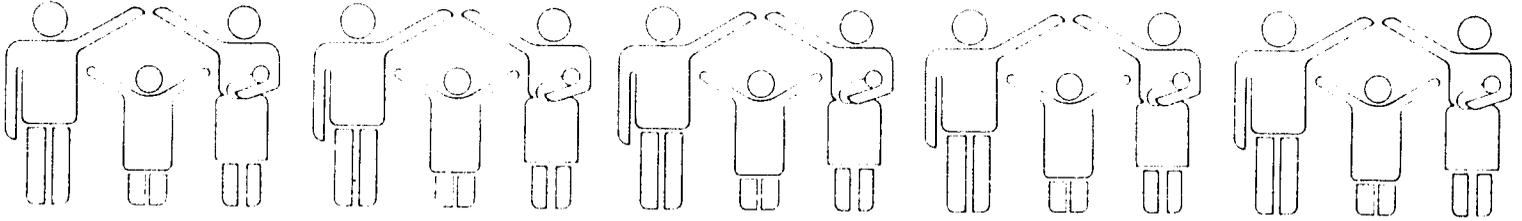


INSTITUTE FOR REPRODUCTIVE HEALTH



• Natural Family Planning

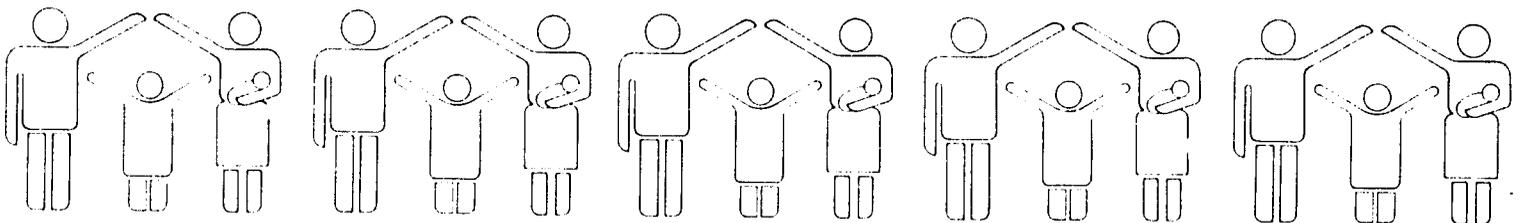
• Breastfeeding

• Reproductive Health Research

TECHNICAL PROGRESS REPORT

Cooperative Agreements DPE-3040-A-00-5064-00
and DPE-3061-A-00-1029-00

April 1, 1991 - December 31, 1991



GEORGETOWN UNIVERSITY • WASHINGTON, D.C.

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I. INTRODUCTION AND EXECUTIVE SUMMARY

This report describes the activities and accomplishments of the Institute for Reproductive Health (formerly the Institute for International Studies in Natural Family Planning) under United States Agency for International Development (A.I.D.) Cooperative Agreements DPE-3040-A-00-5064-00 and DPE 3061-A-00-1029-00 for the period April 1 through December 31, 1991.

During this reporting period, in which the Institute completed its work under a six-year cooperative agreement with A.I.D. and entered into a new five-year agreement, we continued to implement a broad program of work to achieve our goals: to improve fertility awareness and the acceptability, availability and effectiveness of natural family planning (NFP) as well as to increase the availability and acceptability of optimal breastfeeding with a focus on its fertility impact. Our approach involves natural family planning (NFP), breastfeeding (BF), and Lactational Amenorrhea Method (LAM) program development with worldwide, as well as country-specific and subject-specific efforts through strategies encompassing research, education and training, policy, and service delivery.

Because of the different approaches needed to support and develop NFP and fertility awareness programs and to support programs and policy development on the fertility aspects of breastfeeding, the Institute consists of two separate but collaborative divisions: Natural Family Planning and Breastfeeding. The work of the two divisions is presented separately in this report, with cross-referencing as appropriate.

Since the goals of the two cooperative agreements are the same, this report combines the activities and accomplishments of both. It should be noted, however, that while our work under Cooperative Agreement DPE-3040-A-00-5064-00 involved Georgetown University as the major recipient, with the University of Pittsburgh Graduate School of Public Health and the Los Angeles Regional Family Planning Council as sub-recipients, the new cooperative agreement is with Georgetown University. We expect to carry out our work both in-house and with numerous subagreements with a broad base of institutions.

A. NATURAL FAMILY PLANNING DIVISION

The strategy and activities of the NFP Division are designed to transform NFP from a "boutique" method of family planning to a genuine, viable choice for many couples. We emphasize making NFP more "user friendly"; overcoming policy, provider, and user obstacles to NFP; and providing accurate and appropriate fertility awareness information to increase informed choice.

The NFP Division's focus during this reporting period was to complete subprojects and activities undertaken as part of our initial cooperative agreement, identify objectives and priorities for the next five year period, develop a work plan to accomplish our objectives, and initiate activities accordingly.

Subprojects completed include:

- Pilot Project in NFP Group Teaching with Action Familiale/Mauritius, which showed that group teaching is as effective as and more efficient than individual teaching in urban settings but that in more traditional areas, individual teaching may produce better results.
- Prospective Study of NFP Acceptors with Action Familiale/Mauritius, which indicated that the vast majority of clients had a good understanding of the Symptothermal Method, had relatively little difficulty with abstinence, and were able to communicate with their partners about NFP.

- NFP Effectiveness During Perfect and Imperfect Use with the Office of Population Research at Princeton University, which reanalyzed data from the World Health Organization (WHO) multicountry study of the Ovulation Method. Results from this study showed that the Ovulation Method is highly effective when used correctly and consistently, with a first-year probability of failure of 3.4%. However, this method is very unforgiving of imperfect use.
- Training and Motivation for Health Professionals with the Center for Research, Education, and Training (CREST)/India, which provided NFP information and motivational seminars to 355 health care providers, local leaders and managers of health care programs, and trained 88 health care professionals as NFP instructors. By the end of the project, the 88 instructors had given orientation talks to 620 individuals and trained NFP clients.
- Training for Ministry of Health Nurses with the NFP Training and Medical Services Center in Kenya, which trained 19 nurses from the Ministry of Health to become NFP instructors. These 19 nurses established 13 new NFP programs and instructed 332 new clients in NFP.
- Development and Application of an Enzyme Immunoassay for Estrone Conjugates with the University of California at Davis, which demonstrated that a colorimetric endpoint can be used to measure urinary estrogen conjugates and predict the day of ovulation with 4-5 days notice in many women.
- Analysis of Periodic Abstinence Data from the Demographic and Health Surveys (DHS), which showed that in Peru and Sri Lanka, ever-use of periodic abstinence approaches 40%, while in a number of other countries periodic abstinence use ranges from one-fifth to one-third of currently married women. However, in many countries, less than one-third of women who report using periodic abstinence to avoid pregnancy are knowledgeable about the fertile period.
- Sperm Survival and Acrosomal Status in Human Cervical Mucus with the University of California at Davis, which demonstrated that sperm maintenance appears to be a function of hormone related mucus hydration rather than of the presence of qualitatively different types of mucus.

Subprojects continued include:

- Outcome of Pregnancies in NFP: Fetal Effects which discovered no significant increase in spontaneous abortion rates of women who conceived while using NFP compared to other women (although when analysis was restricted to women with prior history of fetal losses, significantly lower loss rates were noted in conceptions on mucus peak and day -1 compared to preovulatory and postovulatory conception). Data collection and analysis continues regarding fetal abnormalities, and plans are being made to combine data from this study with additional data from the Estudios Colaborativos Latino Americanos sobre Malformaciones Congenitales (ECLAMC) to determine sociodemographic characteristics and pregnancy intention of couples experiencing contraceptive failures (in NFP users compared to users of other methods).
- Development of Simplified and Non-Competitive Assays to Measure Steroid Hormones with the Weizmann Institute of Science, to develop new antibodies and configure them into assay technologies which can be utilized as a one-step home test to measure estradiol and progesterone. This will assist women to determine the fertile and infertile phases of their menstrual cycles using a colorimetric endpoint.
- IFFLP Technical Assistance Project, which will continue sub-subprojects in Brazil, the Dominican Republic, and Zambia; develop new initiatives in selected target countries; and emphasize the development, testing, and implementation of a management information system for NFP programs.

- Assessment of Demand for NFP and Factors Influencing its Acceptability, with the University of Nairobi, Kenya, which is investigating sociocultural determinants of, demand for, and acceptability of NFP; identifying factors amenable to policy and program intervention; and providing recommendations to health and family planning providers and program managers.

Subprojects begun include:

- Trial of the Cycle Calculation Method, a pilot project which will test an NFP method of periodic abstinence based on a rule to identify the fertile period. This calculation-based method may offer couples a NFP method that is comparable in efficacy rates to other NFP methods but is simpler to use.
- Intensive Analysis of Peru Periodic Abstinence Data, with a researcher at the College of William and Mary, which will provide further information about periodic abstinence use in a setting in which approximately one-third of all women who use family planning state that this is their current method.

In addition, the proceedings from the conference, "Natural Family Planning: Current Knowledge and New Strategies for the 1990s", co-sponsored by the Institute, A.I.D., and WHO, was published as a special supplement to the American Journal of Obstetrics and Gynecology (AJOG). The "Guide for NFP Trainers" was disseminated in French and prepared for dissemination in Spanish. "NFP: A Good Option" was evaluated and revised for re-printing in English. "Planification Familiale Naturelle et la Glaire Cervicale" was printed and distributed in Francophone Africa by Action Familiale, Mauritius; "La Regulation Des Naissances" was printed by the Mouvement pour la Promotion de la Vie Familiale (PROVIFA) in Cote d'Ivoire, and reviewed for possible wider dissemination in Francophone Africa.

Technical assistance (TA) was provided to programs in Cote d'Ivoire, Kenya, Mauritius, Rwanda, Zambia, Brazil, the Dominican Republic, and Peru, as well as to Cooperating Agencies (CAs). TA by both Divisions was provided to USAID/Port au Prince to conduct a needs assessment for NFP and fertility awareness and breastfeeding in Haiti. Materials were sent to more than 30 institutions in 20 countries.

During the next reporting period, we plan to develop and implement a comprehensive evaluation strategy to assess impact and quality of NFP and fertility awareness field-based activities; begin development of a modular slide set which can be adapted to the needs of multiple users and target audiences; develop and implement a pilot project to communicate simple fertility messages to improve understanding of the fertile and infertile phases of the menstrual cycle among target populations; and initiate a project with the NFP Training Center in Kenya through a new subagreement with the Los Angeles Regional Family Planning Council (LARFPC).

Because the NFP Division carries out the majority of its work through subcontractors and consultants, careful coordination among all project elements is essential to ensure that all involved are aware of each others purpose, strategies, and activities. To increase coordination and enhance our ability to achieve our objectives, a project review meeting will be held with our subcontractors and consultants during the next reporting period.

B. BREASTFEEDING

The GU/IRH goal in breastfeeding is to increase the availability and acceptability of optimal breastfeeding with a focus on its fertility impact. The Breastfeeding Division's three objectives are:

1. Continued testing of the Lactational Amenorrhea Method (LAM), which is an introductory method of family planning which serves to enhance acceptance of family planning and supports women in optimal child health practices;

2. Policy change favoring optimal breastfeeding;
3. Program changes to include the fertility aspects of breastfeeding and the timely introduction of family planning postpartum.

During the reporting period April 1, 1991 - December 31, 1991, the Breastfeeding Division concentrated efforts on completing and securing extensions for subprojects begun under the first project and that will continue into the next cooperative agreement. In addition, the Division identified objectives and priorities for the next five-year period, developed a workplan to accomplish the objectives, and identified and contacted potential new subproject personnel.

The Division has grown in both workscope and staffing. The following projects stand out among the accomplishments during this period but reflect only a small part of the activities during this time.

Under the subject area **LAM: Breastfeeding and Family Planning Interface**, activities consisted predominantly of direct support of the LAM/family planning method and family planning program interface, which includes research pilots, education, and technical assistance for program and policy change for breastfeeding in family planning and child survival programs, as well as timely family planning method introduction by breastfeeding programs.

Projects/subprojects completed or extended included the following:

- Chile: LAM in a Clinical Setting: The first phase of the Institute's project in Chile with the Pontificia Universidad Católica demonstrated the efficacy of LAM in the context of breastfeeding support. The most significant finding to date has been that the efficacy of LAM in clinical trial is higher than 99.5 percent. The method will now be tested among working women.
- Ecuador: LAM in a Family Planning Setting: Institute staff and the Centro Médico de Orientación y Planificación Familiar (CEMOPLAF) in Quito continue to test the LAM guidelines in a family planning service delivery system. From prototype clinics, the family planning choices of potential LAM users were documented: in the original four prototype clinics, LAM acceptors comprised an average of 15 percent of all new family planning clients. Average method continuation was 3.5 months and 75 percent of the method users said that they were satisfied with the method. No pregnancies occurred among the 79 percent of women who used the method correctly.
- Guidelines for Breastfeeding in Family Planning and Child Survival Programs: Approximately 2,900 English, 2,200 French, and 5,000 Spanish copies of this publication have been distributed worldwide since the document's first printing. During this reporting period, the Guidelines were translated into Bahasa Indonesia and Portuguese, and they were distributed at major national, regional, and international conferences in Guatemala, Indonesia, and Togo. Planning was begun for an update of the Guidelines to reflect the state of the art in LAM information and to address a wider audience.
- Guatemala: LAM in LLLI: In Guatemala, the Institute continued to work with La Leche League International (LLLI), on a "Breastfeeding and Natural Child Spacing Project." A two-day national conference on breastfeeding and child spacing as well as other activities resulted in MOH involvement and policy modification. The 18-month extension project, which was signed in November 1991, builds on the accomplishments of the original project and will begin to incorporate LAM into LLLI activities regionally.

- Technical Assistance to Cooperating Agencies: The Breastfeeding Division has designed an organized program of technical assistance that includes presentations and workshops with selected Cooperating Agencies as well as needs assessment and materials for a broader group. This approach was pretested in 1990 with a presentation at JSI and resulted in a second-level presentation by personnel in these projects. The first technical presentation in the newly organized series was given in December 1991 at CEDPA.

Under the subject area **Breastfeeding and Fertility**, the Breastfeeding Division's activities are designed to create support for optimal breastfeeding for its fertility impact on populations. This support includes demographic and biomedical research designed to address controversies and obstacles to optimal breastfeeding. The findings are used in the development of policy, educational materials, and technical assistance. Significant progress included the following:

- University of California at Davis: Effect of Introducing Complementary Foods on Breastmilk Intake and Maternal Fertility in Honduras: The specific aims of this project are to (1) examine the effects on infant breastmilk and total nutrient intake of introducing complementary foods at 16 weeks versus continued exclusive breastfeeding until 26 weeks; and (2) determine if the duration of maternal postpartum amenorrhea is affected by the timing of the introduction of solid foods. The pilot study for this project was initiated in July 1991. Early results indicate full lactation through six months results in fertility delay with no nutritional detriment to mother or child.
- Helping Mothers to Breastfeed, which has been translated into seven languages and widely distributed, has been revised to include LAM and to include reference to this rewrite in the preface. A follow-on agreement with AMREF will support distribution of copies to key persons in Africa with an Institute cover letter.
- Lactancia Materna was developed in conjunction with a major breastfeeding support and research program in Chile and was disseminated at the Institute-sponsored conference on "Advances for Breastfeeding for Health and Child Spacing." The publication has been reviewed and expanded to include a brief proceedings of the meeting (co-funded by PAHO). It is designed to fill a gap in health professional level materials presently available in Spanish that have been developed in the region.
- Breastfeeding: Protecting a Natural Resource: This booklet has been publicly recognized by UNICEF as a major contribution to worldwide policy change in breastfeeding. Since its publication, approximately 9,200 English, 5,000 French, and 6,000 Spanish copies have been distributed to groups such as A.I.D and A.I.D. Cooperating Agencies, USAID Missions, Schools of Public Health, WHO, UNICEF, UNFPA, JHPIEGO, SIDA, AED, La Leche League International, Wellstart, PAHO, and many others. During this reporting period alone, 700 English, 900 French, and 4,500 Spanish copies were distributed. UNICEF/Mexico received 4,000 copies of the Spanish version of the booklet to distribute countrywide. The booklet was distributed at conferences in Indonesia, Togo, and Guatemala.
- Journal Of Tropical Pediatrics Supplement - "Breastfeeding and Borderline Malnutrition in Women": This document is the result of an IRH-sponsored panel entitled "Breastfeeding and Borderline Malnutrition in Women" at the 17th Annual National Council For International Health Meeting in Washington, DC, in June 1990. This publication is part of a series designed to address policy and program obstacles to optimal breastfeeding. To date, IRH has distributed approximately 200 copies of the document in addition to the journal subscribers.
- Breastfeeding Saves Lives: The Impact of Breastfeeding on Infant Survival: This monograph and companion article were prepared by the Center to Prevent Childhood Malnutrition (NURTURE) in conjunction with IRH. The booklet was created to

illustrate the profound effect of optimal breastfeeding practices on infant health and child survival throughout the world. Noteworthy in this document is a page that presents a comparison of breastfeeding to other child survival interventions.

- Videotape: Breastfeeding: Protecting a Natural Resource: Distribution of the video to policy makers around the world continues through a variety of channels including A.I.D., WHO, UNICEF, PAHO, SIDA, and A.I.D. Cooperating Agencies such as AED and Wellstart. In addition to the recognition that the video continues to receive from colleagues at both WHO and UNICEF, the video was recognized by the A.I.D. Breastfeeding Cluster and won an honorable mention in the National Association of Government Communicators Gold Screen Award Competition.

Activities under the third strategy area, **Breastfeeding and NFP Interface**, are designed primarily to introduce LAM into NFP programs and to improve guidelines for NFP use during lactation. The main activities that took place during this reporting period were the following:

- IFFLP: Breastfeeding Division staff met with IFFLP staff to refine their scope of work, to include formulation of guidelines for LAM use in NFP programs and testing the guidelines in a project site or sites. Division staff also planned, with IFFLP, for the IFFLP Zonal/Subzonal meetings to take place during the next reporting period. IFFLP has, on the advice of the Breastfeeding Division, hired a consultant to assist the organization in developing an IFFLP breastfeeding promotion and LAM/NFP policy and strategy and to develop sets of method use guidelines for each NFP method that can be adopted by IFFLP members and programs worldwide.
- NFP Conference Proceedings: "Current Knowledge and New Strategies for the 1990s": The Breastfeeding section in the AJOG supplement explores the use of natural family planning during breastfeeding and the operationalization of the research findings related to the breastfeeding/natural family planning interface. The Breastfeeding Division will use this supplement to serve as a basis for discussion in IFFLP Zonal conferences over the next 12 months to aid in their development of policy on breastfeeding.

In addition, during this reporting period, technical assistance was provided to USAID/Port-au-Prince to conduct, with a consultant to the NFP Division, a needs assessment on breastfeeding for child spacing and natural family planning. In addition, Breastfeeding Division staff assisted A.I.D. in drafting a cable to USAID Missions to inform them about the capabilities of the Institute, especially under its new expanded mandate.

