

PD-ABG 654

84018

**CONTRACEPTIVE TECHNOLOGY  
AND FAMILY PLANNING RESEARCH**

**SEMIANNUAL REPORT**

**1 October 1992 – 31 March 1993**

**Cooperative Agreement**

DPE-0537-A-00-4047-00

DPE-3041-A-00-0043-00

*SUBMITTED TO  
OFFICE OF POPULATION, RESEARCH DIVISION  
UNITED STATES AGENCY FOR  
INTERNATIONAL DEVELOPMENT*

**Fhi** FAMILY HEALTH INTERNATIONAL • Durham, NC 27709 USA

## TABLE OF CONTENTS

I.	Executive Summary .....	1
II.	Introduction .....	4
III.	Semiannual Progress Report	
	A. Contraceptive Technology Development and Clinical Trials .....	6
	B. Condom Technology Evaluation .....	20
	C. Contraceptive Acceptance and Use .....	24
	D. Contraceptive Introduction .....	52
	E. Reproductive Epidemiology .....	63
	F. Institutional Development .....	74
	G. Training .....	81
	H. Information Dissemination .....	84
	I. USAID Mission Program Support .....	93
IV.	Program Management .....	97
V.	Interagency Collaboration .....	101
VI.	Financial Information .....	107
	A. Summary of Expenditures .....	107
	B. Program Area Budgets by Region .....	109

### Appendices

FHI's Medical Barrier Activities  
FHI Staff and Consultant Travel Undertaken  
FHI Staff and Consultant Projected Travel  
Publications List  
Summary - Clinical Trial  
U.S. FDA Applications  
Advisory Committee

## **I. EXECUTIVE SUMMARY**

This report covers work carried out by Family Health International during the six month period, October through March 1993, to implement the program funded by the A.I.D. Office of Population under Cooperative Agreement (DPE-3041-A-00-0043-00), "Contraceptive Technology and Family Planning Research." The program encompasses eight broad areas of activity included in our mandate "to enhance the freedom and abilities of individuals in the developing world to choose voluntarily the number and spacing of their children."

The report documents activities, accomplishments, and future plans for more than 100 subprojects underway or planned during this reporting period.

Program highlights during the past six months have included a continued priority focus on contraceptive development. During FY'92, FHI filed and/or supported applications to the FDA for three products: the Filshie Clip for female sterilization, a thermoplastic male condom, and the female condom, "Reality". Much of the effort within the Research and Development Department during this reporting period has focused on followup activities associated with those submissions. Continued development emphasis has been on further improvements in the thermoplastic male condom, as well as preclinical work to develop an iodine formulation for transcervical delivery to achieve blockage of the Fallopian tubes for non-surgical female sterilization. With the recent marketing approval by the FDA of Depo Provera, FHI's development efforts on long-acting systems for the delivery of steroidal contraceptives, including a norethindrone (NET) 90-day injectable and a biodegradable NET implant, have been continued, but at a lower priority.

Programmatic clinical trials have stressed methods such as IUDs and progestin-only oral contraceptives for use during the postpartum period, in keeping with an organizational priority to strengthen postpartum contraceptive programs. Efforts have also focused on barrier contraceptives, including the drafting of guidelines to improve clinical investigations on barrier contraceptives, and co-sponsorship with CONRAD of an international experts' meeting on barrier contraceptives in the Dominican Republic.

FHI has continued to provide substantial support to the Commodities Division to assure the quality of latex condoms supplied by A.I.D., both through the surveillance of condom production and through quality testing of condoms in the field. A major research program is underway to improve condom quality assessment methods. At A.I.D.'s request, FHI has begun broadening its contraceptive quality testing, surveillance capabilities, and activities to include other products, such as oral contraceptives, IUDs, and spermicides.

Contraceptive acceptability and use studies have continued to address a series of consumer issues related to latex condoms, as well as evaluating consumer preference and functional aspects of the female condom. During this reporting period, work was completed on a three-country study to assess the acceptability of vaginal contraceptive film (VCF). Growing emphasis has been placed on behavioral aspects of barrier/spermicide use. Work has also continued to assist the FDA in simplifying and improving patient instructions for OCs, and to field test improved instructions. FHI is currently working on similar improvements in instructions for progestin-only OCs. FHI's costing work has assumed increasing priority in response to requests (and buy-ins) from several USAID missions. This work emphasizes aspects of improving cost-effectiveness of methods by improving the efficiency of family planning service programs. Research and support to improve the quality of care in family planning programs is receiving greater attention. During this reporting period, FHI and PAHO convened a workshop to develop an integrated model of quality of care in reproductive health.

Following the FDA approval of Depo Provera, FHI's contraceptive introduction work has concentrated on the development of a strategy for introduction or expansion of use of this product in country programs. The strategy uses a combination of needs assessments, information/training and research to address service delivery issues, rather than the traditional introductory clinical trials approach. Work has continued, as well, on collaborative projects with the Association for Voluntary Surgical Contraception (AVSC) to introduce and evaluate immediate post-placental IUD insertion. Support for Norplant introduction also continued in collaboration with the Population Council, AVSC, and JHPEIGO. As a part of FHI's priority to address medical barriers to contraception, a number of educational contraceptive technology update seminars were held, and work continued to develop and produce a series of standardized instructional modules on various contraceptive methods and service issues.

Reproductive epidemiology research continues to emphasize the relationship of contraception and STDs, including HIV infection. Studies addressing this relationship were completed during this reporting period in Thailand, Dominican Republic and Zambia. Another major focus of FHI's epidemiologic work is the assessment of benefits and risks for various contraceptive methods, and providing support to A.I.D., its overseas missions, and programs in responding to controversies. As an example, FHI prepared materials for missions and country programs to help them interpret and put in perspective the findings of studies published in a recent issue of JAMA that indicated an association between vasectomy and prostate cancer.

FHI has provided institutional development support to Family Health Research Centers in several countries for a number of years, but began a program five years ago to phase out core support to these programs as they mature and are able to secure research support from multiple sources. Only four FHRCs continued to receive core support during this period. Most of the continuing programs in this area are funded through mission add-ons.

FHI places a high priority on ensuring that research results reach developing country audiences. Scientific articles and information on research findings are routinely shared with researchers, organizations and health personnel in more than 80 countries. FHI's quarterly bulletin, **Network**, now reaches more than 45,000 health professionals, with editions in English, Spanish, and French. FHI's information dissemination program also responded to more than 2,000 requests for information on contraception and reproductive health during the past six months.

Improving access to contraception by addressing medical barriers to contraceptive use is an area of a high priority for FHI. Staff of several divisions are involved and the work overlaps many of the major areas discussed above. An interdivisional working group at FHI coordinates these efforts among the various divisions and maintains a high level focus on programs to carry out the strategy in this area.

The following sections describe in more detail the program of work implemented during the past six months, and summarizes activities planned for the next reporting period. A special appendix catalogues the projects and activities that are included as part of our "Medical Barriers" work, although these projects are included in the eight major areas that constitute the areas of activity supported through the cooperative agreement.

## **II. INTRODUCTION**

Family Health International (FHI) is pleased to present the Semiannual Progress Report for the period October, 1992 through March, 1993, under its Contraceptive Technology and Family Planning Research Cooperative Agreement (DPE-3041-A-00-0043-00). Also included in this report are projects funded under a no-cost extension of Contraceptive Research Agreement DPE-0537-A-00-4047-00.

Under these Cooperative Agreements, FHI works toward the goal of "enhancing the freedom and abilities of individuals in the developing world to choose voluntarily the number and spacing of their children." The purpose of this work is to increase the means available to developing country couples to achieve their desired family size by developing and introducing a range of safe, effective, and acceptable methods of family planning and by enhancing the capacity of family planning researchers and programs in developing countries to evaluate and provide these methods.

Programs to carry out a diverse set of activities are organized into eight areas specified by the Cooperative Agreement:

- o contraceptive technology development and clinical trials
- o condom technology evaluation
- o contraceptive acceptance and use
- o contraceptive introduction
- o reproductive epidemiology
- o institutional development
- o training; and
- o information dissemination

During this reporting period, some changes were made to FHI's organizational structure. Under the new structure, six research and program divisions have implemented the work of the Cooperative Agreement during the current reporting period: Clinical Trials; Materials Technology; Contraceptive Use and Epidemiology; Service Delivery Research; Policy Research and Utilization, and Field Operations. These divisions have received technical support from Biostatistics, Regulatory Affairs and Quality Assurance, and Scientific Support Services. Communication and collaboration has been improved by the creation of interdivisional working groups.

This report summarizes progress during the reporting period toward achieving objectives and outcomes of project plans outlined under the eight program areas in the Annual Workplan for Fiscal Year 1993 submitted to A.I.D. in January, 1993. A progress report is provided for each project listed in the Workplan. The objectives of each subproject as stated in the Workplan are given at the beginning of each subproject progress report, followed by a brief summary of activities ongoing and completed during the reporting period, and major results, accomplishments and/or problems. Activities planned for the next six months are outlined. Projects and activities that are included as part of FHI's initiative to reduce medical barriers to contraception are cataloged in a separate appendix. The budget section is organized by the eight program areas, with an annual budget and expenditures for the reporting period, as well as projected expenditures for the coming six months shown for each subproject.

### **III. Semiannual Progress Report**

#### **A. Contraceptive Technology Development and Clinical Trials**

##### **1. Program Area Summary**

Contraceptive development is an essential aspect for improving family planning programs. Family Health International's (FHI's) commitment to expanding contraceptive choices in the developing world is reflected by its research in contraceptive methods and in programmatic mechanisms for contraceptive delivery.

FHI conducts clinical trials to obtain approvals from the United States Food and Drug Administration (USFDA) and local regulatory agencies in order to expand the availability of contraceptive options. These clinical trials are conducted to (a) introduce new contraceptives; (b) evaluate the safety of worldwide large-scale usage; and (c) provide information about the safety, efficacy, and acceptability of these methods when used within diverse cultures and societies.

In responding to the needs of couples throughout the world, FHI is concentrating clinical development and evaluation activities on long-acting steroidal contraceptives and on female and male sterilization procedures. FHI also recognizes the importance of spermicides and barrier methods for contraception and the prevention of sexually transmitted diseases (STDs). Currently, FHI is investigating a variety of new products including a male condom and a female vaginal pouch, both of which are plastic.

To achieve its goals, FHI's contraceptive development program draws on the expertise and the close collaboration of its various divisions. Collaboration also extends to outside organizations such as Contraceptive Research and Development Program (CONRAD), Association of Voluntary Surgical Contraception (AVSC), and the Pan American Health Organization (PAHO). This cooperation enables FHI to expedite implementing contraceptive development and introduction programs. Likewise, FHI's extensive international network, developed over the past 20 years with collaborating clinical investigators, has played an essential role in achieving its goals in developing contraceptives.

## **2. Progress Reports**

### **a. Long-Acting Steroid Delivery Systems**

#### **o NET 90-Day Injectable Microspheres**

Objective: To develop and secure U.S. regulatory approval for an injectable contraceptive that is expected to be safe and provide efficacy for 90 days. The formulation will contain less than half the equivalent steroid found in other available injectable contraceptives.

Ongoing and Completed Activities: Medisorb, a company established by Stolle and Dupont to further develop microsphere technology, has reformulated the NET-90 (norethindrone) microspheres. Two solvent solutions were identified and non-GMP batches were tested in baboons. Further testing is planned under GMP.

Results, Accomplishments, Problems: Initial results from baboon testing using the non-GMP batches were promising. Further studies were projected for early 1993 under GMP with the anticipation that one or both of the products would be deemed acceptable for production. If favorable results are obtained, this may justify proceeding to clinical evaluation. However, many problems with the overall effectiveness as well as the ability to mass produce this product must be resolved. Medisorb receives technical and financial input from Dupont and is trying to address these problems.

Next Six Months Planned Activities: During the next six months, FHI expects completion of the baboon study using the GMP drugs. Pending the results of these studies, the issue of the production of this product will need to be addressed.

#### **o NET Pellet Implants**

Objective: To develop an inexpensive, biodegradable contraceptive implant that (a) will be effective for 12 to 18 months, and (b) can be removed at any time.

Ongoing and Completed Activities: Currently, CONRAD and Cornell Medical Center in New York are conducting a Phase II-A clinical trial, comparing the pharmacokinetics of two sets of NET Pellets: (a) four pellets, 2.75 mm diameter x 8 mm length, and (b) five pellets, 3.0 mm diameter x 8 mm length. All 39 subjects have been enrolled and follow-up continues with no pregnancies or serious AEs to date.

**Results, Accomplishments, Problems:** The IND for this product was transferred to Endocon, the manufacturer. Future work with this product is uncertain and is dependent upon FHI/A.I.D. negotiations with the manufacturer.

**Next Six Months Planned Activities:** Subject follow-up for safety and efficacy parameters will continue. An interim analysis of norethindrone levels will be performed when data is received for all subjects who have participated for one year. The last subject enrolled is expected to have her one year visit in late April. An amendment to this protocol will extend follow-up in this study past the originally projected 24 months to evaluate the tail of norethindrone levels in the blood of subjects.

o **Norplant**

**Objectives:** To: (a) use Norplant (levonorgestrel implant, Leiras Pharmaceuticals, Turku, Finland) subdermal implants in Phase III pre-introductory clinical trials, introducing the method into countries without previous implantable contraceptive experience; (b) provide training to physicians in inserting and removing Norplant properly and also in patient counseling; and (c) determine the implant's overall acceptability in different populations.

**Ongoing and Completed Activities:** Follow-up in the pre-introductory trials will continue for all enrolled subjects until the implants have been used five years or until they are removed. Currently, the trials involve approximately 1,370 subjects at 11 centers, located in four countries. Subject enrollment and follow-up have been completed as planned in the expanded trials. Bilateral support continues for programs in El Salvador, Senegal, and Pakistan. Final country reports have been completed for five countries (Bangladesh, the Philippines, Sri Lanka, Nepal, and Singapore).

**Results, Accomplishments, Problems:** Regulatory approval of Norplant is pending in Senegal and continues to be sought in Ghana, the Philippines, and Pakistan. FHI continues to coordinate area activities with Leiras. As stated above, final five-year country reports were completed for five countries (Bangladesh, the Philippines, Sri Lanka, Nepal, and Singapore). One- and two-year reports were completed for Pakistan and Ghana, respectively. These reports were to be placed into the regulatory file for submission, thereby assisting countries seeking regulatory approval. Furthermore, data analysis has been completed for the Norplant worldwide database.

Next Six Months Planned Activities: To continue follow-up of all remaining Norplant clinical trials. Final country reports will be prepared for Bangladesh and Nepal (expansion centers), Nigeria, and Haiti. An interim report will be prepared for Pakistan as part of a continued effort to assist this country in gaining regulatory approval for NORPLANT. FHI will submit a paper for publication on data results contained in the Norplant worldwide database. Furthermore, the clinical trial results will be disseminated at both the regional and international levels.

**b. Barrier Contraceptives and Spermicides**

**o Thermoplastic Condoms**

Objective: To develop one or more cost-competitive plastic condoms that meet or exceed the performance of latex condoms for durability, reliability, comfort, and ease of use while providing extended shelf life under adverse environmental conditions.

Ongoing and Completed Activities: During the past six months, significant progress has occurred on both the roll-on/ring condom (two designs) and the slip-on condom. Additional information was provided to the FDA in February 1993 regarding the roll-on/gel ring condom. The review process, coupled with the need to generate additional technical information, is anticipated to continue. A final configuration was identified for the roll-on/knit ring condom and a patent application was filed. Automated equipment has been received for the fabrication of both roll-on and slip-on condoms. Equipment has been received for the manufacture of knit rings. Equipment is on order which will stress-soften condom blanks and attach the knit ring in a continuous operation.

Results, Accomplishments, and Problems: Outcomes of activities for the past six months are divided between the two product categories as follows:

Roll-on/Ring Condom: Accomplishments for the period included a response to FDA queries regarding the 510(k) for the roll-on/gel ring condom.

Two acceptability studies were conducted with the roll-on/knit ring product in order to confirm a final configuration. An IDE was filed with the FDA to support NIH funded clinical trials and product was manufactured for these trials. Equipment to fabricate condom blanks was received and validated. A patent application for the roll-on/knit

ring condom was filed in November 1992. Accelerated stability results indicate no significant loss in tensile or air burst properties after storage for three months at 70°C.

Slip-on Condom: Accomplishments for the period included the receipt of semiautomatic equipment for condom fabrication. Acceptability results were reported which indicated the product design was well received. Nine experimental films have been received for evaluation with this design. Product conceptualization and fabrication was demonstrated to A.I.D. personnel.

Next Six Months Planned Activities: The next six months of planned activities will be divided between the two product categories as follows:

Roll-on/Ring Condom: FHI will respond as appropriate to the next communication from the FDA regarding the 510(k) roll-on/gel ring condom.

FHI's Clinical Trials Division will conduct the Phase I trial of the roll-on/knit ring condoms which have been fabricated by MTD. MTD will manufacture larger quantities of these condoms to be used for a comparative clinical trial of this product versus latex condoms. Biocompatibility testing on the final product, including viral permeability testing, will be initiated. A three year stability study of stress-softened condoms will begin. The automated stress-softening machine will be received and validation of all Pilot Plant equipment will be completed.

Slip-on condom: Completion of equipment modifications and fine tuning of the manufacturing process will be conducted. Experimental materials will be evaluated and three candidate materials will be selected for preliminary stability, product safety, and acceptability research.

o **Acceptability of Prototype Plastic Condoms**

Objective: To test successive iterations of prototype plastic condoms to improve the device's performance, acceptability, and functioning.

Ongoing and Completed Activities: FHI has submitted the results of a clinical use study to the U.S. Food and Drug Administration (USFDA) as part of its requirements for a 510(k) application for the plastic condom. FHI also completed a study of 150 couples to determine appropriate ring size (retention mechanism) for a newly selected ring material. These results were used to select the retention ring size for upcoming clinical trials. Furthermore, FHI completed a product

refinement study with 40 couples using the slip-on condom. The study addressed donning problems and subject preferences for materials, and it assessed the condom's breakage rates.

Results, Accomplishments, Problems: Several design problems have been identified with the slip-on condom, and revisions have been suggested. Further in-use testing has been delayed because production equipment and appropriate materials to make condoms are not yet operational or fully researched. The equipment has been installed and experimental runs (products) have been made.

Next Six Months Planned Activities: Refinement studies will be continued for roll-on and slip-on prototypes. FHI plans a larger study (>100 couples) for the new slip-on design.

o **Female Condom**

Objective: To assess the contraceptive efficacy and safety of the female condom or vaginal pouch (Reality, Wisconsin Pharmacal, Jackson, WI), obtaining information necessary for USFDA's approval of this device. To meet this objective, FHI is collaborating with CONRAD to carry out the clinical trials.

Ongoing and Completed Activities: In December 1992, FHI participated in the USFDA Advisory Panel review of the Reality Female Condom PMA. The Advisory Panel voted to recommend approval of the device pending final agreements between FDA and Wisconsin Pharmacal. FHI continues to respond to questions from the FDA reviewers. In addition, a manuscript detailing results of the clinical investigation is in preparation.

Results, Accomplishments, Problems: In December 1992, FHI participated in the USFDA Advisory Panel review of the Reality Female Condom PMA leading to the Advisory Panel recommending approval of the device.

Next Six Months Planned Activities: FHI will continue participating in related activities leading to USFDA's review and approval of the PMA.

o **Vaginal Contraceptive Film**

Objective: To test the safety, efficacy, and acceptability of spermicidal vaginal contraceptive film (C-film) as a possible addition to or substitution for vaginal tablets used in USAID programs.

Ongoing and Completed Activities: Discussion with USAID representatives led to a postponement of this project until new C-film preparations are readied for clinical trials.

Results, Accomplishments, Problems: Due to delays in developing new C-film products, work on this project has been postponed. It is expected that new C-film products could be ready for clinical testing in the near future.

Next Six Months Planned Activities: Preparation for the evaluation of Vaginal Contraceptive Film use-effectiveness studies will begin.

o **Vaginal Contraceptive Tablets**

Objective: To provide technical support to Pakistan's National Research Institute of Fertility (NRIFC) for a clinical trial that compares two vaginal tablets (Neosampon and Conceptrol).

Ongoing and Completed Activities: Final data cleaning was completed and a final report prepared. Results from 172 women (85 in the NeoSampon group and 87 in the Conceptrol group) were analyzed. As the report cautions, conclusions drawn are tentative due to the high discontinuation and lost-to-follow-up rates. Only 29.4% of the NeoSampon users and 27.6% of the Conceptrol users completed the study. The results suggest that the users had similar experiences with the two products and no statistically significant differences were found in discontinuation due to accidental pregnancy, nor in medical problems or conditions reported. The gross cumulative life-table discontinuation rate  $\pm$  standard error was  $15.2 \pm 4.77$  per 100 women for NeoSampon and  $22.5 \pm 6.91$  per 100 women for Conceptrol.

Results, Accomplishments, Problems: The report was completed in the fall of 1992 and distributed to the NRIFC.

Next Six Months Planned Activities: None at this time since the study is now complete.

o **Condoms and Spermicide Use**

Objective: To assess the effect of providing condoms and spermicides having different package instructions to Colombian women who are at high risk for sexually transmitted diseases. The study will also test whether or not providing condoms and spermicides will encourage combined contraceptive use, as opposed to the women only using one of the two methods separately.

Ongoing and Completed Activities: Recruitment was completed in 1992. No monitoring visits by FHI personnel have occurred since the last report due to travel restrictions. The center has been requested to forward case report forms for final processing. A final report is expected by the end of fiscal year 1993.

Results, Accomplishments, Problems: Difficulties continue in accurately reimbursing the principal investigators. Recent Colombian political problems have resulted in a continued travel ban that has delayed final monitoring activities and the investigator has not been able to mail data forms to FHI.

Next Six Months Planned Activities: Once case record forms have been retrieved, final data cleaning will be performed and a final report prepared. If travel restrictions are lifted, a final monitoring visit will be conducted prior to the end of fiscal year 1993.

o **Lea's Shield**

Objective: To develop a new barrier method with the potential of being used continuously for 48 hours, preferably without a spermicide. FHI is collaborating with CONRAD to complete this project.

Ongoing and Completed Activities: CONRAD has primary responsibility for managing and monitoring the project. FHI continues to serve as the project's data manager and will provide statistical analysis once the field work is completed. FHI assists the CONRAD monitor in performing data quality checks and verification. Additionally, interim analyses have been generated for CONRAD's review.

Results, Accomplishments, Problems: The resolution of data quality issues, identified by FHI, must be transmitted through CONRAD, which can result in delays. Recruitment is expected to be completed this spring.

Next Six Months Planned Activities: FHI will continue to provide CONRAD with data quality reports in order to monitor data quality. Interim analyses will be performed at CONRAD's request.

o **Barrier Guidelines**

Objective: To develop standardized guidelines for conducting clinical investigations on barrier contraceptive methods.

Ongoing and Completed Activities: Using a list of methodological issues in the barrier contraceptives study and approved by various USAID Cooperative Agencies, preliminary drafts have been developed for review. A manuscript reviewing these suggested guidelines is under development.

Results, Accomplishments, Problems: Conflicts from other ongoing projects may limit the time needed to complete guidelines within this project's established timeline.

Next Six Months Planned Activities: A draft and final version of guidelines will be developed and published by the end of fiscal year 1993.

o **Barrier Conference**

Objective: To provide partial support for an international experts meeting on barrier contraceptives.

Ongoing and Completed Activities: The conference was held in Santo Domingo, Dominican Republic on March 22 to 25, 1993.

Results, Accomplishments, Problems: The conference was well attended with approximately 200 registrants.

Next Six Months Planned Activities: Proceedings will be finalized and published by CONRAD, with editing and production assistance from FHI.

o **Pilot Study of the Physical Characteristics of Spermicidal Preparations**

Objective: To perform a pilot study of the speed of disintegration of various spermicidal preparations, and to assess the feasibility of further work to develop an in-vitro testing system which could mimic vaginal conditions. The two major characteristics of interest would be the speed of disintegration and the speed of mixing with simulated or real vaginal fluids and/or semen.

Ongoing and completed activities: The pilot study will be a joint effort of the Clinical Trials Division and the Materials Technology Division. We are in the process of (1) ordering the equipment specified in the U.S. Pharmacopoeia for the testing of pill disintegration times, (2) reviewing the literature, and (3) making contacts with others in the field to get advice on this project.

**Results, Accomplishments, Problems:** None at this time.

**Next Six Months Planned Activities:** During the next six months, we plan to conduct preliminary tests on the time to disintegration for vaginal foaming tablets and vaginal contraceptive film, trying out different variations and modifications of the standard method used for pills. We also plan to prepare a draft report on the feasibility of developing an in-vitro testing system which would mimic vaginal conditions and could be used to test the physical characteristics of spermicides/microbicides.

**c. Oral Contraceptives (OCs)**

**o Oral Contraceptives**

**Objectives:** To compare the efficacy, safety, and acceptability of oral contraceptive (OC) formulations. The study objectives are to (a) provide the scientific rationale for A.I.D.'s procurement decisions in reducing OC dosage; and (b) demonstrate the safety, efficacy, and acceptability of progestin-only OCs (POCs) for lactating women.

**Ongoing and Completed Activities:** Work focused on analyzing, publishing, and disseminating the completed studies' most relevant clinical and programmatic information, including POCs in lactating women, and the following comparative trials: triphasic versus low-dose combined formulations, and various low-dose combined formulations.

**Results, Accomplishments, Problems:** Final analyses have been completed on the following: POC in the postpartum period (paper published), low-dose combined formulations (in review) and triphasic versus low-dose combined formulations (submitted and being revised). The results of the POC trial demonstrated that POCs are a safe and effective method of postpartum contraception for lactating women. Trial results from the study comparing two low-dose combined OCs indicated that Lo-Femenal was more effective, demonstrated better cycle control, and was tolerated better than Loestrin. The differences seen were both statistically and clinically significant. Results of the triphasic versus low-dose combined OC trial showed no clinically or statistically significant difference between Triquilar and Lo-Femenal on menstrual cycle control. Both products were well-tolerated and were considered acceptable contraceptive methods.

After completing these activities, all of the original FHI safety, efficacy, and acceptability strategies on OCs will be completed. FHI initiated a multicenter study in breastfeeding women comparing clinical and programmatic outcomes of POC initiation at six-weeks postpartum or initiation at return of menses or six months--whichever comes first.

**Next Six Months Planned Activities:** The paper on low-dose combined formulations will be submitted for publication. Data will be provided to country programs supported by USAID about the acceptability of switching from a standard-dose pill to a low-dose pill and vice versa. Follow-up for the POC Initiation Study will continue.

#### **d. Female Sterilization**

##### **o Nonsurgical Female Sterilization via Iodine Compound**

**Objective:** To evaluate the safety and efficacy of the transcervical/intratubal delivery of an iodine compound as a nonsurgical method of tubal sterilization. This sterilization method could be an inexpensive, less invasive alternative to surgical sterilization for women in the developing world.

**Ongoing and Completed Activities:** Pre-clinical dose-titration studies in the pig and rabbit models are being developed.

**Results, Accomplishments, Problems:** FHI has eighteen months of stability/viscosity data on the new formulation, and the data show that the compound is able to maintain a fairly constant state under normal conditions and temperatures. Preliminary pre-clinical studies completed in February, 1993 indicated that tubal closure could be achieved in the

pig model using the present formulation at 5.5% iodine concentration. This has provided the foundation for the next series of pre-clinical studies. Our ultimate goal is to establish this compound's preclinical efficacy at iodine concentrations equal to or lower than the 4.14% concentration of the original formulation.

Next Six Months Planned Activities: FHI expects that preclinical studies in the pig and rabbit models will continue throughout 1993.

o **Filshie Clip Tubal Sterilization**

Objective: To obtain USFDA approval of an effective and easy-to-use tubal occlusion device that limits tubal damage, thus facilitating potential sterilization reversal.

Ongoing and Completed Activities: FHI submitted the 77-volume PMA to the USFDA. Updated safety reports will be filed as required.

Results, Accomplishments, Problems: Although the Filshie Clip PMA was submitted to the USFDA on September 9, 1992, they have not yet responded as to whether our submission has been filed, in spite of their statutory obligation to do so. We have contacted them about the delay, but have not received any indication of when they may respond.

Next Six Months Planned Activities: FHI's Regulatory Affairs and Clinical Trials Divisions will interact with the USFDA throughout the PMA review process. FHI anticipates that some staff time will be needed to respond to USFDA's queries. Interim safety reports will need to be submitted.

e. **Male Sterilization**

o **No-Scalpel Versus Standard Incision Vasectomy**

Objectives: To (a) evaluate the safety and efficacy of different techniques for performing percutaneous vasectomy, and (b) introduce these techniques into programs in numerous countries (Indonesia, Guatemala, Bangkok, Sri Lanka and Brazil).

Ongoing and Completed Activities: Approximately 1,400 procedures have been completed. Data collection for the comparative trial of the no-scalpel vasectomy (NSV) and standard incision has been completed. All studies have been closed. Data have been cleaned, and computer programs modifications are being made. The analysis plan has been revised.

**Results, Accomplishments, Problems:** Competing priorities led to a delay in work on the analysis.

**Next Six Months Planned Activities:** The analysis will be completed following the revised analysis plan and a multicenter report will be completed. A paper for publication will be drafted.

**o Time to Infertility after Vasectomy**

**Objective:** To determine the time and number of ejaculations following vasectomy that are associated with (a) the achievement of infertility, (b) the loss of sperm motility, and (c) the loss of sperm eosin staining.

**Ongoing and Completed Activities:** Although initiation of this project in cooperation with AVSC is on hold, FHI and AVSC remain committed to this project and are in the process of developing the necessary protocol and subagreements.

**Results, Accomplishments, Problems:** The current ban on travel to Colombia has pre-empted a clinic site visit for evaluation of investigator credentials and clinic suitability. In light of the continued travel ban, AVSC visited two alternative sites in Mexico and is in the process of choosing one site for this study.

**Next Six Months Planned Activities:** This is a collaborative project with AVSC. It is expected that site training and study initiation will occur in late summer.

**f. Intrauterine Devices (IUDs)**

**o TCu 380A Intrauterine Devices**

**Objective:** To provide data on safety, efficacy, and acceptability of the TCu 380A (Copper T 380A intrauterine device, Finishing Enterprises, North Tonawanda, NY) intrauterine device compared with standard devices currently provided by family planning programs in numerous countries.

**Ongoing and Completed Activities:** Data cleaning was completed in October 1992 and final consultant reports will be completed by summer 1993. A number of manuscripts are planned.

**Results, Accomplishments, Problems:** A 29-page monograph detailing FHI's IUD research effort was published and distributed to family planning agencies and organizations throughout the world. Papers were published using data from these studies.

Next Six Months Planned Activities: A few remaining consultant reports will be completed. A number of manuscripts are planned, highlighting several aspects of the study.

**g. Other Projects**

- o Lactational Amenorrhea Method (LAM) Clinical Trials**  
Objective: To determine the efficacy of the lactational amenorrhea method at two sites (Karachi and Manila).

Ongoing and Completed Activities: All aspects of the field research are fully operational. Five hundred women are enrolled in each center in the study and will be followed for 12 months after admission. Currently, approximately 80% of the data collection has been completed.

Results, Accomplishments, Problems: The results of the research will not be available for quite some time. However, excellent co-investigators in the field have accomplished recruitment with relative ease.

Next Six Months Planned Activities: Data collection will continue during the next six months and beyond.

## **B. Condom Technology Evaluation**

### **1. Program Area Summary**

The primary purpose for this program area is to provide assurance that condoms, and certain other contraceptives distributed by United States Agency for International Development, are of the highest practical quality. Accomplishing program objectives requires well-equipped laboratories and an expertly trained staff. Major equipment has been added to the laboratory during the last six months, including two automated airburst test systems, a computer network, and an oil-free compressed air supply. Procedure modifications and employee training have accompanied these facility upgrades. During this period, the laboratory was awarded accreditation by the American Association of Laboratory Accreditation. A technical advisory team has been named to provide independent evaluation and recommendations on the laboratory and its operation.

The various contraceptive testing and research programs have been pursued productively. The second year of the prospective aging study was completed and the second iteration of human use testing of prospectively aged condoms was initiated. A new collaborative study to assess the effect of carrying condoms in wallets was begun. Field stock evaluation and complaint activities involved several countries. New projects for quality assurance and compliance on other contraceptives, including IUDs and oral contraceptives, received increasing emphasis. Additional products and test methodologies are to be brought under this surveillance program in the coming months.

### **2. Progress Reports**

#### **o Condom Production Surveillance Program**

Objective: To assure pre-distribution quality of condoms procured by A.I.D. for developing country programs.

Ongoing and Completed Activities: The 1992-93 procurement contracts with Ansell and Aladan ended in March 1993; monthly surveillance visits continued through December 1992 at Aladan and February 1993 at Ansell. The new 1993-94 contract has been awarded to Aladan as sole contractor. Surveillance visits will resume in April.

Results, Accomplishments, Problems: During the last six months significant improvements were made to the MTD laboratory which will significantly enhance testing efficiency. Two automatic air inflation test units, supported by a customized computer network system, were

installed to accommodate anticipated increase in testing. A group of experts has been recruited to monitor and advise MTD on technical issues relating to surveillance and research activities. An inter-laboratory condom testing study, contracted through PATH, was completed.

Next Six Months Planned Activities: FHI will initiate evaluation of production at the Aladan facilities in Eufaula, Alabama, and Colonial Heights, Va. Quality monitoring of the A.I.D. central warehouse (Panalpina) will be initiated on an as needed basis to insure product quality. Increases in the level of production sampling and/or supplemental sampling at the warehouse level may become necessary if there are significant changes in product performance or production levels. Production and shipment data will continue to be accumulated and analyzed monthly.

The initial meeting of the technical advisory group will be convened. Inter-laboratory studies will be commissioned to assess data correlation among collaborating laboratories (FHI, Aladan, PATH and other commercial laboratories).

o **Field Stock Evaluations/Complaints**

Objective: To assess the quality of contraceptive stocks in warehouses in selected less developed countries (LDCs) and to evaluate, upon request, inventories of questionable quality and recommend to USAID Missions their proper disposition.

Ongoing and Completed Activities: A field stock evaluation was conducted in Honduras. Condom field complaints from Rwanda, Tanzania, and Zimbabwe were addressed, followed by recommendations for disposition to the Commodities and Program Support Division (CPSD) of A.I.D.

Results, Accomplishments, Problems: Stock levels in Honduras were found to be generally acceptable and storage conditions ranged from marginally acceptable to very good. Due to emphasis being placed on laboratory enhancements, other field surveillance activities were postponed.

Next Six Months Planned Activities: Product complaints will continue to be handled in a responsive manner. Technical assistance in quality monitoring of contraceptive stocks distributed by USAID will continue to be provided. A minimum of two field stock evaluations will be conducted.

o **Prospective Aging Study**

Objective: To determine the shelf life of latex condoms packaged in various ways and stored under various conditions in LDCs for up to five years.

Ongoing and Completed Activities: Samples for study lots I and II were retrieved from the Mexico storage sites and have been evaluated. The second iteration of human use testing of aged condoms was initiated in February, 1993. Environmental monitoring of all storage sites is ongoing.

Results, Accomplishments, Problems: Not Applicable.

Next Six Months Planned Activities: An interim study report outlining the laboratory test results, use breakage rates, and an assessment of product storage conditions will be issued to A.I.D. and the participating manufacturers. Retrieval of condom samples will be performed in all storage sites, including Niger.

o **Research and Test Method Development**

Objective: To investigate the utility of new and modified physical test methodologies in the evaluation of latex condoms.

Ongoing and Completed Activities: A second condom wallet study was initiated in collaboration with Dr. Glaser of Emory University in Atlanta, GA. The study is designed to determine whether condoms are adversely affected by wallet storage. A comparison of laboratory test results generated on condoms before and after storage will be conducted when all condom samples are returned.

Results, Accomplishments, Problems: Not Applicable.

Next Six Months Planned Activities: The wallet study will be completed and a report of its findings issued. A stability study designed to assess the shelf-life of OCs, IUDs, vaginal foaming tablets, and Depo-Provera will be initiated.

o **Human Use Trials**

Objective: To correlate the performance of condoms in laboratory tests to the breakage rate during vaginal intercourse, and to identify design or materials issues that influence breakage.

Ongoing and Completed Activities: The second iteration of the Prospective Aging Study human use component was initiated in February 1998 using condom samples from the study sites and represents two years of storage.

Results, Accomplishments, Problems: Not Applicable.

Next Six Months Planned Activities: The human use trial will be completed. No new studies are currently planned.

o **Contraceptive Quality Surveillance**

Objective: To assure that contraceptive products distributed by A.I.D. comply with the respective product specifications at the time of manufacture. In addition, proper storage and distribution procedures in the field will be assessed to ensure each product's acceptability.

Ongoing and Completed Activities: Operational audits were conducted at Ayerst-Wyeth (Guayama, Puerto Rico), and Sharp Packaging (Conshohocken, PA) for OC manufacture, and at Finishing Enterprises (Buffalo, NY) for IUD manufacture; representative samples from each manufacturer are being evaluated.

Results, Accomplishments, Problems: Not Applicable.

Next Six Months Planned Activities: Reports of audits conducted in March will be issued to CPSD. Subsequent quarterly audits will be performed at Finishing Enterprises, Wyeth, and Sharp Packaging (June and September). Comprehensive reviews of production and quality assurance documentation will be conducted in addition to random sampling and evaluation of lots produced between scheduled audits. The MTD laboratory will acquire technical expertise and equipment to perform physical testing of various contraceptive products and their components.

Introductory visits to UpJohn Pharmaceutical (Depo-Provera) and Ortho Pharmaceutical (vaginal foaming tablets) will be planned.

Periodic field sampling and evaluation of all CPSD contraceptive products will continue to assess product and manufacturing quality.

## **C. Contraceptive Acceptance and Use**

### **1. Program Area Summary**

Many factors influence whether and how effectively contraceptive technologies are used by consumers. In addition to the biomedical issues of safety and efficacy, consumer characteristics and preferences, and aspects of service delivery such as provider attitudes and cost and quality of services, all influence whether individuals adopt and continue to use contraceptives successfully. FHI's research on programmatic aspects of family planning seeks to help couples in the developing world to control their fertility and increase their satisfaction with contraceptive methods. While much of the research in this area is specific to a particular contraceptive technology, FHI's programmatic research is also responsive to issues identified by country-level family planning programs and USAID missions.

FHI is currently focusing on six priority areas for research in contraceptive acceptability and use:

#### **o Acceptability Research**

As an integral part of the process of contraceptive development and introduction, acceptability research helps to answer questions about consumer preferences for a method, whether acceptors understand how to use it, and perceptions of safety and efficacy as they relate to whether consumers adopt and continue to use the method.

#### **o Research on Correct Use of Methods**

Research by FHI and others has found that many users do not use temporary contraceptive methods as instructed. This research has also found that users of temporary methods often lack sufficient knowledge to use those methods correctly. Research leading to improving compliance for widely used methods, such as oral contraceptives and condoms, could have a significant impact on continuation rates and the reduction of unintended pregnancies.

#### **o Cost Research**

Costs of contraceptive services and ability to pay are important issues for clients, providers, and donors. Studies at both the program and user level can provide information to guide decisions to select the least costly mix of contraceptive services.

- o **Evaluation of Family Planning Services/Quality of Care Research**

The quality of services provided can have a major impact on the safety and acceptability of contraceptives, as well as on continuing use. Relevant study areas include provider attitudes, obstacles to contraceptive use, adequacy of follow-up, reasons for discontinuation and informed choice.

- o **Breastfeeding and Postpartum Contraception**

Many behavioral and programmatic factors affect the use of contraception in the year after the birth of a child. Exploratory research is needed in order to learn what women know and what they want in terms of postpartum contraception. Programmatic research will help to improve the correspondence between women's needs during the postpartum period and the nature of services delivered.

- o **AIDS and Family Planning**

Consistent with the need for effective programs to prevent the spread of HIV infection, we are considering developing research on AIDS and family planning to evaluate the impact of AIDS on family planning programs and procedures, and the contribution of family planning programs to AIDS prevention. Projects in this area would be supported from AIDSCAP, USAID Mission add-ons or non-AID sources.

## 2. **Progress Reports**

### a. **Acceptability Research**

- o **Small versus Standard Condoms**

Objective: To determine consumer preference for the standard or the smaller condom and to determine breakage rates for the two condom sizes.

Ongoing and Completed Activities: Studies have been completed in Nepal and Sri Lanka. The Nepalese investigators have issued a final report and the Sri Lankan data have been analyzed. Using data from both sites, a composite report was written. An additional study, similar to the study discussed above, was initiated in the Philippines in November. Data collection has been completed and analysis is in progress.

**Results, Accomplishments, Problems:** A total of 271 participants from the two sites tested 1347 standard (52mm) and 1350 smaller (49mm) condoms. Among Sri Lankan participants, slippage (in this study, defined as slipping off completely) was reported almost twice as often with the smaller condoms as with the standard condoms, 2.3% and 1.2% respectively. In Nepal, slippage occurred significantly more frequently with standard condoms (26 of 750 condoms used) than smaller condoms (3 of 750 condoms used). There were no significant differences in the condom breakage rates of the two devices in either country. Breakage figures in Sri Lanka were 2.2% for the smaller condom and 2.7% for the standard condom. In Nepal, these figures were 3.2% and 4.0%, respectively. Participants responded more favorably to the standard condoms with respect to ease of donning. However, they more frequently reported that the smaller condoms stayed on better and were more comfortable. Responses to other questions concerning device acceptability did not indicate a clear user preference of one condom over the other.

