided assistance to CEIPLAN to conduct an initial review of their existing materials and to develop a project proposal. A subagreement with CEIPLAN to carry out these activities has been approved by the Institute and submitted to AID.

ATLF/Peru. ATLF requested and received technical assistance from the Institute to design a project for materials development and outreach. This project is considered particularly timely, given the recent results from the Peru DHS indicating that 41% of women using a family planning method use some form of periodic abstinence. The vast majority of these women are not aware of modern NFP methods and are basing their abstinence patterns on an incorrect understanding of the menstrual cycle. Thus, ATLF is in a unique position to provide this information through a comprehensive IEC program. An Institute consultant worked with ATFL staff and a Peruvian IEC specialist to develop an IEC project for possible Institute funding. It is anticipated that this project will be initiated early in the next reporting period.

Action Familiale/Mauritius. One component of the comprehensive project the Institute expects to

support with Action Familiale is an IEC program design to increase the awareness and use of NFP in Mauritius. This program will serve as a model to other African NFP programs and will allow an assessment of the impact of a coordinated IEC effort. Preliminary discussions have been held with Action Familiale staff regarding this project. During the management/outreach workshop planned for several African NFP programs in June (in collaboration with Johns Hopkins University PCS and The Development Group, Inc.), Action Familiale staff will further design this project, which is expected to begin in late 1987.

Impact of Outreach on Natural Family Planning Client Levels/Cuenca, Ecuador. The Institute is collaborating with the Programa de Paternidad Responsable y Planificacion Familiar Natural, of the Archdiocese of Cuenca, Ecuador, to design a project to test the impact of an expanded outreach program on the number of NFP acceptors. This project involves collection of baseline data on the previous and current outreach activities and number of NFP acceptors, focus groups to provide information on which to base an expanded outreach program, a comprehensive IEC program designed to meet the needs and interests of the community, and an evaluation of the results of the IEC program in terms of IEC acceptors and general community support for NFP. The project is currently being reviewed by AID and is expected to begin during the next reporting period.

E. Improve Management and Outreach Capability of NFP Service Providers

The management and outreach capabilities of NFP service providers are key ingredients in the success of NFP programs. Typically, these institutions are operating outside the mainstream health and social service infrastructure of their countries and have not had the benefit of the training and technical assistance that has been provided to many multi-method family planning programs. As a result, the majority of NFP institutions lack effective management and outreach systems, including a range of program areas such as supervision, community education, human resource allocation, planning, budgeting, and staff development. During this reporting period, the

Institute developed a strategy for addressing this need.

Through a contract with The Development Group, Inc., a management training and consulting firm with extensive experience in organizational development, the Institute is working with Action Familiale/Mauritius (AF), the Family Life Movement of Zambia (FLMZ), and the Family Life Promotion Center of Liberia (FLPL) to strengthen their management and outreach capabilities. This project (further described in Section VII) potentially can be expanded to other countries and regions to support the development of NFP institutions.

F. Plans for the Next Six Months

During the next six months, the following activities are planned:

- o The NFP Trainers Learning Package will be reviewed by Institute staff and selected external reviewers; it will be revised according to these recommendations and will be made available for limited distribution and field testing. Arrangements will be made for Spanish and French translations of the package.
- o A Training of Trainers course will be conducted for participants from Asia and Anglophone Africa, and arrangements will be made for the Spanish Training of Trainers course. Follow-up plans will be developed for the participants in the English course.
- o Technical assistance will be provided to
 - (a) CENPAFAL/Colombia to evaluate and follow-up their training and motivation seminars;
 - (b) CEVIFA/Bolivia to finalize their instructors training program and begin program activities;
 - (c) FPOP/Philippines to implement their instructor's training program; and (d) Xavier University to further develop the training and materials for the modified mucus method study.
- o The results of the needs assessment for instructors update training in Ecuador will be analyzed; and the training program will be planned and conducted.
- o The CENPLAFAM/Brazil instructors update program will be finalized and the initial session will be conducted.

