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AND FAMILY PLANNING RESEARCH**

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EXECUTIVE SUMMARY

This report covers work carried out by Family Health International (FHI) during the 6 month period, April 1 through September 30, 1993, to implement the program funded by the USAID Office of Population under Cooperative Agreement (DPE-3041-A-00-0043-00), "Contraceptive Technology and Family Planning Research." The program encompasses four 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 four program areas are: contraceptive technology development and approval, improved service delivery, benefits and risks of contraceptive methods, and research utilization activities. 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 6 months have included a continued priority focus on contraceptive development. FHI's highest priority in the area of barrier contraceptives is the development and the FDA approval of a thermoplastic male condom; work continues on two distinctive product designs, a roll-on and a slip-on condom. The Phase II clinical trial of the REALITY™ female condom conducted collaboratively by FHI and CONRAD was the basis for FDA approval of this product during the reporting period. FHI has also begun work to evaluate the efficacy of a relatively new product, Vaginal Contraceptive Film.

Research and development for a delivery system for long-acting steroids continues; priority projects in this area have been a long-acting biodegradable norethindrone implant system (NET pellets), and a 90-day norethindrone injectable microsphere contraceptive (NET-90). In addition, FHI has been working with PATH to develop a sterile, single use, pre-filled mechanism (Uniject) that can be used to deliver injectable contraceptives such as depotmedroxyprogesterone acetate (DMPA).

Preclinical work (using pigs and rabbits) to develop an iodine formulation for transcervical delivery to achieve blockage of the fallopian tubes for non-surgical female sterilization is ongoing.

FHI has continued to provide substantial support to the Commodities and Program Support Division to assure the quality of latex condoms supplied by USAID, 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 USAID's request, FHI has broadened its contraceptive quality testing and surveillance activities to include other products, such as oral contraceptives, IUDs, and spermicides.

An important component of FHI's program is the introduction of new contraceptive methods into family planning programs and service delivery systems, as well as expanding

the availability of existing methods. At present, FHI's efforts to introduce and/or expand availability and use of contraceptive methods are focused on DMPA and Norplant, and on methods for postpartum and postabortion contraception.

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. A study was completed to determine consumer preference for standard and smaller condoms in three sites in the Philippines; a study of the acceptability of three N-9 spermicides among STD clinic users in Lusaka, Zambia was completed. Growing emphasis has been placed on behavioral aspects of barrier spermicide use. During this reporting period, field work was completed and data analysis begun on a three-country study of methods for identifying condom users at risk of breakage and slippage. Work has also continued to assist the FDA in simplifying and improving OC use instructions, and to field test the improved instructions.

Improving access to contraception by reducing medical barriers to contraceptive use is an area of high priority for FHI. An interdivisional working group involving staff of several divisions is coordinating FHI's efforts and maintaining a focus on programs to carry out the strategy in this area. Specific activities during this reporting period include participation in several USAID-sponsored CA interagency groups and activities addressing barriers to contraceptive use, contraceptive technology update (CTU) seminars for policy-makers and health care providers, and research in several countries. Development and production of CTU modules continues to be a high priority, with production work on the injectables module completed during this reporting period.

FHI expanded its work in improving resource allocation and quality of care (QOC) for family planning services during this reporting period. Analyses of the economics and costs of family planning services continue to be an area of assistance, with projects in Bangladesh, Honduras and Ecuador. A study on the impact of adding an additional method, Norplant, was completed in Thailand. FHI continues to collaborate with PAHO on improving quality of care in Latin America's family planning programs; an integrated model of quality of care in reproductive health was drafted in collaboration with PAHO and IPAS during this reporting period. Work in Haiti was begun to assess the quality of Norplant clinical and counseling service provision within the Haitian NGO family planning sector.

Reproductive epidemiology research is emphasizing the relationship of contraception and STDs, including HIV infection. The final analysis of a study in Zambia addressing this relationship was completed; study protocols were approved and initiated in the Dominican Republic and Zambia. Another major focus of FHI's epidemiologic work is the assessment of benefits and risks for various contraceptive methods. Work continues on the development of a life-table model (OCRISK) to evaluate the effect of combined OCs and progestin-only methods in terms of longevity and deaths caused or averted among users and non-users of these methods. FHI research also examines the relationship between contraception and cancer. FHI is studying the relationship between vasectomy and prostate cancer in the United States and Korea, and completed the final report for a

case-control study conducted in Jamaica examining the relationship between DMPA use and cervical cancer.