**Next Six Months Planned Activities:** Data analysis will be completed and a final report will be issued in later summer 1993.

o **Acceptability of Female Condoms**

**Objective:** To determine consumer preferences and evaluate functional aspects of the female condom.

**Ongoing and Completed Activities:** Several studies are under development. Two studies center on female condom (device) acceptability and male involvement in the decision to use the female condom and male acceptance of the device. A third study involves the determination of the acceptability of re-use of the female condom. The latter study will include a laboratory evaluation and testing to determine the impact of use on device integrity and microbial retention. Probable sites are Mexico, Malawi and the United States. A study protocol on male attitudes and opinions has been developed. A study protocol has been developed for Malawi and a protocol for the female condom re-use study is under development.

**Results, Accomplishments, Problems:** The Mexican Ministry of Health has been contacted and approved the import of the female condom into Mexico. The U.S. Food and Drug Administration is reviewing an application to allow export of the device to Mexico.

**Next Six Months Planned Activities:** A study has been developed on male attitude and opinions of the female condom. The study will be

conducted in Mexico City with married couples from two socioeconomic groups. A group of commercial sex workers will be interviewed about client opinions as well. The study will be initiated pending availability of funds and USFDA approval to export the device. Devices for the Malawi study will be obtained from Chartex International in London. The Malawi study will be initiated in late summer 1993. The female condom re-use study will be conducted in the U.S. and initiated in late summer 1993.

o **Task Force on Acceptability of New Methods**

Objective: To provide a forum for discussion and information sharing on current contraceptive acceptability research.

Ongoing and Completed Activities: Acceptability research newsletters continue to be published quarterly.

Results, Accomplishments, Problems: Two editions of the newsletter have been issued.

Next Six Months Planned Activities: Future editions of the newsletter will be issued quarterly.

o **Zambia: Spermicide Acceptability Among STD Clinic Attendees**

Objective: To evaluate the acceptability of three spermicide products (Intercept Vaginal Suppositories, Conceptrol Vaginal Suppositories and Delfen Contraceptive Foam) among 150 men and 150 women at high risk for acquiring STDs in Lusaka, Zambia.

Ongoing and Completed Activities: Data have been cleaned and analyzed, and a draft final report has been written.

Results, Accomplishments, Problems: Most participants tested positive for an STD at admission. Continued product use throughout each two week study period was low (females: 51% to 59%, males: 78% to 80%). Most often, interrupted use was attributed to personal reasons (unrelated to acceptability). All three products were rated favorably along a wide range of acceptability parameters. No one product was strongly preferred over the others. Three months after study completion, most participants reported current use of a spermicide (females: 78%, males 79%).

Next Six Months Planned Activities: The final report will be disseminated and an article will be written for journal submission.

o **Kenya: Foaming Tablets/User Dynamics**

Objective: To assess among providers and consumers possible reasons for the ten-fold increase seen in use of foaming tablets in Kenya during the last year. The study will determine who uses foaming tablets and how and why tablets are being used.

Ongoing and Completed Activities: Family Planning Association of Kenya (FPAK) staff completed data collection in June and a final report was disseminated in October 1992.

Results, Accomplishments, Problems: The data show that a sizable number of foaming tablet users use this method to bridge the gap before they can adopt a more effective method. According to users, as well as service providers, the family planning program would suffer if foaming tablets were no longer provided.

Next Six Months Planned Activities: There are no activities planned.

o **Vaginal Contraceptive Film (VCF) Acceptability Study**

Objective: The primary objective of this study is to assess whether vaginal contraceptive film is preferred over vaginal foaming tablets among current vaginal foaming tablet users in Kenya, Mexico and the Dominican Republic.

Ongoing and Completed Activities: Final reports were disseminated: Kenya, December 1992; Mexico, March 1993; Dominican Republic, March 1993.

Results, Accomplishments, Problems: In Kenya, this multi-site study evaluated a convenience sample of 51 current foaming tablet acceptors. This study population expressed a strong preference for contraceptive film over foaming tablets. An overwhelming majority (86%) would prefer to use contraceptive film in the future if they had a choice of both methods ( $p < 0.01$ ). Only two participants complained that the contraceptive film stuck to the finger during insertion and over three-fourths (78%) thought the contraceptive film was easier to insert than foaming tablets ( $p < 0.01$ ).

In the Dominican Republic, the 52 participants who completed the study reported a much lower preference for contraceptive film over foaming tablets. Slightly over half (52%) said they would choose contraceptive film if both methods were available. More participants found foaming tablets easier to insert (56% vs 33%) with almost half (48%) complaining that the contraceptive film stuck to their fingers during insertion.

In Mexico, the 59 participants who completed the study reported a statistically significant preference for contraceptive film over foaming tablets (58% vs. 30%,  $p < 0.01$ ). Similar to the Dominican Republic participants, 61 percent of the Mexican participants complained that the contraceptive film stuck to their fingers during insertion.

Next Six Months Planned Activities: None.

o **Acceptability Paper Writing**

Objective: To write/publish papers on completed acceptability studies.

Ongoing and Completed Activities: Five papers are in various stages of development. These papers are about female condom acceptability, latex condom failure and spermicide acceptability.

Results, Accomplishments, Problems: A paper entitled, "Can condom users likely to experience condom failure be identified?" will be published in Family Planning Perspectives in the July/August 1993 issue.

Next Six Months Planned Activities: Efforts will be made to complete at least three papers and have at least one published in a major contraceptive journal.

b. **Research on Correct Use of Methods**

o **Instructions/Compliance**

Objective: To help the USFDA standardize and simplify OC use instructions to recommend to OC manufacturers.

Ongoing and Completed Activities: In FY91, FHI presented a proposal for standardized and simplified OC use instructions to the USFDA. The USFDA committee unanimously accepted FHI's proposal and recommended its use "as a guide" for the manufacturers' patient package inserts. In 1992, under a separate contract, FHI worked with one OC manufacturer, Mead-Johnson, to help that company comply with the USFDA's new labeling recommendations. FHI then worked with the USFDA in making final modifications in its recommendations. FHI continues to work with A.I.D. and other organizations toward developing internationally standardized instructions for use of the combined pill and is now working with the USFDA on drafting the guidelines for labeling of progestin-only oral contraceptives.

**Results, Accomplishments, Problems:** Ortho Pharmaceuticals has already included the new instructions in the patient package inserts for its two new oral contraceptives: Ortho-Cept and Tri-Cept. It is anticipated that Ortho, Wyeth, Syntex and other companies will start including the new instructions in the PPIs of their already available brands in the next few months. A paper on the current range of instructions in OC patient package inserts appeared in *Family Planning Perspectives* (May 1992) and articles were requested by *Fertility Control Review*, 1:2 (1992) and *The Female Patient* (April 1993, in press). The instructions for two or more missed pills (based largely on IPPF's instructions) continue to be somewhat controversial among U.S. service providers.

**Next Six Months Planned Activities:** FHI will continue to work with the USFDA and other organizations to help them understand and apply these instructions in practice, including a training workshop for Planned Parenthood nurse practitioners in June.

o **Analysis of Egyptian Demographic Health Survey (DHS) Data on OC Compliance**

**Objective:** To use the 1988 Egypt DHS module on OC compliance to further examine the quality of pill use and knowledge in that country.

**Ongoing and Completed Activities:** Preliminary regression analysis has been completed and is now being refined, using new SUDAAN software to account for a complex sample design. This is the largest, most representative OC compliance data set we have had to analyze.

**Results, Accomplishments, Problems:** The analysis has been progressing slowly as we have installed and learned the new SUDAAN software but should be completed in the next two months. [Note: The paper comparing more limited data on OC compliance from four countries is to appear in the May-June issue of International Family Planning Perspectives].

**Next Six Months Planned Activities:** To complete the modeling, analysis and paper on Egypt's DHS reported pill compliance.

o **Mexico: OC Knowledge and Practices of Mexican Institute of Social Security (IMSS) Rural Midwives and Their Recent OC Acceptors**

Objective: To determine OC knowledge, compliance and continuation among women who receive OCs from IMSS midwives and find ways to improve training of the rural midwives who serve as OC providers.

Ongoing and Completed Activities: All field activities have been carried out. Interviews were completed with 870 OC acceptors and 263 midwives. Data analysis is nearly complete and the final report begun.

Results, Accomplishments, Problems: There were problems recruiting the expected number of acceptors due to problems with service statistics. As a result, the number of midwives included was doubled, extending the data collection period. Knowledge among both providers and users had been found to be poor, according to preliminary results.

Next Six Months Planned Activities: The final report is expected to be completed in the next two to three months and a paper to be presented at APHA in October.

o **Mexico: Testing of New OC Instructions**

Objective: To test a modified version of the FHI-developed and USFDA-approved instructions for OC use prepared for U.S. manufacturers.

Ongoing and Completed Activities: The second round of testing of USFDA-approved OC use instructions (originally developed by FHI), including four focus groups (FGs) has been completed and a draft report has been prepared.

Results, Accomplishments, Problems: The focus groups pointed out two very important aspects that the questionnaire data did not provide: 1) to further shorten the instructions; and 2) to re-organize the instructions to make them easier to follow. We have also added a section spelling out what to do when 2-3 pills are missed late in the cycle. This makes the instructions more complete but may be confusing to some OC users.

Next Six Months Planned Activities: The final report will be submitted to A.I.D. in April and then a decision will be made on the next step to take.

o **Mexico: OC Use (Phase II)**

Objective: To revise training of rural midwives and clinicians using results of the rural midwife study and testing of new instructions for OC use and to evaluate the impact of that training on changes in OC knowledge and use among providers and acceptors.

Ongoing and Completed Activities: None.

Results, Accomplishments, Problems: This project has been postponed to allow for completion of data analysis and report writing for the Phase I study of rural midwives and OC use. IMSS has expressed interest in modifying the training materials for midwives but has not followed through thus far.

Next Six Months Planned Activities: FHI will encourage IMSS to involve us in revising the training materials to strengthen midwives' correct knowledge of OC use. This project was postponed for one year to allow time for IMSS to incorporate the results from the Phase I midwife study and for new instructions in the training of providers.

Next Six Months Planned Activities: None.

o **India: OC Use**

Objective: To develop a better understanding of the potential of and barriers to increasing the acceptance and use of OCs in Uttar Pradesh, India.

Ongoing and Completed Activities: This project consists of two parts: preparation of a background review paper which assesses the perceptions of advertising agencies, pharmaceutical manufacturers and distributors of OCs in Uttar Pradesh about their roles in oral contraceptive promotion; and conducting a consumer market research survey to assess the preferences and buying habits of OC users, with a comparison of users who rely on the free distribution system and those who buy OCs from the market. To date, the background review paper has been drafted and is now undergoing revision.

Results, Accomplishments, Problems: The background review paper was completed despite delays caused by civil unrest. The consumer market survey has been designed but is pending until an organization is identified to conduct the survey.

Next Six Months Planned Activities: The background review paper is scheduled for completion in May, 1993. A survey firm for the consumer market research will be identified and the survey conducted.

o **Revision of Package Labeling for Progestin-Only OCs (POCs)**

Objective: To develop package labeling and inserts appropriate to POCs, with simplified text for the patient information, and also to create an indexed POC bibliography/database.

Ongoing and Completed Activities: A monograph analyzing the literature available on each issue related to use of progestin-only pills is being prepared. The final labeling recommendations will be based on the findings and conclusions discussed in this document.

Results, Accomplishments, Problems: The monograph, probably the most complete documentation of the literature to date, should be completed by early May. The task is taking longer than originally anticipated because the literature on which it is based is much more extensive than originally realized, now including nearly 200 references. The full database now contains over 500 references.

Next Six Months Planned Activities: The actual drafting of the labeling will begin in May, after a final review of the background monograph by the FDA, A.I.D., and experts on the various topics included. The provider labeling will be written first, and once approved, simplified for the patient package insert. We plan to complete the project by September 1993.

o **U.S.: Measuring OC Compliance Using the MEMS Device**

Objective: To measure daily pill taking behavior using the MEMS™ (Medication Event Monitoring System), a computerized pill dispenser, and comparing those data to various personal and service system characteristics, and with data recorded on a diary card.

Ongoing and Completed Activities: PHSC approval of research protocol was completed and received, and two study sites were selected. Questionnaire development is near completion, as well as other final preparations for project initiation.

Results, Accomplishments, Problems: The study was due to begin in January but was delayed due to Ortho Pharmaceutical's long review process for the study protocol and release of the MEMS™ devices.

Next Six Months Planned Activities: Data collection is scheduled to begin May 1 at the Wake County Health Department, to be followed by data collection at the UNC-CH Student Health Service in September. The same study will be conducted concurrently at the University of Michigan.

o **OC Compliance**

Objective: To provide tools for better measurement of OC compliance; to develop strategies for increasing the use-effectiveness of the method, first by increasing correct knowledge among both users and providers; and to better understand the relationship between problems with pill taking, compliance, and continuation of the method.

Ongoing and Completed Activities: The development of a network of OC compliance experts and professionals has continued. Invited presentations were given at an Oral Contraceptive Compliance Meeting for Ob/Gyn professionals held in Copenhagen. A planned operations research project with the Population Council in Egypt on ways to improve OC compliance by providing educational materials in OC packaging, has been canceled by USAID/Cairo.

Results, Accomplishments, Problems: The applied research project in Egypt was canceled when USAID ceased to distribute pills there. FHI is now exploring other sites for such a study.

FHI has continued to work with organizations providing OCs, with experts on various aspects of OC compliance and also with the media. FHI's work is now frequently cited in the OC literature and FHI is often consulted by researchers and family planning programs. Pharmaceutical companies, such as Mead-Johnson, Wyeth, and the Australian Family Planning Association request advice and review of materials and publications.

FHI's Procite databases for combined and progestin-only pills have continued to grow, each now containing several hundred citations. These databases serve as resources for FHI staff and other researchers working in these areas.

The possibility of putting U.S. pills over-the-counter is gaining interest. FHI planned to participate in an FDA meeting on this subject, but unfortunately, the meeting was canceled. FHI plans to attend a working meeting at the Kaiser Foundation in July.

**Next Six Months Planned Activities:** Priority will be given to two areas: 1) testing of OC use instructions in at least two countries and then designing an operations research project to determine the effect those new instructions have on the knowledge and practice of OC use by acceptors and providers; and 2) continuing our work with the USFDA to develop labeling for the progestin-only pill. Non-prescription distribution of OCs is another area of interest, especially as it relates to correct and continued use. Finally, development of new projects in the area of OC compliance and securing other sources of funding for projects will be a continued priority, as will disseminating information about what is known in this area.

o **Bangladesh: In-Depth Study of Condom Use in**

**Objective:** To explore among rural Bangladeshis the patterns of use and misuse of purchased and free condoms.

**Ongoing and Completed Activities:** The final report was completed and the project consultant, Dr. Steve Folmar, visited Bangladesh to debrief the USAID mission. Dr. Folmar also made a presentation to FHI staff on the study results.

**Results, Accomplishments, Problems:** The quantitative questionnaire had to be revised numerous times by project staff and the consultant. Among the more interesting results:

- o Over 10% of the male condom users surveyed reported that at least sometimes, they use two condoms ("double bagging") simultaneously out of fear of breakage;
- o A similar percentage (13%) reported that they at least sometimes unroll the condom before putting it on (the "sock technique");
- o An even more common practice (40% of men reported they least sometimes do this) is to begin sex without a condom and to end with a condom (the "just in time" approach);
- o Re-use is very uncommon (1%).
- o Over 40% of users have experienced problems with condoms breaking, another 17% with tearing and 5% with condoms leaking. But these are fairly rare events (i.e., in the past 3 months, about 2% of condoms were reported as breaking).

**Next Six Months Planned Activities:** Dr. Folmar has planned a series of papers to be prepared and submitted for publication.

**o Condom Use/Misuse**

**Objective:** To assess the predictive strength of retrospective data on condom failure (condom breaking or slipping off completely). The study will also assess specific behaviors with respect to their impact on condom failure.

**Ongoing and Completed Activities:** Field work is complete in the Dominican Republic and Mexico. The study has been initiated and is in progress in the Philippines. Data from Mexico have been cleaned and analysis is in progress.

**Results, Accomplishments, Problems:** The primary study objective has been changed to test the hypothesis that condom users at above average risk for condom failure may be easily identified by gathering minimal information on prior condom use. The secondary objective is to identify behaviors that may lead to condom failure. Preliminary analysis suggests that past breakage/slippage is a good predictor of continued condom failure. Due to time constraints, Kenya will not be a fourth site and the study will be completed with three sites only.

**Next Six Months Planned Activities:** After the data have been collected, FHI staff will travel to the Philippines to provide technical assistance for data entry and preliminary analysis. Site specific reports will be written and disseminated. An article will be prepared for publication.

**c. Cost Research**

**o Thailand: Cost of Norplant Delivery by Nurses**

**Objective:** To determine safety, impact on contraceptive use and couple-years of protection (CYP) and the cost of provision of Norplant by nurses.

**Ongoing and Completed Activities:** All data have been collected. The analysis of the medical data is being finalized.

**Results, Accomplishments, Problems:** The introduction of Norplant added little to contraceptive prevalence. Five hundred and fifty women were interviewed concerning their previous contraceptive use and their reasons for choosing Norplant. Eighty-eight percent of women said they had used contraception previously, and 96 percent of women said they would have used another effective method of family planning (mainly

injectables and OCs) if Norplant had not been available. The marginal cost of a Norplant insertion was \$25.47, as compared with \$2.64 for an IUD insertion and \$1.45 for a first visit to receive injectables.

Next Six Months Planned Activities: A paper will be completed and submitted for publication.

o **Ecuador: Evaluation of IUD Follow-up Schedules**

Objective: To compare the costs and effectiveness (in terms of problem detection) of various follow-up schedules for IUD acceptors.

Ongoing and Completed Activities: A final report has been drafted and the results of the study have been presented to CEMOPLAF staff and public health policymakers in Ecuador.

Results, Accomplishments, Problems: The study results showed that if CEMOPLAF recommended that IUD acceptors make one follow-up visit in the first year (instead of the four follow-up visits that CEMOPLAF currently recommends), the number of medical problems detected would decline from 641 to 598 per 10,000 insertions. However, costs to CEMOPLAF and to clients would fall from approximately \$100,000 annually to \$64,000. As a result of this study, CEMOPLAF has decided to recommend that IUD acceptors make one follow-up visit in the first year of use. The timing of this one visit had not yet been decided, but will likely be between 15 and 45 days post-insertion.

Next Six Months Planned Activities: The final report will be completed and disseminated.

o **Honduras: Economic Analysis of ASHONPLAFA Programs**

Objective: To use economic criteria to evaluate various aspects of ASHONPLAFA's (The Honduran IPPF affiliate) family planning service delivery. This project is funded with add-on funds from USAID/Honduras.

Ongoing and Completed Activities: Cost estimates have been calculated for services provided in ASHONPLAFA's six clinics and in the community-based distribution (CBD) and contraceptive social marketing (CSM) programs.

Results, Accomplishments, Problems: Costs in the larger clinics are considerably lower than in the smaller clinics. For example, an IUD insertion costs approximately \$10 in large clinics, compared to \$17 in small clinics; a female sterilization in large clinics costs \$44, while in

small clinics the cost is \$62. These differentials in cost are caused by lower client loads in small clinics, which results in higher fixed costs per client. In terms of cost per CYP, female sterilization in large clinics is the least costly method, followed by IUDs in large clinics and female sterilization in small clinics. The costliest method is condoms distributed by the CBD program, which cost approximately \$51 per CYP.

Next Six Months Planned Activities: Data analysis will be completed. The final report will be written and the study results will be presented to ASHONPLAFA's Senior Management.

o **Bangladesh: Cost of Family Planning**

Objective: To determine expenditures on family planning and source of funding over the period 1985-1990.

Ongoing and Completed Activities: Data on expenditures by both the government and cooperating agencies were collected and analyzed.

Results, Accomplishments, Problems: A preliminary report has been prepared and presented to USAID/Dhaka. Findings showed the government provided about 30% of the funding for family planning with most of the rest provided by donors. USAID and the World Bank were the primary donors. The major programs for which funds were to be allocated included civil works (construction of health and family planning facilities), human infrastructure (mostly training), and family planning service delivery including contraceptives and support to NGOs.

Next Six Months Planned Activities: Presentations will be made and a final report prepared.

o **Mexico: IUD Follow-up Visits**

Objective: To determine the impact on health and costs of reductions in the recommended number of IUD revisits.

Ongoing and Completed Activities: A total of 1,714 new IUD users were recruited for this study. Half of these users were told to return for check-ups four times in the first year and the other half were told to return only twice. In addition, the costs of return visits were estimated.

Results, Accomplishments, Problems: Follow-up is ongoing. This portion of the study will determine the safety of a reduction in recommended check-ups.

Next Six Months Planned Activities: Follow-up will be completed in October 1993 and the data will be analyzed.

o **Bangladesh: Cost of Methods/Delivery Systems**

Objective: To determine the cost of different method-delivery system combinations.

Ongoing and Completed Activities: A subagreement has been finalized.

Results, Accomplishments, Problems: Not applicable at present.

Next Six Months Planned Activities: The protocol will be finalized in May 1993 and data collection will begin in August 1993.

o **Ecuador: Technical Assistance in Sustainability**

Objective: To provide technical assistance in Ecuadorian family planning PVOs in the area of cost recovery and resource generation.

Ongoing and Completed Activities: The scope of work and subagreement were written and approved. The project was initiated on April 1, 1993.

Results, Accomplishments, Problems: None.

Next Six Months Planned Activities: FHI will coordinate the training of CEMOPLAF staff in research methodology and economic analysis. Programmatic research studies will be started in September.

o **Kenya: Costing of Family Planning Methods through the Family Planning Association of Kenya (FPAK)**

Objective: To determine and to compare the costs of alternative method-delivery system combinations.

Ongoing and Completed Activities: The study is being developed.

Results, Accomplishments, Problems: Not applicable at present.

Next Six Months Planned Activities: A site visit is scheduled to develop the project.

o **Kenya: Risks and Benefits of Removing the Clinic Visit in CBD Programs**

Objective: To determine the costs and benefits of removal of the clinic visit for acceptors of OCs in a CBD program.

Ongoing and Completed Activities: The study is being developed.

Results, Accomplishments, Problems: Not applicable at present.

Next Six Months Planned Activities: A site visit is scheduled to develop the project.

o **Cost Research Paper Writing**

Objective: To conduct secondary analysis of data collected on completed studies, and to write papers for publication and presentations based on these analyses.

Ongoing and Completed Activities: Two presentations on cost research were given at the 1992 APHA meeting. One presentation compared the costs of immediate postpartum IUD insertion with the costs of insertion before hospital discharge and with a standard interval insertion. The study found that immediate postpartum insertions cost 28 percent less per client than interval insertions. The second presentation summarized the findings of the "Cost of Norplant Delivery by Nurses in Thailand" study.

Results, Accomplishments, Problems: Several papers are being finalized to submit for journal publications. These include "Assessing the Impact of Reducing the Number of IUD Revisits" and "Impact of Introducing Norplant on Contraceptive Use and Costs: an Example From Thailand."

Next Six Months Planned Activities: Submit additional papers for publication and presentations.

o **Introduction of an Injectable Contraceptive in an Ecuadorean Family Planning Program**

Objective: To assess the clinical performance, acceptability and method continuation of Depo-Provera, and to test the efficiency and cost-effectiveness of different systems of supply and resupply of Depo-Provera. This project is being done in conjunction with the Population Council; FHI's role will be limited to providing financial support for the local Research Supervisor and to technical assistance for the study of cost-effectiveness of Depo-Provera introduction and re-supply strategies.

On-going and Completed Activities: In collaboration with the Population Council, a scope of work and a proposal for work with CEMOPLAF, the local family planning organization in Ecuador, have been drafted and are nearing final approval.

Results, Accomplishments, Problems: Activities are progressing as planned.

Next Six Months Planned Activities: Forms for the study will be designed and pretested. Client recruitment for the study of acceptability and continuation will begin.

o **Mexico: Intercept Survey of Injectable Users**

Objective: To determine the user characteristics, contraceptive use history, and reasons for injectable use among current users. A group of OC users will provide comparative data. This study will help develop clearer strategies for social marketing.

Ongoing and Completed Activities: This study is being developed.

Results, Accomplishments, Problems: Not Applicable.

Next Six Months Planned Activities: Finalize the study design and initiate the study.

d. **Evaluation of Family Planning Services/Quality of Care Research**

o **Brazil: Evaluation of Sociedade Civil do Bem-estar Familiar no Brasil (BEMFAM) Reproductive Health Approach to Family Planning**

Objectives: 1) To determine the impact of a risk classification strategy upon contraceptive use and method selection among new clients; 2) to determine the impact of the Johns Hopkins Program for International Education in Gynecology and Obstetrics clinical training in IUD management and insertion and minilaparotomy (sponsored by JHPIEGO) on physicians' activities several years later; 3) to assess the cost of physician training; and 4) to determine knowledge, attitudes and practices of paramedics regarding reproductive health.

Ongoing and Completed Activities: The baseline and six month follow-up questionnaires for new clients in the BEMFAM Ceará program have been completed. Follow-up interviews of the physicians in the state of Pernambuco whose training was sponsored by JHPIEGO are also complete. The KAP survey of health agents in the Ceará program

has been analyzed and the final report has been written. Results were presented at the American Public Health Association meeting in November 1992 and in Ceará at a two-day workshop for state health leaders and BEMFAM staff in January 1993.

Results, Accomplishments, Problems: Contacting the physicians in Pernambuco who were trained as early as 1984 was difficult since addresses have changed. Nevertheless, approximately 75% of physicians were interviewed and of these, only about one in four have inserted an IUD or performed a minilaparotomy in the past month. Three-fourths of the 500 new clients were reinterviewed on average eight months later. At baseline, new clients showed very little interest in the IUD and in female sterilization, the two methods the physicians have been specially trained to provide. At follow-up, contraceptive prevalence had increased from 73% to 76%. Only one woman was using an IUD and 13 had been sterilized. Women who had been classified at risk were no more likely to use an IUD or to get sterilized than women not at risk. Based on the JHPIEGO budget and program-wide service statistics, we estimated that the training cost per IUD insertion was \$106. The KAP survey for health agents indicated low levels of knowledge regarding the efficacy and functional mechanism of IUDs and subsequently resulted in some personnel change and modifications in training. One of the most positive findings of the study was the increase in the proportion of women who had a Pap smear (38% to 57%).

Next Six Months Planned Activities: None.

o **India: Evaluation of Social Marketing Program and Conference**

Objective: To create a database of condom users in Uttar Pradesh in order to help condom-providing agencies, especially social marketing agencies, better serve their customers.

Ongoing and Completed Activities: The evaluation has been completed, with a final report on the project presented to the Mission in March, 1993.

Results, Accomplishments, Problems: Delays occurred in completing the project, due to social unrest in the areas in which the surveys were conducted. Also, the date of the formal presentation of the results of the evaluation was delayed due to the unavailability of the selected presenter. This has now been resolved and the presentation is scheduled for the end of April. As a result of this program, annual

condom sales have increased from fewer than 16 million pieces in 1968-69 to 320 million in 1990-91. Condoms provided by the program represent one-third of the total of condoms distributed annually in India. India's social marketing program is characterized by a unique collaboration between the government and the business sector, thus resulting in the expansion of both the type and numbers of outlets where condoms might be available. This program is largely operated by the participating corporations and industries under the overall policy directives and coordination of the government. Recently, an agency exclusively devoted to social marketing began operating in India. Also, through this program, the name "Nirodh" became a generic name for condoms in India. Awareness of Nirodh is nearly universal, even in rural India.

Next Six Months Planned Activities: Results of the survey will be presented to the India Ministry of Health, and copies of the report will be distributed to appropriate agencies.

o **Honduras: 1991 Family Health Survey**

Objective: To measure national and regional trends in important health and family planning indicators.

Ongoing and Completed Activities: Field work was completed in April 1992. A total of 8,088 women aged 15-49 were interviewed on a wide range of topics in family health and family planning. The data have been analyzed by both the Honduran Ministry of Public Health (MOPH) and National Family Planning Association (ASHONPLAFA). The MOPH final report addresses all topics in the questionnaire, while the ASHONPLAFA product addresses only fertility and family planning. Currently, the two institutions are finalizing their respective reports with technical assistance from FHI. The MOPH report was summarized in a 28-page document with four-color processing including photographs; FHI managed this production and delivered the 1,000 copies to USAID/Honduras.

Results, Accomplishments, Problems: Results indicate that contraceptive prevalence among women in union aged 15-44 has increased from about 41% in 1987 to about 48% in 1991-92.

Next Six Months Planned Activities: FHI will now focus on secondary analysis and collaborate with Honduran counterparts in the writing of articles suitable for publication.

o **Service Expansion and Technical Support (SEATS) Project Evaluation**

Objective: To assist SEATS/John Snow, Inc. (JSI) service delivery interventions by providing collaborative research/evaluation technical assistance.

Ongoing and Completed Activities: A "quality of care evaluation" in Togo has been developed and set for FY'93 implementation. A client satisfaction survey, to identify quality of care interventions at selected family planning clinics in Togo, has been developed with SEATS and the Togolese Ministry of Health.

Results, Accomplishments, Problems: The political situation in Togo has slowed the project development process.

Next Six Months Planned Activities: Project development with SEATS staff in Lomé and Harare will continue.

o **Service Delivery Cooperating Agencies Field Activities in Quality of Care**

Objective: To document and assess field activities of service delivery Cooperating Agencies (CAs) in the area of quality of care; to document field uses of service delivery guidelines (one component of quality of care).

Ongoing and Completed Activities: FHI's paper on Service Quality Improvement (SQI), an integration of the Bruce Framework of quality of care and Total Quality Management (TQM), an improvement process used in industry and health care, was revised and accepted for publication by *International Family Planning Perspectives*. Presentations on SQI were given at Management Sciences for Health (MSH) at an IPPF regional workshop on quality of care in India and at IPPF in London. FHI is discussing with IPPF the possibility of field testing the SQI process at a family planning association. FHI finished a catalog of assessment and improvement tools for quality of care and collaborated with PAHO on a quality of care workshop (see below). FHI serves on the working group revising service delivery guidelines.

Results, Accomplishments, Problems: More organizations are seeing the utility of using a quality improvement process to improve quality of care. Interest in SQI has been generated. The catalog has gathered together for the first time a comprehensive list of quality of care assessment and improvement tools.

Next Six Months Planned Activities: FHI will continue to work with INTRAH, Pathfinder and others to harmonize service delivery guidelines. As part of FHI's medical barriers work, FHI will study the use of Service Delivery Guidelines at the field level. FHI will continue to seek opportunities through collaborating with service delivery CAs to field test SQI. FHI will participate with Pathfinder on a regional workshop on quality of care in Bangladesh.

o **PAHO/FHI Workshop: Integrated Model for Quality of Care in Reproductive Health**

Objective: To convene a workshop of PAHO and FHI staff to develop an integrated model of quality of care in reproductive health, including family planning, maternal health and STDs/HIV.

Ongoing and Completed Activities: The workshop was held at FHI and was attended by staff from PAHO, FHI, A.I.D., IPPF and IPAS.

Results, Accomplishments, Problems: A framework of quality of care was developed incorporating the components of family planning, maternal health, and STDs/HIV. Based primarily on the Bruce Framework of quality of care, the integrated model will contain three levels of quality for each element, and will include indicators to assess the elements of quality. The levels will indicate a basic level of quality below which services should not be offered. As programs gain experience and resources, they should aim to provide higher levels of quality. The elements in the model include, at the service level, information to clients, technical competence, client-provider interaction, choice of methods, approaches and technologies, acceptability of services, and comprehensiveness and continuity of care. Two elements of resources include financial and human.

Next Six Months Planned Activities: FHI will continue to work with PAHO to fully develop the integrated model, taking primary responsibility for the family planning component. FHI will also draft the report of the workshop and will work with PAHO to draft a paper, based on the integrated model, to be submitted to the PAHO Bulletin. FHI will work with PAHO to set up a Michigan Fellows position to help implement the integrated framework in two countries in Latin America.

o **Country Level Analysis of Unnecessary Medical Barriers**

Objective: To identify unnecessary medical barriers in specific countries and at sites within countries, and to design appropriate intervention strategies to remove these barriers.

Ongoing and Completed Activities: A tool to assess medical barriers has been drafted, including sections on barriers at the policy and service delivery levels, and the impact of medical barriers at the client level.

Results, Accomplishments, Problems: The medical barriers assessment tool has been shared with colleagues in Kenya, Jamaica and Pakistan, and with the Futures Group and INTRAH.

Next Six Months Planned Activities: The assessment tool will be tested in Kenya and Jamaica and its implementation in Pakistan will be discussed. To seek additional countries, e.g. Burkina Faso, in which to implement the assessment.

- o **Medical Barriers: Service Delivery Guidelines and Practices**  
Objective: To study service delivery guidelines and practices at the local level.

Ongoing and Completed Activities: Discussions have been held with IPPF to ascertain their interest in conducting a study of the dissemination and utilization of their new service delivery guidelines.

Results, Accomplishments, Problems: No results are available at this time and no problems are foreseen.

Next Six Months Planned Activities: FHI will work with the East, Southeast Asia and Oceania Regional Bureaus, and possibly with other regional bureaus, to conduct such a study. IPPF is interested.

- o **Reproductive Health Paper Writing**  
Objective: To conduct secondary analysis on data collected on completed studies, and to write papers for publication based on these analyses.

Ongoing and Completed Activities: Staff continue to analyze data and draft research papers based on reproductive health field investigations.

Results, Accomplishments, Problems: Following are papers/presentations which FHI staff have completed during the reporting period:

- "Standardizing the instructions for oral contraceptive use." *The Female Patient*, April 1993. (Williams-Deane & Potter)

- "Pregnancy and lactation as determinants of bone density in post-menopausal women." *American Journal of Epidemiology*, forthcoming. (Zhang)
- "Use-effectiveness of oral contraceptives and quality of care." Submitted to *Int'l Family Planning Perspectives*. (Fontaine & Potter)
- "Does women's work improve their well-being: Women's work and nutrition in the urban Philippines." Presented at Population Association of America Annual Meeting, April 1993; submitted to *Economic Development and Cultural Change*. (Bisgrove & Popkin)
- "Instructions for OC use: Pros and cons of various alternatives." Presentation at OC Compliance meeting, Copenhagen, January 1993. (Potter)
- "Factors associated with acceptability and success of natural family planning use." Presented at PAA Psychosocial Workshop, April 1993. (Bisgrove)

Next Six Months Planned Activities: Staff will continue to analyze data and draft research papers. The following are papers currently in progress:

- "Oral contraceptive compliance and continuation in Egypt: Findings of DHS research." (Trottier)
- "Can rural midwives provide oral contraceptives?" (Potter & Zuniga)
- "Factors associated with copper-T IUD removal for bleeding/ pain: A multivariate analysis." (Zhang)
- "The effect of husband counseling on Norplant acceptability in Bangladesh." (Amatya)
- "Comparative analysis of pilot interventions to slow the spread of AIDS among commercial sex workers in Ghana, Mali and Cameroon." (Macauley & Nichols)

- "An Evaluation of Reproductive Health as an Approach to Family Planning in Ceará, Brazil." (Bailey)
- "Pregnancy intentions and subsequent pregnancies: A prospective study in Honduras." (Hubacher & Janowitz)

**e. Breastfeeding and Postpartum Contraception**

**o Secondary Analysis: Growth of Breast-fed Babies**

Objective: To determine whether or not the growth rates of normal exclusively breast-fed babies are different from those of normal bottle-fed infants.

Ongoing and Completed Activities: FHI is providing Dr. Soledad Diaz with funding to analyze the results from a Chilean data set. Data have been abstracted from clinical records, entered into computerized data files, and verified. Preliminary tables have been submitted by the subcontractor.

Results, Accomplishments, Problems: Preliminary results show differences in growth rates by (a) child's gender, (b) birth weight, and (c) type of feeding. Apparently, bottle-feeding and mixed feeding are associated with lower birth weights.

Next Six Months Planned Activities: The subcontractor will continue data analysis and report writing.

**o Breastfeeding/HIV Paper Writing**

Objective: To conduct secondary analysis and preparation of manuscripts on breastfeeding, lactational amenorrhea, and HIV and breastfeeding.

Ongoing and Completed Activities: FHI is conducting secondary analyses on breastfeeding patterns, NFP symptoms and efficacy of the symptothermal method.

Results, Accomplishments, Problems: The manuscript, "Symptothermal method use during breastfeeding" was completed and distributed to FHI and external reviewers. This prospective study was conducted among experienced NFP users in Sydney, Montreal and Birmingham (U.K.) in order to describe the relationship between an objective measurement of ovulation and the natural symptoms of fertility during breastfeeding. Daily urinary estrogen and

pregnanediol glucuronide assays were used to estimate the date of ovulation and to determine potentially fertile days. A standard set of Sympto-thermal Method (STM) rules was applied to daily STM records to assess the correspondence of the natural symptoms of fertility to the underlying hormonal profile. The results show that an integrated set of common rules for STM use during breastfeeding is highly sensitive but only moderately specific in its ability to "screen" for ovulation. The STM symptoms and rules accurately identified 83.6% of the potentially fertile days, but abstinence was also recommended on 50% of the days which were not fertile. Only 3% of the days were falsely identified to be safe when they really were fertile.

Next Six Months Planned Activities: FHI plans to submit the above-mentioned manuscript for publication.

o **Bellagio II**

Objective: To organize and conduct a conference which evaluates new data relative to the Bellagio Consensus.

Ongoing and Completed Activities: None.

Results, Accomplishments, Problems: This conference will be held during FY'94.

Next Six Months Planned Activities: Conference plans will be discussed further with WHO (co-sponsor) in September 1993.

o **Breastfeeding/Postpartum Contraception**

Objective: To develop research activities regarding postpartum contraception during breastfeeding, including projects to evaluate the impact and acceptability of newly introduced postpartum contraceptives or new postpartum programs.

Ongoing and Completed Activities: None.

Results, Accomplishments, Problems: None.

Next Six Months Planned Activities: Pending funding availability and priorities.

o **Breastfeeding and Women's Status**

Objective: To define barriers to breastfeeding that involve the conflict between breastfeeding and women's work and improvements in women's status, and to propose ways to overcome those barriers.

Ongoing and Completed Activities: A mini-Technical Advisory Group (TAG) meeting was sponsored by FHI and Wellstart International on March 25-26 on the topic of women's work and breastfeeding.

Results, Accomplishments, Problems: The mini-TAG defined the criteria for a mother-friendly workplace for the World Alliance for Breastfeeding Action, identified specific activities for Wellstart to initiate, and created a long and short-term strategy for addressing the conflict between women's work and breastfeeding.

Next Six Months Planned Activities: A report of the meeting will be prepared. A paper on "Breastfeeding and Women's Health" will be presented at a conference on "Breastfeeding and Feminism" at Georgetown University in September 1993.

f. **Other**

o **AIDS and Family Planning**

Objective: To understand more about how LDC family planning programs are affected by the AIDS epidemic and to enhance their potential contributions to AIDS prevention.

Ongoing and Completed Activities: A paper ("Delivering Family Planning Services in the Era of AIDS/STDs") was completed and presented at the IPPF 40th anniversary in New Delhi and at the SAC meeting in Barcelona. It will be published as part of the proceedings of the IPPF meeting. A report on the BEMFAM (Brazil) HIV Risk Assessment study (funded by AIDSTECH) was finalized and disseminated. A report on attempts to integrate AIDS and FP in Jamaica and Thailand was drafted.

Results, Accomplishments, Problems: FHI participated in two meetings on AIDS, STDs and family planning, and contributed to the proceedings for the IPPF meeting. During a trip by an FHI staff member to Jamaica in September 1992, issues regarding integration of AIDS prevention for high risk women and family planning were explored.

Next Six Months Planned Activities: Dr. Nancy Williamson, currently working at the A.I.D. Office of Health, AIDS Division, will continue to work in this research area.

o **Operations Research**

Objective: To develop a new A.I.D. research program to study the impact of family planning on women's lives.

Ongoing and Completed Activities: FHI continued to provide administrative support to Dr. Judith Seltzer, who is developing this program in collaboration with Dr. Sawon Hong of A.I.D. The project paper was revised.

Results, Accomplishments, Problems: The report, "The impact of family planning on women's lives: A conceptual framework and research agenda" was finalized and disseminated.

Next Six Months Planned Activities: Dr. Seltzer will continue to work with Dr. Hong in this area.

## **D. Contraceptive Introduction**

### **1. Program Area Summary**

FHI's contraceptive introduction activities focus on projects that support integration of new contraceptive methods into family planning programs and service delivery systems. To achieve this objective, FHI works with host country governments, non-governmental organizations, and local and international health and population agencies to develop strategies for program introduction and to assist in the planning and implementation of activities aimed at increasing method use.

During the first half of FY '93, in response to the FDA approval of the method, FHI developed an introduction strategy for Depo-Provera, using an innovative methodology. FHI collaborated on a Depo-Provera meeting and is developing programmatic studies on various aspects of the method.