Technical assistance continues to be provided to many international donors. Breastfeeding Division staff have been proactive in correspondence with UNFPA, UNICEF, World Bank, and IPPF. With WHO, Breastfeeding Division staff have been working on a document, The Technical Rationale for Global Action on Breastfeeding: Proceedings on the Expert Meeting Towards the Innocenti Declaration, which will be a companion piece to the extremely popular WHO publication The Physiological Basis of Breastfeeding.

Institute staff continue to be actively involved in working groups with other Cooperating Agencies, including the Working Group on Perinatal Family Planning Education and Counseling Training and the Working Group on the Family Planning Training Materials Database. In addition, Institute staff continue to review Cooperating Agencies' breastfeeding materials and regularly review articles for peer reviewed journals.

The Breastfeeding Division continues to refine its audiovisuals. A one-hour slide presentation was finalized during this reporting period, and has been given in Guatemala and Indonesia. The presentation is available in English and Spanish, and will shortly become available in French. Other slide presentations are underway, including shorter (30-minute and 20-minute) presentations. Work has also begun on the development of a LAM training videotape.

During the next reporting period, the Division plans to begin to test LAM with working women in Chile; expand the Ecuador study into more clinics in the country to assess ongoing acceptability of LAM and operational methods to ensure the timely introduction of complementary family planning during breastfeeding; begin to plan a clinical trial of LAM at Georgetown University Medical Center; expand field projects into Africa and Asia, as well as expand IRH assistance to USAID Missions; update several key publications and slide presentations; publish guidelines to assist working women with achieving optimal breastfeeding, as well as several journal articles reporting project results.

The Division also plans to conduct a meeting to bring together IRH and other experiences in LAM to assess the state of the art and to receive input for future planning. In addition, Breastfeeding Division staff hope to finalize an agreement with the new Wellstart project to expand IRH work in key areas.

The Institute is extremely pleased with its progress during this reporting period. IRH and its collaborating institutions have accomplished a great deal worldwide in the areas of Natural Family Planning and Breastfeeding. With the award of our new five-year Cooperative Agreement, we have begun to expand our mandate and the areas of the world in which we work.

The Institute remains dedicated to working with A.I.D./Washington, USAID Missions, LDC public and private sector programs, agencies, and institutions and other Cooperating Agencies to carry out our broad-based program of research, pilot projects, training, information, education, and communication, technical assistance, and policy development and change.

John T. Queenan, M.D.
Principal Investigator

II. NATURAL FAMILY PLANNING

A. OBJECTIVES

The objectives of the NFP Division have evolved over the past six years from discussions with our Technical Advisory Group (TAG), A.I.D., and other experts. They were confirmed by the recommendations developed during our conference "NFP: Current Knowledge and New Strategies for the 1990s", held in December, 1990. The primary emphasis of these recommendations was to continue our focus on effectiveness of method use and quality of services while increasing our efforts to expand fertility awareness and NFP availability to a wide audience.

The Institute's objectives in NFP are to:

1. Develop and test reliable, **simplified methods** for defining the fertile period.
2. Increase knowledge of and support for NFP and fertility awareness by **policy makers, health/family planning professionals, and the public.**
3. Improve, expand, and evaluate **programs** to increase availability, acceptability, and quality of NFP services and fertility awareness information.
4. Enhance **clients'** fertility awareness and knowledge, acceptance, and effective use of NFP.

The following discussion describes the strategies we employ to achieve our objectives, the activities undertaken as part of each strategy, and planned activities for the next reporting period (January 1 - June 30, 1992).

B. ACTIVITIES

1. **Objective:** Develop and test reliable, simplified methods for defining the fertile period.

- a. **Strategy:** Support and encourage research and testing to develop a simple, inexpensive home test kit for detection and prediction of ovulation.

- (1) Multicenter Study of the Hormonal Definition of the Fertile Days of the Cycle by Home Monitoring for NFP

The purpose of this study, in which the Institute may participate as one of five centers in a study being coordinated and partially supported by the WHO Natural Methods Task Force, is to (1) establish temporal relationships between hormonal events and fertility signs, (2) compare menstrual cycle phases as determined by clinical symptoms with those determined by hormone data, (3) determine if use of the Ovarian Monitor (developed by Dr. Jim Brown in Australia) will reduce days of abstinence, and (4) make a qualitative assessment of the Ovarian Monitor. During this reporting period, the Institute met with Dr. Earle Wilson, Manager of the WHO Natural Methods Task Force, and Mrs. Wilma Stevenson, President of the Maryland/D.C. NFP Providers Association, which would be the field site for the study, to discuss a number of technical and implementation issues. While most points were resolved to mutual satisfaction, we continue to be concerned about lack of specificity in the protocol and the lack of availability of comprehensive understandable instructions for 1) women participating in study and 2) lab personnel who are supposed to repeat the tests that the women perform. Institute staff prepared participant instructions based on three documents obtained from Professor Jim Brown and his colleague Dr. Len Blackwell of Australia. The

instructions for using the meters are not consistent in these documents, and none are designed for use in the study. The Institute's version of the instructions was sent to WHO for their review prior to use. We have not received a response from WHO during this reporting period.

The results of the Ovarian Monitor in previous studies, as reported at the Institute/WHO Conference in December, 1990, were published in the American Journal of Obstetrics and Gynecology (AJOG) supplement.

The Georgetown University Andrology Laboratory has begun running tests using the Ovarian Monitors with frozen urine. The results do not appear to show the expected trends, and we have experienced some difficulties with the calibration of the monitors.

Planned Activities: We will perform additional tests using fresh urine samples and share the results with WHO and Dr. Brown. We will make a decision regarding whether to continue with this study within the next three months. Our decision will be based on the results of our continued testing of the monitors, the availability of study subjects (who will be required to spend approximately 1+ hours per day for six months collecting urine and testing it with the monitors), and the availability of funds.

(2) Comparison of Home Colorimetric Test Kit to Determine the Post-ovulation Non-fertile Period to NFP Symptothermal Signs and Symptoms

The purpose of this study, which is being supported by Quidel (formerly Monoclonal Antibodies, Inc.) and carried out by the Maryland/D.C. NFP Providers Association, is to (1) determine if women can perform the kit assay and interpret results, (2) compare NFPCheck™ Assay results to urine pregnanediol levels, and (3) compare both of these to NFP chart data. The Institute's role in this study is to provide Quidel with the study population, provide technical expertise at recruitment meetings, act as liaison between Quidel and the Provider's Group and coordinate efforts with the Provider's Group to collect data and specimens for Quidel.

Technical assistance was provided to Quidel for development of subject instructions for the NFPCheck™ device. A total of 61 women have been enrolled in the study and have begun using the NFPCheck™. The study is expected to be completed during the next reporting period.

Planned Activities: We plan to continue our coordination role in the study and to serve as a technical resource to Quidel and the field site.

(3) Development of Reagents to Assay Urinary and Salivary Steroid for One-Step Detection of Hormonal Changes

The purpose of this study, which the Institute is supporting with the Weizmann Institute in Israel, is to (1) develop new assay technologies to measure small molecules, and (2) incorporate these technologies into a one-step test to measure estradiol and progesterone and their metabolites. During this reporting period, the final report on Phase I of the study was received. Results indicate that the measurement of small molecules in a one-step immunometric assay is feasible. These non-competitive assays vastly reduce the time needed to detect the presence of hormones and/or their metabolites. To date, various anti-idiotypic antibodies have been produced against primary antibodies to estradiol, estrone glucuronide, progesterone, pregnanediol glucuronide and human hormone.

We also received a proposal from Weizmann Institute for Phase II of the study to continue efforts to develop novel estrogen tests to predict the fertile period in women. The initial proposal was reviewed in Singapore at the Institute's Biomedical Ad Hoc Review Committee meeting. The reviewers recommended that the investigators focus their efforts from production of novel reagents and assay configurations to finished product and show feasibility by incorporating industry contacts in their proposal. A revised proposal was received in response to Ad Hoc Committee's review. Reviewers of the latest proposal recommend funding the project for two more years with emphasis on 1) developing reagents for tests most likely to be used for predicting potential fertility, and 2) producing data to convince industrial partners that the materials are suitable for incorporation into a self-test.

The results of the early phase of this study, presented at the Institute/WHO conference, were published the December 1991 AJOG.

Planned Activities: The Institute will communicate with the investigators regarding the comments of the reviewers. We expect a revised proposal which will form the basis of a subagreement with Weizmann Institute for Phase II of the study.

(4) Development of a Simple Device to Normalize Urines

A proposal was received from the University of California at Davis to field test a non-laboratory kit assay to determine reliability by focusing on specific aspects of the assay format which may be easily modified to enhance a non-laboratory application. The expected outcome is the development of a simple device test which will normalize urines to account for their relative water content. The prototype device is proposed to be made available to the Institute personnel for use in biomedical studies.

This proposal was reviewed by the Institute's Biomedical Ad Hoc Committee at its September meeting. The committee recommended that this project not be funded as it would add a separate step in any home test. In addition its overall complexity was felt to be far more at this stage, than could be incorporated into a kit format.

The Institute has communicated these recommendations to the investigator.

Planned Activities: We will continue to discuss a revised proposal with the investigators.

(5) Development and Application of an Enzyme Immunoassay for Estrone Conjugates

This study, conducted by investigators at the University of California at Davis, demonstrated that a colorimetric endpoint can be used to measure urinary estrogen conjugates and predict the day of ovulation with 4-5 days notice. The study was completed during this reporting period, and a proposal for further work was received from the investigators and reviewed by the Institute's Biomedical Ad Hoc Committee. While the committee recognized the scientific merit of the research, it recommended that the Institute not fund it further because it lacked sufficient practical application to our objectives. This recommendation has been communicated to the investigators, and they have been encouraged to seek funding elsewhere. Results of this study were published in the December 1991 AJOG.

Planned Activities: There are no plans to pursue this activity in the future.

- b. **Strategy:** Support research on parameters of the fertile period which can contribute to improved practice of NFP.

(1) Evaluate Properties of Cervical Mucus that Determine Receptivity to Sperm

A proposal was received from the University of California at Davis to study the survival of sperm in early proliferative phase mucus, and relate them to mucus hydration and to the number of days before ovulation. The proposal was reviewed by the Institute's Biomedical Ad Hoc Committee. While the reviewers recognized the scientific merit of the proposed study, they found that its relevance to Institute priorities needed to be addressed. This has been communicated to the investigator, and he has been encouraged to address these issues with the Institute and A.I.D. Other minor modifications were also suggested.

The final report on the study the Institute supported with this researcher on a similar topic, Sperm Survival and Acrosomal Status in Human Cervical Mucus, was submitted. The results of this study showed that human sperm can be actively maintained in a fertile state in cervical mucus. NFP abstinence has typically been linked with sperm survival analysis studies where it has been demonstrated that sperm can live for up to five days. However, less is known about what specific mucus properties in the pre-ovulatory period interact with sperm to influence sperm survival and penetrability.

Cervical mucus in various stages of proliferation were collected in normal cycling women. Results have shown that there are progressive changes in the mucus ultra-structure from the early proliferative phase to ovulation. These appear to be more a function of mucus hydration than the presence of altering amounts of qualitatively different types of mucus. This fact is markedly different from currently accepted characterizations of mucus. Sperm are capable of penetrating and surviving (three hours) in the early proliferative phase mucus, more so than previously appreciated. Such penetrability appears linked to the presence of mucus cells which may permeabilize the inherently more dense mucus microstructure to sperm. However, such cells can also phagocitize sperm rapidly. The functional integrity and potential fertility of mucus are not yet known. In the next report, the results of further investigations will be reported.

Ultrastructural features of mucus were also studied. It appears that changes in the early proliferative phase mucus do not appear to be necessarily coupled to either urinary or serum estrogen levels. Thus, other factors must also be involved in the control of mucus quality and/or secretion. While basic in nature, this information appears to be shedding new light on sperm-mucus interaction.

Results of this study were published in the December 1991 AJOG.

Planned Activities: The Institute will continue to look for opportunities to support research in this area, with an emphasis on studies with relevance to our objectives and practical application to NFP use.

(2) Prediction of Ovulation and Monitoring of the Fertile Period

A review article on this topic was published by Institute faculty in *Advances in Contraception* in 1987. Various commercially-available devices to assist women in assessing and monitoring their clinical signs and symptoms of fertility were described. Given continued interest in this area and the development of new/improved devices, we would like to up-date this article. We have been contacted by a researcher who is interested in a brief fellowship with the Institute to work with us on this revision.

Planned Activities: We will make arrangements for the researcher's visit and work with him to revise the article.

- c. **Strategy:** Develop and test simplified methods of NFP to increase acceptability, efficacy, and continuation.

(1) Trial of the Cycle Calculation Method

We hope to show that the Cycle Calculation Method (a specific calendar method) has comparable efficacy rates to other NFP methods commonly in use (OM, STM) but is simple to use. If this is true, then the CCM can be offered as a NFP method which does not require daily assessments of fertile signs and symptoms. This may lead to increased acceptability and continuation of the use of NFP.

We plan to conduct a pilot study to 1) assess the acceptability of cycle calculation as a family planning method, 2) gauge the rate of recruitment for a larger full-scale trial, 3) assess the materials used to teach the method, and 4) estimate the effectiveness of the cycle calculation method.

If the results of the pilot study are promising, we plan to conduct a larger full-scale study to establish an efficacy rate for the method. The pilot study will be conducted in 1-2 sites.

Planned Activities: We plan to submit the protocol to the appropriate review boards during our next reporting period. We will have a consensus meeting of all the important players who have been involved in the development of the protocol in Feb/March 1992 to finalize the protocol.

(2) Modified Mucus Method

For the past several years, the Modified Mucus Method (MMM) of NFP, developed by Dr. Kathleen Dorairaj in India, has gained popularity and recognition in some countries -- particularly in parts of Asia and Africa. Unlike other NFP methods, it does not require a woman to chart her fertility signs and symptoms, it relies on sensation rather than visual observation of cervical mucus, and it requires fewer days of abstinence. The Institute is not directly involved in studies of this method. However, we continue to monitor results of other studies of the MMM (such as the one being conducted by Johns Hopkins University with support from WHO) and are considering how we could best approach this issue. Dr. Dorairaj's paper on the MMM, presented at the Institute/WHO conference, was prepared for publication.

Planned Activities: We will maintain contact with other researchers and field programs using the MMM and develop an appropriate strategy for the Institute in this area.

2. **Objective:** Increase knowledge of and support for NFP and fertility awareness by policymakers, health and family planning professionals, and the public.

- d. **Strategy:** Conduct research on key issues to overcome barriers to NFP and fertility awareness.

(1) Outcome of Pregnancies in NFP: Fetal Effects

The purpose of this study is to determine whether pregnancies associated with aged gametes result in more frequent incidence of spontaneous abortion and/or congenital malformation than other pregnancies. The first phase of this study, which is being

conducted by the University of Tennessee with field sites in several countries, was completed during this reporting period. Preliminary data indicate that there is no significant increase in spontaneous abortion rates of women who conceived while using NFP (although when analysis was restricted to women with prior history of fetal losses, significantly lower loss rates were noted in conceptions on mucus peak and day -1 compared to preovulatory and postovulatory conception). Data collection and analysis continues regarding fetal abnormalities. Site visits were conducted to the two Chilean universities that are participating in the study.

The investigators have indicated that although the participating centers are functioning very well, they have not been able to collect a sufficient number of cases to allow a definitive answer to the question of congenital abnormalities. They will submit a proposal to the Institute for support for an additional three years. In addition, their proposal will request support to combine data from this study with data from the Estudios Colaborativos Latino Americanos sobre Malformaciones Congenitales (ECLAMC). ECLAMC will also add questions to their standard form, with which they collect data from several participating hospitals throughout the region, to provide information on sociodemographic characteristics and pregnancy intention of couples experiencing contraceptive failures (in NFP users compared to users of other methods).

The results of this study, presented at the Institute/WHO conference, were published in the December 1991 AJOG.

Planned Activities: Following a site visit to Chile in January, we expect to receive the proposal for this project. As soon as we have reviewed it at Georgetown, we will prepare a subagreement with the investigator and submit it to A.I.D.

(2) Analysis of Periodic Abstinence Data from the Demographic and Health Surveys (DHS)

During our original cooperative agreement with A.I.D., we contracted with the Institute for Resource Development (IRD) to conduct separate analyses of periodic abstinence data from their surveys. One of our subrecipients, the University of Pittsburgh Graduate School of Public Health, received relevant data tapes from IRD and was responsible for analyzing them more thoroughly, emphasizing intensive analysis of data from countries with high levels of periodic abstinence use. IRD completed its work, indicating the following: (1) highest levels of current use of periodic abstinence are observed in Bolivia, Peru, and Sri Lanka (15 - 18% of all currently married women [CMW]); (2) other countries with significant current levels of periodic abstinence among CMW include Togo, Kenya, Ghana, Ecuador, and Colombia; (3) in several countries with very low levels of contraceptive use (such as Mali, Uganda, Senegal, and Burundi), a large percent of family planning users rely on periodic abstinence; and (4) in many countries, large percentages of CMW who state that they are periodic abstinence users do not know when during their menstrual cycles they are most likely to become pregnant. These results were prepared for publication.

The University of Pittsburgh has submitted draft tables and a draft paper of periodic abstinence in Peru. They have verbally assured us that a revised paper on Peru and final tables, with accompanying text, will be completed, although the time line for this is unclear.

Planned Activities: We have discussed another project with IRD, in which they will analyze data from selected DHS II and III countries, write country reports, and prepare a comparative report. We expect to receive a proposal from IRD in early

1992. No further work in this area is contemplated with the University of Pittsburgh, pending receipt of their reports.

(3) Intensive Analysis of Peru Periodic Abstinence Data

The purpose of this project, which is being carried out by an investigator from the College of William and Mary, is to provide more analytical information about sociodemographic and behavioral aspects of periodic abstinence use. The general analysis of contraceptive behavior, which examines the determinants of contraceptive use and use-effectiveness, has been completed. Preliminary findings are that for all contraceptive types, systemic variability in use-effectiveness is evident. Older women always do better, and the effect of age for contraceptors is magnified relative to the same effect for noncontraceptors, indicating a behavioral component in addition to whatever fecundability effects occur with age. (Both the Peru and Dominican Republic Experimental DHSs were used for this work.)

With the Peru data, an analysis of periodic abstinence specific variables and their effect has begun. Exceedingly preliminary findings are that women's characteristics play a more important role than program characteristics in determining use-effectiveness, and that those who report significant problems with periodic abstinence are likely to be current pill users. Whether these women are past users or not is not clear, so it is premature to draw conclusions regarding method switching from these results.

Planned Activities: During the next reporting period, the analysis will be completed and a final report will be prepared and submitted to the Institute. The investigator will present the results at the annual meeting of the Population Association of America.

(4) Further Analysis of Contraceptive Failure of the Ovulation Method

This research was carried out by investigators at the Office of Population Research, Princeton University. Their reanalysis of data on the ovulation method (OM) of NFP collected by WHO yielded the following conclusions. The method is effective during perfect (correct and consistent) use, with a first-year probability of failure of 3.4%. However, it is extremely unforgiving of imperfect use, with a first-year probability of failure of 84.2% if the method is not used correctly. During the initial year, 87% of the cycles were characterized by perfect use. Nevertheless, the 13% of cycles characterized by imperfect use had a tremendous impact on the overall failure rate. During the first year of typical use, 22.5% of the women in the clinical trial became accidentally pregnant. These results were published in the December 1991 AJOG.