- o The FEMAP breastfeeding training and education materials will be finalized, and the supervisors and educators training program will be conducted.
- o Numerous Institute publications will be prepared, including the NFP Glossary, the NFP and breastfeeding information packages, and monographs; the special NFP edition of the International Journal of Fertility will be edited and submitted for publication; and the breastfeeding/childspacing booklet will be published.
- o The AMIDEM monograph on breastfeeding and childspacing will be prepared for publication, and the first sections of the CPAIMC case study will be ready for review.
- o Plans will be made for the Latin American Nursing School round table, and the Javeriana University Nursing School survey will be initiated.
- o Projects with PROVIFA/Ivory Coast, CEIPLAN/Mexico, and PPRPFN/Ecuador will be initiated.
- o A management/outreach workshop for three African NFP programs will be conducted, and a follow-up strategy will be developed. Initial plans will be made for conducting a similar workshop in Latin America.

V Technical Assistance

The Institute continues to respond to technical assistance requests from natural family planning organizations in developing countries as well as other cooperating agencies providing NFP services. During this reporting period, Institute staff and consultants have assisted with the design and implementation of NFP training programs, development of educational and promotional materials and refinement of various NFP research proposals.

In response to a request from CENPLAFAM/Brazil for assistance in conducting an NFP training course in Curitiba, Parana-Brazil, the Institute contracted with two Colombian physicians to lecture on the sympto-thermal method at the "First NFP Seminar for Physicians and NFP Instructors from the Southern Region of Brazil" and at an NFP training course for local instructors and infirmiry students. The Institute is also assisting CENPLAFAM in meeting its obligation to the Ministry of Health to train Ministry staff in NFP and to expand its service delivery programs. As part of this effort, a consultant is working with CENPLAFAM to design a long-term service delivery and training plan which will present NFP in a broader context than strictly the ovulation method approach currently being used by CENPLAFAM.

In meeting its responsibility to provide adequate technical monitoring of the various activities being conducted under its contract with CENPAFAL/Colombia, the Institute has reviewed the training design and educational materials developed by the CENPAFAL staff. Specifically, a member of the Institute's training staff has worked with CENPAFAL to modify the training design in order to encourage greater trainee participation, to develop an evaluation component for the training program and to focus the educational materials on not only teaching the method accurately but on recruiting new clients. The training staff also continues to work with CEVIFA/Bolivia to design a training program which is intended to not only update the teaching skills and knowledge of CEVIFA's instructors but will also be a major component of a nationwide campaign to increase the acceptance and use of NFP in Bolivia.

Members of the Institute's training staff traveled to the Philippines to assist the Family Planning Organization of the Philippines with designing a training program which is to be implemented as part of a research project aimed at comparing the effectiveness of selected approaches in the promotion of NFP acceptance and use in a multi-method

family planning program. While in the Philippines, the staff also continued to assist Xavier University with the development of materials to teach the principles of a Calendar-Rhythm and Mucus Method. The teaching materials and training design will be used in the initial phase of an operations research project to determine the acceptability and effectiveness of the method.

Technical assistance in the development of NFP educational and promotional materials has also been provided during this period to organizations in Mexico, Brazil and Peru. The Institute is assisting CEIPLAN/Mexico in its efforts to recruit an adequate number of NFP users to participate in its research project with Family Health International. The project is a prospective study of the use effectiveness rates of the ovulation method of NFP in Mexico City. The Institute has developed a project to assist CEIPLAN's outreach efforts through the production of mass media as well as educational materials targeted at potential and current NFP users. The materials developed will not only contribute to the successful implementation of the research activity being funded by FHI but should be suitable for use in several countries.

An Institute consultant continues to assist CPAIMC/Brazil with the development and implementation of an NFP program for lower income women in Rio de Janeiro. During this period the consultant traveled to Brazil to assist CPAIMC's staff with developing a computer program for analysis of use effectiveness and continuation rates. The staff has also begun to document their organization's progress in a format which will serve as a case study of NFP project development within a multi-method setting. The same consultant was sent to Peru to assist ATLF with the development of a twenty month project to produce and distribute NFP promotional materials. The project is expected to begin this May.

With the assistance of an Institute staff member and consultant, a project has been developed with the Academia Mexicana de Investigacion en Demografia Medica to analyze the associations between breastfeeding and child spacing and their impact on infant mortality in Mexico during the period of 1971-1982. The project is scheduled to begin this May. An Institute consultant has been working with a biomedical researcher at the Catholic University of Chile to refine a proposal to study the childspacing effect of full nursing during the first six months post-partum and on the acceptance and effectiveness of NFP following this period. The project is expected to begin this summer.