Norplant introduction activities continued in Senegal, and development of introduction plans in El Salvador and Haiti were renewed. In all three countries, the expansion and introduction projects are being carried out in collaboration with JHPIEGO, and other CAs as appropriate, with funding provided by local USAID Missions. A similar Norplant introduction strategy was drafted in response to a request by the USAID Mission in Mali.

In the area of postpartum contraception, FHI is providing technical assistance to ongoing studies of the clinical and programmatic outcomes of both immediate post-placental insertion (IPPI), and insertion of IUDs before hospital discharge in Kenya and Mali. Recruitment in both studies was completed in FY'92. All follow-up data (through six months) will be collected and final analysis of the data performed during FY'93. Other sites where postpartum IUD evaluation is being considered include Egypt and Niger.

FHI has participated in three contraceptive technology update (CTU) activities during the first half of FY'93. One was a two-day symposium in Cairo followed by two governorate-level guest lectures on recent developments in contraceptive technology. Another involved FHI's participation in two sessions of the annual meeting of the Philippines Obstetrical and Gynecological Society. The third involved FHI's contribution to the family planning component of a 5-day maternal and child health seminar held in Alma Ata, Kazakhstan.

## **2. Progress Reports**

### **a. Depo-Provera Introduction**

#### **o Depo-Provera Introduction Strategy**

Objective: To develop a strategy for the introduction or expansion of Depo-Provera use in priority country programs.

Ongoing and Completed Activities: An FHI ad-hoc interdivisional working group was convened in December 1992. Following discussion, a document was written, outlining various roles for FHI in A.I.D.-supported Depo-Provera introduction activities. These roles are based on an approach which requires few new in-country clinical trials. Instead, the proposed approach focuses on issues specifically related to ensuring introduction of high quality services to the broadest number of women. Such issues include: guidelines for provision; training of service providers; information and education programs for providers and clients; counseling; the logistics of distribution; systems to ensure follow-up injections at the appropriate time; cost issues and exploration of private and social marketing of the product.

Results, Accomplishments, Problems: The written strategy has been reproduced and shared with FHI staff, A.I.D./Washington, selected USAID Missions and other organizations. FHI has instituted a working group on contraceptive introduction which will focus on Depo-Provera activities.

Next Six Months Planned Activities: FHI will continue to develop Depo-Provera projects through further dissemination of the strategy and by seeking field opportunities for Depo-Provera introduction.

#### **o Meeting on Depo-Provera**

Objective: To convene a CAs meeting on Depo-Provera to share information and experiences with the method and its delivery in family planning programs and to develop strategies for introduction of the method into country programs.

Ongoing and Completed Activities: A meeting, co-sponsored by FHI, AVSC, the Population Council and other Cooperating Agencies was held in New York on March 4, 1993.

Results, Accomplishments, Problems: Approximately 100 persons from USAID Cooperating Agencies attended the meeting and exchanged information on the worldwide experience with Depo-Provera. Existing resources and gaps that need to be addressed by USAID-supported programs were identified. The elements of quality involved with different service delivery models were also considered.

Next Six Months Planned Activities: The Population Council and FHI will prepare and disseminate a final report on the meeting. This report will contain a summary of recommendations from the meeting.

**o Assessment of Community-based Distribution of Depo-Provera**

Objective: To assess the provision of Depo-Provera through CBD programs in terms of numbers of women reached and quality of care. CBD programs will be compared to clinic provision with respect to the numbers of injections provided through each system, guidelines for provision through each system and compliance with these guidelines, and determining the level of acceptance and use patterns of Depo-Provera through each system.

Ongoing and Completed Activities: Not applicable.

Results, Accomplishments, Problems: An appropriate CBD site has not been identified.

Next Six Months Planned Activities: The search for an appropriate site will continue.

**b. Norplant Introduction**

**o Norplant Introduction in Senegal**

Objective: To provide technical support to ensure the continued smooth introduction of Norplant as a routine contraceptive choice in Senegal.

Ongoing and Completed Activities: In November 1992, FHI convened a Norplant Information Day in Dakar for clinicians and media representatives to update their knowledge on Norplant and the progress made under Senegal's introduction strategy. FHI worked with Senegal's Norplant Coordinating Committee to design a programmatic research project aimed at identifying the strengths and

weaknesses of Norplant service delivery from the client's perspective. FHI is supporting the University of Dakar's teaching hospital in implementing the study. FHI provided technical assistance to the university in developing the study protocol, including questionnaires for family planning acceptors, hiring and training interviewers and a study coordinator, and in pre-testing and finalizing questionnaires. The "Client Perspective Study" was officially launched in January 1993, and data collection began in March at the five Norplant pilot clinics.

Results, Accomplishments, Problems: Approximately 150 policymakers, clinicians and counselors received scientific and programmatic information about Norplant and its introduction into Senegal's national family planning program. Countless more Senegalese became aware of the new family planning option as a result of media coverage on the Norplant Information Day. Approximately 200 Senegalese women per month have selected Norplant as their method of contraception since services began in July 1992. Satisfaction rates and counseling techniques for Norplant relative to other methods are being assessed through client interviews at the five pilot clinics.

Next Six Months Planned Activities: Data collection for the "Client Perspective Study" will be completed. FHI will conduct focus groups with Norplant discontinuers and the husbands of Norplant acceptors to gain complementary information on the clients' experiences with Norplant. FHI will continue to support the Norplant Coordinating Committee in planning and monitoring the Norplant program. FHI will also continue to coordinate efforts with other A.I.D. Cooperating Agencies (JHPIEGO, AVSC, the Population Council) in providing technical assistance to all aspects of Norplant introduction in Senegal. FHI will explore opportunities for strengthening the I.E.C. component of Norplant Introduction, which could include developing all-methods educational materials and providing training in counseling.

o **Norplant Introduction in El Salvador**

Objective: To provide technical support to the Ministry of Health (MOH), Social Security Institute (ISS), Asociación Demográfica Salvadoreña (ADS) and ANTEL (the health care agency serving communications workers) to ensure the coordinated introduction of Norplant as an alternative contraceptive choice in El Salvador.

Ongoing and Completed Activities: In January 1993, FHI and JHPIEGO representatives traveled to El Salvador to review the Norplant introduction strategy with the member institutions of the National Norplant Introduction Committee (MOH, ISS, ADS, ANTEL) and USAID/ES. Training and information needs for the member organizations and program evaluation were discussed. During the introduction period, Norplant services will be limited to the San Salvador metropolitan area. The Norplant introduction activities will be implemented over a two year period beginning June 1993, and will be financed with USAID add-on funds.

Results, Accomplishments, Problems: A scope of work was prepared and submitted to USAID/ES for review and preparation of a PIO/T. FHI and JHPIEGO will collaborate in all programmed activities with JHPIEGO leading the in-country training of physicians and counselors, and FHI leading in the development of management information systems, IEC materials and program evaluation. Specific FHI activities will include: 1) the development of a unified information system for the inclusion of Norplant services into each institution's family planning recording system; 2) the adaptation of Norplant IEC materials for potential acceptors, as well as support for IEC program activities for clients, providers and the medical community; 3) the evaluation of the Norplant introduction program and its impact on incremental costs and contraceptive use in the four participating institutions.

Next Six Months Planned Activities: Providing the PIO/T is approved, FHI plans to 1) participate in the Norplant provider training course to promote the utilization of the unified MIS by all institutions, and 2) initiate the development of Norplant specific materials for acceptors.

o **Norplant Expansion in Haiti**

Objective: To provide technical support to expand Norplant service provision in Haiti.

Ongoing and Completed Activities: Prior to this reporting period, FHI's activities in Haiti had been severely curtailed since the September 1991 coup d'état and subsequent restrictions of foreign assistance to Haiti. However, in October 1992, USAID/Port-au-Prince received permission from AID/Washington to resume restricted technical support to PVOs through cooperating agencies working in Haiti before the coup. In March 1993, FHI participated in a meeting

in Port-au-Prince of these cooperating agencies and Haitian PVOs. The meeting was sponsored by USAID/PAP and PAPFO (the IPPF Field Office) as a first step to re-initiate pre-coup activities.

Results, Accomplishments, Problems: As a result of the pre-introductory clinical trials conducted by FHI and three Haitian PVOs, Norplant is available in 17 clinics/family planning centers, which average about 400 insertions per month. Success with Norplant has been achieved in spite of the interruption of FHI technical assistance and with no publicity whatsoever. The high demand has been generated by satisfied clients recruiting new acceptors solely by word of mouth. Major problems encountered to date include ensuring an adequate supply of Norplant and ensuring quality counseling to women considering this method. During this reporting period, FHI met with PAPFO, PROFAMIL, INHSAC, and USAID/PAP to continue development of the Norplant expansion strategy.

Next six months' planned activities: FHI will: 1) finalize the Norplant Expansion Strategy and secure funding from USAID/PAP; 2) assist in the establishment of a private sector coordinating committee to serve in an advisory and planning capacity for the coordination of all Norplant expansion activities; 3) develop and initiate agreements with Haitian PVOs responsible for implementation of the training, IEC, commodities, client management systems, and research/evaluation components. The Norplant expansion will be funded by an add-on from USAID/PAP.

**o Technical Assistance to Norplant Clinical Trial and Acceptability Studies in Egypt**

Objective: To continue technical assistance to the Egyptian Fertility Care Society (EFCS) Norplant clinical trial and acceptability studies.

Ongoing and Completed Activities: The clinical trial began in July 1988 at five university teaching hospital centers, involving 1536 women. Follow-up is continuing, as is reporting on the trial. During the past six months, the seventh semiannual report on the clinical trial was finalized and distributed. FHI provided library support to the EFCS during this same period.

Results, Accomplishments, Problems: As noted in the seventh semiannual report on the clinical trial, method effectiveness has proven to be quite high, especially through the first two years. A total of 17 pregnancies have been reported, of which 13 occurred in

the third year or later. Follow-up rates are good at all five centers. Funding for FHI's role in this project ends 31 March 1993. Follow-up will continue. Despite the long experience with Norplant in Egypt, the method has yet to be approved for general use by the Egyptian government.

Next Six Months Planned Activities: None.

**c. Postpartum Contraception**

**o Evaluation of Immediate Post-placental IUD Insertion in Kenya and Mali**

Objective: To promote the use of IUDs as an appropriate postpartum contraceptive method through support of provider training programs, implementation of clinical and programmatic research studies to increase postpartum IUD acceptability, development of informational and educational materials, and assessment of the costs of postpartum IUD programs. This project will assess the clinical and programmatic impact of immediate post-placental IUD insertion introduction on contraceptive use and service delivery costs.

Ongoing and Completed Activities: The study in Kenya was initiated in January 1992. Recruitment into the study is complete, and 218 postpartum IUD acceptors and nearly 200 non-acceptors have been interviewed. About 60% of acceptors have returned for their six-month follow-up visits. Interviewing should be completed by June 1993. Data collection for the Mali study began in March 1992. Recruitment is complete with 110 postpartum IUD acceptors and 275 non-acceptors having been interviewed. Nearly 70% of the acceptors have had their six-month follow-up interviews, and the rest are expected to be completed by July 1993. Data for the cost component of the Kenya study were analyzed at FHI and results presented at the APHA meeting in November 1992.

Results, Accomplishments, Problems: Preliminary analysis of the clinical data have found very low rates of expulsions in Kenya (4 total or 1.9 per 100 women at six months), but a higher number of expulsions and displacements in Mali (8 expulsions and 13 displacements thus far). Overall, women seem satisfied with postpartum IUD use. The cost component of the study in Kenya demonstrated that the two insertion procedures (immediate insertion and insertion before hospital discharge) and follow-up care in the Maternity Ward's postpartum IUD program are less costly than interval insertions and care offered in the hospital's MCH clinic. On

a relative basis the differences are substantial; the first year marginal costs of interval insertions are 41% higher than the IPPI counterpart. In terms of stretching hospital resources, over 140 IPPI clients could receive services for the same cost that would provide services to 100 interval IUD clients. From an economic standpoint, the message is clear: the postpartum IUD program deserves continued support.

Next Six Months Planned Activities: Six-month follow-up visits in both Kenya and Mali should be completed by July 1993. Data entry will be completed and analysis of the two studies should be completed by October 1993.

#### **d. Contraceptive Technology Update (CTU) Seminars**

##### **o Development of Standardized Instructional Modules**

Objective: To develop and produce standardized instructional modules on selected topics that would be used in CTU seminars.

Ongoing and Completed Activities: During this reporting period, work continued on the Lactational Amenorrhea Method (LAM) and Postpartum Contraception Methods modules. Work was begun on the Injectables, Reduction of Medical Barriers, Barrier Methods and Oral Contraceptives modules.

Results, Accomplishments, Problems: Because related materials had been developed on Postpartum Contraception and LAM, these modules were initially chosen for development. Work on the LAM module was temporarily suspended after an initial review. A clearer definition of the intended audience is being sought to properly target the messages to be conveyed.

During this same period, USAID/Washington suggested that the demand for modules on other topics was more pressing. This was particularly true of the Injectables module due to the FDA approval of Depo-Provera. To respond to this request, development was initiated on the following modules: Injectables, Oral Contraceptives, Barrier Methods and Reduction of Medical Barriers.

Next Six Months Planned Activities: During the remainder of this fiscal year, production will be completed on six modules. Production will begin on the IUDs module.

o **Distinguished Lectures Symposium and Guest Lectures on Contraception in Egypt**

Objective: To identify lessons learned in family planning and how to apply them to the provision of services in Egypt; to update Egyptian clinicians, particularly new postgraduate physicians, on current contraceptive methods; and to identify social, programmatic and medical factors affecting the use of different methods.

Ongoing and Completed Activities: FHI and the National Population Council (NPC) of Egypt co-hosted a two-day symposium in Cairo and two half-day governorate-level guest lectures in El Menia and El Gharbia. At the meetings, international and Egyptian family planning experts presented the latest scientific information on contraceptive methods and programmatic information specific to Egypt. Emphasis was placed on dispelling out-dated rumors and surmounting barriers to family planning services.

Results, Accomplishments, Problems: A total of 450 Egyptian clinicians received up-to-date information on contraception from international experts. They also learned from senior level Egyptian physicians about medical, behavioral and programmatic factors affecting the acceptance of family planning in Egypt.

Next Six Months Planned Activities: Based on participant evaluations from these meetings, FHI and the NPC will conduct a fourth symposium in the summer of 1993. Its length will be extended to four days to allow time for participants to formulate recommendations for improving access to family planning in Egypt. The recommendations will be distributed to policy-makers for action.

o **Maternal and Child Health Seminar in Alma Ata, Kazakhstan**

Objective: To provide technical assistance and support for a five-day seminar for approximately 150 health professionals and policymakers from the five Central Asian Republics on current contraceptive methods which will assist in the reduction of the high abortion rate throughout the region.

Ongoing and Completed Activities: FHI and JHPIEGO collaborated on the family planning components of the regional seminar on maternal and child health held 11-15 January 1993. Wellstart

International coordinated the contribution from the various cooperating agencies. FHI and JHPIEGO collaborated on the family planning components. An evening session for health care providers in Alma Ata was held on 12 January and attended by approximately 80 people.

Results, Accomplishments, Problem: The seminar represented a growing interest in the Central Asian Republics to address the high rate of maternal and infant mortality and the high number of abortions. A key constraint facing the family planning programs in the Central Asian Republics is the lack of contraceptives.

Next Six Months Activities: None.

o **OB/GYN Society (POGS) Annual Meeting in Philippines**

Objective: To update Filipino obstetricians and gynecologists on their technical knowledge of reproductive health, family planning and undergraduate training in ob/gyn.

Ongoing and Completed Activities: The POGS meeting was held November 26-28, 1992 in Manila, Philippines. Dr. Thomas Petrick, FHI's Corporate Director of Medical Affairs attended the meeting and made two presentations on behalf of FHI. Over 750 persons participated in the conference and the presentations on undergraduate OB/GYN training and updates in contraceptive technology were both well-attended. Depo-Provera, approved by the USFDA shortly before this conference, was the focus of many questions and some debate in the contraceptive technology session.

Next Six Months Planned Activity: None. This activity is now completed.

o **Contraceptive Technology Update in Pakistan**

Objective: To update the knowledge of Pakistani health care providers and policymakers regarding contraceptive methods, with special emphasis on removing unnecessary medical barriers to service delivery as well as quality of care issues.

Ongoing and Completed Activities: Two two-day conferences will be conducted in collaboration with the National Research Institute of Fertility Control (NRIFC), with approximately 200 participants at each meeting. The meeting in Karachi will be May 23-24, followed by one in Lahore May 26-27, 1993. Speakers have been identified, and the agenda is now being finalized.

Results, Accomplishments, Problems: Lead time for planning this conference was approximately three and one-half months, which made arranging expert speakers difficult. No other problems are foreseen.

Next Six Months Planned Activities: The conferences will be conducted and proceedings disseminated to the appropriate institutions. Follow-up activities based on issues identified during the conference will be evaluated.

## **E. Reproductive Epidemiology**

### **1. Program Area Summary**

Research on the non-contraceptive risks and benefits of family planning methods helps programs address concerns about safety and indicates those family planning methods that may or may not be suitable for users with special needs or risk factors.

During this reporting period, our major emphasis has been on STDs, including HIV infection. There is as yet poor measurement of HIV risk with use of barrier contraception. There may be differing effects on bacterial STDs versus HIV infection. We are examining the local effects of frequent insertion of spermicides. We are also studying whether hormonal contraception increases susceptibility to HIV infection.

Another priority area of study is the enhancement and use of a computer life-table model that takes into account the risks and benefits of contraceptive use on specific diseases and estimates the net effect of contraceptive use on life expectancy. We have used the program to estimate deaths caused or averted by low-dose oral contraceptives and to analyze the impact of Depo Provera use. We will extend these assessments to developing countries for which requisite data are available, allowing us to compare demographic impacts in different countries based on local disease patterns.

Little research has focused on the factors affecting contraceptive safety and efficacy among various sub-groups of women, including women with diabetes and other chronic diseases and fertile women older than 40 years. Although contraindications to certain methods of family planning may be more common in these groups, so are the contraindications to pregnancy, making more acute their need for appropriate contraception. Analysis has been completed on data collected in a trial examining the hematologic effects of OC use among women with sickle cell disease.

Use of oral contraceptives (OCs) affects the incidence of several reproductive cancers; it is well established that OCs reduce the risk of endometrial and ovarian cancer, yet the Pill may be associated with a slight increase in the risk of cervical cancer. The effect of progestin-only methods is less well understood. A study was done in Jamaica to measure the association between cervical cancer and DMPA and analysis has been completed on the main hypothesis. Further analysis using this data are being done.

## **2. Progress Reports**

### **a. Contraception and STDs**

#### **o Thailand: Spermicide Use and STDs**

Objective: To compare the incidence of gonorrhea and chlamydial infection among women using nonoxynol-9 film plus condom versus women using a vaginal placebo plus condoms. The study design was a randomized placebo-controlled trial.

Ongoing and Completed Activities: The study, involving 343 Thai women, has been completed, primary analysis has been completed and information dissemination is ongoing.

Results, Accomplishments, Problems: Women who used spermicide decreased the rate of cervicitis caused by gonorrhea and chlamydia by 25%. Women who were consistent users (>75%) reduced the rate of infection by 40%. A presentation was given at the International Society for STD Research and an article was published by *The Lancet*. The article has been selected for inclusion in the *1993 Year Book of Obstetrics and Gynecology*.

Next Six Months Planned Activities: Secondary analysis of genital irritation has been completed and an article was submitted to a journal. Article revisions may be necessary or submission to another journal may be required. The data indicate no increases in specific complaints such as dysuria, genital burning or genital itching among the N-9 film group. More significantly, there was no increase in genital ulcers or yeast infections in the N-9 film group.

#### **o Zambia: Spermicide Use and HIV**

Objective: To measure the association between condom and spermicide use and HIV infection among couples discordant on HIV infection. Cohort methodology was used for this study. Vaginal suppositories containing 100 mg of N-9 and silicone lubricated latex male condoms were provided to all study participants. Each woman chose which method(s) to use.

Ongoing and Completed Activities: Follow-up was completed at the end of February 1993 on 114 couples. Data cleaning and analysis are in progress.

Results, Accomplishments, Problems: Interim analysis shows that consistent condom use is associated with reduction in the HIV rate (rate ratio 0.5). Spermicide use reduces the rate among the female seronegatives, but not among male seronegatives.

Next Six Months Planned Activities: Data analysis will be conducted on the final data set.

o **Dominican Republic: Effects of Frequent Use of Nonoxynol-9**

Objective: To assess the local irritation of varying frequencies of use of spermicidal suppositories using Phase II methodology.

Ongoing and Completed Activities: Data analysis was completed and an article was submitted to a journal. The results have been disseminated at several meetings. The article is to be published in an upcoming issue of the *International Journal of STD & AIDS*.

Results, Accomplishments, Problems: The study involved 190 subjects. Four frequencies of N-9 were tested; once every other day, once per day, twice per day and four times per day. Vaginal suppositories containing 150 mg of N-9 were used as the test product. Women with the highest spermicide insertion frequency (four times per day) had a substantial increase in epithelial disruption, but there was not a consistent increase in the incidence of irritation with increasing frequency of spermicide use. N-9 use every other day was the same as placebo use when comparisons of epithelial disruption were made. Once per day and twice per day use of N-9 were about 2.5 times as likely to produce epithelial disruption as placebo and 4 per day use of N-9 was about 5 times as likely to produce epithelial disruption as placebo. Perceived irritation symptoms and demonstrable epithelial disruption were not closely associated.

Next Six Months Planned Activities: None.

b. **Contraception for Women with Special Needs**

o **Jamaica: Sickle Cell Disease and OCs**

Objective: To evaluate the effects of a low-dose oral contraceptive on hematologic parameters and sickling crises in women with sickle cell disease.

Ongoing and Completed Activities: Data analysis to evaluate the effects of OC use on hematologic and clinical parameters has been completed, and the data on adverse experiences have been tabulated and summarized. A final annual report has been prepared and was submitted to the USFDA in December 1992 and the IND was withdrawn.

Results, Accomplishments, Problems: Only eight of the 30 patients enrolled in the study completed both phases of this crossover clinical trial, therefore crossover analysis would not yield statistically stable estimates. For this reason, the principal study findings are based on a parallel analysis of the data for the first phase of the study (i.e., comparing women randomly assigned to receive the placebo first to those assigned to receive the active medication first). Mean level of hemoglobin, percentage of iron saturated cells, and red blood cell count increased significantly in the group assigned the active medication compared to the group assigned the placebo.

Because women with sickle cell disease experience frequent disease-related problems (sickling crises, leg ulcers, bone pain, etc), OC use is often erratic and/or of short duration and is therefore probably not the appropriate contraceptive method for these women. Furthermore, due to the lack of compliance, it is difficult to draw any conclusions about the possible effect of OCs on women with this disease (whether adverse or beneficial).

Next Six Months Planned Activities: None.

- o **Nigeria: Norplant Use by Women with Sickle Cell Disease**  
Objective: To evaluate the safety of Norplant in women with confirmed sickle cell disease.

Ongoing and Completed Activities: Analysis of hematologic parameters pre- and post-insertion has been completed. An article was submitted and accepted by the *International Journal of Gynecology and Obstetrics* and will be published in 1993.

Results, Accomplishments, Problems: Overall, there were no clinically or statistically significant changes in hematologic parameters following Norplant insertion in 23 women who were followed for a mean of 12.4 months after insertion. Norplant has no obvious adverse effect on young women with mild to moderate HbSS

disease and appears to be a safe and appropriate contraceptive for these women.

Next Six Months Planned Activities: None.

- o **Mexico: Vitamin B6 and Oral Contraceptive Continuation**  
Objective: To measure the effect of vitamin B6 on early side effects of a low-dose oral contraceptive and discontinuation reasons.

Ongoing and Completed Activities: Analysis of the data has been completed, the investigator has finished the final report and a draft of the paper has been finalized.

Results, Accomplishments, Problems: No difference in treatment groups was observed. A randomized triple blinded clinical trial was conducted among 124 women. There was no discernable effect of Vitamin B6 on common OC-related effects. The fact that in both treatment groups there was a significant decrease in severity of all OC side effects could be potentially explained by a placebo effect. Problems included a high percentage of women who discontinued OCs or were lost to follow-up, which was higher among women in the Vitamin B6 group.

Next Six Months Planned Activities: The paper will be submitted to a journal by the principal investigator.

**c. Assessment of Risks/Benefits and Maternal Health Studies**

- o **Benefits and Risks of OCs**  
Objective: To evaluate the impact of known benefits and risks of OC use and hormonal methods on numbers of deaths in various countries.

Ongoing and completed activities: Ongoing activities for this project include 1) compilation of OC prevalence, mortality and population data for various countries; 2) the development of FPRISK software including efforts to improve the efficiency and breadth of existing software; 3) analyses performed in response to specific requests from countries; 4) efforts to estimate the cost of performing country-specific analyses as software is refined; 5) identification of the appropriate audience for the software; and 6) a presentation on the impact of increasing OC use in India was made by Dr. Judith Fortney at the International Conference on Fertility Regulation.

**Results, Accomplishments, Problems:** An update of the epidemiologic literature on benefits and risks of oral contraceptives has been accomplished, and incorporation of new studies will be ongoing. New staff are being trained in the use and development of the FPRISK software, and the process of transferring software support from an out-of-house consultant/developer to the Scientific Support Services Division is underway. The shift of support is gradual as software continues to require support. It was decided that the complexity of the model and its interpretation precludes transfer to PCs. Country-specific analyses will be performed in-house with specifics supplied by in-country contractors. Based on the India analysis, sensitivity analyses will be performed using data of known quality.

**Next Six Months Activity:** Papers will be prepared on the impact of oral contraceptive use on mortality in the United States and Latin American countries. The development of a database for the literature on benefits and risks of OCs is starting.

o **US: Bone Mineral Density and Use of OCs in Perimenopausal Women**

**Objective:** To evaluate the association between history of OC use and bone mineral density.

**Ongoing and Completed Activities:** Three papers on the relationships between OC use, lactation and exercise and bone density were published or accepted for publication. These papers include:

- Zhang J, Feldblum PJ, Fortney JA. "Moderate physical activity and bone density among perimenopausal women."
- Feldblum PJ, Zhang J, Rich LE, Fortney JA, Talmage RV. "Lactation history and bone mineral density among perimenopausal women."
- Fortney JA, Feldblum PJ, Talmage RV, Zhang J, Godwin SE. "Bone mineral density and history of oral contraceptive use."
- Zhang J, Feldblum PJ, Fortney JA. "Validity of self-reported height and weight among perimenopausal women." (letter)

**Results, Accomplishments, Problems:** History of OC use does not have strong association with bone mineral density. Lactation history is associated with increased lumbar bone mineral density. Physical activity is associated with more substantial increases in bone density.

Next Six Months Planned Activities: None.

o **Oral Contraceptives and Blood Pressure**

Objective: To describe current family planning practice in developing countries as it pertains to the collection of blood pressure measurements, interpretation of these measures, and follow-up in users of hormonal methods.

Ongoing and Completed Activities: This project is in development.

Results, Accomplishments, Problems: Not applicable.

Next Six Months Planned Activities: A questionnaire which presents several case studies of women with various combinations of baseline and follow-up blood pressures will be field tested in Jamaica. The questionnaire will present several case studies of women who have various combinations of baseline and follow-up blood pressures. Staff will be asked to describe actions taken under these varying conditions. In addition, a form will be developed to abstract information on particular prescribing patterns or discontinuation of hormonal methods in relation to blood pressure changes.

d. **Contraception and Cancer**

o **Jamaica: Case-control Study of Cervical Cancer**

Objective: To determine the relationship between use of DMPA (depomedroxyprogesterone acetate) and the risk of cervical cancer.

Ongoing and Completed Activities: The analyses of the relationship between DMPA and squamous cervical carcinoma in situ (CIS) have been completed. Conditional logistic regression techniques were used to estimate the odds ratio for cervical cancer status comparing current and former DMPA users with women who had never used DMPA, adjusting for other confounding variables. In addition, unconditional logistic matching variables were treated as covariates. When the two methods were compared, the unconditional logistic regression yielded similar estimates of the odds ratio, and because no cases were lost on matching criteria, this approach was preferred since it afforded slightly greater precision and power. Additional analyses have been performed to evaluate the effects of duration of DMPA use, time since first use, time since last use, and age at first DMPA use. The results of these analyses are being summarized in a manuscript suitable for publication.

**Results, Accomplishments, Problems:** The management of data needed to evaluate the completeness of matching and to define the analysis populations for the CIS and invasive cervical cancer analysis are complete. One hundred sixteen CIS cases and 306 controls were available for the DMPA-CIS analysis. Only 27 cases and 196 controls were available to evaluate the relationship between use of DMPA and the risk of invasive cervical cancer. Additional variables needed for multivariate analyses have been created and checked. Analyses completed to date have focused on describing the relationship between use of DMPA and CIS. The crude odds ratio comparing the history of ever having used DMPA among CIS cases and controls was 1.7 (95% CI: 1.1-2.7). This suggests that cases were more likely than controls to have used DMPA. After controlling for the effects of confounding variables, the crude odds ratio fell to 1.1 and the 95% confidence interval included 1.0, indicating that current or former use of DMPA does not independently increase the risk of CIS. These findings should reassure current and former users of DMPA.

**Next Six Months Planned Activities:** To the extent allowed by the number of subjects available for analyses, similar analyses will be performed to evaluate the relationship between DMPA use and invasive cervical cancer. Further analyses will examine the relationships between OC use and barrier method use with risk for cervical cancer. In addition, other non-contraceptive risk factors for cervical cancer including smoking and parity will be analyzed. Findings from these analyses will be summarized in a series of three manuscripts for publication. A meeting will be organized to present and discuss the study results with health and family planning providers and decision makers in Jamaica.

o **Vasectomy and Prostate Cancer**

**Objective:** To evaluate the putative association between vasectomy and subsequent prostate cancer internationally.

**Ongoing and Completed Activities:** In March 1993, subsequent to the publication of two cohort studies indicating an association between vasectomy and prostate cancer, NIH held a meeting to evaluate research needs and priorities regarding this relationship. FHI staff attended the meeting, which called for more research. No changes in current practice of providing vasectomy were recommended. A packet of materials was prepared by an FHI task force which was sent to USAID Missions (by A.I.D.), to FHRCs and to family planning organizations worldwide.

Results, Accomplishments, Problems: WHO is planning a multi-center study; FHI will collaborate with WHO and concentrate on developing the Korea or Nepal site, neither of which could provide enough relevant cases alone.

Next Six Months Planned Activities: FHI will work with WHO on site development. The pilot study will take place in October 1993.

**e. Extended Funding Opportunities**

**o Kenya: Reversible Contraception and Risk of HIV Infection in Women**

Objective: To evaluate the relationship between various reversible contraceptive methods, particularly oral contraceptives, and HIV infection in women.

On-going and Completed Activities: A pilot study to demonstrate the feasibility of conducting a full-scale nested case-control study was completed in 1992. Funding for the pilot study was provided by A.I.D./Population, the National Institute of Child Health and Human Development (NICHD), WHO, and Ortho Pharmaceutical Corporation. Plans for a submission of a new proposal to NIH for the full-scale study have been made and preliminary work on the proposal has begun.

Results, Accomplishments, Problems: While the pilot study showed that a sufficient number of women can be recruited into the study and that the incidence of HIV infection in the study population is high enough for statistical analysis, the overall follow-up rate was unacceptably low. Strategies for increasing follow-up and expanding the proposal to consider the association between IUD and DMPA and HIV infection have been made.

Next Six Months Planned Activities: A proposal for the full-scale study exploring the relationship between OCs, IUDs, DMPA and HIV infection will be submitted to NIH in May 1993. Study initiation would start in late FY'93 or early FY'94 if funding is secured. A cohort of 16,500 HIV seronegative women would be established over 18 months and followed for a one-year period.

**o N-9 Use and HIV**

Objective: Using randomized controlled trial methodology, we plan to assess the HIV prophylactic effect of N-9 use among women.

Ongoing and Completed Activities: A proposal was submitted to NIH in January 1993. A revised proposal will be submitted May 1, 1993.

Results, Accomplishments, Problems: None.

Next Six Months Planned Activities: A proposal will be prepared for submission to WHO for a study in Madras, India.

o **Cervical Infection and Condom Use**

Objective: To assess the efficacy of N-9 lubricated condoms for prevention of gonorrhea and chlamydial infection compared to that of silicone lubricated condoms with a randomized controlled trial.

Ongoing and Completed Activities: The first draft of the proposal has been given to the investigators in the Dominican Republic for review.

Results, Accomplishments, Problems: None.

Next Six Months Planned Activities: FHI will submit a proposal to NIH for funding.

o **Low-dose OC Use by Older Women**

Objective: To determine prospectively the safety of low-dose OC use by older women, as indicated by cardiovascular parameters.

Ongoing and Completed Activities: An original proposal for funding, submitted to the NIH in October 1990, was not funded.

Results, Accomplishments, Problems: The proposal is being re-conceptualized to address reviewers' comments.

Next Six Months Planned Activities: A new proposal will be submitted.

o **Brazil: Oral Contraceptives and Diet**

Objective: To determine if dietary consumption of lactose modifies the relationship between oral contraceptives and gonadotropin levels.

Ongoing and Completed Activities: A proposal was submitted to NIH in November 1992.

Results, Accomplishments, Problems: None.

Next Six Months Planned Activities: FHI expects to receive review comments and approval/disapproval in May 1993.

o **U.S.: Vasectomy and Prostate Cancer**

Objective: To evaluate the putative association between vasectomy and subsequent prostate cancer.

Ongoing and Completed Activities: Development of a case-control study in a screening population in the U.S. will be developed in collaboration with the American Urologic Association.

Results, Accomplishments, Problems: None.

Next Six Months Planned Activities: A joint proposal will be submitted to NIH.

o **Thailand: Oral Contraceptive Use and Risk of Gestational Hypertension**

Objective: To assess if oral contraception increases the risk of pregnancy-induced hypertension and determine how long before conception it is necessary to stop using OCs.

Ongoing and Completed Activities: A site visit to Thailand was made to assess the feasibility of this study. A proposal has been developed and will be submitted to the Rockefeller Foundation.

Results, Accomplishments, Problems: None.

Next Six Months Planned Activities: FHI will seek funding for this study.

o **DMPA and Osteoporosis**

Objective: To examine (1) whether DMPA use reduced bone density and to what extent; (2) whether low-dose calcium supplementation prevents bone loss among DMPA users; and (3) whether bone mass is regained after DMPA use ends and if so, how long it takes.

Ongoing and Completed Activities: A concept proposal has been submitted to the Scientific Projects Committee for their review.

Results, Accomplishments, Problems: None.

Next Six Months Planned Activities: To seek funding and potential collaborators, and to develop a proposal.

## **F. Institutional Development**

### **1. Program Area Summary**

FHI's Institutional Development program focuses on institutions in selected countries that share a common interest in family planning research, training, and information dissemination. FHI has focused on a limited number of organizations called Family Health Research Centers (FHRCs). Only four received core support for staff salaries and certain overhead costs during this reporting period: Mali, Bangladesh, Egypt, and Kenya. The FHRCs have received the bulk of FHI's resources for Institutional Development, i.e., broad-based technical assistance, training opportunities, and core support. However, other institutions are strengthened through less intensive activities, such as support for their national and international meetings, technical assistance in select areas, and training opportunities for staff.

With over 15 years of experience in institutional development, FHI began reviewing its conceptual framework in this program area two years ago. A monograph was drafted during the past year which explores the institutional development literature and documents FHI's accrued experience and the lessons learned.

Likewise, FHI's understanding of what contributes to a strong organization is being put into an evaluation framework. This will allow FHI, other donors, and the institutions themselves to assess organizational strengths and weaknesses. If funding can be found, the monograph and evaluation framework will be published and distributed to interested cooperating agencies and donor agencies.

FHI will continue to foster the existing FHRC network through collaborative research, information dissemination, and other means. FHI will provide training, technical assistance, and financial support to carefully selected institutions, where bilateral or non-A.I.D. funding is available, to strengthen and support clinical and programmatic research. During FY'93, FHI will explore closer collaboration in institution strengthening with other agencies, most notably the Human Reproduction Program of WHO.

## **2. Progress Reports**

### **a. Documentation and Evaluation of Institutional Development**

#### **o Institutional Development Monograph**

Objective: To publish and disseminate a monograph on FHI's institutional development experience, which will be useful to other donors and technical assistance agencies in planning their own activities in this area.

Ongoing and Completed Activities: Editing began on the draft monograph written during FY'92.

Results, Accomplishments, Problems: Financial support for final editing, publication and dissemination is needed.

Next Six Month Activities: Complete editing of monograph, if funding is available.

#### **o Institutional Assessment Indicators**

Objective: To develop, test and disseminate performance indicators used to assess the strengths of institutions in the field of reproductive health.

Ongoing and Completed Activities: Minor editing of the indicators was completed and alternative formats for making the document more reader-friendly were reviewed.

Results, Accomplishments, Problems: Funding for the editing, field-testing, and distribution of the document is needed.

Next Six Months Activities: Locate funds to complete this project.

### **b. Family Health Research Centers (FHRCs)**

#### **o Bangladesh Institute of Research for Promotion of Essential and Reproductive Health and Technologies (BIRPERHT)**

Objective: To strengthen and support the BIRPERHT to help meet the research needs of the Bangladesh family planning program.

Ongoing and Completed Activities: Bridging support was provided for staff salaries and certain overhead costs through December 31, 1992, while a transition to World Bank project support took place. This period marked the end of 17 years of FHI core support for BIRPERHT. FHI will continue to include BIRPERHT in communications with the FHRC network.

Results, Accomplishments, Problems: BIRPERHT successfully used FHI's core support funding to strengthen itself into a highly credible indigenous research organization. FHI training and technical assistance also played a role in BIRPERHT's reaching this goal.

Next Six Months Activities: Technical backstopping and miscellaneous support will be provided on an "as needed" basis.

o **Egypt: National Population Council (NPC)**

Objective: To strengthen the institutional capacity of the NPC to plan and coordinate family planning activities in Egypt, with special emphasis on research. This project is supported by add-on funds.

Ongoing and Completed Activities: FHI provided technical assistance to staff of the Research Management Unit (RMU) in biomedical and programmatic study design and protocol development, data management and analysis and study implementation and monitoring. Through a subagreement with E. Petrich and Associates (EP&A), FHI provided assistance to the Central Office of the NPC and twenty Governorate offices in management and management systems, program planning and evaluation. Specifically, EP&A staff and consultants provided technical assistance to NPC staff in: revising chapters of the NPC Operating Procedures Manual based on comments by the Manual Development and Review Committee; collecting data for the fourth year of the family planning cost study; developing a computerized Population Information System and training NPC staff in its use; and training NPC staff in developing evaluation plans.

Results, Accomplishments, Problems: The RMU approved two programmatic research projects for funding; it awarded funding to the three previously approved biomedical studies (two postpartum IUD studies and one study that looks at the use of oral contraceptives in women with a history of viral hepatitis), which are now being implemented. RMU staff conduct regular monitoring visits of these studies. The paper "Introducing Operations Research: the Case of

Egypt," resulting from earlier activities conducted under this project, was accepted for presentation at an international conference.

Next Six Months Planned Activities: FHI will provide training to RMU staff and study investigators in report writing and information dissemination, including preparing scientific papers. FHI will also support the participation of the RMU research officers at intensive, short-term Epidemiology programs in the U.S. FHI will present its paper "Introducing Operations Research: the Case of Egypt" at the meeting of the International Union for Scientific Study of Population.

o **Kenya: Reproductive Health/Institutional Development Project (IDP)**

Objective: To strengthen the capacity of the University of Nairobi Ob/Gyn Department to manage a broad-based contraceptive and reproductive health research program; to plan, design, implement and evaluate contraceptive and reproductive health research in support of the Kenyan family planning program; to develop a network of trained investigators throughout Kenya interested in all phases of family planning research. This project is supported by add-on funds.

On-going and Completed Activities: With technical assistance from FHI, staff of the Reproductive Health Research Unit analyzed data and prepared final reports for three studies: a Physicians' KAP Survey, a study of Barriers to Contraceptive Use, and Acceptability of Three Family Planning Methods. A workshop on Randomized Clinical Trials Methodology was conducted for 20 IDP staff and investigators. The protocol and questionnaires for a study of OC compliance among clinic and CBD clients were developed, and a two-part workshop on reducing medical barriers to contraception was held (jointly sponsored by FHI and the Population Council).

Results, Accomplishments, Problems: A survey of physicians' knowledge and practices revealed that, while the majority held generally favorable attitudes toward family planning, many lacked sufficient knowledge to provide effective counseling and services to couples wishing to control their fertility. A study of barriers to contraceptive use among urban and rural couples using no method revealed a clear discrepancy between the commonly stated desire to space or limit births and the lack of use of family planning methods to accomplish it. Barriers include limited knowledge about available methods (including misconceptions about side effects), lack of communication between husbands and wives on fertility issues, and the perception that an insufficient selection of methods is available.