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*, is published in English, French and Spanish, with a combined distribution of more than 40,000 copies per issue. During this reporting period, the translation of the *Reduction of Medical Barriers* issue into Russian was completed and printed. FHI's information dissemination program responded to more than 2,000 requests for information on contraception and reproductive health during the past six months. FHI also provides support to USAID, its overseas missions, and programs in responding to controversies and misinformation, as needed. During this reporting period, FHI prepared and distributed 2,000 sets of materials in English and Spanish on the safety and use of progestin-only contraceptives (POCs) by breastfeeding women to researchers and media in Latin America and to selected health agencies in the U.S., at the request of USAID/Honduras and PAHO. In response to a request from USAID/Kenya, FHI worked with members of the Kenyan media to counteract misinformation being spread that condoms supplied by USAID were contaminated with HIV.

FHI has provided institutional development support to Family Health Research Centers (FHRCs) in several countries for a number of years, but began a program 5 years ago to phase out core support to these programs as they mature and are able to secure research support from multiple sources. During the last 6 months, FHI has provided technical assistance in the planning, design, implementation and dissemination of findings of contraceptive and reproductive health to governments and/or organizations in five countries. Most of the continuing programs in this area are funded through mission add-ons.

The following sections describe in more detail the program of work implemented during the past 6 months, and summarize activities planned for the next reporting period.

I. INTRODUCTION

Family Health International (FHI) is pleased to present the Semiannual Progress Report for the period April 1, 1993 through September 30, 1993, under its Contraceptive Technology and Family Planning Research Cooperative Agreement (DPE-3041-A-00-0043-00).

Under this Cooperative Agreement, 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.

This Semiannual Progress Report summarizes progress during the reporting period toward achieving objectives and outcomes outlined in the Annual Workplan for Fiscal Year 1993 submitted to USAID in January, 1993. The report is organized differently from previous reports, and reflects changes in FHI's organization and the refinement of program directions. Section II of the report, Program Areas, presents an overview of FHI's work and accomplishments in the following priority areas:

A. Contraceptive Technology Development

- Barrier Contraceptives and Spermicides
- Long-Acting Steroids
- Female Sterilization
- Male Sterilization

B. Improved Service Delivery

- Quality Assurance of Contraceptives
- Introducing Methods and Expanding Method Availability
- Improving Contraceptive Acceptance and Use
- Improving Access to Contraception
- Improving Resource Allocation and Sustainability
- Improving Quality of Care

C. Benefits and Risks of Contraceptive Methods

- Long-term Effects of Contraceptive Use
- Contraception and STDs

D. Research Utilization Activities

- Publications/Information Dissemination
- Conferences/Workshops
- Research Capacity Building

In Section III of the report, Subproject Descriptions, more detailed information is presented for individual FHI subprojects during the reporting period. Subproject descriptions are organized under the following headings:

A. Global Initiatives for Improvement in Contraceptives

- Contraceptive Technology Development
- Contraceptive Quality Assurance
- Increasing Contraceptive Compliance
- Benefits and Risks of Contraceptive Methods

B. Regional/Country Programs

- Africa
- Latin America/Caribbean
- Asia/Near East

A brief description is given at the beginning of each subproject progress report, followed by the objectives. Major accomplishments of the subproject are summarized, with those from this reporting period presented separately; any problems affecting subproject implementation are mentioned. Activities planned for the next six months are outlined. Following the title of each subproject, a number appears in parentheses. This number is an internal FHI subproject identifier for management and accounting purposes only.

Section IV, Program Management, provides a brief outline of FHI's management structure for this Cooperative Agreement. Section V, the financial section, is organized by program areas, with a budget and expenditures for the reporting period, as well as projected expenditures for the coming six months shown for each subproject.

II. PROGRAM AREAS

A. Contraceptive Technology Development and Approval

1. Barrier Contraceptives and Spermicides

The current AIDS pandemic as well as the increasing rates of other sexually transmitted diseases in many parts of the world has highlighted the need for new and improved barrier contraceptives which might also offer protection against these diseases. FHI has a number of initiatives underway related to the development of new and improved barrier contraceptives and spermicides.

Barrier Methods: The highest priority is the development and FDA clearance of non-latex condoms which offer the possibility of improved strength, reliability and shelf life, as well as possibly improved user acceptability, when compared with latex condoms. FHI has developed two distinctive product designs which use the same sheath design but differ in their retention mechanisms. One design rolls on in a manner analogous to the standard male latex condom, and the other is a slip-on design which can be donned bidirectionally.

In addition to its work on non-latex condom development, FHI continues to evaluate other forms of barrier contraceptives and spermicides. The Phase II clinical trial of the REALITY™ female condom conducted collaboratively by FHI and CONRAD formed the basis for FDA approval of this product during this reporting period. In addition, we are conducting the data processing and analysis for a CONRAD-sponsored Phase II clinical trial of the Lea's Shield™, a new device which is a cross between a cervical cap and a diaphragm, which may possibly be used without a spermicide. Following the completion of this study, FHI will conduct a Phase III clinical trial which is necessary for FDA approval of this product.