VI. Other NFP Activities

A. International Conferences and Seminars

During this reporting period Institute staff participated in international conferences in Singapore, Madras and Washington, DC. The Institute's principal investigator, Dr. John T. Queenan, attended the XII World Congress on Fertility and Sterility held in Singapore. Dr. Queenan's participation in the congress provided an opportunity for him to present the Institute's plans in the area of ovulation prediction and to encourage other scientists to collaborate with the Institute. Diane Vogelsang, a member of the Institute's training staff, participated in the World Congress in Family and Culture held in Madras, India. Ms. Vogelsang chaired a workgroup for twenty participants to discuss ways in which the family can have a positive impact on the community and society. Ms. Vogelsang also participated in an exposure program that visited families and an orphanage in Madras and learned about existing and future NFP programs and plans in India. Rosalia Rodriguez-Garcia, the Institute's Director of Education and Communication, participated in a panel presentation at the Annual Conference of the Society for International Development. The panel discussed issues related to the appropriateness, cost-effectiveness, long-term effects and ethical aspects of social marketing related to family planning and infant nutrition.

In the next six months, the Institute is planning to participate in a one day session devoted to NFP at the Fourth Annual Meeting of the Society for the Advancement of Contraception. Topics for discussion will include the Efficacy of Modern Methods of NFP, Status of New Assays to Predict Ovulation and NFP During Lactation. The Institute staff has also been involved in the planning of the Fifth National and International NFP Symposium to be held during the summer of 1988 in Los Angeles, CA. In addition, the Institute is collaborating with NIH to conduct a conference on non-radiometric technology, scheduled for October 1987.

B. Worldwide NFP Coordination

As AID's primary technical resource for NFP, the Institute has continued to expand the roles of the

Resource Center and the Data Center to collect, generate, analyze and disseminate information on NFP. (See Section III.C.3 and IV.B.1.)

In addition, the Institute has collected and disseminated information about the NFP and breastfeeding activities being supported by cooperating agencies and USAID missions. In December, a report was proposed on the FY '85 and '86 expenditures and FY '87 and '88 projections of USAID mission. The FY '85 total NFP and breastfeeding funding for bilaterally funded projects was \$725,000. For FY '86, the projected amount was \$985,000, with \$1,568,000 anticipated for FY'87. These figures are based on responses from USAID missions to a cable requesting this information sent by the Institute in the prior reporting period. A similar cable was sent in March, requesting information on FY '86 expenditures and FY '87 and '88 obligations. Responses are expected by mid-May, and a similar report will be prepared. In February, the Institute requested information from cooperating agencies on their NFP and breastfeeding expenditures and obligations during FY '86, '87 and '88. By the end of this reporting period, the majority of responses had been received. A report will be prepared and disseminated by early May.

Institute staff have participated in a number of meetings with other organizations that support NFP and breastfeeding activities to plan collaborative programs. The Institute Director participated in the WHO HRP Natural Methods Task Force meeting in March, and the Task Force Manager attended the Institute's TAG meeting in November. (See Section III.C.2 for a description of planned Institute/WHO collaboration.) He also will attend the May TAG meeting and present an overview of WHO's activities in NFP and breastfeeding. The Institute also is working with the PCS project at Johns Hopkins University and the IFFLP to develop a training/technical assistance program in management and outreach for NFP programs in Africa; with Pathfinder on a project with CPAIMC/Brazil; with IFFLP on the publication of scientific papers form an international congress on NFP; with WHO, FHI, and IPPF on a brochure on breastfeeding as a method of childspacing; with the Carolina Population Center on a longitudinal study in the Philippines.