Results of a prospective study of acceptors of OCs, IUDs and injectables (N=1349) show a high level of client satisfaction with each of the three methods. Major factors associated with method dissatisfaction and/or discontinuation were related to compliance (among OC users) and medical complaints related to side effects (IUD and injectable users). Principal recommendations in the final report for this investigation are: 1) more counseling of clients, both before and after acceptance, and 2) improved training for service providers. Support for some key staff and basic operating expenses of the Reproductive Health Research Unit at the University of Nairobi Ob/Gyn Department will cease at the end of FY '93. Senior project staff will need to seek and obtain funding on a project-by-project basis from the USAID Mission and from private foundations and organizations. (Funding will be provided for completion of specific ongoing activities, such as the OC Compliance Study.)

Next Six Months Planned Activities: Three workshops are planned for the next six months: a Contraceptive Technology Update, a Strategic Planning Workshop, and an Information Dissemination Workshop. Expansion of the OB/GYN Department will also be undertaken so that it can house the Reproductive Health Research Unit. The OC Compliance Study will be initiated, and a formal needs assessment for reducing medical barriers to contraception will be conducted.

o **Mali: Technical Assistance to the Family Planning Association of Mali (AMPPF)**

Objectives: To strengthen the institutional capabilities of the AMPPF to carry out family planning research to improve service provision.

Ongoing and Completed Activities: FHI continued providing technical assistance in the development of the computerized client information system (CIS) and the publication of the AMPPF's semiannual bulletin. The evaluation of the IEC campaign in Baguineda was completed and a preliminary report was prepared. The evaluation consisted of interviews with 18 community "motivators" trained by the AMPPF and focus-group discussions with various population groups (e.g., young men, women of child-bearing age). At AID/Bamako's request, assisting AMPPF in the development of a strategic plan was postponed. Discussions were held with AMPPF and AID/Bamako to identify future AMPPF technical assistance needs for possible bilateral funding.

**Results, Accomplishments, Problems:** During this period the first reports from the computerized client information system were generated; reports of critical service-delivery data for the July-September and October-December 1992 trimesters were prepared and distributed to AID/Bamako and to the Ministry of Health, Solidarity, and Aged Persons. In light of the rapid growth of the CIS data base, further assistance to the AMPPF in data management is needed. The third issue of the AMPPF bulletin was printed and distributed; the fourth issue is in preparation. Preliminary results of the Baguineda IEC campaign evaluation highlighted the need for better follow up and supervision of community motivators as well as the need for regular supply of contraceptive products.

**Next six months' plans:** FHI and the AMPPF will (1) prepare the fourth semiannual bulletin; (2) complete the Baguineda evaluation report; (3) develop a double-entry validation program for the CIS; (4) set priorities for areas of future collaboration and formalize agreements to implement these activities. Based on discussions with the AMPPF and AID/Bamako, the CIS, information-resource development, Contraceptive Technology Updates, and an institutional assessment/strategic planning exercise were tentatively identified as future areas of FHI/AMPPF collaboration.

o **Niger: National Family Health Center (CNSF)**

**Objective:** To strengthen the institutional capabilities of the CNSF to carry out reproductive health research to improve service provision.

**Ongoing and Completed Activities:** From recommendations at a contraceptive technology update conference in 1991, FHI developed and submitted a scope of work to the USAID Mission for an introductory study of post-delivery IUD insertions. Plans for the study were discussed and revised in October 1992. The study will be carried out by the Directorate of Family Planning, CNSF's parent organization.

**Results, Accomplishments, Problems:** Bilateral funds for the project were not available during this six-month period. The Niger USAID Mission has notified FHI that funding will be available starting April 1993.

Next Six Months Activities: FHI expects to begin the introductory study of post-delivery IUD insertions with the Directorate of Family Planning. During the next six months, this will involve the development of data collection instruments, the training of clinical and interviewing staff, and initiation of data collection activities.

**c. Microcomputer Development**

**o EPI INFO-based maternal Care Monitoring Software (PC-MCM)**

Objective: To produce and make available to clinicians an elementary, PC-based obstetrics care management system.

Ongoing and Completed Activities: No new work was done on this project during the past six months. The draft package, including data entry templates, standard tables programming and user documentation, is completed.

Results, Accomplishments, Problems: This has been a lower priority project for FHI. The necessary staff have been unavailable to work on this project due to higher priority activities.

Next Six Months Activities: In-house testing of tables programming will be completed and a user manual will be finalized. A committee meeting will be held to determine any future project-related action.

## **G. Training**

### **1. Program Area Summary**

FHI fosters the strengthening of skills of collaborating investigators, research staff, and program managers through formal and informal training, including workshops, seminars, individual training, technical assistance, and fellowships. FHI has supported the development of various training curricula for use with FHRC staff, as well as non-FHRC personnel, mainly in the areas of research methodology, data analysis, and research management. Training will continue to be an important part of FHI's capacity-building effort, both in conjunction with institution-strengthening efforts and for individual investigators and scientists with research interests compatible with the mandate of FHI. Many training activities are listed under other program areas, (institutional development, contraceptive introduction, and information dissemination); this section includes only those training activities that do not fall into the three other areas.

The program for this year included support of selected FHI collaborators' attendance at international meetings. Their attendance served to increase their knowledge about reproductive health and family planning topics and about research methods and results.

### **2. Progress Reports**

#### **a. General Support**

##### **o Non-Staff Conference Travel**

Objective: To enhance collaboration with our international network of investigators and consultants by providing assistance for their attendance at meetings and workshops.

Ongoing and Completed Activities: Dr. Halida Akhter presented the results of the Five-Year Experience with Norplant in Bangladesh (a study conducted jointly with FHI) at the VIIIth International Meeting of the Society for the Advancement of Contraception (SAC) held in Barcelona, Spain, October 28-31, 1992.

Results, Accomplishments, Problems: The five-year experience with Norplant in Bangladesh was shared with the international participants. The study found no pregnancies, a cumulative discontinuation rate at five years of 41.2, and a high level of acceptability.

Next 6 Months Planned Activities: Due to budget constraints, there are no participants being sponsored for the next six months.

o **Argentina: Association of Research in Human Reproduction (ALIRH) Annual Meeting**

Objective: To provide support to the ALIRH annual meeting.

Ongoing and Completed Activities:

FHI, in collaboration with the Association for Voluntary Surgical Contraception (AVSC), will conduct a symposium on recent advances in contraception during the ALIRH conference. The meeting is scheduled to take place May 23-26, 1993 in Buenos Aires, Argentina. FHI will sponsor three speakers, Dr. Roberto Rivera, Dr. Linda Potter, and Mr. David Hubacher.

Results, Accomplishments, Problems: None.

Next Six Months Planned Activities: None.

o **Mexico: Latin American Symposium on Sexual Health and Family Planning**

Objective: To provide support for the Latin American Symposium on Sexual Health and Family Planning scheduled for November 30 - December 4, 1992 in Mexico City, Mexico.

Ongoing and Completed Activities: FHI organized a session on "Contraception for Adolescence," including scientific presentations on oral contraceptives, IUDs, implants and injectables, and barrier methods. FHI sponsored the attendance of three Latin American investigators to participate as speakers in the FHI sponsored round table discussion.

Results, Accomplishments, Problems: Relationships were strengthened with Latin American investigators and FHI has had the opportunity to collaborate with IPPF/WH, UNFPA, the Population Council, and Pathfinder International (Boston) on an important regional event.

Next Six Months Planned Activities: None.

o **Mexico: Journalists Workshop**

Objective: To increase the dissemination of accurate, relevant and timely information on family planning and reproductive health (including AIDS) through the news media to the public and policy makers.

Ongoing and Completed Activities: We proposed this workshop to A.I.D. and USAID/Mexico at the beginning of January, and recently to the National Population Council of Mexico (CONAPO) and the Mexican Social Security Institute (IMSS). Specifically, the workshop will be designed to: a) build the participants' skills in reporting on family planning and reproductive health issues, b) examine and put into practice ways to overcome obstacles to effective reporting on these topics, and c) create a network of skilled journalists and health and family planning professionals that will encourage the flow of information.

Results, Accomplishments, Problems: Concurrence from USAID/Mexico is pending.

Next Six Months Planned activities: If the workshop is approved, we plan to conduct the training needs assessment, workshop and evaluation.

## **H. Information Dissemination**

### **1. Program Area Summary**

FHI publishes scientific articles and disseminates information on key research findings to collaborating researchers, organizations, and health personnel in more than 80 countries. The Information Dissemination Program targets health providers, policymakers, and the media through technical and non-technical publications, and technical assistance in information dissemination.

Each year, FHI staff and collaborating researchers publish findings in national and international scientific journals. The most important findings are selected by FHI for broader dissemination to appropriate health personnel through publications, workshops, and meetings. FHI reaches more than 30,000 subscribers who work in health and development with its international health bulletin, Network (in English, French and Spanish), as well as 40,000 readers who receive individual copies upon request, and many others through its Scientific Article Translation Series. It is able to mobilize quickly to disseminate timely information to USAID Missions, investigators, other organizations and the media on new and urgent issues, such as vasectomy and prostate cancer.

FHI's information program priority is ensuring that reproductive health research results reach developing country audiences in order to improve knowledge of reproductive health, support improvements in health policy, complement efforts to introduce new contraceptive technologies such as Depo-Provera, and answer programmatic questions related to family planning service delivery.

In FY 1994, FHI plans to continue its emphasis on reaching physicians with information to help remove medical barriers which limit access to contraceptives in developing countries. It plans to continue expanding the circulation of its regular publications, to disseminate information more aggressively to policymakers and to increase the amount of technical assistance given to health personnel and developing country media in the area of information dissemination. The topics that will be given greatest priority in these dissemination efforts are medical barriers to access to contraception and quality services, new contraceptive technologies, especially Depo-Provera, costing, and family planning and STDs.

## 2. Progress Reports

### a. Regular Publications

#### o **FHI's International Health Bulletin (Network)**

Objective: To disseminate comprehensive and timely information on contraceptive technology and reproductive health, in particular recent research findings in an in-depth but non-technical fashion to developing country family planning and health personnel, scientists, government officials, media, donors, and sister agencies.

Ongoing and Completed Activities: The issue of Network (13:2) on breastfeeding was distributed in October to more than 7,000 subscribers, with 673 sent with press releases to US and international media. Network (13:3) on reducing medical barriers and improving access to contraception was completed, and 17,500 were printed, with 10,000 distributed to date. In March, a press release on the issue went to 937 US and international reporters, and a letter introducing the issue went to all individuals and agencies involved in USAID Reduction of Medical Barriers working groups. (An issue on AIDS and women (13:4), was nearly completed in March under FHI's AIDSCAP Cooperative Agreement.)

Results, Accomplishments, Problems: The RMB/IAC issue, the first publication disseminated by an A.I.D. collaborating agency to address all major areas of focus contained in the Reduction of Medical Barriers Initiative, reached an expanded audience through steady efforts to increase the mailing list and total circulation of Network. In addition, targeted mailings of both the breastfeeding and reduction of medical barriers issues to experts and agencies interested in these particular topics enhanced the impact of Network as a source of scientific information for audiences such as USAID Missions and health personnel in ministries.

Next Six Months Planned Activities: Two issues of Network will be completed, one with a special section on Quality of Care and other articles on contraceptive technologies (14:1) and one on adolescents and family planning (14:2). The mailing list will continue to expand from approximately 8,500 to about 12,000. Press releases will be sent to an expanded media list. Planning of themes for FY 94 will be completed. Efforts to place Network material by recasting articles for publication in regional news publications in Africa and Asia will continue.

o **Network en español**

**Objective:** To produce two 36-page issues of FHI's reproductive health and family planning bulletin in Spanish in order to provide current and comprehensive information in a non-technical but scientifically credible way to health providers, ministries, USAID Missions, policymakers, and media in Latin America and the Caribbean.

**Ongoing and Completed Activities:** FHI translated and published 12,000 copies of issue 8(1) on breastfeeding. Copies were sent to 8,600 recipients, including approximately 1,000 mailed to Latin American journalists with an accompanying news release.

More than 11,300 copies of an index to Volumes 1-7 listing Spanish-language articles from 1986-92 were published, and approximately 7,000 were mailed along with the breastfeeding issue to regular subscribers and media.

Production of issue 8(2), the first comprehensive publication by a collaborating agency on reduction of medical barriers available in Spanish for Latin American health providers and policymakers was completed. Printing is scheduled for April.

The Pan American Health Organization provided FHI its mailing list of 2,500 Latin American family planning providers and ob/gyns. PAHO's list was downloaded into FHI's new integrated on-line mailing list database system and is being checked for duplications. Information obtained from several hundred Spanish-language respondents to a recent survey of readers' interests was entered into the new database.

**Results, Accomplishments, Problems:** Through sustained efforts to increase circulation, FHI has substantially increased the flow of pertinent, accurate and timely information to Latin America. One hundred and fifty requests for new subscriptions are received each month. Subscriptions have increased 12 percent, from approximately 8,600 to more than 10,900 in this reporting period.

**Next Six Months Planned Activities:** Production of the issue on improving access to contraception will be completed and copies will be disseminated to approximately 10,900 regular subscribers. Bulk issues will be offered to USAID Missions and health agencies involved in AID's Reduction of Medical Barriers Initiative. FHI will translate, publish and distribute another two issues of the Spanish-language

bulletin, including one on women and AIDS funded by FHI's AIDSCAP Division and the Office of Health, and will disseminate accompanying press releases. Work to increase circulation of the bulletin will continue.

o **Network en français**

**Objective:** To produce two 36-page issues of FHI's reproductive health and family planning bulletin in French in order to provide current and comprehensive information in a non-technical but scientifically credible way to health providers, ministries, USAID Missions, policymakers, and media in francophone Africa and Haiti.

**Ongoing and Completed Activities:** FHI translated and published 8,000 copies of issue 8(1) on breastfeeding. Copies were sent to 6,400 subscribers, and an additional 650 were sent with a press release to francophone news media in Africa. A nine-page index to Volumes 1-7 of Network en français covering 1986-1992 articles was published and distributed to subscribers and francophone media. Production of issue 8(2), the first comprehensive publication by a collaborating agency on reducing medical barriers available in French, is currently underway. Printing is scheduled for May.

The French mailing list was cleaned and added to FHI's new integrated on-line mailing list database system, and information obtained from 176 respondents to a recent survey of readers' interests was entered into the new database.

**Results, Accomplishments, Problems:** Through sustained efforts to increase circulation, FHI has substantially increased the flow of pertinent, accurate and timely information to the francophone developing world. As a result of a targeted effort to increase circulation of the French bulletin, 371 francophone African journalists were added to the mailing list. Requests for new subscriptions are received nearly every day. Direct readership has increased by approximately 7%, while circulation to media has increased by 134% since the last reporting period.

**Next Six Months Planned Activities:** Production of the issue on improving access to contraception will be completed and disseminated to 6,400 regular subscribers. Bulk issues will be offered to USAID Missions and health agencies involved in AID's Reduction of Medical Barriers Initiative. FHI will translate, publish and distribute

another two issues of the bulletin, including one on women and AIDS funded by FHI's AIDSCAP Division and the Office of Health, and will disseminate accompanying press releases. Work to increase circulation of the French bulletin will continue.

**o Article Translation Series**

Objective: To translate and publish key scientific articles not currently available in French or Spanish-language medical journals in order to provide current research findings on reproductive health and contraception to investigators in Francophone Africa, Latin America and Haiti.

Ongoing and Completed: FHI selected five scientific articles recently published in English-language journals for translation into Spanish and four articles for translation into French.

Results, Accomplishments, Problems: The materials are in translation.

Next Six Months Planned Activities: FHI will translate, review, lay out and print five scientific articles in Spanish and four in French, and distribute them to investigators and physicians in Latin America, Francophone Africa and Haiti. Work to increase circulation to physicians in targeted countries will continue.

**b. Information Dissemination**

**o Information Dissemination Program**

Objective: To disseminate information on reproductive health to the field and to collaborating organizations worldwide, especially on controversial issues, new technologies, and new research findings on contraceptive safety; and to provide technical assistance in effective communication strategy development and information dissemination in order to enhance the ability of health personnel in the field to improve family planning services.

Ongoing and Completed Activities: FHI responded to 2,065 requests for information on contraception and reproductive health from USAID Missions, health personnel, policymakers, and other organizations in this reporting period, representing a more than 100 percent increase in requests over the same period last year.

FHI's on-line integrated mailing list system containing more than 18,000 records searchable by language, type of organization, country, and identified areas of interest (IUDs, injectables, breastfeeding, STDs, etc.) was developed, and all FHI divisions were trained in its use and maintenance. In anticipation of two scientific journal articles being published linking vasectomy and prostate cancer, interpretive materials were written, the new mailing list database was used to generate a list of researchers interested in vasectomy, and packets were distributed to 2,018 USAID Missions, researchers and developing country media in English, French and Spanish. Publications staff continued work to increase FHI mailing lists for Network and other information dissemination purposes.

Results, Accomplishments, Problems: As a result of coordinated dissemination of materials on vasectomy and prostate cancer, balanced and accurate articles on the risks and benefits of vasectomy appeared in countries around the world, and USAID Missions and investigators were prepared to respond to any related controversy. A total of nine English, two French and two Spanish press releases were issued by FHI over the reporting period to hundreds of publications and broadcast media in the United States and developing countries, including a press release on a contraceptive technology seminar held in Alma Ata on family planning in the Central Asian Republics. FHI media efforts resulted in news coverage of research findings in media such as the *Washington Post*, the *New Scientist*, the (Colombia) *Tribuna Médica*, the Vietnamese Service of the Voice of America, and major daily newspapers in Sri Lanka, Tanzania, and Bangladesh.

Next Six Months Planned Activities: Expanded information dissemination efforts will focus on the introduction of Depo Provera in country programs, quality of care, and follow-up to the issue on improving access to contraception (reduction of medical barriers). A release on the French and Spanish Network issue on reduction of medical barriers will be mailed by May. Timely press releases will be circulated on important FHI work. An FHI working paper series will be established. A one-day seminar for 19 Kenyan journalists on family planning, co-sponsored by the African Council on Communication Education, as a follow-up activity to the September 1992 journalism training workshop, will be held in Nairobi in May, 1993.

o **Library**

Objective: To provide information services to FHI staff, consultants, visitors and projects; to support the dissemination of information on contraceptive research.

Ongoing and Completed Activities: FHI's in-house library collection was maintained and library services provided to FHI staff and investigators. Library automation software was installed and a three-day training session for library and Scientific Support staff was completed. Standards for cataloging record formats were reviewed and established. New monographs are being added to the database and retrospective conversion of older material has begun. In addition, with funding from AIDSCAP, technical assistance was provided to the AIDSCAP Project in developing their library and information services.

Results, Accomplishments, Problems: Three new CD-ROM databases have been added. In-house databases have expanded and new ones were developed for trip reports, paper proposals, working papers, books on AIDS, Network articles and other documents. Five library staff members have been trained to process catalog records. Indexes of Network articles in English, Spanish and French were produced. Technical assistance was provided to other divisions for the development of databases in biostatistics, breastfeeding and progesterone-only oral contraceptives. An average of 85 searches and 83 document requests per month were completed.

Next Six Months Planned Activities: Routine library services will continue. Retrospective conversion of book records available from the Library of Congress and the National Library of Medicine should be largely completed. Other catalog data sources will be explored and original cataloging will be done. The automated public access catalog will become available for staff use. Development of the working paper series and database will be completed.

o **Publications Catalogue**

Objective: To make available a listing of current FHI scientific publications in order to facilitate dissemination of research findings on contraception.

Ongoing and Completed Activities: The information staff have entered reference information for new FHI publications into the PROCITE database. Staff continued to update the database, and work to design and print the catalogue has begun. A database of FHI working papers has been developed and maintained.

Results, Accomplishments, Problems: The annual list of FHI publications and working papers was produced and the database was made available to all FHI staff, some of whom received training in use of the database.

Next Six Months Planned Activities: Publications staff will design, typeset, print and distribute the Publications Catalogue to approximately 10,000 health providers, USAID Missions, ministries and researchers to provide them the opportunity to access FHI monographs, non-technical publications and scientific journal articles on contraception.

o **Reducing Medical Barriers to Contraception**

Objective: To reduce the medical barriers to contraceptive service in developing countries among health providers and policymakers that are expressed in outdated policies and practices; and to encourage collaborating agencies to include a focus on improving access to contraception.

Ongoing and Completed Activities: FHI has continued to participate in the Interagency Task Force on Medical Barriers through participation in three working groups, including chairing the Organized Educational Events subcommittee and contributing to a March meeting on Depo-Provera introduction. FHI will continue to develop a strategy for overcoming key medical barriers that effectively limit contraceptive use at selected sites in specific countries. Work will include performing on-site analysis and policy review of the determinants of these medical barriers, verifying assumptions about levels of correct information on the part of health providers, and developing a prototype program designed to remove barriers at selected sites.

Results, Accomplishments, Problems: Work on developing FHI's strategy and coordination of reduction of medical barriers activities with other collaborating agencies has proceeded, and key issues in improving access to contraception have been articulated. These are being addressed through education and training, policy revision and research activities addressed elsewhere in this report.

**Next Six Months Planned Activities: To continue to manage and coordinate FHI's overall efforts in reduction of medical barriers, and to outline a monograph on key topics for dissemination to policy and provider audiences.**

# **I. USAID Mission Program Support**

## **1. Program Area Summary**

When requested by USAID Missions, FHI works with host government authorities, cooperating agencies, and other donors to contribute to the overall development, management, and promotion of national family planning programs. In Nigeria, following FHI staff participation in a management review exercise, significant FHI involvement in the Family Health Services (FHS) Project has evolved under a bilaterally funded add-on to FHI's Cooperative Agreement. In Nepal, a government request for an FHI staff Resident Advisor resulted in the USAID Mission endorsement of a one-year assignment supported through add-on and central funding. FHI has relocated one of its senior researchers to Kathmandu for a one-year period to serve as Resident Advisor to the MOH and National Planning Commission.

## **2. Progress Reports**

### **o Nigeria: Family Health Services Project**

Objective: To support the Nigerian Family Health Services (FHS) Project through the provision of long- and short-term technical assistance, including support for the Project Administrator and Deputy Project Administrator positions, and through the implementation of complementary FHI activities aimed at strengthening policy-relevant research and its utilization in Nigeria. This project is funded through a bilateral add-on to FHI's Cooperative Agreement.

Ongoing and Completed Activities: FHI has supported the FHS Project Administrator since September 1991, and the Deputy Administrator since January 1992, through a subagreement with the International Science and Technology Institute, Inc. (ISTI). During the period covered by this report, the subagreement with ISTI was revised to permit various adjustments between line items and to provide additional funds. Almost all of the additional funds will be used towards the local production of an orientation video for the FHS Project. Apart from its role with ISTI and the FHS Administrators, FHI staff and consultants have worked on specific projects as requested by USAID/Lagos and the FHS Project. One such task, the institutional assessment of the Planned Parenthood Federation of Nigeria (PPFN), has been completed. The resulting report will be disseminated once it is fully reviewed and approved by USAID/Lagos.

Another report, a technical analysis with recommendations for a research component in the FHS-II Project, was drafted in North Carolina and is pending incorporation of various review comments. A third large activity, the evaluation of the impact of training conducted under the FHS Project, is on-going. Data collection was subcontracted by FHI to the Operations Research Unit at Obafemi Awolowo University; FHI staff provided technical assistance with the survey design and with the on-going analysis. A final report documenting the impact of FHS training is expected by June 1993. Lastly, during this reporting period, FHI's Director of the Field Operations Division attended the FHS II Project Design Workshop, held February 22-26, 1993 in Lagos. During this meeting several activities complementary to FHI's role with the FHS Project, namely contraceptive technology update training and costing studies, were identified as potential projects for FHI development.

Results, Accomplishments, Problems: With a project the size and complexity of FHS, one of the key needs is sound management. FHI assists in meeting this need through its role with ISTI and the FHS Administrators. The other activities undertaken to date by FHI were likewise identified as needs by USAID/Lagos and the FHS Project. The PPFN assessment, the training evaluation and the recommendations for contraceptive research should all prove useful in designing future project activities. The PPFN report was completed in FY92; it will be more widely disseminated once it has been fully reviewed by USAID/Lagos. The completion of the technical analysis paper, with recommendations for contraceptive research in Nigeria, was delayed due to a changeover of staff at FHI; the report will be completed during the next reporting period. No problems are anticipated with the training impact study report. In the past, FHI has been hampered in developing complementary activities in Nigeria by USAID/Lagos's understandable desire to minimize the already large number of visitors from the various Cooperating Agencies who travel to Nigeria to work with the FHS Project. The representation of FHI at the Project Design meeting was, in this respect, a new opportunity for FHI to identify country needs with which our organization might appropriately assist. FHI is now optimistic that complementary activities can move forward with another installment of bilateral funding.

Next Six Months Planned Activities: Support for the FHS Administration will continue through FHI's subagreement with ISTI. This is likely to include the provision of a facilitator for a June 1993 planning workshop for the newly configured FHS staff. In addition, a

proposal has been received from the Association of General and Private Medical Practitioners of Nigeria for FHI to provide support and a speaker for a contraceptive technology update (CTU) activity in mid-May. If approved, the scope of the speaker's assignment may be enlarged to do forward planning for a larger CTU at the Annual Meeting of the Association in March, 1994. FHI is also moving forward with planning costing studies, preferably in conjunction with other Cooperating Agencies working with the service delivery providers in Nigeria.

o **Nepal: FHI Support to USAID/Kathmandu and the Government of Nepal**

Objective: To assist the GON's Population Division of the National Planning Commission and Ministry of Health to formulate population policies and programs, and to conduct policy and programmatic research in population and family planning. This assistance is supported through a combination of add-on and central funding.

Ongoing and Completed Activities: To accomplish this objective, FHI has relocated Dr. Shyam Thapa to Kathmandu for a one-year period to serve as Technical Advisor to the MOH and National Planning Commission. Dr. Thapa has been in Kathmandu since January, 1993, and has established offices within the FP/MCH Division and the Planning Commission. He has collaborated in drafting the USAID Priority Country Strategy, the Safe Motherhood Program Initiative, and assisted in the design of the Family Planning Logistics Status Study and other program development activities. In addition, he has implemented a locally funded and managed program of small research grants and dissemination projects for which he also provides technical assistance. To date, the "Exploratory Study on High Risk Behavior for Women in Nepal" has been funded.

Results, Accomplishments, Problems: The priority country strategy paper is now in draft form and undergoing revision. Data now being collected by the "Exploratory Study on High Risk Behavior for Women in Nepal" is being used to create a profile of women practicing high risk behavior in order to assess their risk of pregnancy and of contracting STDs. in order to formulate appropriate policies by the GON. Problems were encountered by Dr. Thapa in establishing a residence and office, which has slowed administrative response and made communications difficult between Dr. Thapa and FHI.

**Next Six Month Planned Activities:** The "Exploratory Study on High Risk Behaviors" will be completed, and results submitted to the GON and USAID. Dr. Thapa will fund and manage 2-3 other small research projects under this same program, and continue to assist the GON in the implementation of FP programs and policies, and continue to serve as resource person to USAID/Kathmandu.

## **IV. Program Management**

### **o North Carolina Headquarters**

Under FHM's organizational structure, the Contraceptive Technology and Family Planning Research Cooperative Agreement is implemented by two departments, the Research and Development Department and the Population Programs Department. Both departments have undergone reorganization during this reporting period.

The divisions comprising the Research and Development Department have remained the same: Biostatistics Division, Clinical Trials Division, Materials Technology Division, Regulatory Affairs and Quality Assurance, and Scientific Support Services Division. However, two divisions, Clinical Trials and Scientific Support Services, have been reorganized internally.

The basic underlying premise of the Clinical Trials reorganization was to consolidate resources and provide efficient and timely coordination of all facets of the division's projects. Clinical Trials is now comprised of six distinct groups (Clinical Affairs Group, Clinical Operations Group, Data Management Group, Medical Writing/In-Service Group, Monitoring Group, and Special Programs), each under the leadership of an Associate Director/Associate Medical Director. All projects have a team that is responsible for coordination of activities which is facilitated by a Project Coordination Manager. The team guides and manages the project from inception to completion and interacts with the interdivisional teams.

The reorganization of the Scientific Support Services Division (SSS) was in response to changing requirements from the other divisions supported by SSS and to streamline the management structure. The new organization consists of five groups (Clinical Applications, Management Information System, Systems and Operations, Network Development, and Technical Services). The first four of these groups are headed by an Associate Director, while Technical Services is led by the Technical Services Coordinator. All group members report directly to the leader, eliminating one complete level of management from the previous structure.

The emergence of Management Information Systems and Network Development as separate groups underscores the growing activity in these areas. Previously, most new applications implemented were in

the area of clinical data management. However, the acquisition of one major software package and the implementation of another has greatly changed this area. Simultaneously, the demand for new, non-clinical applications necessitated the growth of the MIS group. Until recently, the FHI Network was virtually limited to one county in North Carolina; we now have computer installations on three continents, all telephonically connected, hence, the increased emphasis in this area.

Effective January 1, the Population Programs Department was reorganized to respond more effectively to the evolving challenges and opportunities of A.I.D.'s worldwide population program. The Department now consists of four divisions which work together closely to develop and implement programs of broad interest for FHI's population/family planning agenda, and concentrates resources and efforts in a number of countries that are of major importance for FHI's current and future programs.

The Contraceptive Use and Epidemiology Division focuses on research related to various contraceptive technology-related issues, such as acceptability, compliance, benefits and risks, and contraception and STDs. Ongoing studies of LAM (Lactational Amenorrhea Method) are also managed in this division.

The Service Delivery Research Division concentrates its efforts on research that addresses the provider side of family planning. Included in the research agenda of this division are the economics of family planning, quality of care, and research to evaluate and support service delivery programs.

The Policy and Research Utilization Division strives, through its work, to improve the dissemination and use of research findings to strengthen family planning programs and address policies that impede the provision of family planning services. The division includes FHI's information programs and a new emphasis on training as a key element of research utilization.

The Field Operations Division is responsible for the development and coordination of strategies for countries that are the focus of FHI's population/family planning programs. Field Operations will also be responsible for the institutional strengthening program and will provide support to the growing number of overseas staff and offices.

Newly formed interdivisional working groups provide a mechanism for collaboration among divisions in key program areas. Interdivisional working groups, with representation from each division, have been formed for the following priority areas: Contraceptive Introduction, Improving Access to Contraception/Reduction of Medical Barriers, Postpartum Contraception, Adolescent Reproductive Health, Family Planning & STDs/HIV.

o **Field Offices**

FHI strives to balance a centrally-funded research and support agenda of broad relevance to programs worldwide with meeting particular program needs in regions and specific countries. FHI also recognizes the importance of country-level input into the broader issues for setting global research and development priorities. To this end, FHI has strengthened its field presence through the establishment of a regional office in Kenya and the placement of advisors in selected countries.

An FHI Africa Regional Office was established in January 1992, headed by a Senior Representative from FHI's staff. The regional office and support to the Kenya country program were strengthened with the addition to the staff, in January 1993, of a research associate. The regional office continues to facilitate communication with individual USAID missions regarding future population activities, the development of interagency collaborative efforts with regional and local representatives of other CAs, and more efficient program development and monitoring of FHI supported activities in the region.

A resident advisor to the Ministry of Public Health in Nepal was placed in January, 1993. This FHI staff member is assisting the GON's Population Division of the National Planning Commission and Ministry of Health to formulate population policies and programs and to conduct policy and programmatic research in population and family planning.

In addition, FHI appointed a senior resident advisor for Southeast Asia in March, 1993. This advisor is funded through FHI corporate funds.

o **Development of a Management Information System**

A management information system (MIS) to create a company-wide database of projects and activities has been under development for several months, and is ready to be released for staff use. This MIS will consolidate basic information from all the divisions, and allow staff to have access to reliable, up to date information that can be used for monitoring and reporting purposes. Staff effort will be streamlined by having project information entered and maintained in a single electronic location. Access to a central database will expedite report writing and minimize duplication of effort across division lines. The MIS will also provide budget planning and project management support for staff.

The first stages of user testing for the MIS have been completed. The key portions of the system will be in operation by the end of FY'93.

## V. INTERAGENCY COLLABORATION

FHI attaches great importance to collaboration with other organizations, including A.I.D. cooperating agencies, in order to maximize the usefulness and effectiveness of resources and to enhance the utilization of research results. Aside from frequent and valuable routine interaction with other agencies (including WHO/HRP, IPPF, CONRAD, the Population Council, etc.), FHI has participated in several collaborative projects during this fiscal year.

### o **Norplant Worldwide Database**

FHI has managed and maintained the combined database from the Population Council- and FHI-sponsored clinical trials of Norplant. The database was used to answer safety questions and summarize worldwide clinical trial experience. Data collection ceased on September 30, 1991, and analysis of the data has recently been completed. A manuscript of the trial results has been submitted for publication in *Studies in Family Planning*.

### o **Norplant Introduction**

FHI has taken the lead role in developing country-specific Norplant introduction strategies in El Salvador, Haiti and Senegal. Collaborating with JHPIEGO in each of these three countries, FHI staff have participated in joint team visits to meet with national counterparts to prepare the introduction plans. During FY'92 the Senegal introduction strategy was fully initiated with training, information and education, and research activities undertaken by FHI, JHPIEGO, AVSC and HealthCom. In FY'93 the research component of the Senegal Introduction Strategy was begun with a study of the clients' perspective of Norplant at the clinics in Dakar. JHPIEGO is conducting a complementary analysis of the clinical and counseling components of Norplant services. The El Salvador and Haiti projects will be initiated in FY'93, with specific components being coordinated by FHI, JHPIEGO, or other CAs and international health organizations as appropriate.

### o **Evaluation of Immediate Post-placental IUD Insertion**

FHI is collaborating with AVSC on a training and research project designed to evaluate the acceptability of immediate post-placental IUD (IPPI) insertion. The project is being carried out in Kenya and Mali. AVSC sponsored the clinical training of physicians and nurse-midwives in the IPPI insertion technique. FHI arranged focus group discussions (FGDs) through a PATH consultant to determine postpartum contraceptive needs and interests. AVSC plans to use the FGD findings to develop IEC materials targeted at postpartum women. The research phase of the project began in

FY92 to assess both clinical and programmatic outcomes, including provider skill, IUD performance, timing of insertion, user satisfaction, cost, and impact on contraceptive use. The studies will be completed and analysis performed during FY93. FHI and AVSC will disseminate the findings and recommendations to service providers and policymakers, as well as family planning researchers.

o **Improving Access to Contraception (IAC)**

Along with Population Communications Services (PCS), FHI has been designated as a lead coordinating CA for work in improving access to contraception through reducing medical barriers. FHI participates in each of the IAC working groups: country level analysis, service delivery guidelines, and organized educational events (chaired by FHI) as well as related task forces. FHI helped design and analyze a questionnaire on medical barriers addressed to USAID health and population officers. FHI collaborates with other agencies on organized educational events to reduce medical barriers.

o **Quality of Care in Service Delivery**

FHI is represented on the Committee on Service Delivery of the EVALUATION project. The committee is currently developing indicators to assess quality of care in family planning. Following up on a workshop held jointly with CEDPA in FY92, FHI has worked with service delivery CAs to expand the use of SQI (Service Quality Improvement) as a mechanism to improve family planning services. FHI participated in an MSH panel on quality improvement, in an IPPF workshop on Quality of Care in South Asia and a PAHO/FHI workshop to develop an integrated model of Quality of Care in Reproductive Health (family planning, maternal health and STDs/HIV). An FHI staff member was a guest editor on a supplement to MSH's *Family Planning Manager* on continuous quality improvement (CQI) for family planning.

o **SEATS**

FHI and the JSI/SEATS Program have a Joint Memorandum of Understanding to work together in selected low-prevalence countries to increase the acceptance of contraception and provide quality services. Under this collaboration, FHI will collaborate in the evaluation of SEATS service delivery interventions. To date, FHI has participated in the design of a client satisfaction survey at selected family planning clinics in Lomé, Togo; other work is likely to occur in Burkina Faso, Cameroon and possibly Malawi. Under the Joint Memorandum of Understanding, FHI funds the research technical assistance, while SEATS supports all direct in-country service delivery intervention costs.

- o **Kenya: Study of Reversible Contraception and HIV in Women**  
FHI has completed a pilot study in Kenya to demonstrate the feasibility of conducting a full-scale nested case/control study to evaluate the relationship between reversible contraceptive methods (OCs, IUDs, DMPA) and the risk of acquiring HIV infection. The pilot study was jointly funded by A.I.D., the National Institute of Child Health and Human Development (NICHD), the World Health Organization (WHO), and Ortho Pharmaceuticals. A proposal for the full scale study, expanded to seven sites in Nairobi, Kenya, will be submitted to the National Institutes of Health (NIH) in May, 1993. If funding is secured, the study will be initiated in the last quarter of 1993.
  
- o **Nigeria: Family Health Services (FHS) Project**  
The FHS Project is a complex program involving five prime contractors and numerous subcontractors, aimed at increasing the acceptability and availability of family planning information and services throughout Nigeria. Following a Management Review of the project in 1991 (coordinated by the Population Technical Assistance Project), FHI was asked by A.I.D. to become involved in the management and support of the project. With an add-on to our Cooperative Agreement, FHI's involvement began in September 1991. Through a subagreement with ISTI, FHI has continued to support the FHS Project in FY93 by providing long term technical advisers (LTAs) to serve as Project Administrator and Deputy Administrator. The Administrator and Deputy Administrator work closely with the Nigerian Federal Ministry of Health, state and local health authorities, the private sector, USAID/Lagos, and the Project's many contractors to strengthen the service delivery orientation of the FHS Project, coordinate its components, and improve strategic planning for the current Project and beyond.

FHI is providing other short term technical assistance as appropriate, including the completion of a collaborative project with the Operations Research Unit of Obafemi Awolowo University to evaluate the impact of training provided under the FHS Project. In consultation with USAID/Lagos, FHI will also seek to develop complementary projects, to study programmatic issues and increase access to contraception in Nigeria. Toward this end, the Director of FHI's Field Operations Division attended the FHS II Project Design Workshop in February, 1993. During this meeting, several activities complementary to FHI's role with the FHS project, namely contraceptive technology update training and costing studies, were identified as potential projects for FHI development.

- o Brazil: Evaluation of BEMFAM's Reproductive Health Approach to Family Planning**  
 FHI has worked with JHPIEGO since 1990 to develop and implement an evaluation component within the JHPIEGO/BEMFAM family planning training program. The training program has emphasized the concept of reproductive risk assessment, both by physicians and paramedic health agents, in an effort to achieve the best possible method selection by new family planning clients as well as good technique by providers. All in-country costs of the project were funded by JHPIEGO, with FHI contributing the salary and travel costs of the evaluation research specialist. In FY'93, data analysis was completed and the results presented at the APHA annual meeting in November 1992, and via a final report and a seminar in Ceará, Brazil in January 1993 for state and private health care providers.
- o Honduras: 1991 Family Health Survey**  
 In designing the questionnaire for the 1991 Honduran Epidemiology and Family Health Survey, FHI cooperated with several organizations, including SOMARC, HealthCom and World Rehabilitation, to include program relevant questions. At the country level, FHI worked closely with Management Sciences for Health (MSH) and the Academy for Educational Development (AED). Data analysis was completed with the help of MSH, AED, and WELLSTART; copies of the final reports will be sent to these agencies.
- o Ecuador: Evaluation of Follow-up Schedules for IUD Users**  
 In FY'93, FHI completed a project with the Population Council's INOPAL II Project and with CEMOPLAF, an Ecuadorian PVO, to evaluate the impact of different IUD follow-up schedules. The objective of the study was to determine whether fewer scheduled follow-up visits could reduce costs without compromising safety. Results of the study showed that under a less stringent follow-up policy the number of undetected IUD-related problems would rise slightly, but costs to CEMOPLAF and clients would be greatly reduced. Study results were presented in March 1993 to CEMOPLAF service providers and other Ecuadorian health entities (Ministry of Health, Social Security Institute), as well as representatives of international organizations working in Ecuador (USAID, PAHO, UNFPA, CARE). As a result of these presentations, CEMOPLAF decided to reduce from four to one the number of recommended follow-up visits for IUD acceptors; the timing of the one remaining visit has not yet been determined, although it likely will be fixed at between 15 and 45 days post-insertion.

- o Ecuador: Institutionalization of Sustainability-Related Research and Evaluation Capabilities in a Family Planning Organization**

CEMOPLAF, an Ecuadorian PVO, is seeking ways to become more self-sufficient, focusing primarily on cost-control and income generation. USAID/Ecuador is helping CEMOPLAF to strengthen its capabilities in sustainability-related research and evaluation through an add-on to the Population Council INOPAL II project and FHI. The project will begin in FY93, and will continue for 2.5 to 3 years. FHI and INOPAL will provide training in economic analysis of programs, analysis of market segments, basic research methodology, and use of a management information system. FHI will also give technical assistance in design and analysis for several small research studies related to the general theme of institutional sustainability. INOPAL II is purchasing computer hardware and software to support CEMOPLAF's evaluation unit, while FHI and INOPAL II are sharing the costs of the training and research activities.
- o Ecuador: Introduction of an Injectable Contraceptive in a Family Planning Program**

CEMOPLAF, an Ecuadorian PVO, wants to add Depo-Provera (DMPA) to its contraceptive method mix. The Ecuadorian Ministry of Health (MOH) has agreed to allow the agency to introduce Depo-Provera as part of a programmatic research study to examine DMPA's acceptability, costs and impact on contraceptive use in Ecuador. FHI, The Population Council INOPAL II project, and World Neighbors will collaborate with CEMOPLAF to develop and evaluate this project, which will begin in FY93 and continue into FY94.
- o PATH Condom Technology Evaluation**

FHI is working with PATH to supplement and complement our own condom technical evaluations. FHI is currently funding a package integrity study designed to evaluate the stability of latex condoms stored under elevated temperature and humidity for a four year period. FHI is also funding a collaborative technical assistance program that will further enhance the technical expertise of the two organizations by consulting with one another on condom technology issues. PATH will be conducting semiannual inter-laboratory studies with FHI to monitor and improve data correlations among referee laboratories. These projects were initiated in FY92 and will continue through FY94.