Additional analysis was carried out on the OM data set to develop a rule for the proposed Cycle Calculation study. Preliminary analysis shows that approximately 92% of cycles can be covered using a simple rule to define the fertile period.

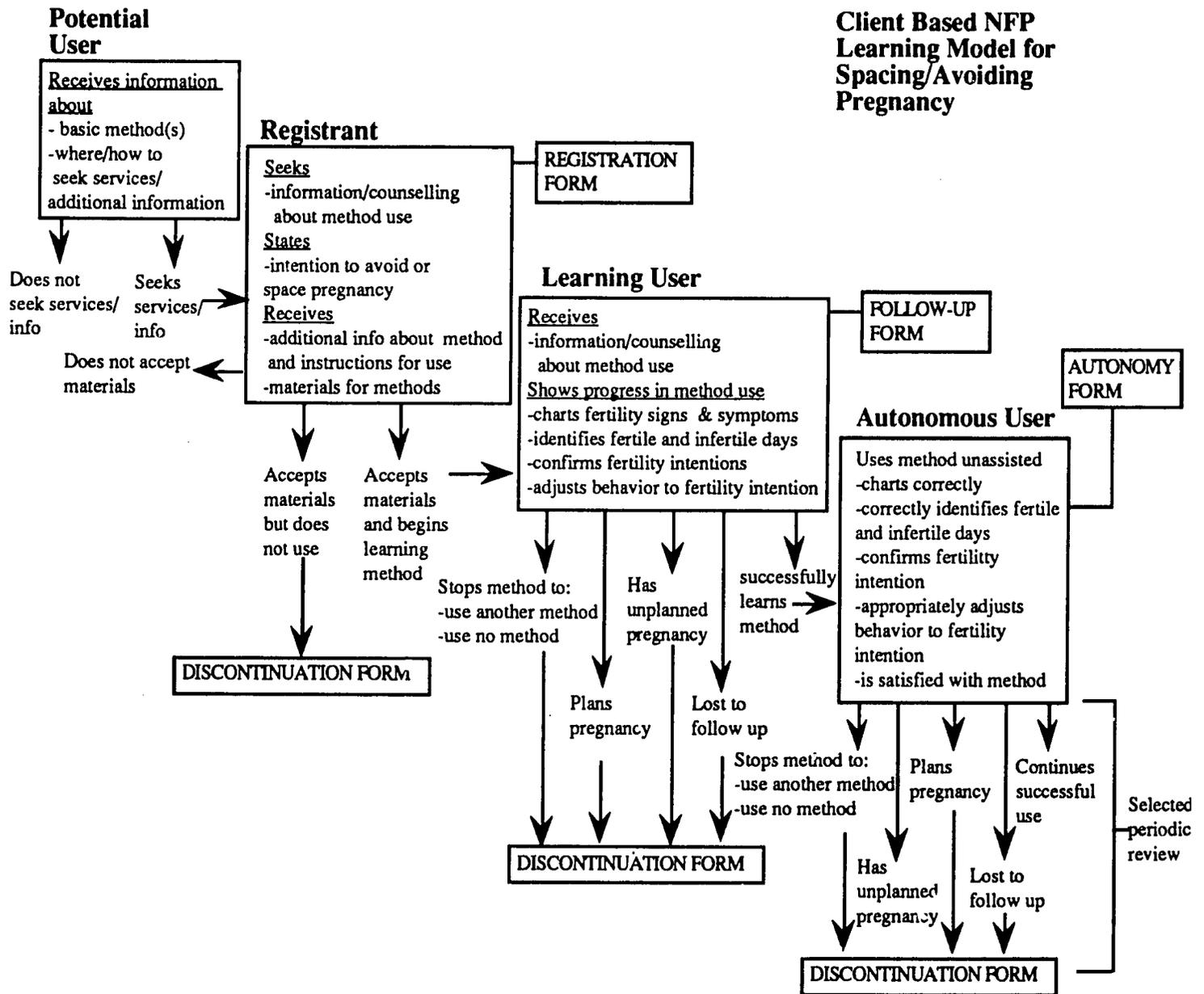
Planned Activities: The investigators will be invited to participate in expert meetings on the planned Cycle Calculation Method study, where the specific rule to be used in the Cycle Calculation study will be selected.

(5) Prospective Monitoring of NFP Services and Users

A potential source of information about efficiency and effectiveness of NFP services and methods is routine data, collected prospectively, from NFP programs. As part of our comprehensive effort with IFFLP (see section II.3.b.(1) of this report), we are collaborating with colleagues in the field to design, implement, and

test a management information system (MIS) to collect data from 10-15 NFP programs worldwide. During this reporting period, we held several planning meetings, including Institute and IFFLP staff and technical experts (one from Johns Hopkins University and the other an Institute evaluation consultant). IFFLP is surveying its members to determine which of them are currently collecting program and client data on a variety of topics.

To assist us in our planning for an MIS, we developed a chart to illustrate a client based NFP learning model for spacing and avoiding pregnancy:



Planned Activities: We expect to receive a proposal from Johns Hopkins to analyze and report the results of the IFFLP survey, revise the MIS currently being offered by IFFLP to its members (based on the NFP Learning Model), assist with MIS testing and implementation, and analyze and report data collected by the MIS. The proposal also will indicate the kinds of questions that can be answered by more in-depth research with selected NFP groups. However, it will be important to establish a solid MIS and analyze basic data before beginning more sophisticated studies.

(6) NFP Prospective Study

A prospective study of NFP users was conducted by Action Familiale, Mauritius. Information was collected on NFP users (aged 16-35) enrolled in the Action Familiale program. The aim was to collect reliable, representative and accurate information about these subjects in order to determine what factors influence the successful use of the Symptothermal Method (STM) and its failure and discontinuation. The study was undertaken from February 1989 - May 1991 among 1,000 NFP users throughout Mauritius. Eligible users were recruited as they entered the NFP program. The data collected in respondents' home during a first interview and follow-up interviews till clients reach a period of 18 months.

The preliminary tabular analysis of the study data was submitted by Action Familiale to the Institute in its final report. Findings include the following: (1) neither spacers nor limiters find abstinence difficult, although more spacers find it difficult than do limiters, (2) knowledge of the STM is greater among clients with a secondary education than among those with a primary education, (3) among husbands who do not find abstinence difficult, a large percentage are very interested in discussing NFP with their wives, while among those who do have difficulty with abstinence, there is less interest in discussing NFP.

Planned Activities: This study produced a large, complex data set which will require much more analysis. We have sent the final report to A.I.D. requesting guidance on how this can be accomplished. During the next reporting period, we will work with Action Familiale to develop a plan for carrying out this analysis.

(7) Group Teaching NFP

The purpose of this 24 month pilot project, which was conducted by Action Familiale in Mauritius, was to develop, implement and evaluate a model for group teaching of NFP. Recent changes in the socio-economic situation in Mauritius had challenged the viability of the individual approach. With more and more women in the formal workplace, it became difficult to recruit and retain NFP teachers, meet the demand for NFP with the relatively few teachers available given limited resources, and meet with individual women in their homes during the day. Therefore it became necessary to consider alternative service delivery strategies such as group teaching, in which an NFP teacher can provide NFP instruction to groups of women in the Action Familiale centre, or at the women's workplace or common meeting area. Thus, the problem faced by Action Familiale and other NFP programs operating with similarly limited resources, is how to provide high quality services to an expanding number of NFP users most efficiently and effectively, keeping the strong commitment of the philosophy of Action Familiale that is providing an integrated family life promotion meeting the client's needs. Specific geographic areas were identified for the project and appropriate staff were selected.

The main difficulty in implementing the project was client recruitment. Although 292 clients had been contacted, only 73 followed instruction sessions. The team of teachers and supervisors demonstrated their abilities to recruit, implement NFP client education sessions and provided appropriate follow-up for clients receiving NFP instruction in the group setting. A model curriculum and instructional materials were tested and modified as appropriate to meet the educational needs. Seventy-three clients were instructed in how to use the NFP method following the group teaching model. At the end of the project, 44 clients reached autonomy; and after one year a survey indicated that out of the 44 clients only one dropped out.

Throughout the implementation of the project, quantitative data to measure program costs, method effectiveness, instruction time required for client autonomy along with qualitative information about client's satisfaction and the quality of NFP instruction were obtained. This information was analyzed and compared with existing data on the individual instruction model currently used by Action Familiale. Findings showed that even if recruitment was time consuming, less time was taken to bring a client to autonomy through group-teaching than individual teaching.

Results of this project have been written up for publication.

As a result of these findings, Action Familiale recommended that clients for group teaching be recruited in existing groups and that a course should have minimum of ten clients. They also recommended that the supervisors time with group teaching courses be reduced and that a modified group teaching curriculum program for specific groups should be developed.

Planned Activities: During the next reporting period we will encourage Action Familiale to share the project report with other NFP groups. We also will explore the possibility of editing the report for submission to an appropriate journal.

b. Strategy: Communicate with target audiences to increase their knowledge of and support for NFP.

(1) NFP: A Good Option

This document, which was developed during our initial cooperative agreement in collaboration with the IMPACT project at the Population Reference Bureau (PRB), has been very well received. Its purpose is to encourage policy makers to include NFP in comprehensive family planning efforts. We are unable to meet any further requests for the English version; however we have a sufficient stock of French and Spanish versions. During this reporting period we conducted a survey of several of the major recipients of the document to identify how it might need to be changed when we reprint it. It appears that the needed changes are relatively minor and can be made without substantial re-formatting.

Planned Activities: We plan to modify and reprint the English version and disseminate it as appropriate. We will develop a feedback system to document the ways in which it is being used, the opinions of recipients, and, to the extent possible, its impact. We will request technical assistance from IMPACT to develop this system.

(2) Glossary of NFP Terms

This document also was developed during our initial cooperative agreement. Its purpose is to provide a common terminology which can be used by the NFP field. In the process of reviewing the MIS (see above), it has become clear that certain definitions, particularly those that describe a client's flow through the process of accepting and learning to use NFP (the NFP Learning Model), need to be revised. Several of the terms relating to breastfeeding also need to be updated. The Institute's Breastfeeding Division has provided the definitions in the area.

Planned Activities: As soon as the prototype MIS is developed, we will incorporate the terms utilized by the system, as well as the breastfeeding terms, into the Glossary. It will be reprinted in English, French, and Spanish and disseminated.

(3) Guide for NFP Trainers

The Guide is a resource for trainers who plan, implement, and evaluate training courses for NFP instructors. The first edition has been widely disseminated in English since early 1990. The translation and production of the French and Spanish versions has been an extremely lengthy process. The French version has been disseminated during this reporting period, and the Spanish version is now in production. The demand for the Guide has been quite high. We are now exploring how it can be produced less expensively for wider distribution.

Planned Activities: The Spanish version will be disseminated, and a less expensive English version will be produced.

(4) Natural Family Planning: Current Knowledge and New Strategies for the 1990s
(proceedings of a conference)

An international conference, "Natural Family Planning: Current Knowledge and New Strategies for the 1990s", was held at Georgetown University in December, 1990. It was supported by the Institute, A.I.D., and WHO. The conference, with an attendance of approximately 150 people from 30 countries, offered a forum for representatives of the population and health fields, including both the NFP and multimethod family planning communities, to present research and program results and to exchange ideas and experiences. The proceedings of the four conference sessions that focused on biomedical research have been published as a special supplement to the December 1991 American Journal of Obstetrics and Gynecology (AJOG). The proceedings of the remaining nine sessions and the round table discussions have been prepared for publication as a companion piece to the AJOG document.

Planned Activities: The AJOG supplement will be distributed by the Journal to its approximately 22,000 subscribers worldwide. The Institute will receive 10,000 additional copies for targeted distribution. The companion piece will be published and distributed.

(5) NFP/Fertility Awareness Modular Slide/Audio Set

A great need has been identified for a comprehensive, flexible set of slides that can be used with multiple target audiences (e.g., policy makers, educators, health workers, etc.). We have begun discussions with a consultant to work with us on a four-phase process to:

Phase I: Review appropriate background materials on fertility awareness and NFP; conduct initial discussions with 6-8 key people to identify needs, target audiences, etc.; review existing slides (Institute slides as well as those available elsewhere); and prepare an outline of the final product and a time line/management plan for completion.

Review outline/concept with a larger audience for feedback (NFP programs, other CAs, communications specialists, etc.); incorporate their ideas and revise outline accordingly; identify additional resources for slides.

Phase II: Assemble slides and order ideas and messages to provide a "draft" slide set for initial testing and review.

Phase III: Pre-test slide set with target audiences, revise per feedback, and prepare a copy for final field testing.

Phase IV: Disseminate the slide set for final field testing, make final revisions, and disseminate widely.

Planned Activities: We will contract with the consultant to undertake Phase I of this effort. Institute and IFFLP staff will also solicit input during meetings and field visits.

(6) Natural Family Planning: An Important Option for Child Spacing

An article, "NFP: An Important Option for Child Spacing", authored by the Institute's Principal Investigator and the Director of the NFP Division, was published in Nytt om Uland (News on Health Care in Developing Countries), a journal that provides news on health care to professionals in developing countries. The journal is published by Uppsala University in Sweden with support from the Swedish government.

(7) Training III

An article by the NFP Division Director was published in the Training III newsletter. This publication is disseminated to family planning providers in Region III of the Department of Health and Human Services.

(8) Resource Center

An important component of the Institute's work is the Resource Center, which develops and maintains files of current NFP literature, and prepares and disseminates Institute publications. During the current reporting period, the Resource Center has undergone a reorganization to make it more "user friendly" and to better focus its collection of materials. It also has been responsible for responding to requests, managing the publication of the conference proceedings, and collecting information to develop a mailing list. Further detail about the Resource Center is in section IV of this report.

3. Objective: Improve, expand, and evaluate programs to increase the availability, accessibility, and quality of NFP services and fertility awareness information.

a. Strategy: Conduct research and provide guidelines to improve the use of NFP by women in special circumstances.

(1) Efficacy of the Symptothermal Method in Lactating Women After the Return of Menses.

The purpose of this project, which was conducted in collaboration with the Maryland/DC NFP Providers Group, is to determine (1) the ability of the Symptothermal Method to predict ovarian activity and ovulation in breastfeeding women after the period of lactational amenorrhea, (2) the amount of abstinence actually required for women to avoid pregnancy versus what they identify as necessary based on their observation of clinical signs and symptoms, (3) the relationship of feeding patterns to cervical mucus activity, (4) the relationship of subjective assessments of cervical mucus to the volume of aspirated cervical-vaginal fluid, (5) the reliability of cervical-vaginal fluid volume as a predictor of ovarian activity after the end of lactational amenorrhea, (6) the bleeding patterns, number, and characteristics of ovulatory cycles and ovarian activity in these women, and (7) the ability of basal body temperature to reflect ovulatory activity during this time

period. Preliminary results of this study have been reported previously. Final analyses are still underway.

Planned Activities: The remaining assays will be conducted, and the remaining data will be entered and reviewed. In collaboration with the Breastfeeding Division, we will determine the feasibility of combining data from this study with studies conducted by Family Health International (FHI) and Johns Hopkins University to produce joint papers on (1) the physiology of normal return to fertility postpartum, (2) the effect of breastfeeding practices on fertility, and (3) the daily mucus signs and symptoms most/least predictive of returning fertility and abstinence required by symptoms versus hormonal indicators. The focus of these papers will be to assist NFP providers in giving accurate information to breastfeeding clients.

b. Strategy: Provide financial and technical support for NFP service delivery.

(1) NFP Technical Assistance Project

During our initial cooperative agreement, the Institute supported a major subproject with IFFLP to provide technical assistance and financial support to NFP programs in eight countries. As reported previously, support to programs in Liberia and Zaire were terminated due to political unrest in those countries, and support to the programs in Madagascar and Mauritius (which successfully achieved project objectives) ended. During this reporting period, support was continued through a combination of no-cost extensions and a small interim agreement between the Institute and IFFLP to programs in Brazil, the Dominican Republic, the Cote d'Ivoire, and Zambia. Detailed reports of these subprojects (as well as those which ended in previous reporting periods) were included in IFFLP's final report of its March 1, 1988 - August 16, 1991 subagreement with the Institute. While it appears that majority of subproject objectives were achieved, the difficulty all the programs are experiencing in collecting basic statistics about their clients hampers IFFLP and the Institute's ability to make definitive statements about their results.

During the last few months of this reporting period, the Institute and IFFLP held frequent discussions regarding our new subagreement, which began November 1, 1991 and will continue through March 31, 1996.

Planned Activities: We expect that during the next six months, IFFLP will finalize project development and sign agreements with NFP programs in the Philippines, Zambia, and Brazil to continue their work. In addition, programs to be included in the data collection/MIS effort will be identified and agreements will be signed with at least three of them. The Institute will continue working closely with IFFLP staff to achieve project objectives, particularly in the area of client and program data collection.

(2) Integrating NFP Services into Public Health Programs.

This 14-month pilot project was completed during this reporting period. The Natural Family Planning and Medical Services Center in Nairobi, Kenya developed an NFP instructor's training and program development project in conjunction with Institute staff at LARFPC. The purpose of the project was to demonstrate the feasibility and impact of training public-sector health workers, nurses from Ministry of Health programs, in the delivery of NFP services. Two, eight-week NFP instructor training programs were held with special emphasis on NFP program development. Nineteen nurses completed the training and initiated NFP services in 13 public health program sites. The number of NFP acceptors far exceeded the original expectations; 332 clients were recruited and instructed in the use of NFP.

Additionally, qualitative program development data was collected at all program sites in conjunction with site administrators. The project concluded with a summation conference comprising representatives from the training center, the Ministry of Health, the USAID mission, and faculty from a local school of nursing. The participants reviewed project results and made recommendations for the expansion of NFP services through a variety of health organizations. A three-year continuation project proposal is in the final stages of completion. It will utilize the MIS (described in section B.2.d.(5) of this report) to enrich the evaluation of the impact of this type of program expansion strategy. The continuation project will tentatively begin April 1, 1992.

During a site visit to this project in May, it was determined that USAID/Nairobi is interested in this effort's continuation and expansion, with an emphasis on a more efficient and cost effective approach. We have encouraged LARFPC, which worked with the Training Center to develop and implement the project (during the initial cooperative agreement when LARFPC was one of the two sub-recipients) to continue collaborating with the Training Center to develop a proposal for a new project.

Planned Activities: We expect that LARFPC and the NFP Training Center will submit a proposal to the Institute for a continuation and expansion of this effort. We anticipate that the project will be funded through LARFPC, under a new subagreement with the Institute, beginning in April.

(3) Training and Motivation for Health Professionals.