Spermicides: Spermicidal products offer potential promise in protection against certain sexually transmitted diseases as well as protection against pregnancy. USAID currently provides foaming tablets in its service delivery programs and it is interested in a relatively new product, Vaginal Contraceptive Film™ (VCF™, known as C-film in many countries). In acceptability studies conducted by FHI, VCF™ has been shown to be more acceptable

than foaming tablets. Therefore, FHI has great interest in evaluating the contraceptive efficacy of this product as previous large prospective studies are not available. It is expected that these data will help USAID determine the potential value of this product in its service delivery programs.

Finally, FHI is interested in developing new spermicidal products to improve upon the currently available products in terms of efficacy against both pregnancy and STDs and acceptability. We have conducted initial work to develop methods to evaluate the speed of dissolution of various spermicide preparations to facilitate the evaluation and comparison of spermicide formulations.

Accomplishments during the reporting period in this area include:

- Completion of 6-month accelerated aging studies of the knitted ring roll-on condom with no significant physical property loss observed.
- Initiation at the National Sanitation Foundation (NSF) of analytical studies to quantify the level of methylenedianiline (MDA) in the plastic condom, following a laboratory audit to determine NSF's good laboratory compliance capabilities, as requested by the FDA.
- Completion of biocompatibility studies for the plastic condom which showed no adverse results under the conditions of the studies.
- Completion of a functionality and acceptability study of three lubricated Tactylon™ condoms compared to a standard latex condom.
- FDA approval of the REALITY™ female condom on May 10, 1993.
- Submission to the FDA of the final report on the REALITY™ female condom Phase II clinical trial in August 1993.

2. Long-Acting Steroids

FHI has conducted extensive research towards the development of new and improved long-acting delivery systems for contraceptive steroids. These products would offer women an increased variety of contraceptive choices and would provide hormonal methods requiring less user compliance than oral contraceptives. The priority projects in this area of research and development have been a long-acting biodegradable norethindrone implant system (NET pellets), and a 90-day norethindrone injectable microsphere contraceptive (NET-90) that would provide lower doses and more constant serum levels of steroid than the other currently available injectable contraceptives.

NET Pellets: FHI has worked on the NET pellet biodegradable implant system for almost a decade. Early studies were conducted using hand-made pellets; however, in the mid-1980s the product was licensed to ENDOCON, Inc. which developed two patented, mechanized manufacturing processes to produce the pellets under the name ANNUELLE®. FHI evaluated different doses of these products in a series of clinical studies and is currently conducting a Phase II-A clinical trial of four and five pellet systems.

NET-90: Like our work with the NET pellet system, FHI has worked on the development of the NET-90 since the early 1980s. We have worked during this time with Stolle R & D which developed the product, and more recently with Medisorb, a company established by a joint venture of Stolle R & D and Dupont, to further develop microsphere technology for a variety of compounds. In addition, the Ortho Pharmaceutical Company has acquired the rights to this product and through its research affiliate, the R.W. Johnson Pharmaceutical Research Institute, has been involved in product development. FHI has conducted a series of Phase I, II, and III clinical trials to evaluate the safety and pharmacokinetics of various NET-90 formulations. The main problems plaguing this product has been reproducibility of batch-to-batch production, scale-up of production, and most recently, issues related to the solvent system used in the production. While FHI is working to complete reports from the most recent clinical trials, further work on this product by FHI will depend on the outcome of ongoing negotiations between USAID, FHI and Ortho Pharmaceuticals.

Uniject: While the development of a new low-dose injectable contraceptive is desirable, in many countries, barriers exist to the safe use of injectable contraceptives because of shortages of sterile syringes and the fact that low educational levels of some service providers often make administering proper dosages problematic. FHI has been working in collaboration with PATH to develop a sterile, single use, pre-filled mechanism that can be used to deliver injectable contraceptives such as DMPA and, perhaps eventually, the NET-90 injectable. The product under development is called Uniject and delivers a single dose of product via a disposable, non-reusable device.

Accomplishments during the reporting period in this area include:

- Drafts of a series of final safety reports for the Phase I, II and III clinical trials of the norethindrone 90-day injectable microsphere system which were conducted by FHI. These reports will be submitted to the FDA following their completion.
- Initiation of a draft of a progress report detailing the first 15 months of experience for all subjects in the ongoing Phase II-A clinical trial entitled Pharmacokinetic Evaluation of Biodegradable Norethindrone Implants (NET pellets).