VII. Technical Project Report Summaries

- A. Fluctuations of Salivary Enzymes in the Menstrual Cycle
- B. Multicenter Study of NFP Among Breastfeeding Women
- C. Predictors of Ovulation During Lactation in Manila
- D. The Efficacy of the Sympto-Thermal Method of NFP in Lactating Women After the Return of Menses
- E. Comparison of Various Methods of Breast-Milk Pumping on Prolactin Levels and Milk Volumes
- F. Outcome of Pregnancies in NFP
- G. Client Data System Implementation
- H. Analysis of WFS and CPS Data
- I. CM/BBT Analysis
- J. Breastfeeding Promotion and Education Program
- K. Training of NFP Instructors

TECHNICAL RESEARCH REPORT

Project Fluctuations of Salivary Enzymes
 in the Menstrual Cycle

Number GU-BioM-IM-001

Reporting Period October 1, 1986 - March 31, 1987

Investigator Dr. Michael Zinaman

Statement of Objectives

This pilot project represents an attempt to study the fluctuation in salivary enzyme activity during the normal menstrual cycle. The goal is to determine whether consistent and useful changes can be found in any or all of the four enzyme under study. The project is utilizing reagents and machines for the enzyme determinations supplied by Personal Diagnostics, Inc.

Progress

While technical difficulties with the machines halted the study in the prior reporting period, during the last 5 months we have been more successful. Four women were recruited to measure salivary enzymes and collect daily early morning urines for 3 cycles. Three women successfully did so. The fourth woman conceived during the second menstrual cycle. We therefore obtained a total of 11 menstrual cycles. The hormone analysis was completed during this reporting period. It revealed 2 of the cycles to be anovulatory and 9 to be normal ovulatory cycles, and it confirmed the conception cycle. The enzyme results along with the urinary hormone values have been encoded onto disks and sent to the University of Pittsburg Data Center for analysis.

Plans for the next 6 months

The data analysis is expected to be completed during the month of April 1987. The final results will be presented to TAG during the May meetings. Further dissemination of the results and future plans for study will be dictated by the results.

SEMI ANNUAL TECHNICAL REPORT SUMMARY

PROJECT TITLE: Multicenter Study of NFP Among Breastfeeding Women
NUMBER: BR-US-001 INCLUSIVE DATES OF REPORT: 1 October 86 to 31 March 87
SUBCONTRACTOR: Family Health International
PRINCIPAL INVESTIGATOR: Nancy Williamson, PhD

The long-term objective of this project is to determine the effectiveness of Natural Family Planning (NFP) methods in the prevention of pregnancy among breastfeeding women. This project is designed to determine specifically:

- (1) the relationships between various NFP signs and symptoms (alone and in combination) and the underlying ovarian activity,
- (2) the proportion of subjects who can prospectively identify the first ovulation, and
- (3) the amount of abstinence required by correct prospective application of conventional rules and new rules hypothesized retrospectively based on the data.

This is a multicenter study with a common protocol. SERENA CANADA in Montreal, Westmead Hospital in Sydney, Australia, and the University of Birmingham's Maternity Hospital in England are the three participating centers.

A site visit was made by FHI staff to the Birmingham center during the reporting period. The mothers dislike coming in for ultrasound in the early months of the study because they know from experience that there will be no ovarian activity observed, so going to the hospital for ultrasound is an inconvenient and unrewarding experience until they are returning to fertility.

The laboratory in Melbourne continues to conduct assays of the urine samples in a timely fashion.

After keypunching with 100% verification, FHI staff have loaded 36 admission records, 3691 diary sheet, 291 laboratory results forms and 117 ultrasound records. Data analysis programs are currently being tested. FHI has recently purchased a Hewlett-Packard plotter, and this study will be one of the first to use it for analysis.

In a few cases, very long luteal lengths were observed in ostensibly ovulatory cycles. There are some discrepancies (to be expected) among the luteal lengths as determined by BBT shift, mucus peak and ultrasound.

It is premature to state the relevance of the project's findings in relation to the findings of other investigators since the project is early in the data collection phase. The next six months in this project will continue to be dedicated to data collection and quality assurance.

THE JOHNS HOPKINS UNIVERSITY

SCHOOL OF HYGIENE AND PUBLIC HEALTH

DEPARTMENT OF POPULATION DYNAMICS

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PREDICTORS OF OVULATION DURING LACTATION, MANILA

Progress Report

R. H. Gray

All data are now entered and the analysis is progressing. The main findings since the previous report are as follows:

1. Predictors of Ovulation

Detailed examination of individual data did not reveal obvious predictors of ovulation resumption. However, inspection of aggregate data show clear bimodal clustering of women into two main groups:

- (a) "early ovulators" who ovulate between 10-21 weeks post partum, and
- (b) "late ovulators" who ovulate between 36-69 weeks post partum or who fail to ovulate during the study.