This project was implemented by the Center for Research, Education, Service and Training (CREST) in Bangalore, India. With the technical assistance of LARFPC, CREST developed implemented and evaluated the impact of motivational seminars and NFP instructors' training programs during a 15 month period. Phase I of the project included four, one day motivational seminars to provide basic NFP information as a mechanism for promoting and increasing the acceptability of NFP. The programs targeted individuals who were in a position to promote and expand NFP in India. During Phase II of the project two, ten-day NFP instructors' training programs were conducted for doctors, nurses and community health workers. These programs provided an opportunity to further test the Institute's "Guide for Natural Family Planning Trainers". The evaluation was conducted in part by a participant of the English Training of Trainers program conducted under our original cooperative agreement.

CREST also developed a two part video. The first part of the video provides fertility awareness information and is appropriate for use in high schools as a means of introducing human sexuality. The second portion serves as an introduction to NFP and is an effective teaching aid for instructors to use with clients.

The CREST project resulted in a significant model for bringing NFP information to the attention of local leaders, health service providers and others in a position to promote NFP. In addition a viable model for future instructors' training programs was developed. These programs may be replicated nationally and should support the development of policies and services related to future successful family planning efforts throughout India.

Planned Activities: During the next reporting period, LARFPC will work with CREST to prepare a publishable report of this project.

(4) Guidelines for NFP and Fertility Awareness Incorporation

During our initial cooperative agreement, draft guidelines for incorporating NFP and fertility awareness into other on-going programs (e.g., multimethod family planning, child survival, women in development, and community development programs, etc.) were developed. Although we have not worked further on the guidelines during this reporting period, this remains an important concern for the Institute. Expansion of NFP and fertility awareness beyond traditional NFP programs was identified as a high priority by the participants in the international conference in December 1990, and it is clear that for such expansion to produce the desired results, programs will require considerable guidance in all aspects of planning and implementation.

Planned Activities: We will identify an appropriate consultant to work with us on this effort. The existing draft guidelines will be reviewed, and input from a variety of sources will be solicited.

(5) Evaluation

Under our new cooperative agreement we will support comprehensive NFP and fertility awareness pilot programs in 3 - 5 selected countries. These programs, which will be carried out in conjunction with the International Federation for Family Life Education (IFFLP), the Program for Appropriate Technology for Health (PATH), and other cooperating agencies (CAs) and subcontractors, as well as with in-country counterpart organizations, will test and demonstrate strategies for increasing the impact for NFP and fertility awareness efforts. We need to develop an evaluation strategy to provide the Institute and our colleagues with an approach for evaluating the outcomes of these field projects and assessing their contributions to program impact.

In 1991, A.I.D. implemented a new evaluation project which represents a major initiative to link family planning program efforts to fertility change. The announcement of this new evaluation project stated that "although current evaluation activities allow some determination of how well activities are being done, it is less clear whether or not what is being done is having an impact on fertility and how the various program inputs contribute to that impact." That statement describes the state of evaluation of family planning programs in general, and of NFP programs in particular during this reporting period we have held preliminary discussions with an evaluation/operations research expert regarding our needs and how our evaluation approach can contribute to A.I.D.'s larger effort.

Planned Activities: We will contract with a consultant to work with Institute staff and colleague to develop an evaluation strategy and, subsequently, an evaluation plan.

(6) Technical Assistance

Technical assistance (TA) to USAID missions, CAs, and developing country organizations is a major mechanism to encourage family planning, child survival, and educational programs to include fertility awareness and NFP in their efforts. TA is provided by Institute staff and consultants as well as by several of our subcontractors (particularly IFFLP).

TA to USAID Missions: During this reporting period, assistance was provided to USAID/Port-au-Prince to expand NFP and breastfeeding services in Haiti. A status analysis/needs assessment was conducted in July-August. The Institute team traveled throughout Haiti, meeting the key persons involved in NFP and

breastfeeding groups and organizations. As a result of this trip a strategy was developed to expand and improve NFP services in Haiti. The strategy includes information dissemination, fertility awareness education, development of NFP training materials, institutional development, demonstration of NFP programs and research projects. An extensive report of the findings was submitted to USAID/Haiti.

The Institute also participated in a meeting of cooperating agencies, coordinated by USAID/Lima, to lay the groundwork for the Peru Family Planning Program.

TA to Cooperating Agencies: The Institute assisted JHPIEGO with the development of the NFP and fertility awareness portions of its family planning guidelines for Papua New Guinea; provided materials and review to INTRAH on the revision of its training materials; and, in collaboration with representatives from numerous other CAs, co-authored the final report of the Task Force on Standardization of Family Planning Indicators: Quality of Care.

TA to NFP Programs: Assistance was provided by the Institute and its subcontractors to NFP programs in Cote d'Ivoire (to assess project status and determine how project results can be institutionalized), Kenya (to review project implementation and develop plans for expansion), Zambia (to review project implementation and develop objectives and workplans for a follow-on project), Brazil (to strengthen institutional and project management and data collection procedures), the Dominican Republic (to improve project management and data collection and to identify possible strategies to achieve sustainability), and Peru (to assess institutional needs for TA in management and communication and to contribute to a comprehensive presentation on NFP at the Peruvian Congress on Family Planning).

Planned Activities: As part of the further development of the Guidelines for Incorporating NFP and Fertility Awareness into Other On-going Programs, the Institute will contact numerous CAs and USAID missions regarding their interest in and perspectives on this issue. This is expected to lead to several requests for TA in NFP and fertility awareness. The proceedings from the December '90 conference, which will be disseminated to all CAs and USAID missions as well as to a wide range of field programs, may also lead to requests for TA. In the dissemination cover letter, we will highlight Institute interest in providing TA and suggesting areas in which this assistance could be most useful.

In addition, PRB has requested information from the Institute on NFP programs that could be included in their planned publication on "successful family planning programs". We will work with IFFLP to provide them with this information and encourage them to include at least two NFP programs. A staff member of the International Planned Parenthood Federation/Western Hemisphere Region (IPPF/WHR) requested assistance with staff development in NFP and fertility awareness. We will work with her to meet this request.

4. Objective: Enhance clients' fertility awareness and the knowledge, acceptance, and effective use of NFP.

a. Strategy: Develop and test messages and communication strategies to improve fertility awareness.

(1) Simple Fertility Awareness Messages

Several countries have been identified as potentially appropriate sites for a project that would develop, test, and communicate simple fertility awareness messages

designed to improve the ability of couples who state that they are using periodic abstinence as their family planning method to correctly identify the woman's fertile and infertile phases. According to data from recent DHSs, more than one-third of women in Peru who use any method of family planning use periodic abstinence. We have held preliminary discussions with PATH regarding a pilot project in Peru.

Planned Activities: A PATH staff member will travel to Peru (on a non-Institute activity) in January and will discuss these plans with USAID/Lima and other CAs who can offer advice about an appropriate site and implementing group. We expect to receive a proposal from PATH to develop the pilot project in early January and to have a final project document by the end of the next reporting period. A medical student who will take an elective with the Institute in January will work with us to develop the basic content of the messages. We also will explore the possibility of developing similar pilot projects in Kenya and the Philippines.

b. Strategy: Develop and disseminate materials for clients that can be adapted to a wide variety of program needs.

(1) NFP/Fertility Awareness Modular Slide/Audio Set

The slide set described in section II.B.2b.(5) of this report will include a module that can be used to teach clients.

Planned Activities: See section II.B.2b.(5).

(2) NFP Technical Assistance Project

The project with IFFLP (described in section II.3.b.(1) of this report) has as one of its major foci the development of improved country-specific client materials. IFFLP and the Institute agree that technical assistance will be needed from a consultant or from in-country communications specialists to develop, test, and produce these materials.

Planned Activities: We will collaborate with IFFLP to identify the program(s) most in need of client materials and an appropriate strategy for working with each of them. This will be included in the individual country subproject proposals.

C. ADMINISTRATION

Because the NFP Division carries out the majority of its work through subcontractors and consultants, careful coordination among all project elements is essential to ensure that all are aware of each other's objectives, strategies, and activities.. To increase coordination and enhance the Institute's ability to achieve its objectives, a project review meeting will be held with our subcontractors and consultants in early June. This will enhance subproject collaboration and help us identify priorities for the subsequent year. Tentatively, participants will include all interested Institute staff (including both NFP and Breastfeeding Divisions), representatives from IFFLP, LARFPC, the Maryland/D.C. NFP Providers Group, PATH, the College of William and Mary, the Institute for Resource Development, and other subcontractors; Institute consultants working with us on the MIS, the evaluation strategy, and the modular slide set; and A.I.D. In addition, we may invite a small number of experts who are familiar with the Institute's work and can contribute to our review and discussions. During the next few weeks, we will discuss this meeting with our colleagues, develop an agenda, and make arrangements for the meeting. Tentative plans are to hold the meeting in May.

III. BREASTFEEDING

A. OBJECTIVES

The GU/IRH goal in breastfeeding is to increase the availability and acceptability of optimal breastfeeding with a focus on its fertility impact. The Breastfeeding Division's three objectives are

1. Continued testing of the Lactational Amenorrhea Method (LAM);
2. Policy change favoring optimal breastfeeding;
3. Program changes to include the fertility aspects of breastfeeding and the timely introduction of family planning postpartum.

LAM is an introductory method of family planning which enhances acceptance of family planning and supports women in optimal child health practices.

The Division's strategy to achieve the objectives of refining LAM use, policy change, and program change focuses on three program areas: (1) LAM and the timely introduction of family planning during breastfeeding; (2) the fertility aspects of breastfeeding; and (3) the breastfeeding/NFP interface. In each program area, the Breastfeeding Division provides technical and funding support for research and pilot projects; provides information and education to health professionals and policy makers; and uses findings to support program and policy change, through technical assistance to existing programs, especially addressing family planning organizations, including CA and USAID Mission needs.

B. ACTIVITIES

The following activities took place during the reporting period April 1, 1991 - December 31, 1991.

1. LAM: Breastfeeding and Family Planning Interface

Activities in this area consist predominantly of direct support of the LAM/family planning method and family planning program interface, which includes support, policy change, and research for LAM in family planning and child survival programs, as well as timely family planning in breastfeeding programs.

a. LAM: Research and Pilots

- (1) Chile: Pontificia Universidad Católica
 - (a) Chile: LAM in a Clinical Setting

The first phase of the Institute's project in Chile with the Pontificia Universidad Católica was a case control breastfeeding support intervention study. It has shown the efficacy of LAM in the context of breastfeeding support. The most significant findings to date have been: (1) the efficacy of LAM in clinical trial is higher than 99.5 percent; (2) family planning coverage at six months is increased when LAM is offered to women as a family planning option; (3) infant growth excels under full breastfeeding; (4) with proper support for breastfeeding, women within feeding category demonstrate increased durations of amenorrhea; and (5) the "LAM eligible" population (those fully breastfeeding and amenorrheic) increased when there was support for breastfeeding.

A conference was held in October 1990 to present "Advances for Breastfeeding for Health and Child Spacing." The efforts of the project team, Drs. Perez, Valdes,

and their colleagues, resulted in an extremely successful conference that was attended by more than 350 doctors, nurses, and nurse-midwives. While participants were primarily Chilean, representatives from the Ministry of Health of Honduras and CEMOPLAF/Ecuador also attended; and speakers were drawn from the regional Institute projects. Institute staff were heavily involved in the conference as well, and Institute breastfeeding materials were widely disseminated to all participants. Wellstart's collegial participation added yet another area of expertise and network of potential activity.

As mentioned elsewhere in this document, the Institute received a small grant from PAHO to assist in the preparation of the proceedings of the conference, which should be available shortly in a revised and expanded version of the book Lactancia Materna. During the reporting period progress was made on text revisions.

In addition, two articles were submitted for publication to the Journal of Tropical Pediatrics and Lancet, and four other articles are planned.

Planned Activities: The results of the Chilean research will be published during the next reporting period in The Journal of Tropical Pediatrics and Lancet. Phase II of the Chile project is a two-year extension of the project based on the results of the initial intervention. The extension includes the following areas:

- Final revision and translation of Lactancia Materna;
- Publication of the breastfeeding and LAM reference book, Lactancia Materna;
- Publication of several scientific papers;
- Follow-up to the October 1990 conference, which will include questionnaires and institutional visits to identify LAM supporters;
- A clinical trial of LAM use by working mothers (described below).

(b) Chile: Working Women

The 99.5 percent efficacy of LAM was demonstrated by the above project that was carried out with urban women in Santiago, Chile. However, the women who participated in this study did not plan to work outside their homes. Since worldwide there is an increasing number of women who return to work before the sixth month postpartum, and in Chile, in particular, 30 percent of the female population returns to work at 84 days postpartum, it is essential to determine the protocols and efficacy of LAM use among working women. The project will proceed with the hypothesis that, by supporting working women in achieving optimal breastfeeding, the number of women who maintain full breastfeeding and amenorrhea can be increased, and that by following certain rules or guidelines, LAM can be an effective introductory family planning method for working women.

This project is in the planning stages: a protocol has been written and sent out for review.

Planned Activities: During the next reporting period, it is hoped that the protocol will be refined and approved, recruitment for the project will take place, and the first phase of the prospective clinical trial will begin.

(2) Honduras: LAM in a Mother-to-Mother Setting

The Institute is working with La Leche League International in Honduras. Here the focus is LAM in a Mother-to-Mother Child Survival Support Project. This operations research project encompasses the (1) training of physicians, nurses, and breastfeeding advocates (BAs) who serve the Las Palmas area of San Pedro Sula in breastfeeding and LAM; (2) the initiation of six mother support groups; and (3) the examination of the referral of mothers in the community to family planning services as a direct consequence of LAM training. Research is documenting the effectiveness of breastfeeding advocates in the promotion of breastfeeding practices, communication of LAM, and family planning referral above and beyond the impact of the breastfeeding supportive health services. Technical assistance related to the implementation of the project is being provided through a subagreement with INOPAL.

The project is being carried out with the participation of various institutions, including the Ministry of Health, Social Security, the Municipality of San Pedro Sula, and the neighborhood organizations known as the patronatos. This approach was used to integrate the project's findings and program changes into the existing maternal child health system. This condition was required by the MOH so that the project would not be an isolated endeavor. A number of training activities have taken place, including a five-day regional medical conference on Advances in Infant Nutrition and Child Spacing.

The first phase of the Honduran study of LAM in a mother-to-mother setting has been completed. The continuation project was signed in November 1991. The five specific objectives of the continuation project are the following:

- Execute a follow-up survey to evaluate the impact of a full year of the community intervention;
- Organize four skill training workshops for both La Leche League staff and breastfeeding advocates (BAs);
- Develop educational materials related to exclusive breastfeeding and LAM;
- Plan and execute a national-level medical conference on family planning during lactation for key MOH and Social Security personnel;
- Conduct an end-of-project dissemination meeting for cooperating institutions.

Planned Activities: The second phase of the project, already in progress, is completing survey analysis to assess the impact of the intervention on breastfeeding and on the timely acceptance of family planning by breastfeeding women and will provide written steps for other programs wishing to use this approach. All other activities are proceeding as scheduled.

(3) Ecuador: LAM in a Family Planning Setting

In Ecuador, Institute staff and the Centro Médico de Orientación y Planificación Familiar (CEMOPLAF) in Quito are testing the LAM guidelines in a family planning service delivery system. The project was designed by CEMOPLAF with input from the Los Angeles Regional Family Planning Council and other Institute staff to facilitate the successful integration of LAM into an existing multimethod family planning service delivery system. Future project plans include the introduction of LAM into all twenty of CEMOPLAF's clinics countrywide. Six of the twenty clinics were designated for pilot studies and were the focus of project

monitoring and data collection activities. From these prototype clinics, the family planning choices of potential LAM users were documented, giving an assessment of the acceptability of LAM when it is included as an available family planning method. Follow-up on all LAM acceptors generated descriptive data regarding method continuation, satisfaction, and use of complementary methods of family planning. In order to encourage increased breastfeeding support and behavior change extending beyond study participants, project staff employed an implementation study with a concurrent formative/process analysis of the program components in addition to the statistical analysis of service and follow-up data collected.

During the first phase of the project, a four-day training program was implemented for staff of the demonstration clinics. Participants received two promotional posters to distribute to the clinics, as well as a brochure/booklet for clients to take home. A prototype flipchart was field tested in the clinics. One month after the completion of the counseling course, a post-test was administered to assess how well the training participants had retained the information. The results of the test indicated a general increase in the staff's confidence in the scientific basis for LAM as a family planning method. Paramedical personnel indicated an interest in being involved in LAM and other breastfeeding activities. The project subsequently developed a bimonthly LAM bulletin to distribute to clinics that contains articles reinforcing the training received.

Follow-up on LAM acceptors generated descriptive data regarding method continuation, satisfaction, and use of complementary methods of family planning. An implementation study with a concurrent formative/process analysis of the program components was employed in addition to the statistical analysis of service and follow-up data collected.

The final report of the first phase of the CEMOPLAF project was completed during this reporting period and included the following results: In the original four prototype clinics, LAM acceptors comprised an average of 15 percent of all new family planning clients. Average method continuation was 3.5 months and 75 percent of the method users said that they were satisfied with the method. No pregnancies occurred among the 79 percent of women who used the method appropriately. Two pregnancies occurred due to poor client screening in the clinic, and one pregnancy occurred in a method acceptor who began early supplementation of breastfeeding without initiating a complementary method of family planning.

Also during this reporting period a visit was made to the country by IRH and LARFPC staff to provide technical assistance in the development of operations research and other program elements for the next phase of the LAM project.

Planned Activities: The next phase of this study will assess ongoing acceptability of LAM and operational methods to ensure the timely introduction of complementary family planning during breastfeeding, and will provide written guidance for other free standing family planning programs wishing to introduce LAM. This project will include small operations research studies as well as service expansion and curriculum modification.

Early in the next reporting period, the agreement for the project continuation will be finalized and funded.

(4) Georgetown University Clinical Trial of LAM

It is important that family planning methods offered in LDCs also be formally tested in the United States. In addition, the use of LAM at Georgetown will enhance IRH's ability to serve as a technical resource in this area. Accordingly, a clinical trial of the introduction of LAM among Georgetown patients is planned.

Planned Activities: A protocol for the study will be developed and reviewed, and institutional arrangements will be initiated for the implementation of the study.

(5) Projects in Preparation

New projects related to goals and strategies for completing work from the previous cooperative agreement need to be accomplished during the next five years. Institute staff are exploring opportunities for field projects in Africa and Asia.

Division staff made preliminary visits to Indonesia and Togo during this reporting period. Although both visits were primarily for conference presentations, important contacts were made with groups both in Indonesia (BK.PP-ASI, BKKBN, and University of Indonesia) and in Togo (representatives of all Francophone Africa countries). The Division is following up on these contacts and other requests from several countries, including Egypt, Morocco, Rwanda, and possibly Kenya, Uganda, and India.

Planned Activities: During the next reporting period, project development visits are planned to several sites in Africa and Asia.

(6) Symposia/Conferences

During this reporting period, the Breastfeeding Division experienced its second anniversary. Several projects have been completed and others are nearing completion. It is appropriate at this juncture to bring together IRH and other experiences in LAM to assess the state of the art and to receive input for future planning.