- o **Cooperating Agencies Meeting on Depo-Provera: Providing Quality Services**  
 Working with AVSC and the Population Council, FHI organized a meeting on Depo-Provera: Providing Quality Services, held in New York City on March 4, 1993. The purpose of this meeting was to share information on worldwide experience with Depo-Provera; to assess the resources needed to carry out an introduction program that ensures quality services; and to identify resources already in place and gaps that need to be addressed by the cooperating agencies and in-country organizations. The meeting was co-sponsored by eight USAID cooperating agencies, including the three organizing agencies, and was attended by approximately 100 persons.
- o **Interagency Collaboration Barrier Methods**  
 FHI staff members attended a WHO meeting in Manila, Philippines that brought together representatives of women's health advocacy groups, researchers, and government leaders from Bangladesh, India, Indonesia, and the Philippines. As a result of this meeting, WHO has organized an interagency group on barrier methods to develop projects that respond to the need for the reintroduction of the diaphragm and other female user-controlled barrier methods. The group has met several times and is in the process of designing several related introductory studies on the diaphragm to be conducted by the participating agencies in collaboration with local agencies.
- o **Service Delivery Guidelines: Reducing Medical Barriers in Africa**  
 FHI is working closely with INTRAH to provide assistance in introducing family planning policies and guidelines in Cameroon and Burkina Faso. Working together, a team of FHI and INTRAH staff planned joint in-country site visits. In Cameroon, the joint efforts will include a national seminar and five regional workshops to disseminate new service delivery guidelines, and a study of the impact of these guidelines on provider practices. In Burkina Faso, the joint project hopes to conduct a medical barriers needs assessment and a CTU. FHI and INTRAH have plans to investigate opportunities in other countries in Africa.

## **VI. Financial Information**

### **A. Summary of Expenditures**

**AID/DPE-0537-A-00-4047-00**

#### **Expenditures By Type**

**1 October 1993 - March 31, 1993**

Salaries and Fringe Benefits	<b>\$27,066</b>
Service Centers	<b>416</b>
Consultant, Professional Fees, Contracted Labor	<b>445</b>
Travel - Domestic	<b>0</b>
Travel - Foreign	<b>2,425</b>
Supplies - Medical	<b>0</b>
Printing and Reprints	<b>421</b>
Office/Medical Equipment, Maintenance and Repair	<b>4,477</b>
Freight	<b>210</b>
Registration Fees, Training Grant	<b>0</b>
Other Purchased Services	<b>863</b>
Key punching	<b>0</b>
Other Expenses and Bank Service Charge	<b>27,944</b>
Data Purchases	<b>0</b>
Subcontracts	<b>13,077</b>
General and Administrative Costs	<b><u>15,537</u></b>
<b>Total</b>	<b>\$92,881</b>

AID/DPE-3041-A-00-0043-00

Expenditures By Type

1 October 1993 - March 31, 1993

Salaries and Fringe Benefits	\$2,735,915
Service Centers	381,944
Consultant, Professional Fees, Contracted Labor	128,283
Travel - Domestic	116,258
Travel - Foreign	248,455
Supplies - Office	12,614
Supplies - Medical	23,879
Printing and Reprints	31,365
Office/Medical Equipment, Maintenance and Repair	183,366
Freight	12,508
Registration Fees	28,062
Subscription, Publications	7,365
Other Purchased Services	108,305
Keypunching	6,279
Other Expenses and Bank Service Charges	39,741
Subcontracts	814,614
General and Administrative Costs	<u>\$1,262,610</u>
Total	\$6,141,563

**B. Program Area Budgets by Region**

**1. Contraceptive Technology Development and Clinical Trials Activities by Region and Funding Source**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>AFRICA:</b>			
Ghana SYS - NORPLANT	15,819	17,153	3,941
Kenya SYS - POC in Breastfeeding Women	27,645	22,133	25,847
Nigeria SYS - NORPLANT	60,111	65,180	14,975
Senegal NORPLANT	4,302 *	17,400 *	30,677 *
Zimbabwe SYS - POC in Breastfeeding Women	8,131	6,510	7,602
<b>TOTAL AFRICA</b>	<b>116,008</b>	<b>128,376</b>	<b>83,042</b>
From Central Funds	111,706	110,976	52,365
From Add-On Funds	4,302	17,400	30,677

\* Denotes Mission or Bureau Add-On Funds

**1. Contraceptive Technology Development and Clinical Trials Activities by Region and Funding Source (Continued)**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>ASIA/NEAR EAST:</b>			
<b>Bangladesh</b>			
SYS - NORPLANT	26,892	29,159	6,699
NORPLANT	14,999 *	13,000 *	0 *
NORPLANT Bleeding RX	5,698		(5,698)
	18,001	0	158,451
	<hr/>	<hr/>	<hr/>
	65,590	42,159	159,452
<b>Malaysia</b>			
SYS - POC in Breastfeeding Women	8,131	6,510	7,602
<b>Nepal</b>			
SYS - NORPLANT	949	1,029	236
<b>Pakistan</b>			
NORPLANT Clinical Trials	11,942 *	7,200 *	22,353 *
<b>Philippines</b>			
SYS - NORPLANT	36,383	39,451	9,064
SYS - POC in Breastfeeding Women	4,878	3,906	4,561
	<hr/>	<hr/>	<hr/>
	41,261	43,357	13,625
<b>Sri Lanka</b>			
SYS - NORPLANT	18,033	19,553	4,492
<b>TOTAL ASIA/NEAR EAST</b>	<hr/>	<hr/>	<hr/>
	145,906	119,808	207,760
From Central Funds	118,965	99,608	185,407
From Add-On Funds	26,941	20,200	22,353

\* Denotes Mission or Bureau Add-On Funds

**1. Contraceptive Technology Development and Clinical Trials Activities by Region and Funding Source (Continued)**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>LATIN AMERICA/CARIBBEAN:</b>			
<b>Columbia</b>			
Use of Condoms/Spermicides and STDs	9,881	44,643	86,747
<b>Dominican Republic</b>			
Reality Vaginal Pouch	12,197	10,325	4,205
<b>El Salvador</b>			
NORPLANT	17,473 *	60,632 *	63,751 *
<b>Haiti</b>			
NORPLANT	8,317 *	9,164 *	846 *
<b>Mexico</b>			
SYS - POC in Breastfeeding Women	113,831	91,135	106,431
NSV/Cautery Ligation	2,825	7,535	117,183
Reality Vaginal Pouch	24,394	20,650	8,411
Infer. Vasectomy	10,011	45,724	124,975
	151,061	165,044	357,000
<b>TOTAL LATIN AMERICA/CARIBBEAN</b>	<b>198,929</b>	<b>289,808</b>	<b>512,549</b>
<b>From Central Funds</b>	<b>173,139</b>	<b>220,012</b>	<b>447,952</b>
<b>From Add-On Funds</b>	<b>25,790</b>	<b>69,796</b>	<b>64,597</b>

\* Denotes Mission or Bureau Add-On Funds

**1. Contraceptive Technology Development and Clinical Trials Activities by Region and Funding Source (Continued)**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>USA/EUROPE:</b>			
<b>England</b>			
Barrier Guidelines	21,813	18,750	15,687
Vaginal Methods, Diaphragm	21,278		(21,278)
	<b>43,091</b>	<b>18,750</b>	<b>(5,591)</b>
<b>USA</b>			
Filshie Clip PMA	38,515	31,220	132,908
Plastic Condom Fabrication	30,199	48,586	39,799
Plastic Condoms Materials R & D	34,518	27,866	81,438
Plastic Condom Safety	4,266	17,280	33,613
SYS - NET Microspheres	51,596	63,363	66,984
Plastic Condom Test Dev.	11,470	10,404	57,278
Vaginal Methods, Film			0
Reality Vaginal Pouch	18,850	15,957	6,499
Plastic Condom Testing & Eval.	31,448	13,618	52,094
Tests of Prototype Plastic Condoms	64,215	56,178	64,395
Phase IB Eval. of NET Implants	117,488	97,354	114,376
FDA - Vaginal Barrier Device	130,731	139,402	62,273
Plastic Condom Machine Design & Dev.	75,812	81,056	(15,689)
FS - Nonsurgical/Iodine	14,165	11,675	79,220
Plastic Condoms Process R & D	20,747	18,784	52,415
	<b>644,020</b>	<b>632,743</b>	<b>827,603</b>
<b>TOTAL USA/EUROPE</b>	<b>687,111</b>	<b>651,483</b>	<b>822,012</b>
From Central Funds	687,111	651,483	822,012
From Add-On Funds	0	0	0

**1. Contraceptive Technology Development and Clinical Trials Activities by Region and Funding Source (Continued)**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>INTERREGIONAL:</b>			
<b>Interregional</b>			
Development/Management	653,890	408,648	55,047
Medical Review	26,062	31,322	17,053
Data Management	163,265	115,686	91,521
Plastic Condoms	55,253	31,984	66,470
Contraceptive Research/Development	22,088	17,862	7,063
SYS - General	15,328	6,982	5,716
Quality Assurance Training	1,477	0	(1,477)
Quality Assurance Auditing	4,064	0	(4,064)
R & D Interdivisional SOPS	1,517	0	(1,517)
NORPLANT Worldwide Clinical Data Base	1,784	2,055	39,894
IUD - TCU 380A	43,349	42,177	(793)
Male Sterilization	63,098	66,785	68,327
Regulatory Affairs	73,369	63,858	76,573
General Quality Assurance	49,248	43,053	66,513
Population Biostat Activity	65,522	77,686	72,330
Barrier Conference	12,754	23,193	56,822
Spain: Society Advance Contraception	27,500	42,000	16,282
Scientific Writing	57,794	50,517	85,330
Vaginal Methods/General	28,978	39,939	22,525
<b>TOTAL INTERREGIONAL</b>	<b>1,366,340</b>	<b>1,063,747</b>	<b>739,615</b>
From Central Funds	1,366,340	1,063,747	739,615
From Add-On Funds	0	0	0
<b>TOTAL ALL REGIONS</b>	<b>2,514,294</b>	<b>2,253,232</b>	<b>2,364,978</b>
From Central Funds	2,457,261	2,145,836	2,247,351
From Add-On Funds	57,033	107,396	117,627

**2. Condom Technology Evaluation Program Activities by Region and Funding Source**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>INTERREGIONAL:</b>			
<b>Interregional</b>			
Condom Prospective Aging Study	21,063	16,670	12,520
Condom Quality Testing	18,268	15,111	73,177
Condom Field Evaluations	28,217	40,778	99,690
Condom Functionality Trials	5,436	27,000	64,949
Condom Production Surveillance	242,674	111,037	(99,820)
Contraceptive Evaluations	8,173	2,924	89,286
Development and Management	86,196	51,000	22,780
<b>TOTAL INTERNATIONAL</b>	<b>410,027</b>	<b>264,520</b>	<b>262,582</b>
From Central Funds	410,027	264,520	262,582
From Add-On Funds	0	0	0
<b>USA/EUROPE:</b>			
<b>USA</b>			
Condom Research & Test Dev.	5,344	6,000	32,506
PATH: Condom Research	37,417	24,188	148,861
Special Condom Testing	60,658	43,772	34,204
<b>TOTAL USA/EUROPE</b>	<b>103,419</b>	<b>73,960</b>	<b>215,571</b>
From Central Funds	103,419	73,960	215,571
From Add-On Funds	0	0	0
<b>TOTAL ALL REGIONS</b>	<b>513,446</b>	<b>338,480</b>	<b>478,153</b>
From Central Funds	513,446	338,480	478,153
From Add-On Funds	0	0	0

**3. Contraceptive Acceptance and Use Program Activities by Region and Funding Source**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>AFRICA:</b>			
<b>Cameroon</b>			
Acceptability of Female Condoms	7,371	6,048	18,125
<b>Kenya</b>			
Vaginal Contraceptive Film	3,683	3,231	4,103
FPAK Cost of Family Planning	0	0	23,567
	<b>3,683</b>	<b>3,231</b>	<b>27,670</b>
<b>Multi National</b>			
SEATS: Project Development	677	7,000	45,388
<b>Zambia</b>			
Spermicide Accept. in STD Clinics	15,856	8,555	(7,074)
<b>TOTAL AFRICA</b>	<b>27,587</b>	<b>24,834</b>	<b>84,109</b>
From Central Funds	27,587	24,834	84,109
From Add-On Funds	0	0	0

**3. Contraceptive Acceptance and Use Program Activities by Region and Funding Source (Continued)**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>ASIA/NEAR EAST:</b>			
<b>Bangladesh</b>			
Cost of Methods	3,047 *	2,000 *	157,671 *
Bangladesh In-Depth Condom Study	1,596	3,000	2,883
Cost of Family Planning	20,231 *	15,000 *	32,846 *
	21,075		(21,075)
	45,949	20,000	172,325
<b>India</b>			
OC Studies	2,330 *	10,000 *	38,046 *
Social Marketing Evaluation	11,816	6,208	(14,343)
	14,146	16,208	23,703
<b>Nepal</b>			
FP Strategy Development	239 *	6,903 *	9,550 *
Smaller Condoms	19,378	24,548	9,303
	19,617	31,451	18,853
<b>Pakistan</b>			
LAM Trials	13,716	8,320	9,369
<b>Philippines</b>			
LAM Trials	19,254	11,680	13,153
<b>Thailand</b>			
NORPLANT Delivery by Nurses	7,489	5,000	18,097
	7,489	5,000	18,097
<b>TOTAL ASIA/NEAR EAST</b>	<b>120,171</b>	<b>92,659</b>	<b>255,500</b>
From Central Funds	82,508	52,548	31,730
From Add-On Funds	37,663	40,111	223,770

**3. Contraceptive Acceptance and Use Program Activities by Region and Funding Source (Continued)**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>LATIN AMERICA/CARIBBEAN:</b>			
<b>Dominican Republic</b>			
Vaginal Contraceptive Film	8,594	7,766	9,573
Multi-Site: Condom Use/Misuse	23,334	26,650	22,001
	<b>31,928</b>	<b>34,416</b>	<b>31,574</b>
<b>Ecuador</b>			
Flexible Schedules for IUD FU visits	9,847	10,600	12,625
Technical Assistance Sustainability	1,569	7,600	721
	<b>11,416</b>	<b>18,200</b>	<b>13,346</b>
<b>Honduras</b>			
Cost of FP ASHONPLAFA	12,369 *	15,900 *	5,840 *
1992 Family Health Survey	24,734 *	21,000 *	36,975 *
	<b>37,103</b>	<b>36,900</b>	<b>42,615</b>
<b>Jamaica</b>			
Medical Barriers	0	0	22,634
<b>Mexico</b>			
Study of OC Knowledge and Practices	22,702	22,546	11,751
Multi-Site: Condom Use/Misuse	5,122	5,850	4,829
Revise OC Use Instructions	0	60,000	11,548
Vaginal Contraceptive Film	8,184	7,363	9,117
Oral Contraceptive Use Instruc.	4,254	6,519	4,545
Flexible IUD Revisit	10,894	8,300	28,453
	<b>51,156</b>	<b>110,578</b>	<b>70,243</b>
<b>TOTAL LATIN AMERICA/CARIBBEAN</b>			
From Central Funds	<b>131,603</b>	<b>200,094</b>	<b>180,412</b>
From Add-On Funds	<b>94,500</b>	<b>163,194</b>	<b>137,797</b>
	<b>37,103</b>	<b>38,900</b>	<b>42,615</b>
<b>USA/EUROPE:</b>			
<b>USA</b>			
POC Labeling Instructions	36,185	30,000	22,259
Functionality & Acceptability	14,335	0	8,248
Breastfeeding & Women's Status	5,288	0	(3,584)
	<b>55,808</b>	<b>30,000</b>	<b>26,923</b>
<b>TOTAL USA/EUROPE</b>			
From Central Funds	<b>55,808</b>	<b>30,000</b>	<b>26,923</b>
From Add-On Funds	<b>0</b>	<b>0</b>	<b>0</b>

\* Denotes Mission or Bureau Add-On Funds

**3. Contraceptive Acceptance and Use Program Activities by Region and Funding Source (Continued)**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>INTERREGIONAL:</b>			
<b>Interregional</b>			
Test OC Instructions	155	30,000	23,647
Acceptability Paper Writing	32,961	46,661	37,889
RH Paper Prep. for Completed Projects	73,109	67,800	85,414
Medical Barriers Research	1,418	30,430	88,931
A.I.D./POP Operations Research Program	28,164	8,924	(19,240)
Quality of Care in Serv. Deliv.	28,813	28,567	58,846
Timing Distribution of POCs	4,204	7,500	27,045
Paper Writing for Cost Projects	2,892	20,000	47,844
Task Force on Accept. of New Methods	7,024	4,284	(1,504)
Service Delivery Dev. and Management	39,103	7,500	72,768
Bellagio II Conference	0	6,000	8,824
HIV/BF Paper Writing	898	2,000	4,255
BF & NFP Paper Preparation	37,536	30,000	14,684
Development and Management	253,033	237,519	410,560
Med. Barriers: Mtg. on Serv. Deliv.	11,268	14,239	(11,268)
Measuring OC Compliance MEMS Device	8,304	0	60,381
AIDS and Family Planning	14,570	10,000	(1,323)
OC Compliance	41,637	33,796	20,668
Nepal Regional Office	54,675	72,277	24,100
Quality of Care Workshop/PAHO	19,960	0	(2,463)
<b>TOTAL INTERREGIONAL</b>	<b>659,724</b>	<b>657,497</b>	<b>950,058</b>
<b>From Central Funds</b>	<b>659,724</b>	<b>657,497</b>	<b>950,058</b>
<b>From Add-On Funds</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>TOTAL ALL REGIONS</b>	<b>994,893</b>	<b>1,005,084</b>	<b>1,497,002</b>
<b>From Central Funds</b>	<b>920,127</b>	<b>928,073</b>	<b>1,230,617</b>
<b>From Add-On Funds</b>	<b>74,766</b>	<b>77,011</b>	<b>266,385</b>

**4. Contraceptive Introduction Program Activities by Region and Funding Source**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>AFRICA:</b>			
Kenya			
IUD Introduction	14,885	18,000	19,259
Mali			
Mali Postpartum IUD	8,919	25,000	39,453
Niger			
IPPI Introduction Study	0 *	0 *	52,957 *
Senegal			
NORPLANT Management	838 *	0 *	44,577 *
NORPLANT Management	41,361 *	82,000 *	(17,044) *
NORPLANT Management	4,227		(4,227)
<b>TOTAL AFRICA</b>	<b>70,230</b>	<b>125,000</b>	<b>134,975</b>
From Central Funds	28,031	43,000	54,485
From Add-On Funds	42,199	82,000	80,490
<b>ASIA/NEAR EAST:</b>			
Bangladesh			
Bangladesh PP Contra Meeting	204	500	0
Access NORPLANT Removal	8,323	0	(8,323)
Access NORPLANT Removal	10,633 *	0 *	3,690 *
	19,160	500	(4,633)
Philippines			
Philippines PP Contra Conference	13,679	10,000	0
Egypt			
NORPLANT Support	12,422 *	15,000 *	36,028 *
Jordan			
Birth Spacing Seminar	13,400 *	13,400 *	0 *
Birth Spacing Seminar	12,921	12,600	(12,921)
	26,321	26,000	(12,921)
Pakistan			
CTU Conference	0	0	59,886
Multi National			
ALMA ATA MCH Conference	29,180	0	6,783
<b>TOTAL ASIA/NEAR EAST</b>	<b>100,762</b>	<b>51,500</b>	<b>85,143</b>
From Central Funds	64,307	23,100	45,425
From Add-On Funds	36,455	28,400	39,718

\* Denotes Mission or Bureau Add-On Funds

**4. Contraceptive Introduction Program Activities by Region and Funding Source (Continued)**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>LATIN AMERICA/CARIBBEAN:</b>			
Haiti			
NORPLANT Introduction	6,843 *	5,000 *	11,064 *
El Salvador			
NORPLANT Introduction	303	0	13,180
Ecuador			
Depo. Intro. & Resupply	462	0	22,988
<b>TOTAL LATIN AMERICA/CARIBBEAN</b>	<b>7,608</b>	<b>5,000</b>	<b>47,232</b>
From Central Funds	765	0	36,168
From Add-On Funds	6,843	5,000	11,064
<b>INTERREGIONAL:</b>			
Interregional			
CTU Modules	53,267	40,000	191,379
CTUs for Reduction of Medical Barriers Development & Management	10,401	40,000	244,413
Depo Introduction	144,854	112,422	27,207
Intro POCs to CBD Programs	6,103	0	(6,103)
	381	1,000	0
<b>TOTAL INTERREGIONAL</b>	<b>215,006</b>	<b>193,422</b>	<b>456,896</b>
From Central Funds	215,006	193,422	456,896
From Add-On Funds	0	0	0
<b>TOTAL ALL REGIONS</b>	<b>393,606</b>	<b>374,922</b>	<b>724,246</b>
From Central Funds	306,109	259,522	592,974
From Add-On Funds	85,497	115,400	131,272

\* Denotes Mission or Bureau Add-On Funds

**5. Reproductive Epidemiology Program Activities by Region and Funding Source**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>AFRICA:</b>			
<b>Zambia</b>			
Spermicide Use and HIV Infection	25,263	30,471	1,598
Female Condom & HIV	3,393	0	47,274
<b>TOTAL AFRICA</b>	<b>28,656</b>	<b>30,471</b>	<b>48,872</b>
From Central Funds	28,656	30,471	48,872
From Add-On Funds	0	0	0
<b>ASIA/NEAR EAST:</b>			
<b>S. Korea</b>			
Vasectomy & Prostate Cancer	217	0	4,371
<b>TOTAL ASIA/NEAR EAST</b>	<b>217</b>	<b>0</b>	<b>4,371</b>
From Central Funds	217	0	4,371
From Add-On Funds			

5. Reproductive Epidemiology Program Activities by Region and Funding Source (Continued)

	ACTUAL FY'93 10/82 - 3/93	BUDGET FY'93 10/92 - 3/93	BUDGET FY'93 4/93 - 9/93
<b>LATIN AMERICA/CARIBBEAN:</b>			
Dominican Republic Condoms Cervic	2,696	0	11,515
Honduras Spermicides & HIV	19,605	15,014	21,363
Jamaica Sickle Cell Anemia Case Control Study of CXCA	3,587 8,717	3,241 10,000	(2,582) 28,554
	12,304	13,241	25,972
<b>TOTAL LATIN AMERICA/CARIBBEAN</b>	<b>34,605</b>	<b>28,255</b>	<b>58,850</b>
From Central Funds	34,605	28,255	58,850
From Add-On Funds	0	0	0
<b>USA/EUROPE:</b>			
USA Risks and Benefits of OCs	45,195	85,703	105,030
<b>TOTAL USA/EUROPE</b>	<b>45,195</b>	<b>85,703</b>	<b>105,030</b>
From Central Funds	45,195	85,703	105,030
From Add-On Funds	0	0	0
<b>INTERREGIONAL:</b>			
Interregional Vasectomy TA Low Dose OCs for Older Women	934 426	0 0	(395) 6,620
<b>TOTAL INTERREGIONAL</b>	<b>1,360</b>	<b>0</b>	<b>6,225</b>
From Central Funds	1,360	0	6,225
From Add-On Funds	0	0	0
<b>TOTAL ALL REGIONS</b>	<b>110,033</b>	<b>144,429</b>	<b>223,348</b>
From Central Funds	110,033	144,429	223,348
From Add-On Funds	0	0	0

**6. Institutional Development Program Activities by Region and Funding Source**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>AFRICA:</b>			
<b>Kenya</b>			
Reprod. Health/Res. Inst Dev. Proj.	97,890 *	60,000 *	(20,261)*
Reprod. Health/Res. Inst Dev. Proj.	8,962	12,000	16,961
	106,852	72,000	(3,300)
<b>Mali</b>			
TA to Malien Family Planning Assoc	20,737	26,000	66,543
<b>Niger</b>			
Technical Assistance to CNSF	4,186	2,000	(1,614)
<b>TOTAL AFRICA</b>	<b>131,775</b>	<b>100,000</b>	<b>61,629</b>
From Central Funds	33,885	40,000	81,890
From Add-On Funds	97,890	60,000	(20,261)
<b>ASIA/NEAR EAST:</b>			
<b>Bangladesh</b>			
BIRPERHT	12,819	8,000	6,583
<b>Egypt</b>			
Inst. Dev. Proj. of the NPC	627,246 *	600,000 *	768,421 *
<b>TOTAL ASIA/NEAR EAST</b>	<b>640,065</b>	<b>608,000</b>	<b>775,004</b>
From Central Funds	12,819	8,000	6,583
From Add-On Funds	627,246	600,000	768,421

\* Denotes Mission or Bureau Add-On Funds

**6. Institutional Development Program Activities by Region and Funding Source (Continued)**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>LATIN AMERICA/CARIBBEAN:</b>			
Mexico			
Mexico Collaboration Research Center	909	2,000	0
<b>TOTAL LATIN AMERICA/CARIBBEAN</b>	<b>909</b>	<b>2,000</b>	<b>0</b>
From Central Funds	909	2,000	0
From Add-On Funds	0	0	0
<b>INTERREGIONAL:</b>			
Interregional			
Institutional Development Monograph	3,029	10,000	0
Institutional Assessment Indicators	357	2,000	0
Microcomputer Development	269	500	847
Development & Management	2,185	7,703	48
<b>TOTAL INTERREGIONAL</b>	<b>5,840</b>	<b>20,203</b>	<b>895</b>
From Central Funds	5,840	20,203	895
From Add-On Funds	0	0	0
<b>TOTAL ALL REGIONS</b>	<b>778,589</b>	<b>730,203</b>	<b>837,528</b>
From Central Funds	53,453	70,203	89,368
From Add-On Funds	725,136	660,000	748,160

**7. Training Program Activities by Region and Funding Source**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>AFRICA:</b>			
Cameroon			
Impact of Trng. Svc. Prov. on Guidelines	1,302	0	60,700
<b>TOTAL AFRICA</b>	<b>1,302</b>	<b>0</b>	<b>60,700</b>
From Central Funds	1,302	0	60,700
From Add-On Funds	0	0	0
<b>LATIN AMERICA/CARIBBEAN:</b>			
Mexico			
LA Symposium on Family Planning	15,609	22,000	8,608
<b>TOTAL LATIN AMERICA/CARIBBEAN</b>	<b>15,609</b>	<b>22,000</b>	<b>8,608</b>
From Central Funds	15,609	22,000	8,608
From Add-On Funds	0	0	0
<b>INTERREGIONAL:</b>			
Interregional			
Training	2,144	0	31,067
Conference Travel (Non FHI Staff)	586	3,000	31,680
Development & Management	8,779	13,281	4,025
<b>TOTAL INTERREGIONAL</b>	<b>11,509</b>	<b>16,281</b>	<b>66,772</b>
From Central Funds	11,509	16,281	66,772
From Add-On Funds	0	0	0
<b>TOTAL ALL REGIONS</b>	<b>28,420</b>	<b>38,281</b>	<b>136,080</b>
From Central Funds	28,420	38,281	136,080
From Add-On Funds	0	0	0

**8. Information Dissemination Program Activities by Region and Funding Source**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>AFRICA:</b>			
Gambia Contraceptive Discontinuation Wkshp	27,264	4,000	10,948
Multi National Network in French	48,873	41,000	38,864
<b>TOTAL AFRICA</b>	<b>76,137</b>	<b>45,000</b>	<b>49,812</b>
From Central Funds	76,137	45,000	49,812
From Add-On Funds	0	0	0
<b>LATIN AMERICA/CARIBBEAN:</b>			
Mexico Mexico Journal Workshop	2,253	3,000	62,490
Multi National Network in Spanish	43,252	50,000	60,498
<b>TOTAL LATIN AMERICA/CARIBBEAN</b>	<b>45,505</b>	<b>53,000</b>	<b>122,988</b>
From Central Funds	45,505	53,000	122,988
From Add-On Funds	0	0	0

**8. Information Dissemination Program Activities by Region and Funding Source (Continued)**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>INTERREGIONAL:</b>			
<b>Interregional</b>			
Translations	2,890	3,000	41,581
FHI Library	79,159	97,000	136,642
Publications Catalogue	597	1,000	11,523
Development & Management	182,880	188,594	35,455
NETWORK	93,155	82,000	121,686
Paper Writing	200	2,000	4,142
Medical Barriers to Contraception	84,394	72,000	140,128
<b>TOTAL INTERREGIONAL</b>	<b>443,275</b>	<b>445,594</b>	<b>491,157</b>
From Central Funds	443,275	445,594	491,157
From Add-On Funds	0	0	0
<b>TOTAL ALL REGIONS</b>	<b>564,917</b>	<b>543,594</b>	<b>663,957</b>
From Central Funds	564,917	543,594	663,957
From Add-On Funds	0	0	0

\* Denotes Mission or Bureau Add-On Funds

**9. Other Activities by Region and Funding Source**

	<b>ACTUAL FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 10/92 - 3/93</b>	<b>BUDGET FY'93 4/93 - 9/93</b>
<b>AFRICA:</b>			
Kenya			
FHI Nairobi Office	10,802	11,370	48,480
Office Support	48,079	56,524	13,282
	58,881	67,894	61,762
Multi National			
Africa: Regional Program Development	10,164	10,732	86,724
Africa Development & Management	0	0	28,867
	10,164	10,732	115,591
Nigeria			
Family Health Serv. Project	157,821 *	120,000 *	177,945 *
Dev. & Mgt. of Comp. Activities	1,850 *	5,000 *	276,803 *
	159,671	125,000	454,748
<b>TOTAL AFRICA</b>	<b>228,716</b>	<b>203,626</b>	<b>632,101</b>
From Central Funds	69,045	78,626	177,353
From Add-On Funds	159,671	125,000	454,748
<b>LATIN AMERICA/CARIBBEAN:</b>			
Multi National			
Latin America Devel. & Management	211	0	13,900
<b>TOTAL LATIN AMERICA/CARIBBEAN</b>	<b>211</b>	<b>0</b>	<b>13,900</b>
From Central Funds	211	0	13,900
From Add-On Funds	0	0	0
<b>ASIA/NEAR EAST:</b>			
Multi National			
Asia/NE Devel. & Management	730	0	30,621
<b>TOTAL ASIA/NEAR EAST</b>	<b>730</b>	<b>0</b>	<b>30,621</b>
From Central Funds	730	0	30,621
From Add-On Funds	0	0	0
<b>INTERREGIONAL:</b>			
Interregional			
Interregional Population Coop. Agr. Mgt.	88,524	40,148	44,278
Nepal: Regional Office	0	53,333	124,534
Non-Budgeted Service Centers	382,360	300,000	217,640
Development and Management	18,069	0	198,981
<b>TOTAL INTERREGIONAL</b>	<b>488,953</b>	<b>393,481</b>	<b>585,433</b>
From Central Funds	488,953	393,481	585,433
From Add-On Funds	0	0	0
<b>TOTAL ALL REGIONS</b>	<b>718,610</b>	<b>597,107</b>	<b>1,262,055</b>
From Central Funds	558,939	472,107	807,307
From Add-On Funds	159,671	125,000	454,748
<b>GRAND TOTAL ALL ACTIVITIES</b>	<b>6,616,808</b>	<b>6,025,332</b>	<b>8,187,347</b>
From Central Funds	5,514,705	4,940,525	6,469,155
From Add-On Funds	1,102,103	1,084,807	1,718,192

\* Denotes Mission or Bureau Add-On Funds

**APPENDIX A**

**FHI's Medical Barrier Activities**

# FHI's Medical Barrier Activities

## Introduction

Since 1971, FHI has been dedicated to improving the health of women in developing countries through work in the areas of reproductive health and contraceptive research. FHI's research on the safety and acceptability of contraceptives, for example, has contributed to the amelioration of family planning programs worldwide. The challenge of improving women's health through family planning has recently broadened to include a vital service delivery component: improving access to contraception by reducing unjustified medical barriers to use.

Medical barriers are evident throughout the developing world--partially because current scientific research on the benefits and risks of contraceptive use and alternative service delivery mechanisms frequently do not reach policymakers, clinic managers and providers. This lack of information has prompted FHI to carefully address the issue of accessibility, particularly as it relates to the use of clinical and programmatic research to change service delivery guidelines and provider practices.

FHI has benefitted from its long-standing relationships with investigators in developing countries. Country-level research documenting unnecessary medical barriers has enabled FHI to help promote increased access for women who may have been discouraged by systems which require unnecessary laboratory tests prior to pill prescription, or exaggerated follow-up visits for IUD users. By sharing local and international research results with key officials and members of the family planning community, FHI helps increase the number of women who have access to family planning. Through its research, FHI continues to identify unnecessary practices.

FHI is focusing on three primary areas to address medical barriers; education/training, policy revision, and research. The objectives of each are:

Education and Training. To design and conduct activities (e.g. conferences, meetings, training workshops) at which current scientific information is presented and participants are encouraged to update existing contraceptive practices. Organized educational events are one step towards dismantling outdated practices which limit access to family planning services. Events highlight local/regional experiences and use host-country expert consensus to reinforce key messages.

Policy Revision. To assist national policymakers in amending family planning service delivery guidelines and medical protocols to reflect current knowledge about contraceptive provision, and alert them when new research results become available. Widespread dissemination to encourage use of updated service delivery guidelines is an essential component in the area of reducing medical barriers.

**Research.** To identify and study means of eliminating existing medical barriers and conduct studies that demonstrate the safety and benefits of removing unnecessary medical barriers. RMB research projects address such issues as excessive follow-up schedules for IUD users, incorrect provider and user information on pill use, and the variation between service delivery guidelines and actual service practices.

A new initiative being undertaken with INTRAH in Cameroon and The Futures Group in Jamaica will help determine the impact of specific education/training activities and new medical guidelines on service delivery provider practices. FHI is interested in providing A.I.D. with information on the most effective means of disseminating information aimed at reducing medical barriers.

FHI has also been actively involved with a number of interagency activities during this report period which support reducing medical barriers. FHI has:

- \* Participated in the Interagency Steering Committee on Medical Barriers,
- \* Contributed to three working groups, including as Chair of the Organized Educational Events sub-committee,
- \* Assisted in the planning of the Cooperative Agencies Meeting on Depo Provera held in New York on March 4-5th.

Projects outlined in the subsequent pages illustrate FHI's current efforts in the area of improving access to contraception by reducing medical barriers. Projects related to education, training and policy are grouped together since individual projects often have overlapping objectives in these areas. The projects listed on the following pages are described in the body of the report.

## FHI's Medical Barrier Activities

<b>1. Education, Training and Policy</b>	
o Mexico: OC Use (Phase II) . . . . .	32
o Service Delivery Cooperating Agencies Field Activities in Quality of Care . . . . .	44
o Medical Barriers: Service Delivery Guidelines and Practices . . . .	46
o Meeting on Depo-Provera . . . . .	53
o Development of Standardized Instructional Modules . . . . .	59
o Distinguished Lectures Symposium & Guest Lectures on Contraception in Egypt . . . . .	60
o Maternal & Child Health Seminar in Alma Ata, Kazakhstan . . . .	60
o OB/GYN Society (POGS) Annual Meeting in Philippines . . . . .	61
o Contraceptive Technology Update in Pakistan . . . . .	61
o Kenya: Reproductive Health/Institutional Development Medical Barriers . . . . .	77
o Argentina: Association of Research in Human Reproduction (ALIRH) Annual Meeting . . . . .	82
o Mexico: Latin American Symposium on Sexual Health and Family Planning . . . . .	82
o Mexico: Journalists Workshop . . . . .	83
o FHI's International Health Bulletin (Network) . . . . . (Issue on Reducing Medical Barriers)	85
o Network en español . . . . . (Issue on Reducing Medical Barriers)	86
o Network en Francais . . . . . (Issue on Reducing Medical Barriers)	87
o Article Translation Series . . . . .	88

o	Information Dissemination Program .....	88
o	Reducing Medical Barriers to Contraception .....	91
o	Nigeria: Family Health Services Project (Contraceptive Technology Update) .....	93
o	Service Delivery Guidelines: Reducing Medical Barriers in Africa .....	106
2.	<b>Research</b>	
o	Instructions/Compliance .....	29
o	Mexico: OC Knowledge and Practices of Mexican Institute of Social Security (IMSS) Rural Midwives and Their Recent OC Acceptors .....	31
o	India: OC Use .....	32
o	OC Compliance .....	34
o	Thailand: Cost of Norplant Delivery by Nurses .....	36
o	Ecuador: Evaluation of IUD Follow-up Schedules .....	37
o	Mexico: IUD Follow-up Visits .....	38
o	Kenya: Risks and Benefits of Removing the Clinic Visit in CBD Programs .....	39
o	Country Level Analysis of Unnecessary Medical Barriers .....	45
o	Assessment of Community-based Distribution of Depo-Provera ..	54
o	Kenya and Mali: Evaluation of Immediate Post-placental IUD Insertion .....	58
o	Benefits and Risks of OCs .....	67
o	Oral Contraceptives and Blood Pressure .....	69

## **APPENDIX B**

### **FHI Staff and Consultant Travel Undertaken**

Date of Report: 9-JUL-1993

FAMILY HEALTH INTERNATIONAL  
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-1997

Page: 1

<u>Region</u>	<u>Country</u>	<u>Start Date</u>	<u>End Date</u>	<u>Traveler</u>
AFR	BURKINA FASO	07-JAN-1993	13-JAN-1993	ADRIAN  TO MAKE PRELIMINARY CONTACTS DURING THIS JOINT INTRAH/FHI VISIT REGARDING THE DEVELOPMENT OF REDUCTION OF MEDICAL ACTIVITIES.
AFR	EGYPT	02-OCT-1992	17-OCT-1992	DISTINGUISHED LECTURERS  TO PARTICIPATE IN THE DISTINGUISHED LECTURES SYMPOSIUM AND THE THREE GOVERNORATE MEETINGS. NASH HERNDON WILL COORDINATE PRESS COVERAGE AND INTERVIEW NUMEROUS SOURCES ABOUT THE PROBLEM OF MEDICAL BARRIERS IN THE COUNTRY AND WILL WRITE AN ARTICLE FOR NETWORK. DR. DIGGORY WILL SERVE AS AN EXPERT SPEAKER AT THE SYMPOSIUM AND DRS. POTTS AND EHIWANDIWALLA WILL SERVE AS EXPERT SPEAKERS AT THE SYMPOSIUM AND AT THE THREE GOVERNORATE MEETINGS.
AFR	EGYPT	16-OCT-1992	30-OCT-1992	WASZAK  TO MONITOR ACTIVITIES OF THE STAFF OF THE RESEARCH MGMT. UNIT OF THE NATIONAL POPULATION COUNCIL GIVING PARTICULAR ATTENTION TO: A) THE STATUS OF RECENTLY APPROVED STUDIES; B) PLANS FOR ADDITIONAL PROPOSAL REVIEW; C) STATUS OF OPERATIONS MANUAL DEVELOPMENT; D) COLLABORATION BETWEEN RMU AND FHI STAFF. PROVIDE TECHNICAL ASSISTANCE TO THE RECENTLY APPROVED RMU-FUNDED BIOMEDICAL STUDIES (WITH SPECIAL EMPHASIS ON DATA COLLECTION AND DATA MANAGEMENT). MONITOR ACTIVITIES OF THE FHI/CAIRO STAFF AND FOLLOW-UP AS NECESSARY ON THE DISTINGUISHED LECTURERS SYMPOSIUM.
AFR	EGYPT	29-NOV-1992	04-DEC-1992	MURRAY  TO MEET WITH STAFF AT USAID/CAIRO AND FHI/CAIRO TO PLAN THE CONTENT AND LOGISTICS OF CONTRACEPTIVE TECHNOLOGY UPDATE MEETINGS TO BE CONVENED IN 1993; AND TO FOLLOW-UP ON OTHER ISSUES RELATED TO THE INSTITUTIONAL DEVELOPMENT PROJECT AS NECESSARY.
AFR	EGYPT	12-FEB-1993	26-FEB-1993	WASZAK  TO MONITOR RMU BIOMEDICAL STUDIES/REVIEW NEW PROPOSALS. DISCUSS/DEVELOP MONITORING PLAN FOR RMU PROGRAMMATIC STUDIES. DEVELOP PLANS FOR REPORT WRITING WORKSHOP FOR CURRENT RMU INVESTIGATORS.