The number of breastfeeding episodes or total duration of breastfeeding per day provide the best discrimination between these two groups. The "early ovulators" frequently show declines in feeding frequency or duration at or after the time of ovulation with relatively little change over the 5-6 weeks preceding the ovulatory event. This

suggests a rather acute release of ovarian inhibition, unlike the pattern reported for European or Mexican women. Also, addition of artificial feeds is not a good predictor of ovulation return in our data because women often maintain a high frequency of breastfeeding (i.e., true supplementation). In contrast, other studies show declines in breastfeeding after the introduction of artificial substitutes.

Miriam Labbok and Susi Eslami have applied existing algorithms for the timing of contraceptive introduction during lactation to these data, and shown that all the current approaches would lead to protracted unnecessary overlap between contraceptive use and lactational anovulation, but would also miss ovulatory events.

We are now conducting a multivariate analysis using a proportional hazards model with ovulation as the dependent variable, and breastfeeding, supplementation, menstruation, infant weight, and time post partum as independent variables.

2. Anovular Cycles and Luteal Phase Characteristics

Many women experience anovular bleeding episodes and ovulatory cycles with inadequate luteal phases for prolonged periods of time during sustained breastfeeding. This does not vary systematically with time post partum, and reflects the continuing suppression of fecundability during lactation even after resumption of menses.

SEMI ANNUAL TECHNICAL REPORT SUMMARY

PROJECT TITLE: The Efficacy of the Sympto-Thermal Method of NFP in Lactating Women After the Return of Menses

NUMBER: BR-US-003 INCLUSIVE DATES OF REPORT: January 1 - March 31, 1987

SUBCONTRACTOR: Maryland/DC NFP Providers Association

PRINCIPAL INVESTIGATOR: Wilma Stevenson

The purpose of this project is to determine the efficacy of the Sympto-Thermal Method (STM) of Natural Family Planning with lactating women, particularly during the first three cycles following the cessation of lactation-induced amenorrhea. Specific areas of study will include: the reliability of STM as a predictor of ovarian activity and ovulation in breastfeeding women after the period of lactational amenorrhea; the amount of abstinence required for STM users to avoid pregnancy versus what the user deems necessary; the relationship of feeding patterns to cervical mucus activity; the relationship of subjective assessments of cervical mucus to the volume of aspirated cervico-vaginal fluid; the reliability of cervico-vaginal fluid volume as a predictor of ovarian activity after the end of lactational amenorrhea; the bleeding patterns, number and characteristics of ovulatory cycles and ovarian activity in these women; and the ability of basal body temperature to reflect ovulatory activity during this time period.

The protocol requires subjects to commence participation at twelve weeks postpartum, with participation ending when a subject has experienced at least three periods of postpartum bleeding, at least two of which are determined to be ovulatory.

The study commenced on February 1, 1987. With the long-range goal of recruiting at least 25 eligible subjects over a period of two years, over 75 letters were sent out the first week of February to NFP clients affiliated with the MD/DC NFP Providers Association, and to local obstetricians, gynecologists and pediatricians, informing them of the study and inviting referrals.

To date, response has been favorable; during this reporting period, nine women have been enrolled and are actively participating in the study. Each of them has been screened, interviewed, and taught the study protocol. An additional four women have agreed to participate and are waiting to reach twelve weeks postpartum before beginning. An additional eight women, who are now between one and five months pregnant, have expressed interest in participating in the study; they will be contacted shortly after their due dates to be enrolled. Five of the nine participating women are obtaining periodic cervico-vaginal fluid samples in addition to their other protocol requirements. All of these women are experienced NFP users. Follow-up interviews have been conducted every two to three weeks. Telephone consultation has taken place every one to two weeks per subject. About 163 breastfeeding diaries and 72 urine samples have been collected to date in addition to monthly STM charts. Subjects seem to be adhering to the protocol well, and no significant problems have been reported.

We expect to have at least 12 active subjects by the end of the next reporting period, with at least one subject having completed her participation by that time. An anticipated problem concerns the possibility of subjects losing enthusiasm and dropping out of the study due to lactational amenorrhea lasting for many months. We plan to continue recruitment efforts during the upcoming reporting period and to do all we can within the limits of the protocol to maintain a high level of motivation and quality control among the participating subjects.