Planned Activities: A meeting will be developed as above which will serve as a Division TAG for future strategic planning, review of the current workplan, and assessment of an evaluation strategy.

b. LAM: Education for Health Professionals and Policy Makers

(1) Guidelines for Breastfeeding in Family Planning and Child Survival Programs

The primary purpose of the Guidelines is to assist family planning and child survival program planners in formulating and implementing a breastfeeding component within their programs. Recommended breastfeeding behaviors for optimal child survival and child spacing are outlined, and guidelines for the use of the Lactational Amenorrhea Method (LAM) for child spacing and the introduction of complementary family planning methods during breastfeeding are provided. An outline of considerations for program change is also presented, with the intention that it be adapted or modified, depending on the specific needs, interests, and resources of individual programs and local settings.

Approximately 2,900 English, 2,200 French, and 5,000 Spanish copies of this publication have been distributed worldwide since the document's first printing. In addition, the Guidelines have been translated into Bahasa Indonesia and Portuguese. The Guidelines were distributed at three major conferences during this

reporting period: The National Breastfeeding Congress in Indonesia (400 copies distributed) and the Francophone Africa Infant Feeding and Child Survival Conference held in Lomé, Togo (150 copies distributed); in addition, several hundred copies of the Spanish version were distributed at the May 1991 conference in Guatemala, entitled "Los Ultimos Descubrimientos en Relación a la Excepcionalidad de la Lactancia Materna: Implicaciones y Aplicaciones." This conference, co-sponsored by INCAP, the Guatemalan National Commission for the Promotion of Breastfeeding, and IRH, is described in the Guatemala section of this report. JHFIGO continues to provide the guidelines as one of the documents in their standard information packet and have continued to receive multiple copies of the document for this use. The Institute Resource Center has continued to respond to regular requests for this document.

Planned Activities: Dissemination of the 1990 version of the Guidelines will continue until current supplies are exhausted; in addition, IRH will update this publication (see next item).

(a) Update of the Guidelines for Breastfeeding in Family Planning and Child Survival Programs

IRH is planning to update the Guidelines to reflect the state of the art in LAM information and to address a wider audience. Discussion is underway to work with a consultant to perform this task, with a concentration on user-friendly presentation. The update will include definitions and up-to-date research findings.

The update is still in the planning stages and a consultant is reviewing the document to make recommendations on how to proceed with a revision to best suit the needs of the intended audience.

Planned Activities: During the next reporting period, the Breastfeeding Division will contract with a consultant to assist in carrying out the necessary changes, update, review, and printing of the Guidelines.

(b) Working Women Guidelines: Assisting Working Women Toward Optimal Breastfeeding

This booklet addresses the special needs of women who, due to work or other obligations, are frequently separated from their infants, yet desire to breastfeed in a manner which is optimal for the health of their infants and which contributes to lactational infertility. The booklet is a companion piece to Guidelines for Breastfeeding in Family Planning and Child Survival Programs and has been developed, with input from LARFPC, for health care program planners and health professionals/workers to aid in

- Increasing awareness of the options available to breastfeeding working women, thereby encouraging the development of programs that address the lactation information and support needs of working women who wish to breastfeed, and
- Providing guidance for the health professional or breastfeeding counselor to assist the individual woman to identify and incorporate strategies to lengthen the duration of optimal breastfeeding for child health and child spacing in accordance with the realities of the woman's life circumstances.

During the reporting period, the Working Women Guidelines underwent two revisions. At present, the document is being revised at Georgetown to reflect the concerns of the reviewers and is being reviewed by an outside consultant to determine if the document is appropriate for the intended audience.

Planned Activities: During the next reporting period, the Working Women Guidelines revision will be completed, reviewed in house, sent out for peer review, finalized, and printed.

(2) Other Publications/Papers

Institute staff continue to disseminate information on LAM through presentations (see listing at the end of this report) and publications. In addition to final reports on projects, Breastfeeding Division staff attempt, in-house, and encourage contractors to produce additional articles for publication. As noted above, several articles on the results from the Chile and Honduras projects will be published in various journals and additional papers on more general topics have been requested by American Family Physician, the Journal of Human Lactation, and Avances.

Planned Activities: Breastfeeding Division staff plan to submit four to ten papers and chapters for publication over the next few months.

(3) Support to Professional Organizations

IRH supports acceptance of LAM through participation in medical and professional society meetings and other high-level fora, and by provision of requested assistance to professional organizations.

During this reporting period, IRH staff provided presentations to a number of groups on LAM, including the American College of Preventive Medicine, subcommittees of APHA, and roundtables at NCIH, as well as at the ILCA annual meeting and local and regional LLLI meetings for physicians.

Planned Activities: In addition to continuing this series of activities, including two planned meetings of LLL for physicians, IRH staff plans to create a subagreement with ACNM in support of these activities (see section on LAM in Nurse-Midwifery, below).

(a) Guatemala: LAM in LLLI

In Guatemala, the Institute has been working with La Leche League International (LLLI), on a "Breastfeeding and Natural Child Spacing Project." The original twelve-month training intervention focused on introducing the fertility aspects of breastfeeding into that country's already significant breastfeeding activity. The overall project encompasses three distinct levels of non-hospital based training activities designed to give adequate information to health professionals, community health and family planning workers, and mothers living in marginal urban neighborhoods, about the relationship between breastfeeding and natural child spacing. Through coordination with the National Breastfeeding Commission in all of its activities, this project is creating both policy and behavioral changes.

During the first phase, LLLI staff planned and executed a two-day national conference on breastfeeding and child spacing (co-sponsored by INCAP and the Guatemalan National Commission for the Promotion of Breastfeeding); organized several training workshops (with health related PVOs--AGROSALUD, CARE, and PAMI); evaluated and documented the training strategies developed for both the national conference and training workshops; and developed and field tested context specific, culturally appropriate training materials for counseling mothers in the relationship between breastfeeding and natural child spacing.

In May 1991, the project held a conference entitled "Los Ultimos Descrubimientos en Relación a la Excepcionalidad de la Lactancia Materna: Implicaciones y Aplicaciones." This conference, co-sponsored by INCAP, the Guatemalan National Commission for the Promotion of Breastfeeding, and IRH, included a one-day invitational conference for medical professionals and program planners; a half-day symposium open to the general medical community; and a curriculum development workshop for representatives of the local universities.

The 18-month extension project, which was signed in November 1991, builds on the accomplishments of the original project and will stimulate the expansion of activities regionally. The specific objectives of Phase II of the project are as follows:

- Maintain a designated liaison person to ensure inclusion of LAM in each of six breastfeeding workshops planned for NGOs and government health institutions under the currently funded Child Survival Extension Project as well as to help develop conference proceedings and training workshops;
- Develop and disseminate a book of relevant articles based on conference proceedings of the National Conference on Breastfeeding and Natural Child Spacing, which was held in May 1991;
- Plan and execute a LAM component in Regional La Leche League training workshops;
- Develop subsequent project extension proposals for short-term technical assistance on LAM to five to seven countries who participate in the training workshops.

The IRH consultant has made one trip to Guatemala to monitor activities under the extension project and especially to begin work on the conference proceedings.

Planned Activities: The IRH consultant to this project will return to Guatemala in March to monitor ongoing activities and continue coordination of training workshops.

(b) LAM in Nurse-Midwifery

The American College of Nurse-Midwives (ACNM) Special Projects Section currently receives funding for strengthening nurse-midwifery training and family planning programming worldwide. This group specializes in curriculum and training development and has developed training modules on several topics relevant to postpartum care.

Planned Activities: IRH plans to negotiate a subagreement with ACNM to develop LAM-based curricula and to incorporate LAM into all current nurse-midwifery programming within their purview.

(4) Audiovisuals

User-friendly slide sets and videotapes on LAM in at least three languages will assist the Division in improving dissemination of LAM and enable more personnel to adequately present this issue.

One hour-long slide set with a script exists in English and Spanish, focusing on LAM. The script for this set has been translated into French, but the slides are not yet available. Discussion has begun about a LAM videotape.

Planned Activities: During the next reporting period, Division staff will meet with producers to discuss development of the LAM video. English, French, and Spanish slide sets will be developed for standard 30-minute and 15-minute presentations. In addition, the slide set will be formalized for use by Division staff as well as for second-level use by other Cooperating Agencies.

c. LAM: Technical Assistance

(1) Technical Assistance to Cooperating Agencies

The Breastfeeding Division has designed an organized program of technical assistance that includes presentations and workshops with selected Cooperating Agencies and a needs assessment and materials for a broader group. This approach was pretested in 1990 with a presentation at JSI for Enterprise, MotherCare, and other staff. It resulted in a second-level presentation by personnel in these projects.

The first technical presentation in the newly organized series was given in December 1991 at CEDPA (described below).

Institute staff continue to be actively involved in working groups with other Cooperating Agencies, including the Working Group on Perinatal Family Planning Education and Counseling Training and the Working Group on the Family Planning Training Materials Database.

In addition, Institute staff continue to review Cooperating Agencies' breastfeeding materials and regularly review articles for peer reviewed journals.

(a) CEDPA

On December 12, 1991, all Breastfeeding Division staff met with CEDPA staff to provide a three-hour presentation on IRH, the Breastfeeding Division, and LAM.

The last hour of the presentation was spent discussing CEDPA's programmatic and research needs and interests.

Following this technical presentation, individual Division staff met with interested CEDPA staff to refine project ideas. CEDPA staff also contacted Institute staff with requests for additional publications and with questions about specific materials development (such as research protocols and slide sets).

Planned Activities: During the next reporting period, IRH staff will meet again as a group with CEDPA to discuss specific project ideas and to begin to plan/implement one or two small technical assistance projects.

(b) Others

Planned Activities: During the next reporting period, the Division plans to provide three more technical presentations to three CAs, and to follow up on each presentation provided.

(2) Technical Assistance to Missions

IRH Breastfeeding Division staff provide a variety of technical assistance to Missions upon request, to identify needs, existing LDC resources/materials, and worthwhile activities, under all three Division program areas. During this reporting period, Institute staff assisted A.I.D. CTOs in drafting a cable to USAID Missions

informing them about the capabilities of the Institute, especially under its new and expanded mandate.

Planned Activities: Planned technical assistance includes Peru, Zambia, and, if approved, Indonesia. With the addition of a bilingual Field Project Associate during the next reporting period, activity in this area is expected to increase. The draft A.I.D. cable to the Missions is expected to be finalized and sent.

(3) Technical Assistance to International Donors

IRH Breastfeeding Division staff continue to provide technical assistance to international donors. Specifically, Breastfeeding Division staff continue to participate in UNICEF, UNFPA, World Bank, and other meetings related to MCH issues so that IRH may include LAM on the agendas.

Responses from UNFPA have been increasingly positive towards the role of breastfeeding in pregnancy delay. IPPF literature is supportive of the three parameters of LAM although their policy continues to negate its use.

The World Bank is planning to include LAM in its next publication on available family planning methods, and Breastfeeding Division staff are working with World Bank staff to ensure that positive messages about LAM are conveyed.

Planned Activities: IRH staff plan to continue their efforts, specifically with UNFPA and IPPF, to enhance acceptance of LAM.

(4) Technical Assistance to Other Programs

(a) Recife

In Brazil, the Institute is working with the Population Council INOPAL Project and CEMICAMP to incorporate information about lactational amenorrhea for child spacing into a maternity hospital/MCH family planning service delivery system (IMIP) in Recife. This information will be incorporated into the postpartum family planning service delivery system as an addition to other strategies for managing birth spacing. CEMICAMP personnel are assisting in the design, monitoring, and evaluation of the project, and the Institute is providing assistance in materials development and onsite technical presentations at major meetings as well as training sessions.

CEMICAMP personnel have developed a translation/revision of the Guidelines for Breastfeeding in Family Planning and Child Survival Programs that is compatible with both their program and IRH needs.

Planned Activities: This project will be concluded during the next reporting period and results will be prepared by LARFPC as an article for publication.

2. BF and Fertility: Optimal Breastfeeding for its Fertility Impact

Activities are designed to create support for optimal breastfeeding for its fertility impact on populations. This support includes policy, programs, and education based on demographic and biomedical research and information.

a. BF and Fertility: Research and Pilots

(1) University of California at Davis: Effect of Introducing Complementary Foods on Breastmilk Intake and Maternal Fertility in Honduras

This project is designed to provide key information regarding the optimal timing of complementary feeding of breastfed infants. The World Health Organization currently recommends that complementary foods be given to infants between four and six months of age, but this message is criticized as being too vague, and some have argued that in developing country populations the risks of beginning foods before six months outweigh the potential benefits. A key unknown in this debate is whether complementary foods before six months actually augment total energy intake or merely displace breastmilk. The specific aims of this project are to (1) examine the effects on infant breastmilk and total nutrient intake of introducing complementary foods at 16 weeks versus continued exclusive breastfeeding until 26 weeks; and (2) determine if the duration of maternal postpartum amenorrhea is affected by the timing of the introduction of solid foods.

The pilot study for this project was initiated in July 1991. Ten mothers who were exclusively breastfeeding at four months postpartum were randomly assigned to either begin solid foods at 16 weeks or to continue exclusive breastfeeding (control group) until 26 weeks. The solid foods group was asked to maintain nursing frequency during the ten-week portion of the study.

Average milk volume remained the same in the control group between 16 and 26 weeks. However, volume decreased after solid foods were introduced in the intervention group in spite of the maintenance of nursing frequency by mothers in the intervention group; the mean value was identical to that of the mothers in the control group at 26 weeks. Total time nursing decreased by 55 percent between 16 and 26 weeks in the intervention group, compared to a decrease of only 12 percent in the control group. This suggests infant self-regulation of breastmilk intake, which is consistent with maternal reports of decreased demand for breastmilk in the intervention group.

By 21 weeks postpartum, four of the five mothers in the solid foods group had resumed menstruation, compared to only one of the four mothers in the control group. The time postpartum at which menses returned was 11 and 26 weeks for the two control mothers, and 15, 17, 18, and 20 weeks for the mothers introducing solid foods.

Planned Activities: During Phase II of the project, which will be co-funded by other agencies, possibly including Thrasher Foundation and other A.I.D. subcontractors, approximately 150 mothers who are exclusively breastfeeding their infants at four months of age will be randomly assigned to one of three study groups: (1) control, i.e., continue exclusive breastfeeding until 26 weeks; (2) introduction of complementary foods at 16 weeks, with ad libitum nursing; and (3) introduction of complementary foods at 16 weeks with maintenance of nursing frequency. To minimize family disruption caused by the milk intake measurements, only primiparous mothers who are not employed outside the home will be recruited. Pre-prepared complementary foods will be provided in jars to groups 2 and 3 and will consist of locally familiar fruits, vegetables, and rice and oat cereals with and without egg yolk.

Prior to intervention, all subjects will be visited in their homes at 1, 2, 6, 10, and 14 weeks postpartum to provide guidance in maintaining exclusive breastfeeding and to collect anthropometric and morbidity data. Infant intake and breastmilk composition will be measured by 48-hour test weighing and 24-hour milk sampling

in a central facility at weeks 15-16 (prior to beginning complementary foods in groups 2 and 3), weeks 20-21, and weeks 25-26. During this period (16 to 26 weeks) home visits will be made weekly to collect anthropometric and morbidity data and check on compliance. At 19 and 24 weeks, 12-hour home observations and feeding patterns will be completed. At 25-26 weeks, infant blood samples will be collected for assessment of iron and zinc status. After 26 weeks, subjects will be visited monthly to monitor infant growth (to 12 months) and determine the duration of maternal amenorrhea.

Analysis of co-variance will be used to compare outcomes among groups. The results of this study will be of great importance to policy makers concerned with infant health in developing countries. If the study shows that breastmilk is displaced when solid foods are given, and there is no net increase in energy intake, this will provide strong evidence for changing the WHO recommendation for complementary feeding, particularly if maternal fertility is also affected.

(2) Other Symposium Preparation

(a) Neuroendocrine/ICMER

A symposium on the Neuroendocrine Basis of Lactational Infertility was held by ICIMER with co-sponsorship from WHO and other organizations and individuals. The meeting, held on November 24-26, 1991, was attended by most of the major actors in this area of research. Discussion was both broad ranging and comprehensive on specific topics.

The conclusions of the meeting were that specific individuals, including Drs. Johannes Veldhuis, Soledad Diaz, and Alan McNeilly, would take responsibility to develop specific research agendas to answer questions that remain. In addition, a review article will be prepared for publication in an appropriate journal to stimulate interest and response.

Planned Activities: A letter of agreement will be written between the Institute and ICIMER to support these follow-up activities.

(b) Other

Institute staff plan to prepare a LAM Symposium in the next reporting period, the purpose of which will be to assess the state of the art and to support IRH in strategic research planning.

Planned Activities: Institute staff will begin to plan the meeting, possibly in conjunction with a consultant who will support the logistical component.

(3) GU Clinical Studies

(a) Breastmilk Storage: Bacteriology and Stability of the Lipids and Proteins under Conditions of Non-refrigeration

The first phase of this project was designed to assess breastmilk storage under "normal" conditions ("clean" containers of various composition and temperatures). The ability to express milk for later feeding when the mother is away from the infant can strongly influence women to continue breastfeeding their infants even after they have returned to work. This study is important because it assesses the safety and nutritional value of human milk when stored under conditions which prevail in developing countries. The investigator studied specimens of expressed breastmilk stored at different temperatures to provide guidelines for optimal

preservation of milk constituents. These specimens were analyzed over 24-hour periods for changes in quality that would have a negative impact on infant health.

Several mothers were studied twice, once at six to eight weeks of lactation, and once at six to nine months of lactation. All of the women in the study were mothers of full term infants who were exclusively breastfed during the study period. The milk was collected by breast pump and transported to the lab at ambient temperature. One representative milk specimen was placed in ice immediately after expression. Enzyme activity was quantified and found to remain constant in milk stored for 24 hours at either 15, 25, or 38 degrees C.

During this period, there was a time and temperature dependent decrease in milk pH; however, the milk pH remained constant for the first four hours of storage at all temperatures and did not reach unacceptable levels within 24 hours. Bacteriological analysis revealed no microbial growth during storage at 15 degrees C for up to 24 hours. At higher temperatures (25 and 38 degrees C) there was progressively greater bacterial growth with length of storage, however, further analysis is necessary to assess the safety of these levels.

Planned Activities: During the next reporting period, the agreement for the second phase of this project will be signed and activities will begin.

(b) Osteal Density in Response to Breastfeeding and Weaning

Recent research findings reflect the possibility that the weaning period is a time of rapid redeposition of calcium in maternal bone. There is an endocrinological explanation for this possibility. Since osteoporosis is a concern in maternal health, it is important to verify the patterns of breastfeeding most likely to result in bone restoration.

Georgetown University faculty have produced a concept brief for research in this area.

Planned Activities: A protocol will be developed that is appropriate to the question as it applies in developing countries and will be instituted at Georgetown University.

(c) Colostrum as an Anti-infective Agent

There is much interest in the role of colostrum as an anti-infective agent for use as a prophylactic and curative agent for the neonate. While colostrum is used in Third World settings for postpartum eye wash and treatment of stump infections, there is no laboratory or clinical basis for supporting these activities.

Planned Activities: IRH plans to work with Department Infectious Disease faculty to develop a protocol for in vitro and in vivo testing.