Date of Report: 9-JUL-1993

FAMILY HEALTH INTERNATIONAL  
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-9997

Page: 2

<u>Region</u>	<u>Country</u>	<u>Start Date</u>	<u>End Date</u>	<u>Traveler</u>
AFR	GHANA	13-FEB-1993	25-FEB-1993	FORTNEY TO DEVELOP THE STUDY DESIGN TO EVALUATE THE IMPACT ON MATERNAL AND PERINATAL MORBIDITY AND MORTALITY OF TBA TRAINING.
AFR	GHANA	13-FEB-1993	25-FEB-1993	SMITH TO DEVELOP THE STUDY DESIGN TO EVALUATE THE IMPACT ON MATERNAL AND PERINATAL MORBIDITY AND MORTALITY OF TBA TRAINING.
AFR	KENYA	03-OCT-1992	16-OCT-1992	STEINER TO FINALIZE THE VAGINAL FOAMING TABLET (VFT) REPORT AND PRESENT THE DOCUMENT TO USAID/NAIROBI AND TO WRITE UP THE VCF STUDY IN COLLABORATION WITH THE FAMILY PLANNING ASSOCIATION OF KENYA. (FPAK); TO DISCUSS STUDY CONCEPTS THAT FPAK AND FHI HOPE TO COLLABORATE ON; AND TO INTRODUCE KAREN KATZ TO IDP STAFF.
AFR	KENYA	12-JAN-1993	27-JAN-1993	COLE TO CO-CONDUCT WORKSHOP "THE BASICS OF RANDOMIZED CLINICAL TRIALS WITH AN EMPHASIS ON CONTRACEPTIVE RESEARCH".
AFR	KENYA	14-JAN-1993	23-JAN-1993	CONNELL TO ACT AS A FACILITATOR FOR A CLINICAL TRIALS RESEARCH METHODOLOGY WORKSHOP.
AFR	KENYA	27-JAN-1993	23-FEB-1993	NICHOLS TO WORK WITH STAFF OF THE INSTITUTIONAL DEVELOPMENT PROGRAM, DEPT OF OBSTETRICS & GYNECOLOGY, KENYATTA NATIONAL HOSPITAL, TO REVIEW AND FINALIZE PROJECT REPORTS ON THREE METHOD ACCEPTABILITY, BARRIERS TO CONTRACEPTION, AND CAUSES/PREVENTION OF MATERNAL MORTALITY STUDIES AS CONDUCTED UNDER THE IDP; TO OUTLINE PAPER/RESEARCH NOTES BASED ON ABOVE FOR SUBMISSION TO PEER REVIEW JOURNALS; TO PLAN A CLOSE-OF-PROJECT SEMINAR TO PRESENT THE FINDINGS OF IDP RESEARCH ACTIVITIES TO THE KENYAN POPULATION AND MEDICAL COMMUNITY AND TO DEVELOP A RESEARCH AGENDA FOR THE POST USAID/FHI CORE SUPPORT PERIOD.

134

Date of Report: 9-JUL-1993

FAMILY HEALTH INTERNATIONAL  
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-9997

Page: 3

<u>Region</u>	<u>Country</u>	<u>Start Date</u>	<u>End Date</u>	<u>Traveler</u>
AFR	KENYA	09-FEB-1993	10-FEB-1993	JESENCKY TO MONITOR THE PROGRESS OF IMMEDIATE POST-PLACENTAL IUD INSERTION PROJECT AT NYERI PROVINCIAL HOSPITAL.
AFR	KENYA	09-FEB-1993	10-FEB-1993	ODIEMO TO DRIVE KATHY JESENCKY WHO IS GOING TO MONITOR PROGRESS OF IMMEDIATE POST-PLACENTAL IUD INSERTION PROJECT AT NYERI PROVINCIAL HOSPITAL.
AFR	KENYA	26-FEB-1993	13-MAR-1993	ALLEN TO WORK WITH INVESTIGATORS AT THE UNIVERSITY OF NAIROBI TO PREPARE FOR SUBMISSION OF A PROPOSAL TO NIH. ALSO TO MEET WITH STAFF AT FHI'S AFRICA REGIONAL OFFICE FOR POPULATION ACTIVITIES TO DISCUSS CURRENT AND FUTURE ACTIVITIES.
AFR	KENYA	01-MAR-1993	05-MAR-1993	MCMULLEN TO MONITOR TIME OF PROGESTIN-ONLY CONTRACEPTIVE INITIATION AMONG LACTATING WOMEN STUDY.
AFR	KENYA	02-MAR-1993	05-MAR-1993	OMONDI-ODHIAMBO TO GATHER BASELINE DATA AND TO DETERMINE STATIC CLINIC AND CBD SITES FOR THE PROPOSED PILL COMPLIANCE STUDY.
AFR	KENYA	18-MAR-1993	19-MAR-1993	HUBER TO ASSIST IN THE FACILITATION OF TWO FHI/POPULATION COUNCIL/IDP SPONSORED MEETINGS IN NAIROBI TO ADDRESS THE ISSUES OF IMPROVING ACCESS TO CONTRACEPTIVE SERVICES IN KENYA.
AFR	MALI	18-OCT-1992	24-OCT-1992	MORRISON AMPPF: TO WORK WITH STAFF AT THE AMPPF ON THE COMPUTERIZING OF CLINICAL RECORDS AND TO PLAN A STRATEGIC PLANNING ACTIVITY. MATERNITE HAMDALLAYE: TO MONITOR PROGRESS ON THE INTRODUCTORY STUDY OF POSTPARTUM IUD INSERTIONS.

16

Date of Report: 9-JUL-1993

FAMILY HEALTH INTERNATIONAL  
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-9997

Page: 4

<u>Region</u>	<u>Country</u>	<u>Start Date</u>	<u>End Date</u>	<u>Traveler</u>
AFR	MALI	16-FEB-1993	26-FEB-1993	MORRISON  TO MONITOR THE MALI IPPI STUDY AND PREPARE THE STUDY SITE FOR COMPLETING DATA COLLECTION ACTIVITIES; TO WORK WITH AMPEFF ON ONGOING ACTIVITIES INCLUDING COMPUTERIZATION OF CLIENT RECORDS, THE STRATEGIC PLANNING ACTIVITY AND THE BAGUINEDA EVALUATION AND TO WORK WITH THE SDF TO PLAN FOR NORPLANT INTRODUCTION ACTIVITIES.
AFR	NIGER	24-OCT-1992	30-OCT-1992	MORRISON  TO MEET WITH STAFFS OF THE DIRECTION DE LA PLANIFICATION FAMILIALE, THE MATERNITE CENTRALE AND USAID/NIAMEY TO PLAN FOR AN INTRODUCTORY STUDY OF POSTPARTUM IUD INSERTION.
AFR	NIGER	14-JAN-1993	23-JAN-1993	ADRIAN  TO DISCUSS WITH THE MISSION, MINISTRY OF HEALTH AND UNIVERSITY RESEARCH CORPORATION (URC) THE POSSIBILITY OF DEVELOPING PLANS FOR FOLLOW-UP INFORMATION DISSEMINATION ACTIVITIES 1 1/2 YEARS AFTER THE NATIONAL CONTRACEPTIVE TECHNOLOGY UPDATE (CTU) CONFERENCE.
AFR	NIGER	21-FEB-1993	01-MAR-1993	JESENKY  TO PARTICIPATE IN A CA'S WORKSHOP TO DISCUSS PROGRAMMATIC NEEDS IN THE UPCOMING BILATERAL PROGRAMMATIC NEEDS IN THE UPCOMING BILATERAL PROGRAM.
AFR	NIGERIA	23-JAN-1993	30-JAN-1993	COLE  TO REPRESENT FHI AND PARTICIPATE IN A COOPERATING AGENCIES MEETING TO DISCUSS NEEDS AND PLANS FOR EACH CA'S POSSIBLE INVOLVEMENT IN THE NIGERIA FAMILY HEALTH SERVICES PROJECT. ALSO TO DISCUSS OTHER CURRENT FHI ACTIVITIES IN NIGERIA.

26/1

Date of Report: 9-JUL-1993

FAMILY HEALTH INTERNATIONAL  
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-9997

Page: 5

<u>Region</u>	<u>Country</u>	<u>Start Date</u>	<u>End Date</u>	<u>Traveler</u>
AFR	SENEGAL	17-NOV-1992	28-NOV-1992	MURRAY  TO MEET WITH STAFF AT LE DANTEC, USAID TO MONITOR PROGRESS UNDER NORPLANT INTRODUCTION AND PLAN FUTURE ACTIVITIES; TO FINALIZE PLANS FOR A CLIENT PERSPECTIVE OPERATIONS RESEARCH STUDY RELATED TO NORPLANT (THIS WILL BE COORDINATED WITH POPULATION COUNCIL'S STUDY); AND TO ATTEND THE NORPLANT INFORMATION DAY.
AFR	SENEGAL	06-FEB-1993	21-FEB-1993	KATZ  TO ASSIST FHI STAFF MEMBER, CHARLES MORRISON, IN INITIATING THE RESEARCH PROJECT IN NORPLANT INTRODUCTION IN SENEGAL, TO LEARN MORE ABOUT THE PROJECT, AND TO BE INTRODUCED TO THE PROJECT STAFF AS THE NEW TECHNICAL MONITOR.
AFR	SENEGAL	07-FEB-1993	16-FEB-1993	MORRISON  TO MAKE A WORKPLAN FOR THE NORPLANT CLIENT PERSPECTIVE STUDY, TO PRETEST THE DATA COLLECTION FORMS AND TO TRAIN INTERVIEWERS IN THEIR USE.
AFR	ZIMBABWE	28-NOV-1992	09-DEC-1992	JESENCKY  TO VISIT BINDURA TO ASSURE THAT PROGESTIN-ONLY PILL STUDY IS PROGRESSING SATISFACTORILY, PROTOCOL IS BEING FOLLOWED.
AFR	ZIMBABWE	06-MAR-1993	10-MAR-1993	MCHULLEN  TO MONITOR THE TIME OF PROGESTIN-ONLY CONTRACEPTIVE INITIATION AMONG LACTATING WOMEN STUDY.
ASI	BANGLADESH	23-OCT-1992	17-NOV-1992	HARDEE  TO PARTICIPATE IN A DISSEMINATION WORKSHOP ON THE QUALITY OF NORPLANT SERVICES IN BANGLADESH, INCLUDING PRESENTING A PAPER ON THE WORLDWIDE EXPERIENCE WITH NORPLANT.

100/100

Date of Report: 9-JUL-1993

FAMILY HEALTH INTERNATIONAL  
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-9997

Page: 6

<u>Region</u>	<u>Country</u>	<u>Start Date</u>	<u>End Date</u>	<u>Traveler</u>
ASI	BANGLADESH	09-DEC-1992	14-DEC-1992	KING  TO PRESENT A PAPER AT THE FIRST INTERNATIONAL CONFERENCE FOR OBSTETRICS & GYNECOLOGY AND TO MEET WITH DR. HALIDA AKHTER AND BIRPERHT STAFF ABOUT PAST WORK AND POSSIBILITIES FOR FUTURE COLLABORATION. (ALSO FUNDED BY CO AND AC FUNDS)
ASI	BANGLADESH	07-JAN-1993	20-JAN-1993	JANOWITZ  TO PRESENT FINDING FROM THE STUDY OF EXPENDITURES ON FAMILY PLANNING AT A WORKSHOP TO BE ATTENDED BY STAFF FROM USAID, THE GOVERNMENT OF BANGLADESH, AND THE WORLD BANK; AND TO DEVELOP A SCOPE OF WORK FOR A STUDY ON THE COSTS OF PROVIDING CONTRACEPTIVES THROUGH DIFFERENCE DELIVERY CHANNELS.
ASI	INDIA	18-OCT-1992	26-OCT-1992	WILLIAMSON  TO DISCUSS WITH THE A.I.D. MISSION AND INDIAN FAMILY PLANNING COLLEAGUES POSSIBLE FHI POPULATION PROJECTS IN INDIA AND TO GIVE A TALK ON AIDS AND FAMILY PLANNING AT THE INTERNATIONAL PLANNED PARENTHOOD FEDERATION 40TH ANNIVERSARY MEETING.
ASI	INDIA	20-OCT-1992	26-OCT-1992	CONNELL  TO ATTEND THE INTERNATIONAL PLANNED PARENTHOOD FEDERATION FAMILY PLANNING CONGRESS "MEETING CHALLENGES: PROMOTING CHOICES" AND TO MAKE A PRESENTATION ON NEW TECHNOLOGY FOR CONTRACEPTION AND PREVENTION OF STDS.
ASI	INDIA	22-OCT-1992	30-OCT-1992	RODDY  TO ATTEND THE IPPF MEETING AND PRESENT A PAPER ON A PANEL ORGANIZED BY CDC AND FHI AND TO MEET WITH A.I.D. MISSION STAFF. TO MEET WITH POTENTIAL INVESTIGATORS FOR N-9 AND HIV STUDY.
ASI	INDIA	06-NOV-1992	11-NOV-1992	FORTNEY  TO ATTEND HRP/ICMR MEETING IN BOMBAY AND GIVE PRESENTATION ON RISKS AND BENEFITS OF OCS AND TO ATTEND AIDS IN ASIA MEETING IN NEW DELHI.

140

Date of Report: 9-JUL-1993

FAMILY HEALTH INTERNATIONAL  
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-9997

Page: 7

<u>Region</u>	<u>Country</u>	<u>Start Date</u>	<u>End Date</u>	<u>Traveler</u>
ASI	MALAYSIA	15-OCT-1992	20-OCT-1992	MONTEITH TO ASSIST D. GATES IN THE INITIATION OF THE POC TRIAL AT A NEW SITE IN PERAK STATE.
ASI	MALAYSIA	15-OCT-1992	20-OCT-1992	GATES TO INITIATE THE POC TRIAL AT A NEW SITE IN PERAK STATE.
ASI	NEPAL	24-DEC-1992	- -	THAPA TO RELOCATE TO KATHMANDU FOR ONE YEAR TO SERVE A TECHNICAL ADVISOR TO THE GOVERNMENT OF NEPAL AND USAID MISSION.
ASI	PAKISTAN	08-MAR-1993	18-MAR-1993	PALMORE ISLAMABAD-TO MEET WITH USAID AND GOVERNMENT OFFICIALS TO ASSESS THE NEEDS FOR THE CONTRACEPTIVE TECHNOLOGY UPDATE (CTU) MEETINGS AND TO DISCUSS POSSIBLE PROGRAMMATIC RESEARCH ACTIVITIES. LAHORE-TO MEET REPRESENTATIVES FROM NGOS TO ASSESS NEEDS FOR THE LAHORE CTU. KARACHI-TO MEET WITH REPRESENTATIVES FROM NGOS TO ASSESS NEEDS FOR KARACHI CTU.
ASI	PHILIPPINES	01-OCT-1992	11-OCT-1992	PALMORE TO ATTEND A MEETING SPONSORED BY THE WORLD HEALTH ORGANIZATION ENTITLED "MEETING ON WOMEN'S PERSPECTIVES ON THE INTRODUCTION OF FERTILITY REGULATION TECHNOLOGIES". ALSO, TO MEET WITH REPRESENTATIVES OF THE UNIVERSITY OF THE PHILIPPINES POPULATION INSTITUTE (UPPI), POPULATION COMMUNICATION SERVICES (PCS), UNITED NATIONS FAMILY PLANNING ASSOCIATION (UNFPA), AND THE AGENCY FOR INTERNATIONAL DEVELOPMENT (AID).
ASI	PHILIPPINES	21-OCT-1992	28-OCT-1992	GATES TO MONITOR THE POC TRIAL AT JOSE FABELLA MEMORIAL HOSPITAL.
ASI	PHILIPPINES	30-OCT-1992	07-NOV-1992	JOANIS TO INITIATE A FUNCTIONALITY STUDY OF THE STANDARD VS THE SMALLER CONDOM AND TO TRAIN INTERVIEWERS IN DATA GATHERING.

Date of Report: 9-JUL-1993

FAMILY HEALTH INTERNATIONAL  
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-9997

Page: 8

Region	Country	Start Date	End Date	Traveler
ASI	PHILIPPINES	21-NOV-1992	28-OCT-1992	MONTEITH TO ASSIST D. GATES IN THE MONITORING OF THE POC TRIAL AT JOSE FABELLA MEMORIAL HOSPITAL.
ASI	PHILIPPINES	22-NOV-1992	01-DEC-1992	PETRICK TO PARTICIPATE IN THE SCIENTIFIC PROGRAM OF THE ANNUAL CONVENTION OF THE PHILIPPINE OBSTETRICAL AND GYNECOLOGICAL SOCIETY.
ASI	THAILAND	12-OCT-1992	16-OCT-1992	PALMORE TO WORK WITH UNFPA STAFF TO FURTHER DEVELOP AND CONFIRM PROPOSALS SUBMITTED FOR UNFPA FUNDING AND FOLLOW-UP WITH LOCAL CONTACTS ON THE PROPOSED WORK (TRIP ALSO FUNDED BY CO FUNDS).
ASI	THAILAND	13-OCT-1992	21-OCT-1992	RODDY TO MEET WITH POTENTIAL INVESTIGATORS FOR N-9 AND HIV STUDY AND TO EVALUATE THE CDC STUDY SITE IN CHIANG RAI FOR POSSIBLE USE AS A STUDY SITE.
ASI	THAILAND	04-NOV-1992	27-NOV-1992	KARANJA TO ATTEND THE SIXTH "WORKSHOP RESEARCH METHODOLOGY IN FAMILY PLANNING, SEXUAL BEHAVIOR AND REPRODUCTIVE HEALTH" AT THE INSTITUTE FOR POPULATION AND SOCIAL RESEARCH, MAHIDOL UNIVERSITY IN BANGKOK, THAILAND.
ASI	THAILAND	15-DEC-1992	18-DEC-1992	KING TO VISIT THE ASIA REGIONAL AIDSCAP OFFICE FOR A GENERAL BRIEFING ON REGIONAL ACTIVITIES AND OFFICE MANAGEMENT. (ALSO FUNDED BY HD FUNDS)
ASI	THAILAND	05-JAN-1993	13-JAN-1993	ZHANG TO DEVELOP A STUDY ENTITLED "CONTRACEPTIVE METHODS AND PREGNANCY-INDUCED HYPERTENSION".

142

Date of Report: 9-JUL-1993

FAMILY HEALTH INTERNATIONAL  
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-9997

Page: 9

Region	Country	Start Date	End Date	Traveler
ASI	THAILAND	21-JAN-1993	25-JAN-1993	JANOWITZ TO VISIT UNFPA, DR. SABIHA SYED TO DISCUSS ACTIVITIES IN THE AREAS OF SOCIAL MARKING AND COST RECOVERY AND TO VISIT TFRA, DR. KANCHANA KANASINITH. (ALSO FUNDED BY PR FUNDS)
ASI	THAILAND	22-JAN-1993	22-JAN-1993	FORTNEY IN TRANSIT STOP EN ROUTE TO LAOS AND VIETNAM (TRIP FUNDED BY CO AND HD FUNDS).
EUR	KAZAKHSTAN	08-JAN-1993	17-JAN-1993	TUCKER TO FOLLOW-UP ON PROJECT DEVELOPMENT OPPORTUNITIES AND PROVIDE CONTINUITY BETWEEN CIS COLLEAGUES AND FHI.
EUR	KAZAKHSTAN	08-JAN-1993	16-JAN-1993	POTTS TO SPEAK AT THE CONTRACEPTIVE TECHNOLOGY UPDATE CONFERENCE ON GLOBAL CONTRACEPTIVE TRENDS AND CONTRACEPTIVE SAFETY AND EFFICACY.
EUR	NETHERLANDS	12-NOV-1992	20-NOV-1992	MCMULLEN TO ATTEND A WORKSHOP OF THE DRUG INFORMATION ASSOCIATION, ENTITLED CLINICAL DATA MANAGEMENT IN PRACTICE.
EUR	NETHERLANDS	12-NOV-1992	20-NOV-1992	MENIUS TO ATTEND A WORKSHOP OF THE DRUG INFORMATION ASSOCIATION, ENTITLED CLINICAL DATA MANAGEMENT IN PRACTICE.
EUR	SPAIN	21-OCT-1992	01-NOV-1992	KOETSAWANG TO PARTICIPATE IN THE VIII INTERNATIONAL MEETING OF THE SOCIETY FOR THE ADVANCEMENT OF CONTRACEPTION.
EUR	SPAIN	25-OCT-1992	01-NOV-1992	CHI TO ATTEND THE SAC MEETING AND TO MAKE A PRESENTATION.

1/10

Date of Report: 9-JUL-1993

FAMILY HEALTH INTERNATIONAL  
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-9997

Page: 10

Region	Country	Start Date	End Date	Traveler
-----	-----	-----	-----	-----
EUR	SPAIN	26-OCT-1992	31-OCT-1992	KING  TO ATTEND THE VIII INTERNATIONAL MEETING OF THE SOCIETY FOR THE ADVANCEMENT OF CONTRACEPTION AND CHAIR THE PLENARY SESSION ON AIDS AND CONTRACEPTION.
EUR	SPAIN	26-OCT-1992	02-NOV-1992	RIVERA  TO PARTICIPATE IN THE VIII INTERNATIONAL MEETING OF THE SOCIETY FOR THE ADVANCEMENT OF CONTRACEPTION.
EUR	SPAIN	26-OCT-1992	01-NOV-1992	WILLIAMSON  TO PARTICIPATE IN THE SOCIETY FOR THE ADVANCEMENT OF CONTRACEPTION MEETING AND TO PRESENT A PAPER ON AIDS AND FAMILY PLANNING.
EUR	SPAIN	26-OCT-1992	01-NOV-1992	AKHTER  TO ATTEND THE VIII INTERNATIONAL MEETING OF THE SOCIETY FOR THE ADVANCEMENT OF CONTRACEPTION AND MAKE A PRESENTATION ON THE 5 YEAR NORPLANT EXPERIENCE IN BANGLADESH.
EUR	SWITZERLAND	12-NOV-1992	19-DEC-1992	PONCE DE LEON  TO REVIEW AND DEVELOP POLICY AND SERVICE GUIDELINES FOR DECREASING MEDICAL BARRIERS FOR CONTRACEPTIVE USE AT THE WORLD HEALTH ORGANIZATION.
EUR	SWITZERLAND	23-JAN-1993	27-JAN-1993	PALMORE  TO MEET WITH JANE COTTINGHAM AT THE WORLD HEALTH ORGANIZATION'S HUMAN REPRODUCTIVE RESOURCES FOR RESEARCH DIVISION TO DISCUSS COLLABORATION WITH WOMEN ADVOCACY GROUPS AND DEVELOP A STRATEGY.
EUR	SWITZERLAND	24-JAN-1993	28-JAN-1993	ADRIAN  TO MEET WITH JANE COTTINGHAM AT THE WORLD HEALTH ORGANIZATION'S HUMAN REPRODUCTIVE RESOURCES FOR RESEARCH DIVISION TO DISCUSS COLLABORATION WITH WOMEN ADVOCACY GROUPS AND DEVELOP A STRATEGY.

Date of Report: 9-JUL-1993

FAMILY HEALTH INTERNATIONAL  
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-9997

Page: 11

<u>Region</u>	<u>Country</u>	<u>Start Date</u>	<u>End Date</u>	<u>Traveler</u>
LAT	BARBADOS	18-OCT-1992	23-OCT-1992	TUCKER  TO ATTEND A REGIONAL REPRODUCTIVE HEALTH RESEARCH NEEDS ASSESSMENT WORKSHOP SPONSORED BY THE PAN AMERICAN HEALTH ORGANIZATION. THIS WORKSHOP WILL BRING TOGETHER POLICY MAKERS, SCIENTISTS AND KEY PUBLIC HEALTH PRACTITIONERS FROM THE CARIBBEAN TO DISCUSS ISSUES RELEVANT TO REPRODUCTIVE HEALTH RESEARCH NEEDS IN THIS SUB-REGION. THE ULTIMATE OBJECTIVE IS STRENGTHENING THE ROLE OF RESEARCH IN FURTHER IMPROVING THE REPRODUCTIVE HEALTH STATUS OF THE PEOPLES OF THE CARIBBEAN.
LAT	BRAZIL	23-JAN-1993	05-FEB-1993	BAILEY  TO PARTICIPATE IN A STATEWIDE WORKSHOP IN CEARA TO DISSEMINATE THE RESULTS OF THE EVALUATION OF REPRODUCTIVE HEALTH AS AN APPROACH TO FAMILY PLANNING IN CEARA.
LAT	DOMINICAN REPUBLIC	20-MAR-1993	25-MAR-1993	CONNELL  TO ATTEND THE WORKSHOP "BARRIER CONTRACEPTIVES: CURRENT STATUS AND FUTURE PROSPECTS-AN INTERNATIONAL WORKSHOP".
LAT	DOMINICAN REPUBLIC	20-MAR-1993	25-MAR-1993	MENIUS  TO ATTEND THE WORKSHOP "BARRIER CONTRACEPTIVES: CURRENT STATUS AND FUTURE PROSPECTS-AN INTERNATIONAL WORKSHOP".
LAT	DOMINICAN REPUBLIC	21-MAR-1993	26-MAR-1993	DORFLINGER  TO PARTICIPATE IN THE "BARRIER CONTRACEPTIVES: CURRENT STATUS AND FUTURE PROSPECTS-AN INTERNATIONAL WORKSHOP".
LAT	DOMINICAN REPUBLIC	19-MAR-1993	25-MAR-1993	JOANIS  TO PRESENT A PAPER ON ACCEPTABILITY AND BEHAVIOR AT THE "BARRIER CONTRACEPTIVES: CURRENT STATUS AND FUTURE PROSPECTS-AN INTERNATIONAL WORKSHOP".

145

Date of Report: 9-JUL-1993

FAMILY HEALTH INTERNATIONAL  
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-9997

Page: 12

Region	Country	Start Date	End Date	Traveler
-----	-----	-----	-----	-----
LAT	DOMINICAN REPUBLIC	20-MAR-1993	25-MAR-1993	PRICE  TO PARTICIPATE IN THE PLENARY SEESION OF "BARRIER CONTRACEPTIVES: CURRENT STATUS AND FUTURE PROSPECTS-AN INTERNATIONAL WORKSHOP".
LAT	DOMINICAN REPUBLIC	20-MAR-1993	25-MAR-1993	METCALF-WHITTAKER  TO ATTEND THE WORKSHOP "BARRIER CONTRACEPTIVES: CURRENT STATUS AND FUTURE PROSPECTS-AN INTERNATIONAL WORKSHOP".
LAT	DOMINICAN REPUBLIC	20-MAR-1993	28-MAR-1993	RIVERA  TO PARTICIPATE AS A SPEAKER IN THE "BARRIER CONTRACEPTIVES: CURRENT STATUS AND FUTURE PROSPECTS - AN INTERNATIONAL WORKSHOP" AND TO ATTEND THE MEETING OF THE INTERNATIONAL COMMITTEE FOR CONTRACEPTION RESEARCH (ICCR).
LAT	DOMINICAN REPUBLIC	20-MAR-1993	25-MAR-1993	RODDY  TO PRESENT A PAPER ON HIV AND OTHER STDs AT THE "BARRIER CONTRACEPTIVES: CURRENT STATUS AND FUTURE PROSPECTS-AN INTERNATIONAL WORKSHOP".
LAT	DOMINICAN REPUBLIC	21-MAR-1993	26-MAR-1993	ACOSTA  TO PARTICIPATE IN THE "BARRIER CONTRACEPTIVES: CURRENT STATUS AND FUTURE PROSPECTS-AN INTERNATIONAL WORKSHOP".
LAT	DOMINICAN REPUBLIC	21-MAR-1993	26-MAR-1993	BASSOL  TO PARTICIPATE IN THE "BARRIER CONTRACEPTIVES: CURRENT STATUS AND FUTURE PROSPECTS-AN INTERNATIONAL WORKSHOP".
LAT	DOMINICAN REPUBLIC	21-MAR-1993	26-MAR-1993	HERNDON  TO ASSIST IN THE DEVELOPMENT OF FHI'S MODULES AND SLIDES FOR CONTRACEPTIVE UPDATE SEMINARS AND TO ASSIST CONRAD WITH PREPARING THE PUBLISHED PROCEEDINGS OF THE WORKSHOP "BARRIER CONTRACEPTIVES AN INTERNATIONAL WORKSHOP".

146

Date of Report: 9-JUL-1993

FAMILY HEALTH INTERNATIONAL  
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-9997

Page: 13

<u>Region</u>	<u>Country</u>	<u>Start Date</u>	<u>End Date</u>	<u>Traveler</u>
LAT	DOMINICAN REPUBLIC	21-MAR-1993	26-MAR-1993	REMES TO PARTICIPATE IN THE "BARRIER CONTRACEPTIVES: CURRENT STATUS AND FUTURE PROSPECTS - AN INTERNATIONAL WORKSHOP".
LAT	DOMINICAN REPUBLIC	21-MAR-1993	26-MAR-1993	SENANAYAKE TO PARTICIPATE IN THE "BARRIER CONTRACEPTIVES: CURRENT STATUS AND FUTURE PROSPECTS-AN INTERNATIONAL WORKSHOP".
LAT	DOMINICAN REPUBLIC	21-MAR-1993	24-MAR-1993	SHAIN TO PARTICIPATE IN THE "BARRIER CONTRACEPTIVES: CURRENT STATUS AND FUTURE PROSPECTS-AN INTERNATIONAL WORKSHOP".
LAT	DOMINICAN REPUBLIC	21-MAR-1993	26-MAR-1993	ALVARADO TO PARTICIPATE IN THE "BARRIER CONTRACEPTIVES: CURRENT STATUS AND FUTURE PROSPECTS-AN INTERNATIONAL WORKSHOP".
LAT	ECUADOR	04-JAN-1993	09-JAN-1993	BRATT TO FINISH THE ANALYSIS OF IUD FOLLOW-UP DATA AND DRAFT RECOMMENDATIONS ON A NEW IUD FOLLOW-UP NORM FOR CEMOPLAF.
LAT	EL SALVADOR	17-JAN-1993	22-JAN-1993	FOX TO GIVE TECHNICAL SUPPORT TO NORPLANT INTRODUCTION, ESPECIALLY IN TRAINING AND IEC AREAS.
LAT	EL SALVADOR	21-FEB-1993	27-FEB-1993	OLGUIN TO MONITOR THE ONGOING NORPLANT STUDY.
LAT	HAITI	23-FEB-1993	06-MAR-1993	TROTTIER TO ASSIST IN NEEDS ASSESSMENT AND DEVELOPMENT OF NORPLANT EXPANSION PLAN. ACTIVITIES TO INCLUDE TRAINING, SITE SELECTION, INFORMATIONAL MEETINGS, TRAINING MATERIALS AND POTENTIAL AREAS OF RESEARCH. ALSO, TO MEET WITH USAID/POP STAFF AND KEY MEMEBERS OF HAITIAN NGOS INVOLVED IN NORPLANT ACTIVITIES.

<u>Region</u>	<u>Country</u>	<u>Start Date</u>	<u>End Date</u>	<u>Traveler</u>
LAT	HAITI	21-MAR-1993	26-MAR-1993	SPILSBURY  TO ATTEND A MEETING OF AID COOPERATING AGENCIES IN THE AREA OF FAMILY PLANNING.
LAT	HONDURAS	01-NOV-1992	13-NOV-1992	BRATT  TO TRAIN ASHONPLAFA COUNTERPARTS IN COST ESTIMATION, USING DATA COLLECTED FROM VARIOUS ASHONPLAFA SERVICE DELIVERY DIVISIONS; TO PRODUCE THE TABLES AND AN OUTLINE OF THE REPORT OF THE COST STUDY; AND TO BEGIN DRAFTING THE REPORT.
LAT	HONDURAS	01-NOV-1992	07-NOV-1992	CARTER  TO PROVIDE TECHNICAL ASSISTANCE TO USAID SUPPORTED CONTRACEPTIVE DISTRIBUTION PROGRAM.
LAT	HONDURAS	09-DEC-1992	18-DEC-1992	HUBACHER  TO FINALIZE DRAFT VERSION OF THE ASHONPLAFA REPORT AND TO PROVIDE CONTINUED SUPPORT TO THE MINISTRY OF PUBLIC HEALTH IN THE ANALYSIS OF THE SURVEY DATA AND TO DEVELOP SECONDARY ANALYSIS PLANS FOR PUBLICATION.
LAT	MEXICO	08-NOV-1992	14-NOV-1992	POTTER  TO WORK WITH LIC. ELENA ZUNIGA ON DATA ANALYSIS, MIDWIVES PROJECT. TO WORK WITH DANIEL HERNANDEZ ON FINAL REPORT, OC INSTRUCTIONS PROJECT.
LAT	MEXICO	12-NOV-1992	21-NOV-1992	RIVERA  TO PARTICIPATE AS A GUEST SPEAKER IN THE DELIVERY OF THE ANNUAL PRIZE FOR RESEARCH IN HUMAN REPRODUCTION OF THE FACULTY OF MEDICINE OF THE UNIVERSITY OF SAN LUIS POTOSI. REVIEW AND DISCUSS FUTURE RESEARCH PROJECTS WITH THE SCIENTIFIC RESEARCH INSTITUTE OF THE UNIVERSITY OF DURANGO. TO ATTEND A WORKING MEETING WITH THE GENERAL DIRECTOR OF FAMILY PLANNING OF THE MINISTRY OF HEALTH, AND WITH THE GENERAL DIRECTOR OF FAMILY PLANNING SERVICES OF SOCIAL SECURITY. NOTE: PARTIALLY FUNDED BY HOME DEPARTMENT.

1/8

Date of Report: 9-JUL-1993

FAMILY HEALTH INTERNATIONAL  
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-9997

Page: 15

<u>Region</u>	<u>Country</u>	<u>Start Date</u>	<u>End Date</u>	<u>Traveler</u>
LAT	MEXICO	15-NOV-1992	19-NOV-1992	CARTER TO STUDY SITES AND RETRIEVE SAMPLES FOR THE PROSPECTIVE AGING STUDY.
LAT	MEXICO	28-NOV-1992	05-DEC-1992	LAT AMER FAM PLAN SYMPOSI TO PARTICIPATE IN A ROUND-TABLE DISCUSSION ON "CONTRACEPTION DURING ADOLESCENCE".
LAT	MEXICO	04-JAN-1993	09-JAN-1993	MARTINEZ TO MONITOR "TIME OF PROGESTIN-ONLY CONTRACEPTIVE INITIATION AMONG LACTATING WOMEN" STUDY AND PERFORM A 100% QUALITY DATA COMPARING THE SOURCE DOCUMENTATION.
LAT	MEXICO	04-JAN-1993	17-JAN-1993	IRSULA TO MONITOR "TIME OF PROGESTIN-ONLY CONTRACEPTIVE INITIATION AMONG LACTATING WOMEN" STUDY AND PERFORM A 100% QUALITY DATA COMPARING THE SOURCE DOCUMENTATION.
LAT	MEXICO	04-JAN-1993	17-JAN-1993	OLGUIN TO MONITOR "TIME OF PROGESTIN-ONLY CONTRACEPTIVE INITIATION AMONG LACTATING WOMEN" SUDY AND PERFORM A 100% QUALITY DATA COMPRING THE SOURCE DOCUMENTATION IN VERACRUZ, DURANGO AND TORREON.
LAT	MEXICO	31-JAN-1993	12-FEB-1993	HUBACHER TO ANALYZE THE COST DATA, ESTIMATE THE COST OF FOLLOW-UP VISITS, AND MONITOR PROGRESS OF FOLLOW-UP COMPONENTS.
LAT	MEXICO	07-FEB-1993	20-FEB-1993	POTTER TO COMPLETE FINAL DRAFT OF REPORT OF STUDY OF OC KNOWLEDGE AND PRACTICES OF RURAL MIDWIVES AND THEIR CLIENTS WITH AMIDEM AND IMSS.

199

Date of Report: 9-JUL-1993

FAMILY HEALTH INTERNATIONAL  
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-9997

Page: 16

<u>Region</u>	<u>Country</u>	<u>Start Date</u>	<u>End Date</u>	<u>Traveler</u>
LAT	PUERTO RICO	09-FEB-1993	10-FEB-1993	CARTER TO CONDUCT PRODUCTION SURVEILLANCE AUDITS OF WYETH-AYERST LO-FEMENAL AND OVRETTE MANUFACTURING AND DISTRIBUTION OPERATIONS.
LAT	VENEZUELA	21-NOV-1992	28-NOV-1992	FARR TO ATTEND THE XIV WORLD CONGRESS ON FERTILITY AND STERILITY AND TO PRESENT A PAPER.
LAT	VENEZUELA	21-NOV-1992	29-NOV-1992	SPRUYT TO ATTEND THE FOURTEENTH WORLD CONGRESS ON FERTILITY AND STERILITY AND TO PRESENT A PAPER ON THE ACCEPTABILITY/EFFICACY OF THE FEMALE CONDOM.

150

FAMILY HEALTH INTERNATIONAL  
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Country	State	Start Date	End Date	Traveler
-----	-----	-----	-----	-----
USA	AL	12-OCT-1992	13-OCT-1992	PRICE TO PERFORM PRODUCTION SURVEILLANCE SAMPLING AT ANSELL, INC.
USA	AL	10-NOV-1992	12-NOV-1992	BROWN TO VISIT ANSELL, INC. AND ALADAN TO PERFORM PRODUCTION SURVEILLANCE SAMPLING.
USA	AL	10-NOV-1992	13-NOV-1992	MARTIN TO VISIT ANSELL, INC. AND ALADAN TO PERFORM PRODUCTION SURVEILLANCE SAMPLING.
USA	AL	24-NOV-1992	24-NOV-1992	CARTER TO MEET WITH FRED DIETSCH OF ANSELL, INC. REGARDING EQUIPMENT ACQUISITION.
USA	AL	24-NOV-1992	24-NOV-1992	BROWN TO MEET WITH FRED DIETSCH OF ANSELL, INC. REGARDING EQUIPMENT ACQUISITION.
USA	AL	01-DEC-1992	02-DEC-1992	CARTER TO PARTICIPATE IN A MEETING AT ANSELL, INC. RE: CONDOM TESTING.
USA	AL	02-DEC-1992	02-DEC-1992	BROWN TO ATTEND MEETING ON CONDOM TESTING TECHNOLOGY AT ANSELL, INC.
USA	AL	09-DEC-1992	09-DEC-1992	BROWN TO VISIT ANSELL, INC. AND ALADAN TO PERFORM PRODUCTION SURVEILLANCE SAMPLING.
USA	AL	12-JAN-1993	13-JAN-1993	BROWN TO VISIT ANSELL, INC. AND ALADAN TO PERFORM PRODUCTION SURVEILLANCE SAMPLING.

Date of Report: 11-JUL-1993

FAMILY HEALTH INTERNATIONAL  
DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Page: 2

Country -----	State -----	Start Date -----	End Date -----	Traveler -----
USA	AL	05-FEB-1993	05-FEB-1993	BROWN  TO VISIT ANSELL, INC. TO PERFORM PRODUCTION SURVEILLANCE SAMPLING.
USA	CA	03-NOV-1992	09-NOV-1992	ORONOZ  TO ATTEND 33RD ANNUAL AMERICAN TRANSLATOR ASSOCIATION CONFERENCE.
USA	CA	14-NOV-1992	19-NOV-1992	CUMMINGS  TO ATTEND CLINICAL DATA MANAGEMENT COURSE: "PHARMACEUTICAL RESEARCH AND DEVELOPMENT."
USA	CA	14-NOV-1992	19-NOV-1992	JASINSKI  TO ATTEND CLINICAL DATA MANAGEMENT COURSE: "PHARMACEUTICAL RESEARCH AND DEVELOPMENT."
USA	CA	14-NOV-1992	19-NOV-1992	RAINEY  TO ATTEND CLINICAL DATA MANAGEMENT COURSE: "PHARMACEUTICAL RESEARCH AND DEVELOPMENT."
USA	CA	06-FEB-1993	11-FEB-1993	REUSCHE  TO ATTEND ENTRY-LEVEL CLINICAL RESEARCH ASSOCIATE TRAINING COURSE.
USA	CA	06-FEB-1993	11-FEB-1993	ORONOZ  TO ATTEND ENTRY-LEVEL CLINICAL RESEARCH ASSOCIATE TRAINING COURSE.
USA	CA	06-MAR-1993	12-MAR-1993	RABY  TO ATTEND AMERICAN MEDICAL WRITERS ASSOCIATION REGIONAL WORKSHOP IN ORDER TO GET A.M.W.A. CERTIFICATION AND TO TAKE COURSES RELATED TO CLINICAL TRIALS.
USA	CA	11-MAR-1993	14-MAR-1993	KRUEGER  TO ATTEND AMERICAN MEDICAL WRITERS ASSOCIATION REGIONAL WORKSHOP.

152

Date of Report:11-JUL-1993

FAMILY HEALTH INTERNATIONAL  
DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Page: 3

Country -----	State -----	Start Date -----	End Date -----	Traveler -----
USA	CA	11-MAR-1993	12-MAR-1993	PRICE
USA	CA	16-MAR-1993	21-MAR-1993	TO VISIT HORIZON MEDICAL, ALONG WITH MR. NELSON OF PATH. MONTEITH
USA	CA	16-MAR-1993	21-MAR-1993	TO ATTEND THE SEMINAR, "MONITORING CLINICAL DRUG STUDIES: INTERMEDIATE COURSE." MARTINEZ
USA	CA	16-MAR-1993	21-MAR-1993	TO ATTEND THE SEMINAR, "MONITORING CLINICAL DRUG STUDIES: INTERMEDIATE COURSE." IRSULA
USA	CA	16-MAR-1993	21-MAR-1993	TO ATTEND THE SEMINAR, "MONITORING CLINICAL DRUG STUDIES: INTERMEDIATE COURSE." OLGUIN
USA	DC	23-OCT-1992	26-OCT-1992	TO ATTEND THE SEMINAR, "MONITORING CLINICAL DRUG STUDIES: INTERMEDIATE COURSE." DORFLINGER
USA	DC	25-OCT-1992	26-OCT-1992	TO ATTEND MEETING AT FDA RE: REALITY VAGINAL POUCH. DOMINIK
USA	DC	29-OCT-1992	29-OCT-1992	TO ATTEND MEETING AT FDA RE: REALITY VAGINAL POUCH. PALMORE
USA	DC	29-OCT-1992	29-OCT-1992	TO ATTEND ASSOCIATION OF POPULATION CENTER MEETING. PRICE
				TO MEET WITH REPRESENTATIVES OF AID TO DISCUSS THE PRODUCTION SURVEILLANCE PROGRAM.