TECHNICAL RESEARCH REPORT

Project: Comparison of Various Methods of Breast-Milk Pumping on Prolactin Levels and Milk Volumes

Reporting Period March 1 - March 31, 1987

Investigator Vergie Hughes, B.S.N., R.N.

Statement of Objectives:

The purpose of this research project is to compare the volumes of breast milk obtained and the elicited prolactin rise in a variety of commercially available breast pumps. These will be individually compared to each other as well as to natural infant suckling

Progress:

Despite extensive recruitment efforts both of Georgetown University Hospital and several affiliates, it has proven extremely difficult to get mothers to come in to the hospital without their newborns as the protocol demands. We therefore feel that a revision of the protocol is in order. A letter stating the problems, possible modes of solving them and budgetary revisions is currently being drafted with close consultation of Institute staff members.

Plans for the next 6 months

During the next reporting period we hope to revise the protocol and budget, obtain Institute approval and commence the study. We feel it is likely, pending the protocol approval, that a major portion of the study can be completed in its originally stated time period.

SEMIANNUAL TECHNICAL REPORT SUMMARY

PROJECT TITLE: Outcome of Pregnancies in Natural Family Planning (NFP): Fetal Effects

NUMBER: BR-US-004 INCLUSIVE DATES OF REPORT: 12/1/86 to 4/15/87

SUBCONTRACTOR: The University of Tennessee

PRINCIPAL INVESTIGATOR: Joe Leigh Simpson, M.D., University of Tennessee, Memphis

Although transmission of funds from the Institute to the University of Tennessee has not been completed at this writing, considerable progress had already been made. (Transfer of funds is expected the week of April 27 with our forwarding of funds to the subcontractors planned immediately thereafter.) The objectives of the project remain the same. Progress has been made in devising the various forms necessary for a prospective cohort study. Initial drafts prepared by Dr. Simpson were revised by Drs. Mena, Perez and Tagliabue. This revision was then finalized by Dr. Gray. At present all South American centers are field-testing forms. Some forms have been received; final alterations prior to printing will then be possible. No substantive problems have been identified.

A visit by Drs. Queenan and Simpson (January, 1987) confirmed the ability of the South American subcontractors in Lima and Santiago to adhere to the protocol. Physical facilities were inspected in Santiago, and genetical consultants identified at one (University of Chile). A forthcoming visit to Lima (June, 1987) will similarly verify staff qualifications there. In addition, a brief exploratory visit to Bogota has identified other possible collaborators who could allow this entire study to be performed in South America. On the forthcoming June visit, we expect to designate at least one additional center. The combination of the Santa Fe Foundation and a clinic - Medellin, which in aggregate have at least 25 acceptors per month, have over 500 NFP clients on file. Other sources of NFP patients in Bogota (PAMI, CENPAFAL) have been identified, and we believe can be coordinated to allow inclusion. If Colombian centers are included, funds can be made available through rewriting the existing budget.

Irrespective of whether additional centers are added, no change in experimental design is planned.

During the subsequent quarter, we will begin formally enrolling cases. In fact, Chilean and Peruvian centers have been collecting intake data on women pregnant since January and February.

Dr. Ronald Gray plans to submit an addendum to this report describing progress in determining date of conception. This will be sent directly to the Institute by Dr. Gray.

SEMI ANNUAL TECHNICAL REPORT SUMMARY

PROJECT TITLE: Implementation of Client Data System, Mauritius
NUMBER: OR-MRS-002-87 INCLUSIVE DATES OF REPORT: 10/1/86 - 3/31/87
SUBCONTRACTOR: Action Familiale
PRINCIPAL INVESTIGATOR: Herve Juste, Managing Secretary

The general objectives of this project are to: 1) pilot test a computerized client data system, and 2) develop a model data management module for use by NFP programs in less developed countries. Specific objectives include:

- Revision of testing of client data forms
- Complete necessary staff training
- Implementation and assessment of necessary software enhancements
- Evaluate effectiveness of system operation, including impact on administrative functioning and client services
- Develop simple data management module for other NFP programs in developing countries.

A consultive team has been created consisting of staff and Board members which serves much like a steering committee for this project. Progress to this point has primarily involved the revision of client data forms, preparing data entry programs, training staff, and assessing additional hardware and personnel needs to support the data system.