(4) Data Analysis/Surveys

(a) DHS/IRD/Pittsburgh

Under the last project, DHS carried out a series of analyses in concert with the University of Pittsburgh. Some aspects of this work remain to be completed.

Planned Activities: The final papers produced by DHS are undergoing in-house review and revision for submission for publication. The Country Profiles will be completed in draft and reviewed.

(b) Field Pilots on Indicators/Surveillance

Indicators have been developed based on the definitions for patterns of breastfeeding. It will be necessary to test or pretest the outcomes of the indicators development to establish a surveillance approach to assess changes in the fertility impact of breastfeeding. One possible site for this study is Thailand. This task was not funded in this year's workplan.

Planned Activities: It is desirable that there be at least one field project developed in the next 6-12 months that will address this area.

b. BF and Fertility: Education of Health Professionals and Policy Makers

(1) Textbooks

(a) Helping Mothers to Breastfeed

This text, which has been translated into seven languages and widely distributed, especially in Africa, has been revised and is being reprinted. Based on discussions held with IBFAN in August 1989, the Institute was approached by the author, Dr. Felicity Savage, to support this effort. Discussion included: (1) support for rewriting the section on breastfeeding and child spacing to include LAM; (2) including reference to this rewrite in the preface or foreword; (3) support for the initial printing; and (4) distribution of 200+ copies to key persons in Africa with an Institute cover letter. It is planned that the publisher, AMREF/Africa, will assist in the identification of these persons and will carry out the distribution. Institute staff reviewed the final proofs of the book to ensure accuracy of the breastfeeding and fertility aspects of the text. This volume will also serve as a reference text for the IRH curriculum and will be widely distributed by WHO, TALC, ILCA, and other international organizations.

The first IRH subagreement with AMREF has been completed. Under this first subagreement, the breastfeeding and child spacing section of the text was rewritten to include LAM and the textbook was printed.

Planned Activities: During the next reporting period, IRH will write an additional subagreement with AMREF for wide distribution of the textbook under a joint AMREF-IRH letter.

(b) Lactancia Materna

This draft publication was developed in conjunction with a major breastfeeding support and research program in Chile and was disseminated at the Institute-sponsored conference on "Advances for Breastfeeding for Health and Child Spacing," held in Chile in October 1990.

The publication is undergoing review and expansion to include a brief proceedings of the meeting. Cofunding of the proceedings has been provided by PAHO. This document will serve as a reference text for the Lactation Education curriculum and will be widely distributed, as it is designed to fill a gap in health professional level materials presently available in Spanish that have been developed in the region.

Planned Activities: During the next reporting period, revision of the text in Chile will be completed and the document translated into English in Washington, DC. Final review and printing are planned thereafter.

(c) Text Review - World Health Organization (WHO)

The World Health Organization, in collaboration with the Infant Baby Food Action Network (IBFAN) is in the process of evaluating the breastfeeding content of the most widely used textbooks dealing with infant nutrition. The review concerns texts in English, French, and Spanish. Both pediatric and obstetrics/gynecological textbooks are being examined in terms of their breastfeeding content generally and fertility aspects of breastfeeding in particular. WHO/Geneva has subcontracted with IRH to review these textbooks. To date, IRH has identified a consultant to assist in this task.

Planned Activities: Major texts will be identified, and correspondence will be initiated with the publishers and editors of these books. Based on a structured and detailed critique of the texts, outlines will be prepared as to the appropriate breastfeeding content of pediatric and obstetric texts. Follow-up to the original text review will include preparation of letters to editors, scientific follow-up with responsible authors, and ongoing communication. This task will be carried out under a letter of agreement to be finalized during the next reporting period.

(2) Curricula

The Institute has developed curricula for training different levels of health and health-related personnel in breastfeeding support. All curricula have been developed in the context of an action program plan, designed to result in the immediate application of breastfeeding support activities. These curricular outlines include those for training-of-trainers (TOT), for educators of field health promoters, for program leadership, for hospital-based breastfeeding support (developed by a Wellstart graduate), and for training family planning care providers.

(a) Lactation Education for Health Professionals - Case Studies

Lactation Education for Health Professionals, developed with PAHO, was developed in conjunction with a meeting of Latin American nursing educators. It includes a training module, teaching guidelines, and supporting articles which cover breastfeeding concepts--including fertility aspects--and educational concepts important to implementation of the curriculum. It is addressed to faculties of medicine, nursing, and other health professional schools. Prepared by Institute staff, it was published by the Pan American Health Organization, and distributed in English and Spanish by both organizations.

This is one of several IRH projects that has benefitted from the collaboration of the Institute with the Pan American Health Organization and from the contribution of nursing, medical, and other leaders from Central and South American universities and health services and others around the world.

Phase 1, the development of a core lactation curricular module for the teaching of breastfeeding, has been completed. Phase 2 of this project consisted of testing the breastfeeding module. To achieve this goal, Institute staff provided technical assistance and support to health professionals during the testing process. Evaluation of the testing process included pre-post tests for students and mothers taught by students. The case studies from the sites where the curriculum was tested in university and hospital settings (Chile, Colombia, Costa Rica, Ecuador, Honduras, Mexico, and Peru) are being finalized.

Planned Activities: Time and budget permitting, the case studies need to be summarized and circulated to participating sites, as well as translated for in-house circulation and comment. A standardized format for full presentation of the case

studies should be developed and each study must be written according to that format. Once standard points of analysis for comparison of the individual studies have been established, the studies will be compared and analyzed, focusing on facilitating factors and barriers, identifying lessons learned, and making general recommendations.

(b) Lactation Education for Health Professionals - Annotated Curricular Outline

The Breastfeeding Division plans to annotate the curricular outline from the book Lactation Education for Health Professionals. Many of the groups with whom we collaborate have expressed a need for reference materials so that the elements of the outline may be completed with correct and up-to-date information.

Planned Activities: During the next reporting period, IRH staff will review the curricular outline to determine the work involved in referencing each concept to specific pages in textbooks, preferably those supported by IRH. It is expected that work will begin on this task within six months and printing within two years.

(3) Other Texts

The IRH has conducted a series of workshops and panels, as well as developed articles, to address controversial issues that become obstacles to the acceptance of optimal breastfeeding.

(a) Breastfeeding: Protecting a Natural Resource

This document is a glossy and informative presentation of breastfeeding and its benefits that was developed with IMPACT/PRB. The booklet is targeted to policy makers, health professionals, and breastfeeding advocates, and is available in English, French, and Spanish.

This booklet has been widely disseminated worldwide. Since it was published, approximately 9,200 English, 5,000 French, and 6,000 Spanish copies have been distributed to groups such as A.I.D and A.I.D. Cooperating Agencies, USAID Missions, Schools of Public Health, WHO, UNICEF, UNFPA, JHPIEGO, SIDA, AED, La Leche League International, Wellstart, PAHO, and many others. During this reporting period, 700 English, 900 French, and 4,500 Spanish copies were distributed. UNICEF/Mexico received 4,000 copies of the Spanish version of the booklet to distribute countrywide. The English version of the booklet was distributed in Indonesia at the National Breastfeeding Congress and the French version has been widely distributed through Cooperating Agencies and to all participants in the Francophone Africa Regional Conference on Infant Feeding and Child Survival; and the Spanish version was distributed at a major conference in Guatemala (described in the Guatemala section). The booklet has also been translated into Nepali. The Resource Center responds to frequent requests for the booklet in all languages.

Planned Activities: Dissemination of this document will continue, generally in a project or policy related context to maximize its usefulness.

(b) Breastfeeding Division Fact Sheet

This one-page, front-and-back document describes the Institute's focus on breastfeeding for child spacing and LAM, and the support that the Breastfeeding Division can provide to family planning and child survival programs in developing countries.

The original Fact Sheet was disseminated widely worldwide. The updated Fact Sheet has been available since October 1991 and distribution has begun, although to date it is available only in English.

Planned Activities: The new Fact Sheet will be translated into French and Spanish. IRH plans to update the Fact Sheet on at least a yearly basis.

(c) Journal Of Tropical Pediatrics Supplement - "Breastfeeding and Borderline Malnutrition in Women"

IRH sponsored a panel entitled "Breastfeeding and Borderline Malnutrition in Women" at the 17th Annual National Council For International Health Meeting in Washington, DC, in June 1990. The focus of this panel was on lactation in situations of poor maternal nutritional status. Policy recommendations to improve the likelihood of successful lactation, from the point of view of the mother-infant dyad, were discussed.

The interest generated by this panel was overwhelming, reflecting the great need for information on the effects of breastfeeding not only on infant health and nutrition, but also on the mother herself. Therefore, IRH decided to publish the complete panel presentation where it would be widely available to a broad audience in the international health field. This volume of the Journal of Tropical Pediatrics provides valuable guidance for program personnel and researchers alike. To date, IRH has distributed approximately 200 copies of the document.

Planned Activities: During the next reporting period, IRH will continue to distribute copies of the supplement as requests are received. There were no plans to translate the document into other languages; however, selected articles were translated into French by the Academy for Educational Development for use at their conference on Infant Feeding and Nutrition held in Lomé, Togo, in September 1991, and into Spanish for the conference in Guatemala. Due to high interest, IRH now plans to proceed with complete translations of this document.

(d) WHO Proceedings: "The Technical Rationale for Global Action on Breastfeeding: Proceedings of the Expert Meeting Towards the Innocenti Declaration"

WHO supported IRH's preparation of these proceedings from the Technical Meeting leading to the Innocenti Declaration. The volume is designed to (1) inform and educate health decision makers concerning the technical issues in the protection, promotion, and support of breastfeeding; (2) update the state of the art for all concerned with breastfeeding; and (3) provide a proceedings of the Technical Meeting that was both a culmination of the five years of technical coordination of the Interagency Group for Action on Breastfeeding and a technical background for the Policy Makers Meeting in Innocenti, Italy, July 29-August 1, 1990. The technical papers in this volume bring positive aspects of breastfeeding to the attention of decision makers. The papers present breastfeeding as an essential part of child survival and development including child nutrition, control of diarrheal diseases, birth spacing, and mother's health and well being. Breastfeeding also has a measurable impact on decreasing infant mortality by five to seven million lives per year from what it potentially could be, and in general improves national levels of well being through economic and health savings. The publication will be available in English, French, and Spanish and will be a companion piece to The Physiological Basis of Breastfeeding, a very popular WHO publication.

During this reporting period, IRH and WHO staff coordinated the preparation of the proceedings by discussing changes with authors of the original papers, reworking

several papers, and editing many other papers. The entire volume was then edited and sent to WHO for review. WHO began the review process and has been corresponding regularly with IRH staff to discuss revisions.

Planned Activities: IRH staff expect to refine some papers included in the volume and to review the "Blue Line" of the ready-for-print document. The document's expected publication date is April 1992.

(e) Breastfeeding Saves Lives: The Impact of Breastfeeding on Infant Survival

This monograph and a companion article to be submitted for peer review publication were prepared by the Center to Prevent Childhood Malnutrition (NURTURE) in conjunction with IRH as one of the Center's Policy Series Volumes. The booklet was created to illustrate the profound effect of optimal breastfeeding practices on infant health and child survival throughout the world. Noteworthy in this document is a page that presents a comparison of breastfeeding to other child survival interventions.

IRH received 100 copies of the monograph to distribute. During this reporting period, no major distribution took place.

Planned Activities: A mailing of the document is planned within the next six months. A reprinting of the publication is being considered; however, several changes must be made to the original version. The revised version will receive broader distribution.

(4) Audiovisuals

(a) Videotape: Breastfeeding: Protecting a Natural Resource

Originally, this fifteen-minute, nine-projector slide show was produced with A.I.D. Population, Health, and Nutrition funds for the WHO/UNICEF meeting "Breastfeeding in the 1990s: A Global Initiative," held July 30-August 1, 1990, in Florence, Italy, at the Innocenti Center. The slide show's primary intended audience was a group of approximately 150 ministers of health and other international policy makers as well as representatives of various donor and UN agencies.

The show depicts current knowledge and understanding of the importance of breastfeeding--not only for mothers and children, but for society as a whole. The show presents breastfeeding as a vital natural resource and highlights the many diverse benefits associated with its promotion and protection. It describes how breastfeeding lowers infant mortality and morbidity; provides excellent nutrition for infants and contributes to their growth and development; improves women's health; enhances child spacing; and provides economic benefits for families and nations. The show further emphasizes that policy makers and program planners have a primary role to play in determining the most appropriate actions to take to promote and support breastfeeding. Priorities for action are presented to the decision maker/viewer, emphasizing the importance of changing hospital and health care practices; improving information, education, and communication campaigns; supporting working women to breastfeed successfully; and building family, community, and political support for breastfeeding.

Following the meeting in Florence, numerous requests for copies of the slide show necessitated its transfer to video format for distribution to individual policy makers and various organizations working in international health. The Institute therefore produced the videotape of the slide show in French and Spanish with additional

support from PAHO and Wellstart. In Indonesia, the video has been dubbed in Bahasa Indonesia. Distribution of the video to policy makers around the world is being accomplished through a variety of channels including A.I.D., WHO, UNICEF, PAHO, SIDA, and A.I.D. Cooperating Agencies such as AED and Wellstart.

The video has recently received recognition from colleagues at both WHO and UNICEF. They stress how timely and popular the video is among their field staff, with emphasis on the fact that the production quality lends additional respect and credibility to the subject matter. The A.I.D. S&T Breastfeeding Cluster recognized the video as the best A.I.D.-produced health video of 1990. In addition, the video recently was recognized and won an honorable mention in the National Association of Government Communicators Gold Screen Award Competition.

Planned Activities: During the next reporting period, IRH plans to edit the video to reflect the new Institute name and logo. Distribution will continue worldwide.

(b) Slide Set

Institute staff are frequently asked to give presentations not only on LAM but on the fertility aspects of breastfeeding and general breastfeeding benefits. To be responsive to these requests, and requests from A.I.D. Cooperating Agencies for slide sets they can use in their programs, IRH has given considerable attention to the development of several types of slide sets.

In addition to the already existing one-hour slide set that focuses on LAM and the Guidelines for Breastfeeding in Family Planning and Child Survival Programs, and incorporating LAM into programs, IRH staff are conceptualizing two to three other sets. One set, which is in draft form, is a lengthy (two- to three-hour) modular set which discusses the general benefits of breastfeeding, the physiology of lactation, complementary family planning methods, programmatic aspects of breastfeeding, and plans for action. The various modules can be added, subtracted, and modified to suit the needs of the various audiences.

In addition, IRH is discussing a 30-minute slide presentation as well as a 15- to 20-minute set. IRH staff are discussing these concepts with a slide set producer and with potential consultants.

Planned Activities: IRH staff will identify a consultant to work on producing the two shorter slide sets. Plans are now to keep the draft modular set in house for revision.

(5) Other Projects

(a) Cusco

The field work aspects of this IEC project, Mass Media Demonstration Project for Breastfeeding Promotion have been completed. The two-year program focused on promoting breastfeeding for child spacing and child survival through a series of radio programs developed by Comunicación Andina. Twenty-five minute programs including breastfeeding messages and community health news were broadcast daily over a six-month period. The project enhanced the availability and quality of breastfeeding support services by establishing a small education center in the community, and by providing training and technical support in breastfeeding through training programs in other health service delivery groups. During the radio programs, women were referred and encouraged to use the Comunicación Andina

breastfeeding education center. The center's staff referred women to the MOH service for family planning and other services.

This demonstration project applied qualitative (focus group interviews) and quantitative (survey) research techniques to determine whether a series of educational radio programs increase people's knowledge about breastfeeding and lead to the acceptance by the target population of optimal breastfeeding practices for child survival and child spacing. A pre-intervention survey of 250 mothers with children aged six months and younger was completed prior to broadcasting the radio programs. The survey provided baseline data on current breastfeeding beliefs, myths, and practices of the Quéchuá-speaking population in the Cusco area. Program broadcasting has been completed, and was followed by a post-intervention survey. Project staff members have analyzed the pre-and post-intervention survey data, and the project ended in July 1991. Project staff submitted a draft final report to IRH/GU.

Planned Activities: A consultant will travel to Cusco in March/April 1992 to evaluate the project and to assist project staff in analyzing the data and writing a final report.

c. BF and Fertility: Technical Assistance

(1) Technical Assistance to Cooperating Agencies

IRH continues to publish and disseminate scientifically sound articles as well as to provide technical assistance to Cooperating Agencies and their projects on the fertility aspects of breastfeeding. This assistance includes review of materials and peer review articles. Under this area, the Breastfeeding Division is emphasizing agency-level technical assistance for policy change, including continued information updates, visits to key organizations during country visits, provision of key documents and materials as requested, and other activities.

During this reporting period, Breastfeeding Division staff and the Resource Center responded to numerous requests for information on the fertility aspects of breastfeeding.

Planned Activities: This assistance will continue during the life of the project. During the next reporting period, in addition to IRH responding to requests as needed, several organizations will be targeted to receive specialized assistance on the fertility aspects of breastfeeding.

(2) Technical Assistance to Missions

During this reporting period, the Division provided assistance to the USAID Mission in Haiti. The Deputy Director of the Division traveled to Haiti with a consultant to the NFP Division to conduct a needs assessment on breastfeeding for child spacing and natural family planning. The team submitted a needs assessment to USAID/Port-au-Prince; however, all A.I.D. activities are currently suspended in the country due to the political situation.

As mentioned in section B.1.c., Institute staff assisted in drafting a cable to USAID Missions from A.I.D./W which emphasizes the expanded mandate and capabilities of the project under its new funding agreement.

Planned Activities: The addition of a Field Project Associate will greatly enhance the Division's ability to respond to requests from USAID Missions worldwide. It is hoped that the worldwide cable will generate some specific requests from

Missions. Breastfeeding Division staff will participate in BIG Country Strategy Plans and will plan a series of visits for the coming year.

(3) Technical Assistance to International Donors

(a) WHO Simplified Methodology for Assessing Breastfeeding

In the early 1980s, WHO developed an assessment tool designed to identify fertility return in populations in order to advise family planning programs concerning the breastfeeding/family planning interface. This module has been tested in more than ten sites. However, events have surpassed the original goal; with the development of LAM, each individual may now assess the proper time for complementary family planning. WHO has asked IRH to jointly review the findings of the test sites and develop recommendations concerning module modification and its usefulness in the current understanding of the subject.

Planned Activities: During the next reporting period, IRH staff will begin to undertake this task.

(b) Interagency Coordination

This coordination activity focuses on the fertility aspects of breastfeeding. The new Wellstart project will be taking on the IGAB role formerly played by IRH.

In October, representatives of IRH, WHO/HRP, FHI, Population Council, and A.I.D. met at Georgetown University to discuss each organization's ongoing work and plan of action related to breastfeeding and fertility, to identify other agencies that should be involved in coordination efforts, and to develop a concrete plan of action for a working group that includes specific meetings and processes.

IRH staff are writing up the results from the October meeting between organizations involved in the fertility aspects of breastfeeding.

Planned Activities: During the next reporting period the results of the October meeting will be disseminated and the group will meet again. This working group is expected to continue through the life of the current IRH project agreement.