153

Date of Report:11-JUL-1993

FAMILY HEALTH INTERNATIONAL  
DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Page: 4

Country -----	State -----	Start Date -----	End Date -----	Traveler -----
USA	DC	01-NOV-1992	04-NOV-1992	OMOHUNDRO  TO ATTEND ANNUAL MEETING OF R.A.P.S. IN WASHINGTON, DC;TO ATTEND A.M.W.A. MEETING IN HOUSTON, TX (TEXAS PORTION OF TRIP FUNDED BY TRAVELER).
USA	DC	07-NOV-1992	14-NOV-1992	SPRUYT  TO ATTEND THE APHA ANNUAL MEETING.
USA	DC	08-NOV-1992	13-NOV-1992	CHI  TO GIVE TWO PRESENTATIONS AT ANNUAL APHA MEETING.
USA	DC	08-NOV-1992	13-NOV-1992	CANAMAR  TO ATTEND THE APHA ANNUAL MEETING AND TO ATTEND AN APHA WORKSHOP.
USA	DC	09-NOV-1992	13-NOV-1992	SMITH  TO ATTEND THE APHA ANNUAL MEETING; TO ATTEND "OPERATION RESEARCH DAY," SPONSORED BY THE POPULATION COUNCIL.
USA	DC	09-NOV-1992	13-NOV-1992	WASZAK  TO ATTEND ANNUAL APHA CONFERENCE (AS SECTION COUNCILOR, WILL PARTICIPATE IN MEETINGS OF THE POPULATION AND FAMILY PLANNING SECTION COUNCIL);TO ATTEND "O.R. DAY": ANNUAL MEETING OF OPERATIONS RESEARCH IN FAMILY PLANNING, SPONSORED BY THE POPULATION COUNCIL.
USA	DC	10-NOV-1992	11-NOV-1992	BAILEY  TO PRESENT PAPER AT ANNUAL APHA CONFERENCE.

15

FAMILY HEALTH INTERNATIONAL  
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Country	State	Start Date	End Date	Traveler
USA	DC	10-NOV-1992	12-NOV-1992	FINGER  TO ATTEND ANNUAL APHA MEETING IN ORDER TO MAKE A PRESENTATION ALONG WITH EDITORS FROM POPULATION REPORTS, FAMILY PLANNING PERSPECTIVES, AMERICAN JOURNAL OF PUBLIC HEALTH, AND STUDIES IN FAMILY PLANNING; TO PARTICIPATE IN TASK FORCE ON REPRODUCTIVE HEALTH COMMUNICATION; TO ATTEND MEN/FP TASK FORCE MEETING; TO WORK AT THE FHI BOOTH.
USA	DC	12-NOV-1992	13-NOV-1992	LEWIS  ACCOMPANIED BY KATHY JESENCKY, FHI'S SENIOR REPRESENTATIVE FOR POPULATION ACTIVITIES (AFRICA), TO: REVIEW PLANS & PROGRAMS IN AFRICA REGION; TO MEET WITH AIDSCAP REGIONAL OFFICE STAFF; TO MEET WITH STAFF IN AID/R&D/POP/R OFFICE; TO MEET WITH AID AFRICA BUREAU.
USA	DC	12-NOV-1992	15-NOV-1992	PALMORE  TO PARTICIPATE IN THE MEDICAL BARRIERS STEERING COMMITTEE MEETING AT AID; TO PARTICIPATE IN "O.R. DAY," THE ANNUAL MEETING OF OPERATIONS RESEARCH IN FAMILY PLANNING.
USA	DC	12-NOV-1992	12-NOV-1992	WILLIAMSON  TO DELIVER PROPOSAL, "EFFECT OF DIET ON GONADOTROPIN LEVELS IN OC USERS," TO NIH.
USA	DC	13-NOV-1992	14-NOV-1992	BALOGH  TO ATTEND THE ANNUAL MEETING OF OPERATIONS RESEARCH IN FAMILY PLANNING, SPONSORED BY THE POPULATION COUNCIL.

15

FAMILY HEALTH INTERNATIONAL  
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Country -----	State -----	Start Date -----	End Date -----	Traveler -----
USA	DC	13-NOV-1992	15-NOV-1992	ADRIAN  TO ATTEND THE ANNUAL MEETING OF OPERATIONS RESEARCH IN FAMILY PLANNING, SPONSORED BY THE POPULATION COUNCIL.
USA	DC	13-NOV-1992	13-NOV-1992	MCINTYRE  TO ATTEND THE ANNUAL MEETING OF OPERATIONS RESEARCH IN FAMILY PLANNING, SPONSORED BY THE POPULATION COUNCIL.
USA	DC	13-NOV-1992	13-NOV-1992	WILLIAMSON  TO ATTEND THE ANNUAL MEETING OF OPERATIONS RESEARCH IN FAMILY PLANNING, SPONSORED BY THE POPULATION COUNCIL.
USA	DC	17-NOV-1992	19-NOV-1992	POTTER  TO ATTEND WORKSHOP ON PATIENT INFORMATION AND EDUCATION ABOUT PRESCRIPTION DRUGS.
USA	DC	18-NOV-1992	18-NOV-1992	BAILEY  TO ATTEND TRAINING WORKING GROUP: "EVALUATION PROJECT--BRAZIL."
USA	DC	18-NOV-1992	19-NOV-1992	PALMORE  TO PARTICIPATE IN THE TRAINING WORKING GROUP MEETING OF THE EVALUATION OF FAMILY PLANNING PROGRAM IMPACT.
USA	DC	22-NOV-1992	24-NOV-1992	RIVERA  TO ATTEND THE MEDICAL BARRIERS GUIDELINES WORKING GROUP MEETING TO BE HELD AT AID.
USA	DC	23-NOV-1992	11-DEC-1992	POTTS  TO ATTEND THE MEDICAL BARRIERS GUIDELINES WORKING GROUP MEETING HELD AT AID.

FAMILY HEALTH INTERNATIONAL  
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Country	State	Start Date	End Date	Traveler
-----	-----	-----	-----	-----
USA	DC	24-NOV-1992	24-NOV-1992	HARDEE  TO ATTEND THE MEDICAL BARRIERS GUIDELINES WORKING GROUP MEETING TO BE HELD AT AID.
USA	DC	24-NOV-1992	24-NOV-1992	PALMORE  TO ATTEND THE MEDICAL BARRIERS GUIDELINES WORKING GROUP MEETING TO BE HELD AT AID.
USA	DC	01-DEC-1992	02-DEC-1992	CARTER  TO MEET WITH AID REPRESENTATIVES REGARDING LABORATORY UPGRADE.
USA	DC	01-DEC-1992	02-DEC-1992	PRICE  TO MEET WITH AID REPRESENTATIVES REGARDING LABORATORY UPGRADE.
USA	DC	09-DEC-1992	11-DEC-1992	CONNELL  TO ATTEND FDA ADVISORY COMMITTEE MEETING RE: REALITY VAGINAL POUCH.
USA	DC	09-DEC-1992	13-DEC-1992	DORFLINGER  TO ATTEND REHEARSAL AND FORMAL SESSIONS OF FDA ADVISORY COMMITTEE MEETING RE: REALITY VAGINAL POUCH.
USA	DC	09-DEC-1992	11-DEC-1992	DOMINIK  TO ATTEND FDA ADVISORY COMMITTEE MEETING RE: REALITY VAGINAL POUCH.
USA	DC	09-DEC-1992	11-DEC-1992	FARR  TO ATTEND FDA ADVISORY COMMITTEE MEETING RE: REALITY VAGINAL POUCH.

FAMILY HEALTH INTERNATIONAL  
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Country	State	Start Date	End Date	Traveler
-----	-----	-----	-----	-----
USA	DC	09-DEC-1992	10-DEC-1992	HARDEE  TO PARTICIPATE IN A MEETING OF THE SERVICE DELIVERY WORKING GROUP OF THE EVALUATION PROJECT.
USA	DC	09-DEC-1992	11-DEC-1992	MAYETTE  TO ATTEND THE ECONOMIC OUTCOME AND QUALITY OF LIFE ASSESSMENT CONFERENCE.
USA	DC	09-DEC-1992	11-DEC-1992	STURGEN  TO ATTEND FDA ADVISORY COMMITTEE MEETING RE: REALITY VAGINAL POUCH.
USA	DC	09-DEC-1992	10-DEC-1992	OMOHUNDRO  TO REVIEW REGULATORY DOCUMENTS AT CONRAD RE: LEAS'S SHIELD; TO ATTEND FDA ADVISORY COMMITTEE MEETING RE: REALITY VAGINAL POUCH.
USA	DC	06-JAN-1993	07-JAN-1993	POTTS  TO BRIEF THE MEMBERS OF JHPIEGO AND AID STAFF RE: CONTRACEPTIVE TECHNOLOGY UPDATE CONFERENCE IN ALMA ALTA, KAZAKHSTAN.
USA	DC	07-JAN-1993	07-JAN-1993	TUCKER  TO BRIEF THE MEMBERS OF JHPIEGO AND AID STAFF RE: CONTRACEPTIVE TECHNOLOGY UPDATE CONFERENCE HELD IN ALMA ALTA, KAZAKHSTAN.
USA	DC	13-JAN-1993	13-JAN-1993	DOMINIK  TO ATTEND THE LEA'S SHIELD INVESTIGATOR'S MEETING.
USA	DC	13-JAN-1993	13-JAN-1993	MENIUS  TO ATTEND THE LEA'S SHIELD INVESTIGATOR'S MEETING.

FAMILY HEALTH INTERNATIONAL  
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Country	State	Start Date	End Date	Traveler
-----	-----	-----	-----	-----
USA	DC	13-JAN-1993	13-JAN-1993	PALMORE  TO ATTEND THE AID REDUCTION OF MEDICAL BARRIERS STEERING COMMITTEE MEETING, AND TO HAVE A DISCUSSION RE: CA'S MEETING ON DEPO-PROVERA INTRODUCTION.
USA	DC	13-JAN-1993	14-JAN-1993	RAINEY  TO ATTEND THE LEA'S SHIELD INVESTIGATOR'S MEETING.
USA	DC	13-JAN-1993	13-JAN-1993	STURGEN  TO ATTEND THE LEA'S SHIELD INVESTIGATOR'S MEETING.
USA	DC	13-JAN-1993	13-JAN-1993	OMOHUNDRO  TO ATTEND THE LEA'S SHIELD INVESTIGATOR'S MEETING.
USA	DC	14-JAN-1993	14-JAN-1993	PRICE  TO VISIT WITH DON MARLOWE AT THE FDA AND TO TOUR LABORATORY FACILITIES.
USA	DC	22-JAN-1993	22-JAN-1993	LEWIS  TO MEET WITH JIM SHELTON AT AID TO REVIEW 1993 WORKPLAN.
USA	DC	04-FEB-1993	05-FEB-1993	FLICK  TO PARTICIPATE IN FHI'S 1993 WORKPLAN PRESENTATION TO AID.
USA	DC	04-FEB-1993	05-FEB-1993	HARDEE  TO PARTICIPATE IN FHI'S 1993 WORKPLAN PRESENTATION TO AID.
USA	DC	04-FEB-1993	04-FEB-1993	RIVERA  TO MEET WITH JIM SHELTON AT AID TO DISCUSS CTU MODULE.
USA	DC	04-FEB-1993	04-FEB-1993	ADRIAN  TO PARTICIPATE IN A MEETING AT THE AID POPULATION OFFICE REGARDING THE PRODUCTION AND MANAGEMENT OF CTU MODULES.

Country	State	Start Date	End Date	Traveler
USA	DC	04-FEB-1993	05-FEB-1993	CONNELL TO PARTICIPATE IN FHI'S 1993 WORKPLAN PRESENTATION TO AID.
USA	DC	05-FEB-1993	08-FEB-1993	KENNEDY TO PRESENT THE CONTRACEPTIVE TECHNOLOGY UPDATE MODULE ON THE LACTATIONAL AMENORRHEA METHOD TO THE STAFF OF THE INSTITUTE FOR REPRODUCTIVE HEALTH AT GEORGETOWN UNIVERSITY MEDICAL CENTER, AND TO RECEIVE THEIR CRITIQUE OF THE MODULE.
USA	DC	08-FEB-1993	08-FEB-1993	RIVERA TO ATTEND A WORKING GROUP MEETING ON MEDICAL BARRIERS AT AID.
USA	DC	03-MAR-1993	07-MAR-1993	FARR TO ATTEND CONTRACEPTIVE TECHNOLOGY CONFERENCE, SPONSORED BY THE CONTEMPORARY FORUM.
USA	DC	03-MAR-1993	07-MAR-1993	IRSULA TO ATTEND CONTRACEPTIVE TECHNOLOGY CONFERENCE, SPONSORED BY THE CONTEMPORARY FORUM.
USA	DC	03-MAR-1993	06-MAR-1993	BISGROVE TO ATTEND CONTRACEPTIVE TECHNOLOGY CONFERENCE, SPONSORED BY THE CONTEMPORARY FORUM.
USA	DC	03-MAR-1993	07-MAR-1993	KLIESEN TO ATTEND CONTRACEPTIVE TECHNOLOGY CONFERENCE, SPONSORED BY THE CONTEMPORARY FORUM.
USA	DC	03-MAR-1993	07-MAR-1993	SCHWINGL TO ATTEND CONTRACEPTIVE TECHNOLOGY CONFERENCE, SPONSORED BY THE CONTEMPORARY FORUM.

160

FAMILY HEALTH INTERNATIONAL  
DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Country	State	Start Date	End Date	Traveler
USA	DC	09-MAR-1993	10-MAR-1993	JANOWITZ  TO ATTEND A POLICY WORKING GROUP MEETING ORGANIZED BY THE EVALUATION PROJECT.
USA	DC	15-MAR-1993	16-MAR-1993	STEWART  TO ATTEND A TWO-DAY WORKSHOP DEALING WITH SPSS/PC+ SOFTWARE AND ITS APPLICATION TO THE CONDOM GROUP WORK.
USA	DC	15-MAR-1993	26-MAR-1993	KENNEDY  TO ATTEND A MEETING AT WELLSTART IN WASHINGTON, DC TO NEGOTIATE AN AGENDA FOR THE EXPERTS SEMINAR ON BREASTFEEDING AND WOMEN'S STATUS (MAR 15); TO TRAVEL TO FHI-RTP TO CONDUCT THE ABOVE-MENTIONED SEMINAR AND TO CONTINUE HER WORK IN THE BREASTFEEDING AND NFP RESEARCH AREA (MAR 16-26).
USA	DC	17-MAR-1993	17-MAR-1993	COLE  TO ATTEND A MEETING AT AID REGARDING THE NIGERIA POPULATION PROGRAM.
USA	DC	25-MAR-1993	26-MAR-1993	TUCKER  TO MEET WITH MR. IQBAL NOOR ALI OF THE AGA KHAN FOUNDATION, MRS. MARY ANN KIBARIAN OF THE EMBASSY OF THE REPUBLIC OF ARMENIA, AND AMBASSADOR OTUNBAYRUA OF KYRGYZSTAN TO DISCUSS PROGRAM DEVELOPMENT ISSUES (67% OF TRIP FUNDED BY CORPORATE OFFICE FUNDS).
USA	FL	27-JAN-1993	01-FEB-1993	DUNSON  TO ATTEND THE ANNUAL MEETING OF THE ASSOCIATION OF REPRODUCTIVE HEALTH PROFESSIONALS.
USA	FL	27-JAN-1993	31-JAN-1993	FLICK  TO ATTEND THE ANNUAL MEETING OF THE ASSOCIATION OF REPRODUCTIVE HEALTH PROFESSIONALS.

Country -----	State -----	Start Date -----	End Date -----	Traveler -----
USA	FL	27-JAN-1993	01-FEB-1993	METCALF-WHITTAKER  TO ATTEND THE ANNUAL MEETING OF THE ASSOCIATION OF REPRODUCTIVE HEALTH PROFESSIONALS.
USA	FL	27-JAN-1993	31-JAN-1993	MONTEITH  TO ATTEND THE ANNUAL MEETING OF THE ASSOCIATION OF REPRODUCTIVE HEALTH PROFESSIONALS.
USA	FL	13-FEB-1993	20-FEB-1993	HOVIS  TO ATTEND MEDICAL DEVICE GMP'S AND QUALITY SYSTEMS CONFERENCE.
USA	GA	03-NOV-1992	11-NOV-1992	PONCE DE LEON  TO INTERVIEW WITH THE WOMENS' HEALTH AND FERTILITY BRANCH STAFF AT THE CENTERS FOR DISEASE CONTROL (CDC) IN ATLANTA ABOUT UPCOMING COLLABORATION AT THE WORLD HEALTH ORGANIZATION.
USA	GA	24-NOV-1992	24-NOV-1992	PRICE  TO MEET WITH FRED DIETSH OF ANSELL, INC. TO DISCUSS ACQUISITION OF EQUIPMENT (TRIP WAS CANCELLED DUE TO CANCELLATION OF FLIGHT TO DOTHAN, AL--TRAVELER GOT AS FAR AS ATLANTA, GA).
USA	KY	08-DEC-1992	11-DEC-1992	HOVIS  TO ATTEND "AUDITING FOR GMP" WORKSHOP.
USA	MA	19-OCT-1992	19-OCT-1992	HARDEE  TO PARTICIPATE IN A PANEL DISCUSSION ON TQM AND SQI HOSTED BY M.S.H.
USA	MA	29-OCT-1992	30-OCT-1992	HAWLEY  TO VISIT LAMB EQUIPMENT TO INVESTIGATE EQUIPMENT FOR NET RING OF THE PHASE II PROJECT.

FAMILY HEALTH INTERNATIONAL  
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Country	State	Start Date	End Date	Traveler
USA	MA	29-OCT-1992	30-OCT-1992	JOHNSON  TO VISIT LAMB EQUIPMENT TO INVESTIGATE EQUIPMENT FOR NET RING OF THE PHASE II PROJECT.
USA	MA	09-DEC-1992	11-DEC-1992	ANDREWS  TO ATTEND PRIM&R CONFERENCE--"IRB REVIEW: CHANGES & CHALLENGES."
USA	MA	28-FEB-1993	02-MAR-1993	WILSON  TO VISIT JPS ELASTOMER, DEERFIELD, INC. AND ARGOTECH, INC. TO VIEW THEIR POLYURETHANE FILMS; AND TO VISIT LAMB KNITTING, INC. TO REVIEW EQUIPMENT TRIAL OF THE RAW KNITTING MACHINE.
USA	MD	04-OCT-1992	09-OCT-1992	KELLOGG  TO ATTEND NESUG CONFERENCE AND TO ATTEND SAS COURSE.
USA	MD	04-OCT-1992	09-OCT-1992	TAYLOR  TO ATTEND NESUG CONFERENCE AND TO ATTEND SAS COURSE.
USA	MD	10-OCT-1992	13-OCT-1992	BAILEY  TO MEET WITH JHPIEGO STAFF RE: FAMILY PLANNING IN BRAZIL.
USA	MD	09-DEC-1992	09-DEC-1992	FINGER  TO ATTEND THE MEETING OF THE STEERING COMMITTEE TASK FORCE ON REPRODUCTIVE HEALTH COMMUNICATIONS OF THE APHA TO MAKE DECISIONS RE: TOPICAL EMPHASIS FOR ABSTRACTS TO BE REVIEWED, COORDINATION OF TASK FORCE PROJECTS FOR THE YEAR, GLOSSARY REVIEW, COORDINATION OF MARKETING/MAILING LISTS, AND COORDINATION OF MEDIA RELATIONS; AND TO MEET WITH EDITORS AT POPULATION REPORTS RE: NETWORK TOPICS, MAILING LISTS, AND GLOSSARIES.

Country -----	State -----	Start Date -----	End Date -----	Traveler -----
USA	MI	20-NOV-1992	20-NOV-1992	HOVIS  TO PERFORM QA AUDIT OF NAMSA.
USA	NC	01-NOV-1992	14-NOV-1992	JESENCKY  TO REVIEW AFRICA REGIONAL OFFICE ACTIVITIES WITH FHI/NC STAFF; REVIEW ONGOING PROJECTS AND DISCUSS PROJECT DEVELOPMENT POSSIBILITIES.
USA	NC	16-NOV-1992	19-NOV-1992	KENNEDY  TO CONSULT WITH FHI STAFF RE: NFP AND BF MANUSCRIPTS IN PROGRESS;TO DEVELOP PLANS FOR A PROGRAMMATIC EVALUATION OF THE DISTRIBUTION OF PROGESTIN-ONLY ORAL CONTRACEPTIVE USE BY POSTPARTUM WOMEN;TO BE BRIEFED ON FHI'S DOMESTIC AIDS AND MATERNAL CHILD HEALTH STRATEGIES (KENNEDY TRAVELLED TO FHI-RTP FROM DENVER, CO).
USA	NC	18-DEC-1992	22-DEC-1992	GOULD  TO WORK WITH KAREN HARDEE-CLEVELAND TO FINISH REPORT AND DRAFT A PAPER ON SERVICE QUALITY IMPROVEMENT.
USA	NC	22-JAN-1993	22-JAN-1993	HEDGPETH  TO VISIT KRS PLASTICS IN TAVOR CITY TO INSPECT SLITTER AND TO OBTAIN SLITTED FILM FOR FABRICATING CONDOMS.
USA	NC	15-FEB-1993	25-FEB-1993	MARMOL  TO WRITE A SUMMARY REPORT ON THE RESULTS OF THE 1992/1992 NATIONAL EPIDEMIOLOGY AND FAMILY HEALTH SURVEY.
USA	NC	15-FEB-1993	10-MAR-1993	PINEL  TO WRITE A SUMMARY REPORT ON THE RESULTS OF THE 1991/1992 NATIONAL EPIDEMIOLOGY AND FAMILY HEALTH SURVEY.

1/24

Country	State	Start Date	End Date	Traveler
-----	-----	-----	-----	-----
USA	NC	05-MAR-1993	20-MAR-1993	AMORNWICHET  TO WORK WITH BARBARA JANOWITZ AND STAFF OF THE SERVICE DELIVERY RESEARCH DIVISION ON ANALYSIS OF DATA FROM STUDY ON NORPLANT PROVISION BY NURSES IN THAILAND.
USA	NC	22-MAR-1993	27-MAR-1993	SMITH  TO WORK WITH LYNN ADRIAN ON SLIDES FOR JIM SHELTON REGARDING MEDICAL BARRIERS AND CTU MODULES; AND TO ATTEND THE PAHO/FHI SERVICE DELIVERY WORKSHOP.
USA	NC	24-MAR-1993	28-MAR-1993	GOULD  TO PARTICPATE AS A TRAINER AND FACILITATOR IN THE PAHO/FHI QUALITY OF CARE IN REPRODUCTIVE HEALTH WORKSHOP.
USA	NJ	13-DEC-1992	18-DEC-1992	GLOVER  TO ATTEND CONFERENCE ON APPLIED STATISTICS SPONSORED BY THE AMERICAN SOCIETY FOR QUALITY CONTROL.
USA	NY	29-OCT-1992	30-OCT-1992	HAWLEY  TO RUN OFF SAMPLES FROM EQUIPMENT AT VERTOD, INC.
USA	NY	29-OCT-1992	30-OCT-1992	JOHNSON  TO RUN OFF SAMPLES FROM EQUIPMENT AT VERTOD, INC.
USA	NY	05-NOV-1992	05-NOV-1992	FORTNEY  TO ATTEND A MEETING ON POSTMARKETING SURVEILLANCE PROJECT.
USA	NY	20-NOV-1992	22-NOV-1992	BALOGH  TO MEET WITH AVSC AND JHPIEGO STAFF RE: NORPLANT INTRODUCTION.

165-

Country -----	State -----	Start Date -----	End Date -----	Traveler -----
USA	NY	20-NOV-1992	20-NOV-1992	MORRISON  TO MEET WITH AVSC AND JHPIEGO STAFF RE: DEVELOPMENT OF NORPLANT INTRODUCTION STRATEGY (U.S. AID MISSION HAS REQUESTED THAT THE THREE CAS COLLABORATE ON DEVELOPING A STRATEGY AND DETERMINING TECHNICAL ASSISTANCE NEEDS).
USA	NY	08-DEC-1992	12-DEC-1992	PALMORE  TO MEET WITH AVSC AND POPULATION COUNCIL REGARDING ON-GOING PROJECTS AND FUTURE PROJECT COLLABORATIONS; TO MEET WITH LYNN BAKAMJIAN TO PLAN REDUCTION OF MEDICAL BARRIERS ON ORGANIZED EDUCATIONAL EVENTS.
USA	NY	08-DEC-1992	13-DEC-1992	SMITH  TO WORK WITH THE POPULATION COUNCIL TO PREPARE WORKSHOP PROCEEDINGS FROM THE OPERATIONS RESEARCH WORKSHOP.
USA	NY	08-DEC-1992	08-DEC-1992	WASZAK  TO MEET WITH STAFF AT AVSC TO DISCUSS PROGRESS ON KENYA POSTPARTUM IUD STUDY AND TO EXPLORE WAYS IN WHICH TO STRENGTHEN COLLABORATIVE RELATIONSHIP ON THIS AND FUTURE PROJECTS.
USA	NY	09-DEC-1992	11-DEC-1992	BALOGH  TO ATTEND CONFERENCE ON "RETHINKING POSTPARTUM HEALTH CARE."
USA	NY	10 DEC 1992	12-DEC-1992	KRNNKDY  TO PARTICIPATE IN A SEMINAR ENTITLED "RETHINKING POSTPARTUM HEALTH CARE" AND TO MAKE A PRESENTATION ON THE "ROLE OF BREAST-FEEDING IN FERTILITY REDUCTION."

1/1/93

Country	State	Start Date	End Date	Traveler
-----	-----	-----	-----	-----
USA	NY	13-DEC-1992	16-DEC-1992	JANOWITZ TO ATTEND A NORPLANT COSTING MEETING WITH THE POPULATION COUNCIL AND AVSC.
USA	NY	15-DEC-1992	16-DEC-1992	MONTEITH TO MONITOR THE NET PELLETS PHASE IIA STUDY (#890, CENTER #952).
USA	NY	15-JAN-1993	19-JAN-1993	PALMORE TO MEET WITH AVSC AND THE POPULATION COUNCIL TO PLAN THE COOPERATING AGENCIES MEETING ON DEPO-PROVERA INTRODUCTION.
USA	NY	03-FEB-1993	03-FEB-1993	HERNDON TO ATTEND A MEETING AT THE POPULATION COUNCIL OF COMMUNICATION OFFICERS FROM US-BASED FAMILY PLANNING ORGANIZATIONS.
USA	NY	10-FEB-1993	10-FEB-1993	MONTEITH TO MONITOR THE NET PELLETS PHASE IIA STUDY (#890, CENTER #952).
USA	NY	10-FEB-1993	10-FEB-1993	CONNELL TO MONITOR THE NET PELLETS PHASE IIA STUDY (#890, CENTER #952).
USA	NY	25-FEB-1993	25-FEB-1993	PALMORE TO MEET WITH AVSC STAFF REGARDING MARCH DEPO-PROVERA MEETING.
USA	NY	02-MAR-1993	05-MAR-1993	PALMORE TO ATTEND THE COOPERATING AGENCIES MEETING ON DEPO-PROVERA INTRODUCTION.
USA	NY	03-MAR-1993	05-MAR-1993	FLICK TO ATTEND THE COOPERATING AGENCIES MEETING ON DEPO-PROVERA INTRODUCTION.

1/10/93

Country -----	State -----	Start Date -----	End Date -----	Traveler -----
USA	NY	03-MAR-1993	07-MAR-1993	SMITH  TO ATTEND FHI/AVSC COLLABORATIVE MEETING ON DEPO-PROVERA HELD AT THE NATIONAL ACADEMY OF MEDICINE; AND TO ATTEND FOLLOW-UP MEETING AT AVSC ON INJECTABLES AND IUDS.
USA	NY	03-MAR-1993	05-MAR-1993	HERNDON  TO PARTICIPATE IN THE COOPERATING AGENCIES MEETING ON DEPO-PROVERA INTRODUCTION; TO PARTICIPATE IN A REVIEW OF EXPERTS' SLIDES AND KEY MESSAGES TO BE INCORPORATED INTO FHI'S MODULES (IUDS AND INJECTABLES).
USA	NY	03-MAR-1993	07-MAR-1993	JANOWITZ  TO PARTICIPATE IN THE COOPERATING AGENCIES MEETING ON DEPO-PROVERA INTRODUCTION.
USA	NY	03-MAR-1993	07-MAR-1993	ADRIAN  TO PARTICIPATE IN THE COOPERATING AGENCIES MEETING ON DEPO-PROVERA INTRODUCTION; TO PARTICIPATE IN A REVIEW OF THE EXPERTS' SLIDES AND KEY MESSAGES TO BE INCORPORATED INTO FHI'S MODULES (IUDS AND INJECTABLES).
USA	NY	03-MAR-1993	07-MAR-1993	VINCENT  TO PARTICIPATE IN THE COOPERATING AGENCIES MEETING ON DEPO-PROVERA INTRODUCTION; TO ATTEND THE FOLLOW-UP MEETING ON CONTRACEPTIVE TECHNOLOGY UPDATE PRESENTATIONS FOR IUDS AND INJECTABLES.
USA	NY	03-MAR-1993	04-MAR-1993	RIVERA  TO ATTEND THE COOPERATING AGENCIES MEETING ON DEPO-PROVERA INTRODUCTION.

FAMILY HEALTH INTERNATIONAL  
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Country -----	State -----	Start Date -----	End Date -----	Traveler -----
USA	NY	04-MAR-1993	05-MAR-1993	CHI  TO PARTICIPATE IN THE COOPERATING AGENCIES MEETING ON DEPO- PROVERA INTRODUCTION; TO ATTEND THE FOLLOW-UP MEETING ON CONTRACEPTIVE TECHNOLOGY UPDATE PRESENTATIONS FOR IUDS AND INJECTABLES.
USA	NY	19-MAR-1993	19-MAR-1993	CARTER  TO CONDUCT A PRODUCTION SURVEILLANCE AUDIT OF FINISHING ENTERPRISES.
USA	PA	07-NOV-1992	11-NOV-1992	DUNSON  TO SERVE AS PERSONAL CARE ATTENDANT FOR RANDY DUNSON AT PMA TRAINING PROGRAM.
USA	PA	07-NOV-1992	11-NOV-1992	DUNSON  TO ATTEND PMA TRAINING PROGRAM, "CLINICAL RESEARCH AND DEVELOPMENT."
USA	PA	08-NOV-1992	11-NOV-1992	FLICK  TO ATTEND PMA TRAINING PROGRAM, "CLINICAL RESEARCH AND DEVELOPMENT."
USA	PA	06-DEC-1992	09-DEC-1992	IRSULA  TO ATTEND PMA TRAINING PROGRAM, "CLINICAL RESEARCH AND DEVELOPMENT."
USA	PA	06-DEC-1992	09-DEC-1992	MARTINEZ  TO ATTEND PMA TRAINING PROGRAM, "CLINICAL RESEARCH AND DEVELOPMENT."
USA	PA	16-DEC-1992	20-DEC-1992	TAYLOR  TO ATTEND BARNETT INTERNATIONAL'S TWO-DAY WORKSHOP ENTITLED "WRITING FOR CLINICAL RESEARCH."

169

FAMILY HEALTH INTERNATIONAL  
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Country -----	State -----	Start Date -----	End Date -----	Traveler -----
USA	PA	11-FEB-1993	12-FEB-1993	CARTER  TO CONDUCT PRODUCTION SURVEILLANCE AUDITS OF WYETH-AYERST LO-FEMENAL AND OVRETTE MANUFACTURING AND DISTRIBUTION OPERATIONS.
USA	PA	21-FEB-1993	23-FEB-1993	LEWIS  TO ATTEND DIA WORKSHOP, "DOCUMENT MANAGEMENT AND IMAGING: DOMESTIC AND INTERNATIONAL ISSUES AND SOLUTIONS."
USA	PA	04-MAR-1993	07-MAR-1993	DORFLINGER  TO ATTEND A MEETING AT WYETH.
USA	PA	17-MAR-1993	19-MAR-1993	CARTER  TO ATTEND THE A.S.T.M. CONDOM TASK GROUP MEETING.
USA	PA	21-MAR-1993	25-MAR-1993	MAYETTE  TO ATTEND THE DIA WORKSHOP, "WORLDWIDE ISSUES AND SOLUTIONS FOR CLINICAL DATA MANAGEMENT."
USA	PA	21-MAR-1993	24-MAR-1993	NAILS  TO ATTEND THE DIA WORKSHOP, "WORLDWIDE ISSUES AND SOLUTIONS FOR CLINICAL DATA MANAGEMENT."
USA	PA	21-MAR-1993	24-MAR-1993	DOBBINS  TO ATTEND THE DIA WORKSHOP, "WORLDWIDE ISSUES AND SOLUTIONS CLINICAL DATA MANAGEMENT."
USA	PA	23-MAR-1993	24-MAR-1993	CARTER  TO CONDUCT A PRODUCTION SURVEILLANCE AUDIT OF SHARP CORPORATION.
USA	SC	21-MAR-1993	24-MAR-1993	QUICK  TO ATTEND DIA'S 4TH ANNUAL WORKSHOP ON MEDICAL COMMUNICATION.

FAMILY HEALTH INTERNATIONAL  
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Country	State	Start Date	End Date	Traveler
-----	-----	-----	-----	-----
USA	SC	21-MAR-1993	24-MAR-1993	TENORIO
				TO ATTEND DIA'S 4TH ANNUAL WORKSHOP ON MEDICAL COMMUNICATION.
USA	SC	27-MAR-1993	30-MAR-1993	STURGEN
				TO ATTEND DIA WORKSHOP, "STATISTICAL ISSUES IN THE PHARMA- CEUTICAL INDUSTRY: DESIGN, ANALYSIS AND INTERPRETATION ISSUES IN CLINICAL TRIALS."
USA	TX	03-NOV-1992	08-NOV-1992	BURDAN
				TO ATTEND AMWA'S ANNUAL CONFERENCE, "COMMUNICATIONS FROM THE FRONTIERS OF MEDICINE."
USA	TX	03-NOV-1992	08-NOV-1992	JONES
				TO ATTEND AMWA'S ANNUAL CONFERENCE, "COMMUNICATIONS FROM THE FRONTIERS OF MEDICINE."
USA	TX	03-NOV-1992	08-NOV-1992	KRUEGER
				TO ATTEND AMWA'S ANNUAL CONFERENCE, "COMMUNICATIONS FROM THE FRONTIERS OF MEDICINE."
USA	TX	03-NOV-1992	08-NOV-1992	WADE
				TO ATTEND AMWA'S ANNUAL CONFERENCE, "COMMUNICATIONS FROM THE FRONTIERS OF MEDICINE."
USA	TX	04-NOV-1992	08-NOV-1992	WILLIAMSON
				TO ATTEND AMWA'S ANNUAL CONFERENCE, "COMMUNICATIONS FROM THE FRONTIERS OF MEDICINE."
USA	VA	08-OCT-1992	08-OCT-1992	WELSH
				TO MEET WITH DEVELOPMENT ASSOCIATES TO DISCUSS AREAS FOR POTENTIAL COLLABORATIONS IN INTERNATIONAL HEALTH, FAMILY PLANNING AND AIDS.

171

FAMILY HEALTH INTERNATIONAL  
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Country -----	State -----	Start Date -----	End Date -----	Traveler -----
USA	VA	20-OCT-1992	20-OCT-1992	DALBERTH  TO CONDUCT TRAINING ON SOFTWARE PACKAGE AT CONRAD.
USA	VA	26-OCT-1992	31-OCT-1992	LINK  TO CONDUCT PRODUCTION SURVEILLANCE SAMPLING AT MATRIX AND WINDSOR WAREHOUSE.
USA	VA	26-OCT-1992	31-OCT-1992	MARTIN  TO CONDUCT PRODUCTION SURVEILLANCE SAMPLING AT MATRIX AND WINDSOR WAREHOUSE.
USA	VA	05-NOV-1992	06-NOV-1992	MONTEITH  TO MONITOR PHASE IIA OF NET PELLET STUDY AT CONRAD.
USA	VA	04-DEC-1992	04-DEC-1992	DORFLINGER  TO ATTEND LEA'S SHIELD MEETING AT CONRAD.
USA	VA	04-DEC-1992	04-DEC-1992	DOMINIK  TO ATTEND LEA'S SHIELD MEETING AT CONRAD.
USA	VA	07-DEC-1992	10-DEC-1992	MARTIN  TO CONDUCT PRODUCTION SURVEILLANCE SAMPLING AT MATRIX WAREHOUSE WITH JEFF GODBOLD.
USA	VA	07-DEC-1992	11-DEC-1992	GODBOLD  TO ACCOMPANY ALVIN MARTIN TO MATRIX WAREHOUSE TO CONDUCT PRODUCTION SURVEILLANCE SAMPLING.
USA	VA	17-DEC-1992	18-DEC-1992	POTTS  TO PARTICIPATE IN THE REDUCTION OF MEDICAL BARRIERS WORKING GROUP ON ORGANIZED EDUCATIONAL EVENTS AT CONRAD.

FAMILY HEALTH INTERNATIONAL  
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Country	State	Start Date	End Date	Traveler
-----	-----	-----	-----	-----
USA	VA	10-JAN-1993	15-JAN-1993	CARTER  TO COMPLETE PRODUCTION SURVEILLANCE SAMPLING AT MATRIX WAREHOUSE AND TO ATTEND MEETING AT AID.
USA	VA	14-JAN-1993	14-JAN-1993	PHILLIPS  TO ATTEND TRAINING MATERIALS WORKING GROUP MEETING AT DEVELOPMENT ASSOCIATES.
USA	VA	17-JAN-1993	18-JAN-1993	PALMORE  TO PARTICIPATE IN THE REDUCTION OF MEDICAL BARRIERS WORKING GROUP MEETING ON ORGANIZED EDUCATIONAL EVENTS AT CONRAD.
USA	VA	20-JAN-1993	21-JAN-1993	MONTEITH  TO MONITOR PHASE IIA OF NET PELLETS STUDY AT CONRAD.
USA	VA	01-MAR-1993	02-MAR-1993	LEWIS  TO PARTICIPATE IN AIDSTECH CLOSEOUT WORKSHOP (50% OF TRIP FUNDED BY AIDSTECH FUNDS).
USA	VA	06-MAR-1993	09-MAR-1993	MONTEITH  TO MONITOR NET PELLETS PHASE IIA STUDY (#890, CENTER #908).
USA	VA	21-MAR-1993	23-MAR-1993	CARTER  TO ATTEND CPSD ASSOCIATED MEETING.
USA	VA	23-MAR-1993	23-MAR-1993	FLICK  TO ASSIST IN THE NET PELLET PHASE IIA LAB AUDIT (STUDY #890, CENTER #908).
USA	VA	23-MAR-1993	23-MAR-1993	HOVIS  TO CONDUCT THE NET PELLET PHASE IIA LAB AUDIT (STUDY #890, CENTER #908).

FAMILY HEALTH INTERNATIONAL  
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-OCT-1992 THROUGH 31-MAR-1993  
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-9997

Country -----	State -----	Start Date -----	End Date -----	Traveler -----
USA	VA	23-MAR-1993	23-MAR-1993	MONTEITH  TO ASSIST IN THE NET PELLETT PHASE IIA LAB AUDIT (STUDY #890, CENTER #908).
USA	WA	03-DEC-1992	04-DEC-1992	CARTER  TO VISIT PATH RE: COLLABORATION ON MODIGRAPH OF CONDOMS PER AID/WASHINGTON.
USA	WA	03-DEC-1992	04-DEC-1992	PRICE  TO VISIT PATH ALONG WITH ELI CARTER RE: COLLABORATION ON MODIGRAPH OF CONDOMS PER AID/WASHINGTON.
USA	WA	10-MAR-1993	11-MAR-1993	PRICE  TO VISIT MR. NELSON OF PATH TO DISCUSS DELIVERY SYSTEM PROJECT.