Unanticipated results: Action Familiale has had a much greater problem than anticipated getting field staff to accurately, completely and promptly complete and submit the client data forms. As a result, additional staff time has been allocated to working with staff, checking data quality, and following up on incomplete and inaccurate forms.

Subsequent activity: During the remainder of the project contract, refinements to the present data system will be undertaken on a regular basis. The systematic assessment of the data system will continue and the design of the module for use in other NFP programs will be undertaken.

(Summary should not exceed space available on this page.)

SEMI ANNUAL TECHNICAL REPORT SUMMARY

PROJECT TITLE: Secondary Analysis of Survey Data re: Abstinence & Breastfeed

NUMBER: Intramural INCLUSIVE DATES OF REPORT: 10/1/86 - 3/31/87

SUBCONTRACTOR: _____

PRINCIPAL INVESTIGATOR: _____

1. Objectives

The primary general objective is to gain new knowledge of NFP and breastfeeding patterns and prevalence through the study of data collected in large national surveys in developing countries.

2. Progress to Date

Information available regarding the Peru DHS indicate that the "NFP module" (designed by Institute in collaboration with Westinghouse Applied Health Systems and representatives of Peruvian Census Bureau) was successfully implemented as part of the total survey package. The Institute will be working with the Peruvian Census Bureau and WAHS to plan the analysis of these data.

World Fertility Survey (WFS) and Contraceptive Prevalence Survey (CPS) data tapes continue to be prepared for analysis by the Institute. A number of technical problems have slowed this process, however completion of this conversion is anticipated in April 1987 with preliminary reports forthcoming shortly thereafter. A multi-country analysis of demographic and socioeconomic factors related to periodic abstinence will be conducted, along with a multi-country study of the relationship of birthspacing and breastfeeding to infant and child survival.

Additional data tapes should be available from recently completed Demographic and Health Surveys. Of particular interest to the Institute will be the Liberia DHS and other sub-Saharan African surveys where periodic abstinence use is relatively high. The Institute will be developing strategies for acquiring access to these data, and will engage in appropriate collaborative data analysis plans.

This activity will be managed as part of the Institute's data center and can be considered an ongoing routine function which should generate a series of reports and monographs summarizing our growing pool of knowledge on NFP use.

(Summary should not exceed space available on this page.)

SEMI ANNUAL TECHNICAL REPORT SUMMARY

PROJECT TITLE: CM/BBT Research Project
NUMBER: Intramural INCLUSIVE DATES OF REPORT: 10/1/86 - 3/31/87
SUBCONTRACTOR: _____
PRINCIPAL INVESTIGATOR: Howard Rockette

Objectives:

The primary objectives include:

- analysis of Southeastern Pennsylvania CM/BBT data to establish baseline values
- obtain data from other NFP centers to establish profile of specific delivery systems vis a vis their temperature and mucus rules
- to conduct comparative analyses of chart parameters relative to basal body temperature and mucus patterns
- to develop a set of procedures to assess chart quality of various programs, and to assess the cost effectiveness of this procedure.

Progress:

In addition to the approximately 800 charts obtained from the Family Life Ministry program in Washington, DC, an agreement was made with NFP Center of Greater Washington for the inclusion of ~500 charts from this program. This was of particular importance since theirs is a strictly cervical mucus program, which will permit a more appropriate analysis of mucus parameters than was possible with data from the two other NFP programs in the study. Most of these charts have now been coded and the data set is close to being ready for inclusion in the analysis process. Analysis has been completed on the Western PA and Family Life Ministry data sets and should be completed on NFP Center data by mid May.

A major paper is being prepared which will present profiles and discuss cervical mucus and temperature parameters based on the data from the three above sites. This paper should be available for distribution by June 1, 1987.

Additional Activities:

The Institute has been in contact with WHO regarding the inclusion of data from their multi-center study in subsequent Institute analyses. In addition, negotiations are underway with the CEIPLAN group in Mexico regarding inclusion of their cervical mucus charts in future analyses. Additional monographs also may be forthcoming on such topics as: 1) quality control in NFP and 2) risk of pregnancy analysis of NFP methods based on existing algorithms.

(Summary should not exceed space available on this page.)