(c) Nomenclature/Indices

Terminology regarding breastfeeding and fertility must be consistent across all breastfeeding research and programs and must be reflective of those factors that influence breastfeeding fertility impact. IRH's previous work in this area puts the organization in an excellent position to continue this work.

The definitions, published in Studies in Family Planning, were used as a basis for WHO's development of indices as well as in several other studies. IRH provided a critique of the WHO indices and others.

Planned Activities: IRH plans to continue to provide TA to any group using the definitions in articles for publication or, as in the case of WHO, in the development of indices.

(d) International Breastfeeding Collaborating Centre (WHO Collaborating Centre on Technical Aspects of Breastfeeding)

Over the last four years, the Breastfeeding Division has experienced increasing collaboration with and financial support from a variety of divisions within PAHO

and WHO. In February 1991, IRH was asked to prepare an application for a unit, comprised of the Breastfeeding Division and selected other University faculty, to serve as a WHO Collaborating Centre. The application was developed under the title "International Breastfeeding Collaborating Centre," internally reviewed, and submitted in the spring. After a site visit from PAHO and further revisions in August 1991, the International Breastfeeding Collaborating Centre (IBCC) has been named a WHO Collaborating Centre on Breastfeeding. The IBCC will be based in the Breastfeeding Division of the IRH.

Planned Activities: The IRH will be cofunding projects with IBCC (see section III.B.2.c.3.a., Simplified Methodology, and section III.B.2.b.3.d., Technical Proceedings).

(4) Technical Assistance to Other Programs

(a) Mailing List

The Institute maintains a mailing list of approximately 3,000 names which is constantly growing. This list is divided in 25-30 categories under the major subheadings of breastfeeding, natural family planning, and administration. Under breastfeeding, the categories are based on attendance at meetings; professional interests; organizational affiliation; region of world; relationship to the Institute; and so forth. The list is cross-referenced by language and other categories in which names are included. This mailing list must be constantly updated and maintained to facilitate its use in-house and in coordination with other A.I.D. collaborating agencies to facilitate the distribution of their materials to the appropriate audiences and create linkages between the Institute and these other organizations.

Planned Activities: During the next reporting period, the Resource Center consultant will begin assisting the Resource Center Coordinator in entering the mailing list on the selected database and updating the list to reflect all correspondence received to date. It is hoped that, within six months, the mailing list can be shared with A.I.D. CAs.

(b) Searches

The Resource Center of the Institute has maintained literature on NFP, there is a felt need in the Breastfeeding Division to have an ongoing update of the published literature available to the staff for both publication and technical assistance purposes.

Planned Activities: A subagreement will be developed or in-house capability will be developed to meet this need.

3. BF and NFP Interface

Activities under this area are designed to introduce LAM into NFP and to improve guidelines for NFP use during lactation.

a. BF/NFP: Research and Pilots

The Breastfeeding Division, in conjunction with the NFP Division and IFFLP, has begun to discuss and formulate guidelines for LAM use in an NFP program and will test these guidelines in a project site or sites. Research will be conducted on NFP method introduction during breastfeeding and modification of rules for improved efficacy will continue.

Planned Activities: During the next reporting period, some of the project sites will be identified and discussed at the various IFFLP Zonal/Subzonal meetings and Breastfeeding/LAM Expert Meetings. It is planned that two sites will be identified per region.

b. BF/NFP: Education of Health Professionals and Policy Makers

(1) NFP Conference Proceedings: "Current Knowledge and New Strategies for the 1990s"

These conference proceedings are described in the Natural Family Planning Division section of this report. More than one-quarter of this supplement to AJOG was developed by Breastfeeding Division staff and most of this input specifically focuses on the LAM/NFP interface.

The section explores the use of natural family planning during breastfeeding and the operationalization of the research findings related to the breastfeeding/natural family planning interface. Worldwide, the vast majority of women breastfeed their infants--in many countries for several months. Studies show that women learning natural family planning during lactation, particularly those whose menses have returned, have an increased risk of unplanned pregnancy. Altered hormonal levels may make interpretation of the signs of fertility return (such as mucus) difficult during this time. The Lactational Amenorrhea Method may be a useful adjunct to natural family planning training.

Specific papers from this session focus on biology and policy, observations from a prospective study of breastfeeding users of NFP, ultrasonic patterns of ovarian activity during breastfeeding, ovulation method during breastfeeding, efficacy of the symptothermal method of NFP in lactating women after the return of menses, and preliminary results of an intervention study in Santiago, Chile. Other papers prepared by Division staff cover the efficacy of NFP and LAM. The Division has received numerous requests for reprints.

Planned Activities: During the next reporting period, the Division expects to continue to respond to many requests for reprints of the conference. The proceedings will serve as a basis for discussion in IFFLP Zonal conferences over the next 12 months, aiding in their development of policy on breastfeeding.

(2) Other Materials

In addition to these proceedings, the Breastfeeding Division plans to develop, with IFFLP, materials concerning LAM for NFP programs. Specifically, at the upcoming Zonal/Subzonal Meeting and LAM/NFP Expert Meeting in Sydney, Australia, participants will focus on developing and refining implementation strategies and teaching guidelines.

Planned Activities: IRH staff will attend the meetings in Australia, and later, in Africa, to assist in working on these materials.

c. BF/NFP: Technical Assistance

(1) IFFLP: Policy/Guidelines/Testing

IRH's work with IFFLP is focusing on developing an IFFLP breastfeeding promotion and LAM/NFP policy and strategy and to develop sets of method use guidelines for each NFP method that can be adopted by IFFLP's members and

programs worldwide. These method protocols, guidelines, and training materials will be developed, field tested, translated, and disseminated.

To assist in accomplishing these activities, IFFLP has contracted with a consultant who is assisting the organization and its members, as well as its supported pilot projects, to develop breastfeeding and LAM supportive policies and strategies. This consultant will assist with the development of the protocols mentioned above, as well as with the development of teaching materials and curricula at all levels for the introduction of these protocols into ongoing programs.

Planned Activities: Breastfeeding Division staff will travel to Sydney, Australia, to participate in the IFFLP Subzonal Meeting, but particularly to address participants in the Expert Meeting on Breastfeeding. During this meeting, discussion is expected to focus on the importance of a LAM policy and strategy for IFFLP, country program experiences, the development and refinement of implementation strategies and teaching guidelines for all NFP methods, and method protocol development and refinement. Versions of the materials developed will continue to be refined through the next reporting period.

C. ADMINISTRATION/EVALUATION

1. Division Functional Support

- a. **Personnel:** During this reporting period, Miriam Labbok, MD, MPH, continued as Division Director and Kristin Cooney, MA, was promoted to the position of Deputy Director and appointed to a faculty position in the Department of OB/GYN. Virginia Laukaran, DrPH, joined the Breastfeeding Division as the Senior Associate for Research and received a faculty appointment as Research Assistant Professor in the Department of OB/GYN. Doris Stanley continued in her role as Division Secretary. Lois Schaefer, who worked half-time for the Division, resigned from her position at the Institute and joined the staff of JHPIEGO. Ms. Schaefer's Resource Center duties were assumed and expanded by a consultant who worked fifty percent time for each Division. In addition, the Breastfeeding Division recruited and interviewed for two positions: Breastfeeding Field Project Associate and Secretary.
- b. **Logistics:** Institute staff have devoted considerable time during the reporting period to standardizing operating procedures and forms for both in-house and A.I.D. procedures.
- c. **Budget:** The project fiscal year ends in June 1992. Plans are to write extensions of all ongoing Breastfeeding Division subprojects during the next reporting period and to complete all subagreements planned for this fiscal year.

2. Division Evaluation

As described in our proposal to A.I.D. for the current cooperative agreement, IRH will monitor and evaluate activities that are carried out within the Institute and through formal subcontracts. Evaluation is an ongoing effort.

In the Breastfeeding Division, Dr. Laukaran has been designated to work on formalizing the evaluation and monitoring plan/methodology in the next reporting period.

IV. RESOURCE CENTER

A. GENERAL DESCRIPTION

The Resource Center of the Institute for Reproductive Health is an information center established to support and contribute to education, training, and research in NFP and the fertility aspects of Breastfeeding through gathering and distributing materials. The Resource Center staff assist in all Institute publications, including copy editing, reference work, style conformity, and publication production.

The major undertaking of designing a classification scheme, applying it to the materials held, and developing a bibliographic database has begun. The Resource Center staff hope to have the database up and running within six months. When completed the database will aid in accurately cataloging, filing, and retrieving materials; and provide bibliographic data as needed. The Resource Center is also working on linking with PopLine and MedLine.

B. DISSEMINATION/MAILING LIST

1. Dissemination

The Resource Center continues to receive a large number of requests for Institute publications and/or information on NFP and Breastfeeding. Institute publications frequently requested in this report period are "Lactation Education for Health Professionals," published with PAHO, which was reviewed in a number of journals; and the special supplement of the proceedings of "Natural Family Planning: Current Knowledge and New Strategies for the 1990s," published by the American Journal of Obstetrics and Gynecology; and, "NFP: A Good Option. Both the booklet and the video "Breastfeeding: Protecting a Natural Resource" are also frequently requested in all available languages. An inventory is underway to assess current backlog and total number of materials disseminated, and to maintain an accurate account of materials held.

2. Mailing List

In order to have better quality control and updating ability it was determined that it would be most productive to create an Institute mailing list produced and housed here, rather than with an Institute subcontractor. The Resource Center staff plan to have the mailing list created and entered within six months.

C. LITERATURE AND MATERIALS COLLECTION

With the main phase of the Resource Center move and reorganization completed, Resource Center staff are now focusing on strengthening and expanding the Resource Center collection of materials. Special attention is being given to determining which Breastfeeding, NFP, and Maternal and Child Health journals are needed to complement and support the Institute's programs and research.

The Resource Center is assisting in the expansion and update of the media/slide libraries. The purchasing of required equipment has begun, including a portable video monitor for the Breastfeeding Division and a slide projector.

LIST OF APPENDICES

- 1. List of staff and consultant travel for time period which we are reporting.
Planned travel for next six-month reporting period.**
- 2. Publications**
- 3. Presentations**
- 4. Organization Chart/Staff Listing**

APPENDICES

APPENDIX #1

STAFF AND CONSULTANT TRAVEL DURING REPORTING PERIOD

**NFP DIVISION TRAVEL PLAN FOR STAFF AND CONSULTANTS
JULY 1, 1991 - JUNE 20, 1992**

STAFF:

TRAVELER	SITE	PURPOSE	DATE	STATUS
V. Lamprecht	Haiti	Conduct needs assessment, develop strategy per USAID mission request	7/28-8/10	Completed
V. Jennings	Perú	Participate in Perú CA meeting per USAID mission request; monitor Cuzco project	9/21/29	Completed
J.T. Queenan M. Zinaman	Singapore	Attend FIGO meeting, conduct biomedical TAG meeting	9/10/22	Completed
J.T. Queenan	Brazil	23rd Annual ECLAMC Meeting	11/5/09	Completed
M. Zinaman	Davis, CA	Site visit - final stages of Lasley/Katz studies	11/22/24	Completed
J.T. Queenan	Chile	Project monitoring	1/8-1/14/92	Completed
V. Jennings	New York	Quality of Care/Pop Council	1/30/31	Scheduled
M. Zinaman	London	Meet with Drs. Collins, Bernard, and Keith May of Unipath, Ltd.	Feb-92	Pending
V. Jennings	Australia/Phillipines	IFFLP Zonal Meeting (Australia), project development (Philippines)	Mar-92	Pending
V. Jennings	Perú	Project implementation	Jun-92	Pending

SUBCONTRACTORS:

TRAVELER	SITE	PURPOSE	DATE	STATUS
K. Aumack	Kenya, Mauritius	Project monitoring and development	7/14/28	Completed
R. Sevigny	Zambia, Zaire, Cameroon	Project monitoring	7/15-8/13	Completed
W. Pruzensky	Dominican Republic	Project monitoring	7/21/28	Completed
J.L. Simpson	Brazil	23rd Annual ECLAMC Meeting	11/5/09	Completed
R. Sevigny	Mauritius, Ivory Coast, Rwanda	Project Monitoring and TA	11/18-12/21	Completed
J.L. Simpson	Chile	Project Monitoring	1/8-1/14/92	Scheduled
W. Pruzensky	Chile, Brazil, and Dominican Republic	Project Monitoring	1/12-1/20/92 1/30-2/7/92	Scheduled

APPENDIX #1, (cont.)

**BREASTFEEDING DIVISION TRAVEL PLAN
STAFF AND CONSULTANTS
JULY 1, 1991 - JUNE 30, 1992**

STAFF:

TRAVELER	SITE	PURPOSE	DATE	STATUS
Miriam Labbok	Mexico	TA	7/21-7/26/91	Completed
Kristin Cooney	Haiti	Mission Request	7/28-8/10/91	Completed
Kristin Cooney	Indonesia	TA	8/26-8/30/91	Completed
Kristin Cooney	Togo	TA	9/5-9/14/91	Completed
Kristin Cooney	Indonesia	Project Development	11/20-30/91	Postponed
Miriam Labbok	Chile	Symposium/Project Monitoring	11/20-30/91	Completed
1992				
Virginia Laukaran	Ecuador	Project Monitoring	1/11-1/19/92	Scheduled
M. Labbok	Peru	Big Country Strategy Development	2/8-22/92	Scheduled
Kristin Cooney	Australia	IFFLP Conference	3/6-23/92	Scheduled
Miriam Labbok	Australia	IFFLP Conference	3/6-17/92	Canceled
Kristin Cooney	Indonesia	Project Development	3/29-4/11/92	Postponed
TBD	Other Regional	TA	April, 92	Scheduled
Miriam Labbok	Chile	Project Monitoring	April/May, 92	Scheduled
Miriam Labbok/TBD	Egypt	Project Development	April/May, 92	Scheduled
Miriam Labbok/TBD	Kenya/Uganda	TA/Project Development	April/May, 92	Scheduled
Miriam Labbok/TBD	Morocco	Project Development	April/May, 92	Scheduled
TBD	Geneva	TA	May, 92	Scheduled
TBD	Other Regional	TA	May, 92	Scheduled
Virginia Laukaran	Ecuador	O.R. TA	May, 92	Scheduled
Kristin Cooney	Haiti	Project Development	May, 92	Postponed
Miriam Labbok/TBD	Mexico	Presentation/TA	May, 92	Scheduled
Miriam Labbok/TBD	Brazil	TA	June, 92	Scheduled
Miriam Labbok/TBD	Honduras	TA	June, 92	Scheduled
Kristin Cooney	Togo/Senegal/TBD	Project Development	June, 92	Scheduled
TBD	Egypt	Project Development/Monitoring	June, 92	Scheduled

APPENDIX #1, (cont.)

TBD	Other Co-funded	TA/Project Development	June, 92	Scheduled
TBD	Other Regional	TA	June, 92	Scheduled

SUBCONTRACTORS:

Karen Wade	Mexico	Project Monitoring	6/5-7/91	Completed
Gloria Mejia	Brazil	Project Monitoring	6/27 - 7/8/91	Completed
Karen Wade	Ecuador	Project Monitoring	8/18-25/91	Completed
Gloria Mejia	Brazil	Project Monitoring	11/12-29/91	Completed
Peggy Koniz-Booher	Honduras	Project Monitoring TA	11/10-11/20/91	Completed

1992

Karen Wade	Ecuador	Project Monitoring	1/11-1/19/92	Scheduled
Judy Canahauti	Honduras	Project Monitoring	1/27-2/5/92	Completed
Peggy Koniz-Booher/TBD	Guatemala	Project Monitoring TA	2/14-21/92	Scheduled
Peggy Koniz-Booher/TBD	Honduras	Project Monitoring TA	2/22-29/92	Scheduled
Consultant	Peru	Project Evaluation	March, 92	Scheduled
Gloria Mejia	Brazil	Project Monitoring	April, 92	Scheduled
Karen Wade	Ecuador	Project Monitoring	May, 92	Scheduled
TBD/3-4 others	Costa Rica	Curriculum Meeting	June, 92	Scheduled

APPENDIX #2
PUBLICATIONS

Labbok M: Lactational Amenorrhea, *Lancet*, Vol. 337: 1233, May 1991.

Jennings V, Queenan, J: Natural Family Planning: An important option for child spacing. *NU* ("News on health care in developing countries"), Vol 2:25-28, June 1991

Labbok M: Is the Bellagio Consensus Statement on the Use of Contraception Sound Public Policy? Rejoinder. *Health Transition Review*, 1(1): 111-114, 1991.

Breastfeeding Saves Lives: The Impact of Breastfeeding on Infant Survival. Center to Prevent Childhood Malnutrition in conjunction with the Institute for Reproductive Health, Georgetown University, Center to Prevent Childhood Malnutrition Policy Series Volume 2(1):1-12, July 1991.

Jennings V: Natural Family Planning: New Devices May Simplify this Important Option. Training III, DHHS Regional FP Training Center, Philadelphia, Fall 1991.

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Krasovec K, Labbok M and J Queenan (eds.): Breastfeeding and Maternal Malnutrition, *J. Trop. Peds.*, Suppl., Oct. 1991.

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Foreword, *John T. Queenan*.

The Implications of Poor Maternal Nutritional Status During Pregnancy for Future Lactational Performance, *Katherine Krasovec*.

Nutritional Adjustments in Response to Reproductive Stresses within Guatemalan Women, *Kathleen L. Merchant, Reynaldo Martorell, Jere D. Haas*.

Influences of Maternal Nutrition and Lactation on Length of Postpartum Amenorrhea, *Kathleen M. Kurz, Jean-Pierre Habicht, Kathleen M. Rasmussen*.

Maternal Malnutrition and Breastfeeding: Is There Really a Choice for Policy Makers?, *Sandra Huffman*.

Breastfeeding and Borderline Malnutrition in Women, *Miriam H. Labbok*.

Queenan J, Jennings V, et al.(eds.): Natural Family Planning: Current Knowledge and New Strategies for the 1990s, *American Journal of Obstetrics and Gynecology*, Mosby-Year Book, Inc, St. Louis, MO, December 1991.

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Major Scientific Issues in Natural Family Planning

Natural Family Planning: Looking Ahead, *Queenan J, Moghissi KS*.

Fetal Outcome Among Pregnancies in Natural Family Planning Acceptors: An International Cohort Study, *Simpson JL, Gray RH, Queenan J, Kambic RT, Pérez A, Mena P, Barbato M, Pardo F, Tagliabue G, Bitto A, Stevenson W*.

Natural Family Planning and Sex Selection: Fact or Fiction?, *Gray RH*.

APPENDIX #2 , (cont.)

Human Cervical Mucus: Research Update, *Katz DF*.

Symptothermal and Hormonal Markers of Potential Fertility in Climacteric Women, *Flynn AM, James P, Collins WP, Royston P*.

Breastfeeding: A Natural Method for Child Spacing, *Howie PW*.

Conclusion, *Queenan J, Moghissi KS*.

Ovulation Prediction: Present Developments and Future Needs

Overview and Issues in Ovulation Prediction, *Zinaman MJ, France J*

The Evolution of Reference Methods to Monitor Ovulation, *Collins WP*.