## **APPENDIX C**

### **FHI Staff and Consultant Project Travel**

115

FAMILY HEALTH INTERNATIONAL

INTERNATIONAL/DOMESTIC TRAVEL PLAN: APRIL 1, 1993 - SEPTEMBER 30, 1993

<b>SITE PURPOSE</b>	<b>TRAVELER</b>	<b>DATES</b>	<b>FUNDING CODE</b> 1) AID/POP 2) AID/H 3) OTHER (code # only)	<b>PRIMARY</b>
<b><u>AFRICA</u></b>				
Burkina Faso	Adrian	Apr/May	1	Initiate RMB study guidelines with INTRAH
Burkina Faso (+Cameroon)	Thompson	Apr (1 Mo)	1	Implement RMB studies
Burkina Faso (+Cameroon)	Thompson	Aug (1 Mo)	1	Follow-up RMB studies
Burundi	Spilsbury	May (2 Wks)	2	Monitor cohort surveillance study
Cameroon	Phillips	Mar/Apr (2 Wks)	2	Assess IEC component of AIDSCAP CSW project; work with peer leaders to develop new IEC materials
Cameroon	Adrian	Apr (2 Wks)	1	Initiate RMB study on guidelines with INTRAH
Cameroon (+Burkina Faso)	Thompson	Apr (1 Mo)	1	Follow-up RMB studies
Cameroon (+Burkina Faso)	Thompson	Aug (1 Mo)	1	Follow-up RMB studies
Cameroon	Phillips	Aug/Sep (2 Wks)	2	Develop new IEC materials for AIDSCAP
Egypt	Carter	Sep	1	Field surveillance
Ethiopia	Jesencky	Apr 19-24	1	Discuss program development possibilities with A.I.D. mission and local FP authorities
Ghana	Fortney/Smith, JB	Jun	1,2	USAID TBA training Close out NORPLANT

SITE	TRAVELER	DATES	FUNDING CODE		PRIMARY PURPOSE
			1) AID/POP	2) AID/H	
			3) OTHER	(code # only)	
Kenya	Terwey	Apr	1		Regional office communication
Kenya	Cole	Apr/May (1 Wk)	1		Plan with Jesencky
Kenya	Hardee	Apr/May (10 days)	1		Study initiation of CBD project/FPAK
Kenya (+Nigeria)	Janowitz/Villinski	Jun/Jul (3 Wks)	1		Draft proposal for cost study
Kenya *(or Pakistan)	Palmore	Jun/Jul (2 Wks)	1		Attend Kenya (or Pakistan) CTU
Kenya	Nichols	Jul (Late) (2 Wks)	1		IDP close-of-project seminar
Kenya	Allen	Jul (2 Wks)	1		Develop HIV/reversible contraception study; monitor and close-out studies under IDP regional office affairs
Kenya	McMullen	Aug	1		Monitor POC study
Malawi	Joanis	Jun (1 Wk)	1		Initiate female condom acceptability study
Malawi	Balogh/Jesencky	May (2 Wks)	3		Establish linkages and preliminary contacts; determine program needs for the planned upcoming RFP on FP and child health
Mali (+Niger +Senegal)	Katz	May (3 Wks)	3		Plan follow up survey for "Save the Children:"
			1		Identify research objectives for NORPLANT introduction

111

SITE	TRAVELER	DATES	FUNDING CODE		PRIMARY PURPOSE
			1) AID/POP	2) AID/H	
Mali	Spilsbury	Jun (1 Wk)	1		Monitor NORPLANT introduction
Mali	Katz	Sep (2 Wks)	1		Supervise follow up KAP survey
Niger (+Mali +Senegal)	Katz	May (3 Wks)	1		Implement IPPI study
Niger	Spilsbury	Jun (2 Wks)	1		Attend OR Research Dissemination Conference; monitor IPPI study
Niger	Carter	Sep	1		Monitor Prospective Aging Study
Nigeria	Nichols	Apr/May (2 Wks)	1		FHS Training Evaluation Survey Report
Nigeria	Jesencky	Apr (1 Wk)	1		Plan for CTU
Nigeria	Consultants (2)	May/June (1 Wk)	1		Consultants to CTU
Nigeria (+Kenya)	Janowitz/ Villinski	Jun/Jul (3 Wks)	1		Explore costing opportunities
Senegal (+Mali +Niger)	Katz	May (3 Wks)	1		Monitor NORPLANT introduction study
Senegal	Murray	Jun 14-18	1		Monitor NORPLANT introduction
Zambia	Joanis/ Morrison	Jun (1 Wk) Jun 4-14	1		Initiate female condom and HIV study
Zimbabwe	McMullen	Aug	1		Monitor POC study

118

SITE	TRAVELER	DATES	FUNDING CODE 1) AID/POP 2) AID/H 3) OTHER (code # only)	PRIMARY PURPOSE
<b><u>ASIA/NEAR EAST</u></b>				
Bangladesh	Hardee	Mar 31/Apr 9	1	Participate with Pathfinder in a regional Quality of Care Workshop
Bangladesh	Janowitz/ Hubacher	Apr (Late) (14 Days)	1	Initiation of cost study
Bangladesh	Hubacher	Jul (14 Days)	1	Monitor cost study
Bangladesh	Carter	August	1	Field surveillance
China	Zhang/ Roddy	Sep (1 Wk)	3	Attend the WHO IUD Committee meeting
CIS (+Uzbekistan/ +Kyrgyzstan/ +Kazakhstan/ +Turkmenistan)	Tucker	Apr (3 Wks)	3	Initiate FHI/IPPF activities
CIS (+Uzbekistan/ +Kyrgyzstan/ +Kazakhstan/ +Turkmenistan)	Tucker	Sep (2 Wks)	3	Follow up FHI/IPPF activities
Egypt	Waszak	May (10 Days)	1	Technical assistance to IDP
Egypt	Murray/ Bhiwandi/ Potts (Consultants)	Jun 18/Jul 5 Jun 24/Jul 2	1 1	Coordinate CTUs Consultants to CTU
Egypt	Waszak	Jul (10 Days)	1	Technical assistance to IDP
India (+Pakistan)	Kliesen	May (3 Wks)	1	Facilitate CTU project development

100

SITE	TRAVELER	DATES	FUNDING CODE 1) AID/POP 2) AID/H 3) OTHER (code # only)	PRIMARY PURPOSE
Indonesia	King	Apr 6-10	3	Attend & present at World Congress of Human Reproduction
Indonesia	Bailey	Apr/May	3	Assist in data analysis of Maternal Morbidity Survey (Ford)
Indonesia	Monteith	May	3	Monitor POC study
Indonesia	Fortney/ Smith, JB/ Bailey	Sep	3	Maternal Morbidity Survey (Ford)
Iran	Tucker Fortney	Jul 11-15	3	Attend UNFPA-sponsored Regional Conference on Family Planning
Jordan	Balogh	May (2 Wks)	1	Develop the project paper and PIO/T for a postpartum care project funded by USAID Amman
Malaysia	Monteith	May	1	Monitor POC study
Nepal	Palmore	Jul (1 Wk)	1	Consult with Shyam Thapa and others on future work in Nepal and India; plan regional meeting of CTU experts
Nepal	Carter	Aug	1	Field surveillance
Pakistan (+India)	Kliesen	May (3 Wks)	1	Facilitate CTU project development
Philippines	Monteith	May	1	Monitor POC study
Philippines	McMahan	Jun 13-20	1	Explore opportunities for future FHI involvement

SITE	TRAVELER	DATES	FUNDING CODE 1) AID/POP 2) AID/H 3) OTHER (code # only)	PRIMARY PURPOSE
Philippines	Spruyt	Jul 4-10	1	Technical assistance for use/misuse study
Thailand	McMahan	Jun 3-5	3	Plan new projects in southeast Asia with FHI regional representative
Vietnam	King/ Connell/ Hananberg/ Waszek	Apr 8-18	3	Develop sterilization project
Vietnam	McMahan	Jun 6-13	3	Development of CT Research Methods Workshop
Vietnam	McKay	Jul or Aug	3	Fundraising

10

SITE	TRAVELER	DATES	FUNDING CODE 1) AID/POP 2) AID/H 3) OTHER (code # only)	PRIMARY PURPOSE
<u>CANADA/EUROPE</u>				
Canada	Hardee	Aug (4 Days)	1	Attend a meeting at IUSSP
England	Tucker	Apr (3 Days)	3	Plan FHI/IPPF CIS activities
Finland	Roddy/ Feldblum	Aug 27/Sep 3 Aug 30/Sep 6	1	Attend the International Society of STD Researchers Conference
Italy (+Switzerland)	Fortney	May	3	World Bank/WHO
Norway	Fortney	Aug 2-6		Attend International Preparatory Conference
Sweden	Morrison	May 30/Jun 6	1	STD Behavioral Epidemiology Training
Switzerland (+Italy)	Fortney	May	3	World Bank/WHO
Switzerland	Kennedy	May (1 Wk)	3	Task Force on Natural Methods of Fertility Regulation meeting
Switzerland	Dorflinger	May 25/Jun 4	3	WHO meeting and Steering Committee
Switzerland	King	Jun 22-25	3	WHO Policy & Coordination Committee
Switzerland	King	Aug 20/Sep 2	3	WHO Consultation on Tubal Occlusion
Switzerland	Potter	Sep (Weekend)	3	Attend International Workshop on OC Compliance
Switzerland	Sokal	Sep	3	WHO meeting on Nonsurgical Sterilization

162

SITE	TRAVELER	DATES	FUNDING CODE 1) AID/POP 2) AID/H 3) OTHER (code # only)	PRIMARY PURPOSE
------	----------	-------	---	-----------------

LATIN AMERICA/CARIBBEAN

Argentina (+Brazil/ +Peru)	Beamish	Apr 5-9	1	Conduct needs assessment for journalism workshop
Argentina	Potter/ Hubacher	May 22-25 May 23-26	1	Make a presentation at LA Association of Human Reproduction Research
Argentina	Aznar/ Cravioto/ Diaz/Rivera/ Ulloa	May 24-26	1	Attend ALIRH meeting
Brazil	Bailey	July	3	Development
Brazil	Schwingl	Aug 8-18	3	Initiate study of the effect of OCs on gonadotropin levels according to dietary lactose
Brazil (+Argentina/ +Peru)	Beamish	Sep 5-25	1	Facilitate journalism training workshop
Brazil	Bisgrove	Sep 15-25	3	Training for OC diet study
Chile	Rivera	Apr 17-24	1	Attend CRR/WHO meeting
El Salvador	Olguin	Aug	1	Monitor NORPLANT study
Ecuador	Bratt	May (Mid) (6 Days)	1	Training local researchers in costing analysis
Ecuador (+Guatemala)	Beamish	Jun 1-5	1	Facilitate postpartum conference

SITE	TRAVELER	DATES	FUNDING CODE 1) AID/POP 2) AID/H 3) OTHER (code # only)	PRIMARY PURPOSE
Ecuador	Bratt	Aug (12 Days)	1	Initiation of costing studies
El Salvador	Fox	Jun (1 Wk)	1	Participate in NORPLANT introduction; provide training with JHPIEGO
El Salvador	Beamish	Jul (1 Wk)	1	Develop NORPLANT IEC materials
Guatemala (+Ecuador)	Beamish	Jun 1-5	1	Facilitate postpartum conference
Haiti	Trottier	Apr/May (1 Wk)	1	Develop NORPLANT project
Haiti	Spilsbury	Aug (2 Wks)	1	Monitor NORPLANT introduction
Honduras	Bratt	May (Mid) (4 Days)	1	Develop Economics projects
Honduras	Hubacher	May (Mid) (6 Days)	1	Analyze survey data
Honduras	Hubacher	Aug (8 Days)	1	Analyze survey data
Honduras (+Mexico)	Bailey	Aug	3	Development, develop Hospital Abortion Study
Jamaica	Hardee	Apr (10 Days)	1	Assess the RMB study
Mexico (+Honduras)	Bailey	Aug	3	Development, develop Hospital Abortion Study
Mexico	Carter	May	1	Monitor Prospective Aging Study

SITE	TRAVELER	DATES	FUNDING CODE 1) AID/POP 2) AID/H 3) OTHER (code # only)	PRIMARY PURPOSE
Mexico	Flick	May	1	Initiate TIV study
Mexico	Irsula/ Martinez	May 9-21	1	Monitor POC study
Mexico (From)	Jorge Martinez- Manautou	Jun 30-Jul 2	1	1993 TAC meeting
Mexico	Potter	Jun/Jul (2 Wks)	1	Test OC instructions
Mexico	Hubacher	Jun (8 Days)	1	Initiate new injectables study; monitor progress IUD project (both are costing studies)
Mexico	Hubacher	Sep (8 Days)	1	Implement injectables project; analyze data from IUD study
Mexico	Irsula	Sep 12-24	1	Monitor POC study
Peru (+Argentina/ +Brazil)	Beamish	Apr 5-9	1	Conduct needs assessment for journalism workshop
Peru (+Argentina/ +Brazil)	Beamish	Sep 5-25	1	Facilitate journalism training workshop
Venezuela	Olguin	Apr	3	Monitor RRV vaccine trial
Venezuela	Olguin	Jul	3	Monitor RRV vaccine trial
New LAC Office	Terwey	Aug	2	Provide technical assistance

SITE	TRAVELER	DATES	FUNDING CODE 1) AID/POP 2) AID/H 3) OTHER (code # only)	PRIMARY PURPOSE
<b><u>UNITED STATES OF AMERICA</u></b>				
Alabama	Price	Apr 27/May 2	3	Annual meeting for Biomaterials Society
Alabama	Brownm M/ Carter	Apr	1	Perform production audit at Aladan
Alabama	Brown, M	May	1	Perform production audit at Aladan
Alabama	Brown, M	Jun	1	Perform production audit at Aladan
Alabama	Brown, M	Jul	1	Perform production audit at Aladan
Alabama	Brown, M	Aug	1	Perform production audit at Aladan
Alabama	Brown, M	Sep	1	Perform production audit at Aladan
California	Harris	May 1-5	1	Attend Society of Research Administrators Section meeting
California	Cheek/ Smith, JB	May	1	INTEROP meeting
California	Amatya/ Dominik	Aug 8-12	1	American Statistical Association joint Statistical meetings
California	Smith, JB/ Terwey	Aug	1	Attend INET Seminar
Colorado	Wilson	May	1	ACS; Rubber Division
Colorado	Schwingl/  Zhang	Jun 15-18	1	Present at Society of Epidemiology Research Conference; Attend SER Conference

186

SITE	TRAVELER	DATES	FUNDING CODE 1) AID/POP 2) AID/H 3) OTHER (code # only)	PRIMARY PURPOSE
D.C.	Cole	Apr (2 Days)	1	Meet with Bureaus
D.C.	Palmore	Apr (1 Day)	1	Attend RMB A.I.D. Steering Committee meeting
D.C.	Carter	Apr	1	Meeting with A.I.D.
D.C.	Fortney	Apr	3	Development
D.C.	Price	Apr	1	Meeting with A.I.D.
D.C.	Perez	Apr (1-2 days)	3	FHI business
D.C.	Lewis, JH	Apr (1-2 days)	1,3	FHI business
D.C.	Dorflinger	Apr 12-14	3	NAS Committee meeting
D.C. (+Maryland)	Perez	Apr 20-25	3	Meetings pertaining to Board
D.C.	Herdon	Apr/May (2 Days)	1	Collaboration with CAs on CTU modules
D.C.	Palmore	May (1 Day)	1	Chair RMB Organized Educational Events working Group meeting
D.C.	Perez	May (1-2 days)	3	FHI business
D.C.	Lewis, JH	May (1-2 days)	1,3	FHI business
D.C.	McKay	May	3	Fundraising
D.C.	Carter	May	1	Meeting with A.I.D.
D.C.	RA/QA Asso. (recruiting)	May 3-7	1	RAPS Drug, Device or Biologics Workshop, as appropriate
D.C.	Dorflinger	May 5	3	NAS Committee
D.C.	Welsh	May 10/11	3	Project development/ proposal writing

197

SITE	TRAVELER	DATES	FUNDING CODE		PRIMARY PURPOSE
			1) AID/POP	2) AID/H	
			3) OTHER		
			(code # only)		
D.C.	Palmore	Jun (1 Day)	1		Attend RMB A.I.D. Steering Committee meeting
D.C.	Perez	Jun (1-2 days)	3		FHI business
D.C.	Lewis, JH	Jun (1-2 days)	1,3		FHI business
D.C.	Carter	Jun	1		Meeting with A.I.D.
D.C.	Price	Jun	1		Meeting with A.I.D.
D.C.	Rogers	Jun 1-2	3		Collect photographs necessary for Publications Unit
D.C.	Omohundro	Jun 14-15	1		FDLI Medical Device Update
D.C.	King/ Rivera	Jun 14-26	3		CONRAD TAC
D.C.	McKay/ Adrian	Jun 20-23	3		Attend NCIH meeting
D.C.	Perez	Jul (1-2 days)	3		FHI business
D.C.	Lewis, JH	Jul (1-2 days)	1,3		FHI business
D.C.	Robinson	Jul (2 Days)	1		Discuss information programs with A.I.D.
D.C.	Carter	Jul	1		Meeting with A.I.D.
D.C.	Perez	Aug (1-2 days)	3		FHI business
D.C.	Lewis, JH	Aug (1-2 days)	1,3		FHI business
D.C.	Carter	Aug	1		Meeting with A.I.D.
D.C.	Fortney	Aug	3		Development
D.C.	Price	Aug	1		Meeting with A.I.D.

108

SITE	TRAVELER	DATES	FUNDING CODE 1) AID/POP 2) AID/H 3) OTHER (code # only)	PRIMARY PURPOSE
D.C.	Palmore	Sep (2 Days)	1	Attend RMB A.I.D. Steering Committee and Organized Education Events Working Group meetings
D.C.	Perez	Sep (1-2 days)	3	FHI business
D.C.	Lewis, JH	Sep (1-2 days)	1,3	FHI business
Florida	Lee	Mar 31/Apr 3	1	20th Annual Assistants Seminar
Florida	Romocki	Apr 5-9	3	Monitor Belle Glade project
Florida	Dominik	May	1	Society for Clinical Trials meeting
Florida	Welsh	Jun 7/9	3	Project development/ proposal writing
Florida	Fox	Jul (3 Days)	3	Implement household survey for adolescent peer education HIV prevention program
Georgia	Welsh	Apr (1-2 Days)	3	Project development/ proposal writing
Georgia	Sokal	Apr 19-23	1	CDC Annual Epidemiology Conference
Georgia	2-3 Staff (SSS Div.)	May	1	DECUS Conference
Georgia	Carter	Jun	1	ASTM meeting
Illinois	Bean/ Cameron	Apr 16-17	1	Attend course on publications design
Illinois	McKay	Apr/May	3	Fundraising

128

SITE	TRAVELER	DATES	FUNDING CODE 1) AID/POP 2) AID/H 3) OTHER (code # only)	PRIMARY PURPOSE
Illinois	Dunson	Jul	1	Professional Advancement Workshop
Illinois	Wilson	Aug	1	ACS; National Convention
Indiana	Cole	May	1	Midwest Biopharmaceutical Statistical Workshop
Louisiana	Rogers	May 5-6	1	Attend course on publications design
Maryland	Omohundro	Apr 13-15	1	ASQC - Biomedical Techniques & Tools for FDA Regulatory Submissions EAST 1993
Maryland (+D.C.)	Perez	Apr 20-25	3	Meetings pertaining to Board
Maryland	Roddy	May 24-26	3	Attend working group for NIH on virucides
Maryland (from Egypt) (+North Carolina)	El-Girdi	Jun 21/Jul 14	1	Attend epidemiology course and visit FHI
Massachusetts	Palmore	Apr (1 Day)	1	Visit Pathfinder and MSH for possible collaboration activities
Massachusetts	Johnson/ Wilson	Aug	1	Visit Deerfield Polyurethanes
Michigan	Wilson	Jun	1	Dow Chemical
Michigan	Carter/ Price	Jul	1	Depo-Provera monitoring at Upjohn, Inc.

SITE	TRAVELER	DATES	FUNDING CODE 1) AID/POP 2) AID/H 3) OTHER (code # only)	PRIMARY PURPOSE
Michigan (from Egypt) (+North Carolina)	Said	Jul 11/Aug 4	1	Attend epidemiology course and visit FHI
New Jersey	Hovis	May 17-19	1	Dermal Toxicology
New Jersey	Hedgpeth	Jun	1	CPA Seminar
New York/ Connecticut	McKay	Apr	3	Fundraising/ project development
New York	Fortney	Apr	1,3	UNFPA, Rockefeller
New York	Fox	Apr (3 Days)	3	Develop NY AIDS prevention initiative (USAPI)
New York	Palmore	Apr (2 Days)	1	Follow up CAs meeting on Depo-Provera; work on Summary Report
New York	Tucker	Apr (1 Day)	3	Discuss CIS program with UNFPA
New York	Hardee	Apr 28-30	3	Speak at Cornell
New York	Robinson	May (2 Days)	3	Fundraising at UNFPA and other agencies
New York	Herndon	May (1 Day)	1	Attend Task Force on Communication
New York	Montgomery/ Bolotin	May 8-12	1	SUGI 18 Conference
New York	Monteith	May 10-11	1	Monitor NET Pellets study
New York	Carter	May	1	Production audit at Finishing Enterprises

10

SITE	TRAVELER	DATES	FUNDING CODE 1) AID/POP 2) AID/H 3) OTHER (code # only)	PRIMARY PURPOSE
New York	Palmore	Jun (2 Days)	1	Attend meeting with WHO, IWHC and the Population Council Women's Health Advocacy
New York	Rogers	Jun 3-4	3	Collect photographs necessary for Publications Unit
New York	Monteith	Jun 21-22	1	Monitor NET Pellets study
New York	Monteith	Aug 2-3	1	Monitor NET Pellets study
New York	Carter	Aug	1	Production audit at Finishing Enterprises
New York	McKay	Sep	3	Fundraising
North Carolina	Hawley	Apr	1	Southeast Regional Machine Show
North Carolina	Hedgpath	Apr	1	GMP Assessment
North Carolina (from Colorado)	Kennedy	Apr (1 Wk)	1	Supervise and manage ongoing projects
North Carolina (from Kenya)	Odhiambo	May 1-15	1	Familiarize himself with FHI/NC staff and procedures; project development activities with CUE and SDR staff
North Carolina (from Kenya)	Jesencky	Jun 5-19	1	Update FHI/NC staff on activities in East and Southern Africa; develop strategies and priorities for region
North Carolina (+Maryland/from Egypt)	El-Girdi	Jun 21/Jul 14	1	Attend epidemiology course and visit FHI

SITE	TRAVELER	DATES	FUNDING CODE		PRIMARY PURPOSE
			1) AID/POP	2) AID/H	
			3) OTHER	(code # only)	
North Carolina (+Michigan/from Egypt)	Said	Jul 11/Aug 4	1		Attend epidemiology course and visit FHI
Ohio	Bisgrove/ Cole/ Nichols/ Potter/ Smith, JB	Mar 29/Apr 3	1		Attend Psychosocial Workshop and/or PAA meeting
			3		
			1		
			1		
		Apr 1-4	1		
	Barrows	Mar 30/Apr 3	1		Attend APLIC Board Meeting
Ohio	Nowell	Jun	1		Terminology Conference
Pennsylvania	Carter	Apr	1		Production audit at Sharp Mfg.
Pennsylvania	Connell/ Farr	Apr	1		Biosyn
Pennsylvania	Carter	Jul	1		Production audit at Sharp Mfg.
Puerto Rico	Carter	Apr	1		Production audit at Wyeth-Ayerst
Puerto Rico	Carter	Jul	1		Production audit at Wyeth-Ayerst
S. Carolina	Sturgen	Mar 29-31	1		DIA Statistical meeting
S. Carolina	Cole/ Mayette/ Joanis	Apr 26-27	1		Attend Quality of Life Symposium
S. Carolina	Williamson, C	May 16-19	1		Attend Society for Research Administrators
Texas	Fox	Apr/May (3 Days)	3		Develop US/Mexico border proposal (USAPI)

193

SITE	TRAVELER	DATES	FUNDING CODE 1) AID/POP 2) AID/H 3) OTHER (code # only)	PRIMARY PURPOSE
Texas	McKay	May	3	Project development/ fundraising
Texas	Burdan	Jun 6-9	1	Technical Communica- tions 40th Annual Conference
Virginia	Capps	Apr	3	Computer support
Virginia	Monteith	Apr 14-15	1	Monitor NET Pellets study
Virginia	Sokal	May 10-13	1	Training course in Clinical R&D
Virginia	Monteith	May 26-27	1	Monitor NET Pellets study
Virginia	Brown/ Carter	May	1	Perform production audit at Aladan
Virginia	Brown/ Carter	Jun	1	Perform production audit at Aladan
Virginia	Monteith	Jul 7-8	1	Monitor NET Pellets study
Virginia	Brown/ Carter	Jul	1	Perform production audit at Aladan
Virginia	Brown/ Carter	Aug	1	Perform production audit at Aladan
Virginia	Brown/ Carter	Sep	1	Perform production audit at Aladan
Virginia	Saylor	Every 6 wks	3	Staff training, computers
Virginia	Terwey	As requested	3	Computer manage- ment and support
Virginia	Cheek	As requested	3	Communication support, computers

199

---

SITE	TRAVELER	DATES	FUNDING CODE 1) AID/POP 2) AID/H 3) OTHER (code # only)	PRIMARY PURPOSE
Washington	Price	Jul	1	Monitor Path project
Wisconsin	Potter	Jun 11	1	Train with Planned FNP

---

195

**APPENDIX D**  
**Publications List**

PUBLICATIONS LIST OCT. 1, 1992 - MAR. 31, 1993

92-29 Steiner M, Foldes R, Cole D, Carter E. Study to determine the correlation between condom breakage in human use and laboratory test results. Contraception 1992 Sept; 46(3):279-288.

92-30 Hubacher D, Bailey P, Janowitz B, Barahona F, Pinel M. Estimating infant mortality prospectively in Honduras. J Biosoc Sci 1992 Oct; 24(4):433-445.

92-31 Zhang J, Feldblum PJ, Chi IC, Farr MG. Risk factors for copper T IUD expulsion: an epidemiologic analysis. Contraception 1992 Dec; 46(6):427-433.

92-32 Feldblum PJ, Zhang J, Rich LE, Fortney JA, Talmage RV. Lactation history and bone mineral density among perimenopausal women. Epidemiology 1992 Nov; 3(6):527-531.

92-33 Chi IC. The Multiload IUD: A U.S. researcher's evaluation of a European device. Contraception 1992 Dec; 46(6):407-425.

92-34 Xu JX, Connell C, Chi IC. Immediate postpartum intrauterine device insertion: a report on the Chinese experience. Adv Contr 1992 Dec; 8(4):281-290.

92-35 Hassan EO, Kafafi LH, El Hussein M, Hardee-Cleaveland K, Potter LS. The acceptability of NORPLANT in Egypt. Adv Contr 1992 Dec; 8:331-348.

92-36 Garza-Flores J, Martínez M, Valles de Bourges V, Vázquez-Estrada L, McMullen S, Dunson TR, Pérez-Palacios G. Comparative assessment of two low-dose oral contraceptives, Lo-Femenal and Lo-Estrin, in Mexican women. Adv Contracept 1992 Dec; 8(4):291-301.

92-37 Rivera K, Farr G, Chi IC. The Copper IUD, safe and effective: the international experience of Family Health International. Research Triangle Park NC: Family Health International; 1992.

92-38 Janowitz B, Bratt JH. Costs of family planning services: a critique of the literature. Int Fam Plann Perspect 1992 Dec; 18(4):137-144.

92-39 Cotton N, Stanback J, Maidouka H, Taylor-Thomas JT, Turk T. Early contraceptive discontinuation in Niger and The Gambia. Int Fam Plann Perspect 1992 Dec; 18(4):145-149.

92-40 Russell-Brown P, Williamson N. The role of Caribbean family planning programs in AIDS prevention. In: Lamptey P, White F, Figueroa JP, Gringle R (eds). The Handbook for AIDS Prevention in the Carribean. Research Triangle Park, NC: Family Health International; p.149-159, 1992.

92-41 Lamptey P, White F, Figueroa JP, Gringle R (eds). The Handbook for AIDS Prevention in the Caribbean. Research Triangle Park, NC: Family Health International; 1992. 260 p.

93-01 Chi IC. The safety and efficacy issues of progestin-only contraceptives: an epidemiologic perspective. Contraception 1993 Jan; 47(1):1-21.

93-02 Dunson TR, McLaurin VL, Grubb GS, Rosman AR. A multicenter clinical trial of a progestin-only oral contraceptive in lactating women. Contraception 1993 Jan; 47(1):23-25.

93-03 Roddy RE. Predisposing factors for pelvic inflammatory disease. J Am Acad Physician Assist 1993 Jan; 6(1):42-47.

93-04 Chi IC, Thapa S. Postpartum tubal sterilization: an international prospective on some programmatic issues. J Biosoc Sci 1993 Jan; 25:251-256.

**APPENDIX E**

**Summary - Clinical Trials**

**COUNTRY REPORT**

# **FAMILY HEALTH INTERNATIONAL.**

## **Summary - Clinical Trials October 1, 1992 - March 1993**

### **Country Reports**

1. **Expanded Clinical Research of the Norplant<sup>R</sup> Subdermal Contraceptive Implants in Bangladesh - December 1992**
2. **Clinical Trial of Norplant<sup>R</sup> Contraceptive Subdermal Implants: Final Report on the Five-Year Experience of Three Family Planning Clinics in Haiti - January 1993**
3. **Expanded Clinical Trial of Norplant<sup>R</sup> Contraceptive Subdermal Implants: Final Report on the Experience of Four Family Planning Clinics in Nepal - March 1993**
4. **A Comparative Study of the Diaphragm Only, Diaphragm with Spermicide, and Spermicide Only in London, England - March 19, 1993**
5. **A Comparative Study of Intrauterine Devices, TCu 380A versus TCu 200 in Ouagadougou, Burkina Faso, April 1993**
6. **A Comparative Study of Intrauterine Devices, Copper T 380A versus Copper T 200 in San Jose, Costa Rica, April 1993**

**APPENDIX F**  
**U.S. FDA APPLICATIONS**

201

## **FAMILY HEALTH INTERNATIONAL**

### **U.S. FDA Applications**

During this reporting period (October 1992 - March 1993), FHI's Division of Regulatory Affairs and Quality Assurance has been involved activities related to five Investigational New Drug Applications (INDs), two Investigational Device Exemptions (IDEs), one Premarket Approval Application and one Premarket Notification (510(k) filed with the U.S. Food and Drug Administration (FDA) for new contraceptive products. In addition, the Quality Assurance component of the Division has continued to evolve during this reporting period. A brief summary of the current status of each activity area and regulatory actions taken during this reporting period is provided below.

- o **Iodine Formulation (iIND #29,626)**

The FDA has requested additional toxicology prior to initiating a Phase I clinical study of this product. Efforts are underway to design and implement appropriate studies to respond to the FDA's request. We are presently undertaking dose ranging and toxicology studies in appropriate animal models (pigs and rabbits). Additional details are provided elsewhere in this report.

- o **NET 90-Day Microspheres (IND #18,592)**

No clinical studies are currently ongoing under this IND. A new formulation, which is manufactured with an alternative solvent to chloroform, is currently being tested in baboons. A decision regarding clinical study initiation will be made at the completion of the baboon study.

- o **NET Subdermal Pellets (IND #17,452)**

A Phase II pharmacokinetic and pharmacodynamic study comparing two doses (four and five pellets) was initiated in September 1991 and is continuing.

This IND was transferred to Endocon, Inc. on September 28, 1992. In March, the Director of Regulatory Affairs and Quality Assurance met with representatives of Endocon and the company with which they are jointly working to discuss the status of the project activities and plans for an NDA submission.

- o **Gyne-T Postpartum IUD (IND #29,046)**

The request to withdraw the IND was submitted March 30, 1993.

- o **Norinyl 1+35 (IND #24,871)**

The final report on this investigation was submitted to the FDA on December 8, 1992. The request to withdraw the IND was submitted on January 25, 1993.

202

o **Lea's Shield (IDE #G860182)**

The Phase I postcoital study comparing Lea's Shield with the diaphragm, which was initiated in June, 1991, was completed in December 1992. A draft report has been submitted to CONRAD by the investigator.

As of March, 1993, a total of 244 subjects had been enrolled in the Phase II study that was initiated in August, 1991, and 73 subjects had completed the study as planned. On December 9, 1992 the FDA approved an amendment to the Phase II Efficacy study protocol (submitted November 4, 1992) to discontinue one group, those using the smaller sized device, from the study and to allow recruitment of all women, independent of obstetrical history, to device size #2. Investigators discontinued 36 subjects in compliance with this amendment.

The last annual progress report was submitted to the FDA on April 19, 1993.

o **WPC-333 Vaginal Pouch (IDE #G890203)**

The FDA's Obstetrics and Gynecology Devices Panel met for the second time in December 1992 to consider the PMA for this device which was submitted by Wisconsin Pharmacal. The panel recommended approval of the device with several notations related to labeling and follow-up post-marketing surveillance activities. Subsequent to the Advisory Committee Meeting, FHI was asked by the FDA to conduct an additional analysis of pregnancy rates. This information was submitted on January 29, 1993.

o **Filshie Clip PMA**

The premarket approval application (PMA) for this device was submitted to the FDA on September 9, 1992. On October 13, 1992 FHI submitted additional data as requested by FDA. We are awaiting notification of the PMA filing at this time.

o **Male Polyurethane Condom**

An IDE was submitted for the Male Knitted Ring #1 Polyurethane Condom on December 21, 1992, to allow initiation of an NIH-funded Phase I clinical trial of our knitted-ring condom. The FDA responded that the study should be conducted under abbreviated IDE regulations. This response has important positive implications for future studies conducted with other plastic condoms, in particular the slip-on design.

202

Other regulatory affairs and quality assurance activities that were in progress during this reporting period included the following:

o **Standard Operating Procedures**

A set of standard operating procedures (SOPs) was developed in the first half of 1992 for the Research and Development divisions. During this reporting period, SOP's related to the freezing of data prior to analysis, conducting R&D procedure audits, withdrawing Investigational Device Exemptions (IDEs), and withdrawing Investigational New Drug Exemptions (INDs) were approved and distributed to R&D staff. Other SOP's are in process.

o **Quality Assurance Audits**

A Contract Lab audit was conducted in November 1992 at North American Science Associates, Inc. (NAmsA) to determine their compliance with the Good Laboratory Practices regulation (GLPs) during their pre-clinical testing of the Plastic Condom materials for FHI. A report of the findings was prepared and submitted to FHI senior management.

An audit was conducted in January-February 1993 of FHI's Product and Process Development and Quality Testing Laboratories to determine their compliance with the Preproduction Guidelines for Development of Medical Devices during the development and testing of the Plastic Condom. A report of the findings was prepared and submitted to FHI senior management. Follow-up action is in progress.

A pre-shipment audit was completed in December 1992 for a plastic condom acceptability study, and in January 1993 for a Tactylon condom study.

An audit was conducted on March 23, 1993 of the laboratory performing the norethindrone, progesterone, and estrogen assays for FHI's Norethindrone Pellet study. A report of the findings was prepared and submitted to FHI senior management.

o **Training Activities**

Staff training on validation and documentation of databases and statistical analysis programs, and clinical supply management were conducted in January 1993.

Staff training for Preproduction GMP's was conducted in February, 1993 for FHI's Materials Technology Division.

204

**APPENDIX G**  
**Advisory Committees**

# FAMILY HEALTH INTERNATIONAL

## Advisory Committees

- o **Technical Advisory Committee (TAC)**

The TAC is composed of distinguished scientists in reproductive science and related fields who convene annually to provide guidance on FHI's research directions and progress. The 1993 annual meeting will be held on July 1, 1993. A roster of TAC members (1992-1993) is appended.

- o **Protection of Human Subjects Committee (PHSC)**

The PHSC is established to assure that all FHI research meets ethical standards for the protection of human subjects and informed consent. The Committee is composed of 5-10 members representing a diverse range of scientific and non-scientific disciplines. The composition of the committee complies with federal regulations. The committee convenes at least three times per year to discuss, review and approve/disapprove proposals. The frequency of review is designated by the committee at the time a proposal is approved. Four meetings of the PHSC were held at FHI during this reporting period: October 6, 1992; November 13, 1992; December 15, 1992; and March 5, 1993. A roster of PHSC members (1993) is appended

- o **Expert Meetings**

No specialized Expert Meetings were convened during this reporting period.

**Family Health International**  
**Protection of Human Subjects Committee**

**1993 Roster**

**Clergy**

1993 Dennis M. Campbell, PhD, BD (*Chair*)  
Dean, The Divinity School  
Duke University  
Durham, NC 27706  
919/660-3434(B)

**Obstetrics/Gynecology**

1993 Vanessa P. Haygood, MD (*Vice Chair*)  
Medical Director, Maternity &  
Family Planning for the Guilford  
County Health Department and  
Private Practitioner  
721 Green Valley Road, Suite 101  
Greensboro, NC 27408  
919/230-1111 (B); 292-7010 (R)

**Consumer/Social Science**

1994 Aida Beshara, PhD  
106 Drywood Place  
Cary, NC 27513  
919/481-2892 (R)

**Consumer/Medical Sociology**

1995 Betty E. Cogswell, PhD  
Associate Professor  
Department of Family Medicine  
Clinical Programs Division  
School of Medicine  
University of North Carolina  
Chapel Hill, NC 27599-7595  
919/966-3711 (B); 942-5289 (R)

**Public Health**

1993 Betty H. Dennis, PharmD  
Clinical Associate Professor  
Pharmacy Practice  
School of Pharmacy  
University of North Carolina  
Chapel Hill, NC 27599  
919/962-0030 (B)

\* Nonvoting member

January 1, 1993

**Internal Medicine**

1995 Elizabeth S. Mann, MD  
Associate Professor  
Department of Anesthesiology &  
Associate Dean for Admissions  
School of Medicine  
University of North Carolina  
North Carolina Memorial Hospital, 204-H  
Chapel Hill, NC 27599-3355  
919/966-5136 (B); 962-8331 (B)

**Public Health**

1994 Tom K. Scott, PhD  
Professor, Department of Biology  
CB# 3280, Coker Hall  
University of North Carolina  
Chapel Hill, NC 27599-3280  
919/962-3701 (B); 929-1281 (R)

**Legal**

1994 Steven M. Shaber, JD  
Jordan, Price, Wall, Gray & Jones  
PO Box 2021  
Raleigh, NC 27602  
919/828-2501 (B)

**Burroughs Wellcome Staff**

1994 Michael D. Rogers, PhD (*Ex-officio\**)  
Senior Clinical Research Scientist  
Burroughs Wellcome Company  
Post Office Box 13526  
Research Triangle Park, NC 27709  
919/248-3000 (B)

**FHI Staff**

1994 Evelyn J. Studer, RN, BSN (*Ex-officio\**)  
Institutional Representative  
Protection of Human Subjects Committee  
Family Health International  
Durham, NC 27713  
919/544-7040 (B)

**ClinTrials Staff**

1993 B. Randall Vestal, BS (*Ex-officio\**)  
Director, Regulatory Affairs  
ClinTrials  
Durham, NC 27713  
919/544-3900 (B)

# Family Health International

## Technical Advisory Committee

### 1992 - 1993 Roster

- |      | <b>Physiology</b>  |      | <b>Reproductive Biology</b>   |
|------|--|------|---|
| 1995 | Linda E. Atkinson, PhD (Chair)<br>Senior Scientist<br>Product Registration Manager<br>Alza Corporation<br>950 Page Mill Road<br>Palo Alto, CA 94303-0802<br><br>415/494-5689   | 1994 | Michael John Kennedy Harper, PhD, ScD<br>Department of Ob/Gyn<br>Baylor College of Medicine<br>6550 Fanning Street, Suite 821A<br>Houston, TX 77030<br><br>713/790-3640 (B)<br>FAX: 713/798-7564  |
|      | <b>Obstetrics-Gynecology/<br/>Reproductive Biology</b>   |      | <b>Endocrinology/Reproductive Biology</b>   |
| 1993 | Deborah J. Anderson, PhD<br>Associate Professor<br>Obstetrics, Gynecology &<br>Reproductive Biology<br>Harvard Medical School<br>Director, Fearing Research<br>Laboratory<br>250 Longwood Avenue-SGMB 204<br>Boston, MA 02115<br><br>617/432-0841; 617/432-2190<br>FAX: 617/432-0359 | 1993 | Jorge Martínez Manautou, MD<br>President, Academia Mexicana de Investigación<br>en Demografía Médica, A.C.<br>Bajfo No. 203-1er. Piso<br>Col. Roma Sur Deleg. Cuauhtémoc<br>06760 México, D.F., México<br><br>264/11-60; 564/54-48<br>FAX: 564/5448 |
|      | <b>Epidemiology/Internal &amp;<br/>Preventive Medicine</b>   |      | <b>Epidemiology</b>   |
| 1995 | Willard Cates, Jr., MD, MPH<br>Director, Division of Training<br>Centers for Disease Control (C08)<br>Atlanta, GA 30333<br><br>404/639-3071; FAX: 404/639-2222   | 1994 | Judith P. Rooks, CNM, MS, MPH<br>Independent Consultant<br>2706 SW English Court<br>Portland, OR 97201<br><br>503/243-2253 (R)  |
|      | <b>Obstetrics-Gynecology</b>   |      | <b>Social Science</b>   |
| 1995 | William Droegemueller, MD<br>Chairman, Department of Ob/Gyn<br>University of North Carolina<br>School of Medicine<br>CB# 7570, MacNider Bldg.<br>Chapel Hill, NC 27599-7570<br><br>919/966-5281  | 1994 | Rochelle N. Shain, PhD<br>Professor, Department of Ob/Gyn<br>The University of Texas<br>Health Science Center<br>7703 Floyd Curl Drive<br>San Antonio, TX 78284<br><br>512/567-5051   |

208