SEMI ANNUAL TECHNICAL REPORT SUMMARY

PROJECT TITLE: Breastfeeding Promotion and Evaluation Program - FEMAP
NUMBER: _____ INCLUSIVE DATES OF REPORT: 10/1/86 - 3/31/87
SUBCONTRACTOR: Federacion Mexicana de Asociaciones Privadas de Planificacion Familiar
PRINCIPAL INVESTIGATOR: Rebeca Ramos

Objectives:

The project is designed to:

- a) Develop breastfeeding information, education, and training materials.
- b) Assess whether indigenous volunteer community workers (promotoras) can be trained to effectively promote and teach modern breastfeeding practices to low-income women residing in urban areas in a less developed country.
- c) Assess and compare the impact of information/education programs which are designed as supplements to the one to one counselling provided by the promotoras.
- d) Assess the effect which the breastfeeding promotion program, in its various forms, will have on the prevalence of breastfeeding and on the specific breastfeeding practices which have the greatest impact on child spacing, namely frequency, supplementation and duration.

The project is to be carried out in two stages: the initial IEC/training phase to prepare for the intervention, followed by actual intervention implementation and evaluation.

Progress:

The agreement for the IEC/training activity has been approved and signed by FEMAP. The final research protocol has been approved by USAID and a sub-agreement with FEMAP will be forthcoming. During a recent site visit to FEMAP by E. Ricci and R. Rodriguez, final details of the methodology and of the implementation plan were worked out, including the assignment of interventions to communities. Additionally, recruitment of staff has begun, all IEC materials have been reviewed and designed, and a campaign slogan has been chosen. Initial trianing of FEMAP supervisors and training staff will be conducted the week of 5/4/87 with follow-up sessions in June. Pilot testing of the data collection instruments will begin in May 1987. A copy of the IEC Development Strategy has been developed and is included as an attachment to this report. Institute staff will continue to provide on-site technical support throughout all phases of the project.

(Summary should not exceed space available on this page.)

IEC DEVELOPMENT STRATEGY - FEMAP

MATERIALS	MAIN PURPOSE	TO BE USED BY	FOR	DEADLINE
POSTER(S)	Information about breastfeeding program	FEMAP	General Public	May 87
FLYERS	Information	FEMAP	General Public -- FEMAP Personnel	May 87
PAMPHLETS	Motivation: WHAT - WHY of breastfeeding	FEMAP Workers	Mothers -- General Public	May 87
BOOKLETS	Education "HOW TO" Breastfeed	Promoters	Breastfeeding Mothers	Mid July 87
FLIP-CHARTS	Education and Training	Trainers of promoters and supervisors	Breastfeeding Mothers	May 87
TRAINING GUIDES	Training methodologies of and content of breastfeeding	Trainers and supervisors	Promoters' team leaders	May 87
LESSON PLANS	Simple methodologies for providing education to mothers about breastfeeding	Promoters' team leaders	Promoters -- Mothers	June 87

SEMI ANNUAL TECHNICAL REPORT SUMMARY

PROJECT TITLE: "Information and Training of One Hundred Instructors and Development of NFP Didactic Material"

NUMBER: IR-CO-001 INCLUSIVE DATES OF REPORT:

SUBCONTRACTOR: Centro de Pastoral Familiar Para America Latina (CENPAFAL)

PROJECT DIRECTOR: Eduardo Peña

MOTIVATIONAL SESSIONS Since October 10, 1986

Twenty-four (24) Motivational Sessions were implemented. Five-hundred and thirty-seven participants attended these sessions. Contacts with local health agencies continue. NFP pamphlets have been distributed to participants of the motivational sessions and health agencies throughout the city of Bogota.

TRAINING PROGRAM

The first Instructor's Training Program was held on March 2 thru 13, 1987 and attended by twenty-seven (27) participants.

Follow-up on the progress of each participant will be conducted by CENPAFAL's instructors and the evaluation of NFP knowledge and practicum will be completed prior to their certification.

A second training program is scheduled for May 4 thru 15, 1987. Registration for this program is in progress.

EDUCATIONAL MATERIALS

The "cartilla para Usuarios" was revised and is in process of being evaluated by NFP clients. Results of comments will be considered before final printing. The draft will be sent to Georgetown for approval prior to printing.