Idiometric Assay, the Third Way: A Noncompetitive Immunoassay for Small Molecules, *Barnard G, Karsiliyan H, Kohen F*.

Home Tests to Monitor Fertility, *May K*.

A Prototype for Ovulation Detection: Pros and Cons, *Lasley BL, Shideler SE, Munro CJ*.

Use of the Home Ovarian Monitor in Pregnancy Avoidance, *Brown JB, Holmes J, Barker G*.

The Interface of Breastfeeding, Natural Family Planning and the Lactational Amenorrhea Method

Overview and Summary: The Interface of Breastfeeding, Natural Family Planning, and the Lactational Amenorrhea Method, *Labbok MH, Howie PW*.

Is the Lactational Amenorrhea Method a Part of Natural Family Planning? Biology and Policy, *Gross BA*.

The Natural Family Planning-Lactational Amenorrhea Method Interface: Observations from a Prospective Study of Breastfeeding Users of Natural Family Planning, *Kennedy K, Parenteau-Carreau S, Flynn A, Gross B, Brown JB, Visness C*.

Ultrasonic Patterns of Ovarian Activity During Breastfeeding, *Flynn AM, Docker M, Brown JM, Kennedy KI*.

Ovulation Method Use During Breastfeeding: Is There Increased Risk of Unplanned Pregnancy?, *Labbok MH, Stallings RY, Shah F, Pérez A, Klaus H, Jacobson M, Muruthi T*.

Efficacy of the Symptothermal Method of Natural Family Planning in Lactating Women After the Return of Menses, *Zinaman M, Stevenson W*.

Santiago Breastfeeding Promotion Program: Preliminary Results of an Intervention Study, *Pérez A, Valdés V*.

Natural Family Planning Use-Effectiveness and Continuation

Natural Family Planning Use-Effectiveness and Continuation, *Kambic RT*.

Efficacy Studies in Natural Family Planning: Issues and Management Implications Illustrated with Data from Five Studies, *Labbok MH, Klaus H, Pérez A*.

Effectiveness and Acceptability of the Symptothermal Method of Natural Family Planning in Germany, *Frank-Herrmann P, Freundl G, Baur S, Bremme M, Döring GK, Godehardt E, Sottong U*.

APPENDIX #2 , (cont.)

Further Analysis of Contraceptive Failure of the Ovulation Method, *Trussell J, Grummer-Strawn L.*

Factors Related to autonomy and Discontinuation of use of Natural Family Planning for Women in Liberia and Zambia, *Kambic R, Gray R.*

Measuring Natural Family Planning in Terms of Couple-Years of Protection, *Cuervo L.*

The Modified Mucus Method in India, *Dorairaj K.*

Abstracts Published in the American Journal of Obstetrics and Gynecology

Natural family planning training issues and strategies for the 1990s

Introduction and overview of natural family planning training programs, *Diane Vogelsang, B.A.*

Competency-based approach to training and natural family planning instructor standards, *Mary Catherine Martin, Ph.D.*

An experiential approach to training natural family planning trainers, *Kimberly Aumack, B.A.*

Preparing instructors to educate diverse client populations: The impact of culture, religion, socioeconomic status, and educational levels, *Marie M. Mascarenhas, M.D.*

Training and supervision from small natural family planning programs to national service delivery systems, *Sabina Mwaulu, R.N.*

Training evaluation: Its impact on future instructor training, client education, and natural family planning services, *George Walter, M.D.*

Experience and trends in natural family planning education and outreach

New directions for education and outreach in the 1990s, *Rosalia Rodriguez-Garcia, M.Sc.*

Reaching new populations with natural family planning education, *Leila Mehra, M.D.*

Innovative approaches from population communication services: Implications for natural family planning, *Benjamin V. Lozare, Ph.D.*

Using quantitative data to define natural family planning use: A profile, *Ravi K. Sharma, Ph.D.*

Seeking opportunities for natural family planning expansion: The Serena experience, *Suzanne Parenteau-Carreau, M.D.*

Lessons learned from a mass-media campaign in Peru, *Guillermo Tagliabue, M.D.*

Creating a demand for scientific natural family planning: The Zambian experience, *Lubinda M. Tafira*

Center for Research, Education, Service and Training's fertility education program for youth, *Marie M. Mascarenhas, M.D.*

Teen STAR (Sexuality Teaching in the context of Adult Responsibility) year 4 cohort with one-year after program follow-up (United States) and report of Philippine cohort, *Hanna Klaus, M.D. and David Kardatzke, B.Sc.*

Fertility education for young men, *Stephen A. Burke, M.S.W.*

APPENDIX #2 , (cont.)

Training and educational materials

Issues in the development and dissemination of training and educational materials, *Lois A. Schaefer, M.P.H.*

Materials development, testing, and evaluation: An overview, *Margot L. Zimmerman, B.A. and Premila Bartlett, M.P.H.*

Materials translation: Is that really what you want to say?, *David Bowen, Ph.D. and Margareta Bowen, Ph.D.*

Introduction of natural family planning information into multimethod materials for trainers, *James Lea, Ph.D. and Catherine Murphy, M.Ed.*

Experiences in the field: Confederacao Nacional de Centros de Planejamento Natural de Familia, Brazil, *Maria J. Sogayar, M.A.B.*

Materials development in Zambia: Concept versus reality, *Lubinda M. Tafira*

The development of the International Federation for Family Life Promotion training guide, *Mary Catherine Martin, Ph.D.*

The "Guide for Natural Family Planning Trainers", *Kimberly Aumack, B.A.*

Service Delivery Part I: Current programs and strategies for expansion

Materials in the United States: An example from Los Angeles, *Carmen Minervini, B.A.*

Client teaching materials for francophone Africa, *Isabelle Ecochard, M.D.*

Materials for the modified mucus method, *Kathleen Dorairaj, M.D.*

Current natural family planning programs and strategies for expanding service delivery: An introduction, *Gloria Mejia, M.D. and Antonio Solis, M.D.*

Natural family planning in a family planning program, *Thomas Kring, B.D./M.T.H.*

New approaches to expanding natural family planning, *David F. Skipp, B.A.*

Natural family planning: National program development in Kenya, *Rose Wahome, R.N. and Sabina Mwaulu, R.N.*

Natural family planning through the health sector in India, *Marie Mascarenhas, M.D.*

Natural family planning through the health sector in Brazil, *Maria J. Sogayar, M.A.B.*

Expanding natural family planning through vocational schools for women in Cote d'Ivoire, *Rosalia Rodriguez-Garcia, M.Sc.*

An American national experience: Natural family planning services under the auspices of the Roman Catholic Church, *Theresa Notare, M.A.*

Service Delivery Part 2: Elements necessary for success

Introduction: Principles for meeting increased demand, *Victoria Jennings, Ph.D. and Shelagh O'Rourke, Ph.D.*

A management needs assessment for African natural family planning programs: Process and results, *Darryl N. Pedersen, B.A.*

Targeting quality of care: A strategy for successful periodic abstinence services, *Zoe Kopp, M.P.H.*

APPENDIX #2 , (cont.)

The effect of supervision on program development and quality of services, *Richard St. Mart, B.Sc.*

Automated management information systems, *James Nesbitt, Ph.D.*

Adapting data systems of multimethod programs to incorporate natural family planning, *Lilia I. Cuervo, M.A.*

Budgeting and financial planning in natural family planning programs: In search of the perfect system, *Darryl N. Pedersen, B.A.*

Policy issues in natural family planning

Gaining policy support for natural family planning, *Victoria Jennings, Ph.D.*

Natural family planning: Agency for International Development policy considerations, *Sarah Clark, Ph.D. and Jeffrey Spieler, M.Sc.*

Policies and support for natural family planning: Rationales and future plans, *Jose Donavre, M.D.*

International Planned Parenthood Federation's policy and support for period abstinence: Rationale and future plans, *Zoe Kopp, M.P.H.*

World Health Organization's policy consideration in natural family planning, *Leila Mehra, M.D.*

Understanding policy and the policymaking process: Considerations for initiating policy interest, *Rosalía Rodríguez-García, M.Sc.*

Communicating with developing country policymakers: The case for natural family planning, *Elaine Murphy, Ph.D.*

From policy to norms to services: Developing a consensus for natural family planning, *David F. Skipp, B.A.*

Roundtable Discussions

The missing link - Why natural family planning is still "the best kept secret", *Kay Ek*

Making periodic abstinence more acceptable to natural family planning users, *William Uricchio*

The fertility awareness method: Extent of use, potential, and research needs, *Nancy Williamson*

Toward better marriages through natural family planning, *Irene Osmund-Ruiz*

Providing natural family planning counseling within a family planning clinic, *Carmen Minervini*

A pilot study on teaching natural family planning in general practice, *Cecilia Pyper*

At what stage is natural family planning service delivery, *Hanna Klaus*

Various forms of financial support for natural family planning teachers, *Claude Lanctot*

The promotion of exclusive breastfeeding and the lactational amenorrhea method in natural family planning programs, *Kathy Kennedy*

Social science natural family planning issues

Overview of social science and behavioral issues in natural family planning, *Ravi K. Sharma, Ph.D. and Jeffrey Spieler, M.Sc.*

APPENDIX #2, (cont.)

Knowledge and use of periodic abstinence, *Martin Vaessen, Ph.D.*

Natural family planning use in Peru, *Ravi K. Sharma, Ph.D.*

The 1991 Mauritius contraceptive prevalence survey, *Charles Chen, Ph.D., Jay Friedman, M.P.H., J. Shanker, B.A., S. Kalasopaten, Ph.D. and Leo Morris, Ph.D.*

Psychosocial factors in natural family planning: An overview, *Ravi K. Sharma, Ph.D.*

Psychosexual aspects of natural family planning as revealed in the World Health Organization multicenter trial of the ovulation method and the New Zealand continuation study, *Margaret M. France, M.A.*

A profile of successful versus unsuccessful ovulation method users: Factors associated with unplanned pregnancy and nonadherence to the rules, *Miriam H. Lobbok, M.D., M.P.H., Alfredo Pérez, M.D., and Hanna Klaus, M.D.*

Operations research in natural family planning: Strategies, issues and research approaches

Current status of operations research in natural family planning, *Ed Ricci, Ph.D. and Myrna Seidman, M.P.H.*

Natural family planning program format effectiveness, *Don Kramer, M.S.T.*

A pilot study on teaching natural family planning in general practice, *Elizabeth M. Clubb, M.D., Cecilia M. Pyper, M.D., and Jane Knight, R.N.*

Evaluation of natural family planning programs in Liberia and Zambia, *Robert T. Kambic, M.S.H., Ronald H. Gray, M.D., Claude A. Lanctot, M.D., Mary Catherine Martin, Ph.D., Roseline Wesley, and Richard Cremins*

Using operations research to improve natural family planning program services, management, and policy, *Maria Wawer, M.D., Theresa McGinn, M.P.H., and Regina McNamara, Ph.D.*

Political and practical issues in the implementation of operations research studies in natural family planning, *John Townsend, Ph.D. and Ricardo Vernon, Ph.D.*

Natural Family Planning Guide for Natural Family Planning Trainers (French version), 1991

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Zinaman M, Hughes V, Queenan J, Lobbok M, and B Albertson: Acute Prolactin, Oxytocin Response and Milk Yield to Infant Suckling and Artificial Methods of Expression in Lactating Women. *Peds, March, 1992, In Press.*

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Saadeh, R., Lobbok, M., Cooney, K., and P. Koniz-Booher, eds. (1991). The Technical Rationale for Global Action on Breastfeeding: Proceedings of the Expert Meeting Towards the Innocenti Declaration Geneva: The World Health Organization. In Press.

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APPENDIX #3

PRESENTATIONS

INSTITUTE SPONSORED PRESENTATIONS

April 1, 1991 - December 31, 1991

Title	Meeting	Presenter(s)
Breastfeeding and Maternal/Child Health	Recent Findings Relating to Optimal Breastfeeding, Guatemala May 1991	Labbok M
The Lactational Amenorrhea Method	Recent Findings Relating to Optimal Breastfeeding, Guatemala May 1991	Labbok M
Breastfeeding and Health	INCAP Guatemala, May 1991	Labbok M
Breastfeeding and Family Planning	Wellstart Training Course San Diego, June 1991	Labbok M
The Role of the Institute for Reproductive Health in Latin America	Breastfeeding Support, PAHO June 1991	Labbok M
Breastfeeding Update	Roundtable NCIH Annual Meeting June 1991	Labbok M Wade K
Operational Research on the Lactational Amenorrhea Method	O.R. Conference, Columbia, MD June 1991	Labbok M
Worldwide Definition of Breastfeeding	ILCA Annual Meeting, July 1991	Labbok M
The Lactational Amenorrhea Method: A New Hormonal Family Planning Method	ILCA Annual Meeting, July 1991	Labbok M
The Lactational Amenorrhea Method	WOOMB Ovulation Method Training Meeting, San Antonio, July 1991	Labbok M
Assessing Efficacy in Natural Family Planning	WOOMB Ovulation Method Training Meeting, San Antonio, July 1991	Labbok M
Breastfeeding and Child Spacing: The Lactational Amenorrhea Method	National Congress on Breastfeeding, Jakarta, Indonesia, August 1991	Cooney K
Breastfeeding and Child Spacing	National Breastfeeding Promotion Meeting for Voluntary Women's Organization (PKK), Wisma Kinasih, Caringin, Bogor, Indonesia, August 1991	Cooney K

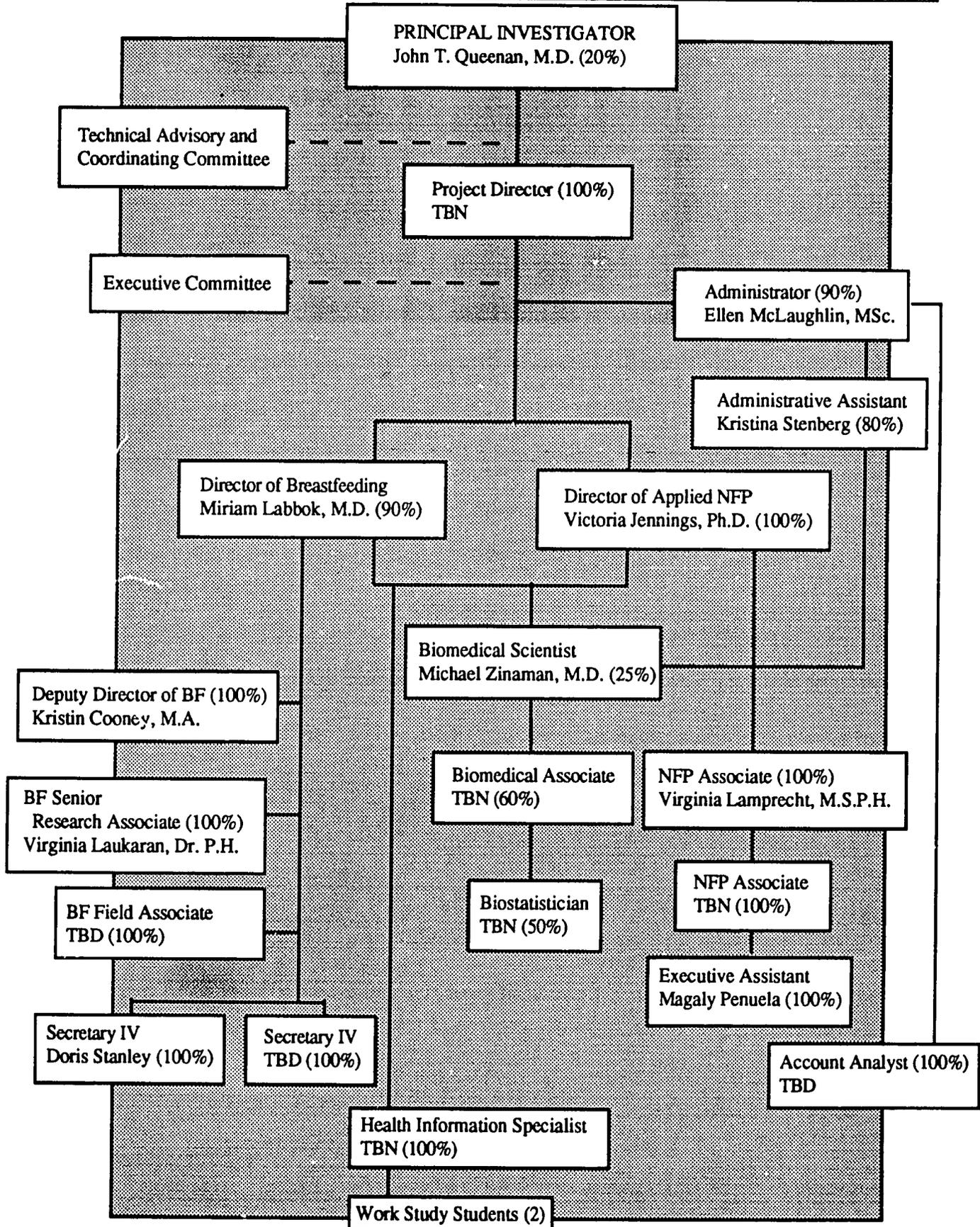
APPENDIX #3, (cont.)

Title	Meeting	Presenter(s)
Planification Familiar Natural: su Importancia en el Peru	2nd National Congress in Family Planning Lima, Peru, September 1991	Jennings V
L'allaitement au sein et l'espacement des naissances	Forum international pour l'Afrique francophone: Alimentation du nourrisson et Survie de l'enfant, Lomé, Togo, September 1991	Cooney K
Allaitement maternel: préserver une ressource naturelle	Forum international pour l'Afrique francophone: Alimentation du nourrisson et Survie de l'enfant, Lomé, Togo, September 1991	Cooney K
L'inclusion de l'allaitement maternel et la Méthode de l'allaitement maternel et de l'amenorrhée (MAMA) dans les programmes de planification familiale	Forum international pour l'Afrique francophone: Alimentation du nourrisson et Survie de l'enfant, Lomé, Togo, September 1991	Cooney K
L'Institut de la Santé Reproductive	Forum international pour l'Afrique francophone: Alimentation du nourrisson et Survie de l'enfant, Lomé, Togo, September 1991	Cooney K
Breastfeeding and Child Spacing	NCLC Lactational Consultant Training	Labbok M
Breastfeeding and Allergy	NCLC Lactational Consultant Training	Labbok M
Breastfeeding and Communicable Diseases	NCLC Lactational Consultant Training	Labbok M
Case Studies	NCLC Lactational Consultant Practicum Training	Labbok M
Breastfeeding Session Moderator	APHA Annual Meeting Atlanta, November 1991	Labbok M
The "Code" Today, An International Update, Panelist	APHA Annual Meeting Atlanta, November 1991	Labbok M
The Lactational Amenorrhea Method	CEDPA December 1991	Labbok M
The Institute for Reproductive Health/ Breastfeeding Division: What We Have to Offer You	CEDPA December 1991	Cooney K
The Institute for Reproductive Health Resource Center	CEDPA December 1991	Beekhuysen D

APPENDIX #4

ORGANIZATION CHART/STAFF LISTING

INSTITUTE FOR REPRODUCTIVE HEALTH AT GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE



FINANCIAL REPORT (UNDER SEPARATE COVER)