- The final design of the Uniject mechanism for DMPA, developed by PATH in collaboration with FHI, has been virtually completed. Fabrication of the finished prototype is nearing completion.

3. Female Sterilization

FHI has a long history of conducting research on female sterilization. This research has improved understanding of the safety and efficacy of various sterilization approaches.

Filshie Clip: During the 1980s, FHI conducted a series of clinical trials in over 20 countries and co-funded a two-species carcinogenicity study of the Filshie Clip, a device manufactured by a British company (Femcare, Ltd.). Based on the results of these studies, a Premarket Approval Application (PMA) was compiled by FHI and submitted to the FDA on behalf of Femcare. It is anticipated that once FDA approval is received, USAID may purchase this device for its contraceptive commodities program and provide women in developing countries yet another contraceptive option.

Non-surgical Female Sterilization: One of the highest priorities for FHI is the development of a non-surgical approach to female sterilization. A non-surgical approach should make sterilization more acceptable to and safer for many women. The major focus of the current program is the development of an iodine-based formulation which can be administered transcervically to cause sclerosis of the fallopian tubes. Significant work on this product, first conceived by a pathologist at Columbia University (Dr. Ralph Richart), has been conducted by FHI. The original formulation required modification because of problems with viscosity. FHI reformulated this product and has continued its research and development efforts with the reformulated product. FHI holds an Investigational New Drug Exemption (IND) on this product; however, we are currently on a clinical hold by the FDA and were advised that further clinical testing of the new formulation will require the submission of additional toxicology information. Toxicology studies in pigs and rabbits have been initiated.

During the 1980s, FHI conducted research on another non-surgical sterilization approach using various formulations of quinacrine. Although USAID has not funded clinical research on quinacrine for several years, FHI conducted a retrospective study of users of quinacrine in Chile funded by the Mellon Foundation to evaluate the incidence of cancer in these users. This dataset also provides an opportunity to gather information on the long-term efficacy of quinacrine and address concerns about possible recanalization of the fallopian tubes many years after the procedure. Results from this analysis may also be relevant to non-surgical sterilization using our iodine formulation.

Accomplishments during the reporting period in this area include:

- Informal communications from the FDA indicating that the Filshie Clip Premarket Approval Application (PMA) would be filed.
- Initiation of pre-clinical dose-titration studies in the pig and rabbit using three doses of the iodine formulation ranging from 2.5% to 5.5%.
- Completion of a quality assurance audit at the Massachusetts College of Pharmacy which is developing the iodine formulation and distribution of the audit report to FHI management.
- Preparation of a draft of an analysis plan to evaluate the pregnancy rates for quinacrine non-surgical sterilization based on data from a retrospective study in Chile.

4. Male Sterilization

FHI has great interest in increasing access to and acceptability of male sterilization. Because of the potential advantages of an approach to vasectomy developed by the Chinese, called no-scalpel vasectomy, FHI conducted a multicenter, multicountry clinical trial which compared the no-scalpel versus standard incision approaches to vasectomy. The no-scalpel approach uses a curved hemostat with sharpened points and a special vas-fixing clamp for the procedure. The advantages of this method are presumed to be that it produces less bleeding and fewer hematomas than the traditional vasectomy procedure. FHI's study involved approximately 1400 procedures in five countries and will provide important programmatic information regarding the no-scalpel procedure.

Although vasectomy has been available for years, there is little definitive information regarding the time and/or number of ejaculations following vasectomy necessary for the achievement of infertility, loss of sperm motility and the loss of sperm eosin staining. Therefore, FHI in collaboration with AVSC and the Instituto Mexicano de Seguro Social (IMSS) in Mexico, is conducting a pilot study to evaluate these questions. The pilot study will be used to design a larger study to better define the time to infertility following vasectomy and to prepare improved guidelines for physicians and patients.

Accomplishments during the reporting period in this area include:

- Completion of the data analysis for the comparative trial of the no-scalpel vasectomy versus the standard incision vasectomy which was conducted in five countries between 1986 and 1992.

- Approval by PHSC in August 1993 of amendments to the original protocol for the study on time to infertility after vasectomy. The site in Mexico to conduct this pilot study was selected by AVSC and training of laboratory personnel to conduct the semen analyses was initiated.

B. Improving Service Delivery

1. Quality Assurance of Contraceptives

One of the most critical factors influencing consistent and long-term contraceptive use is assuring consumers that their chosen methods are effective and of high quality. FHI, through its Materials Technology Division's Product Quality and Compliance (PQC) Group, has placed a high priority on production surveillance and quality assurance testing of contraceptives.

Activities have consisted primarily of a range of projects that evaluate the quality of latex condoms distributed by USAID, although this work has steadily expanded into evaluation of other types of contraceptives, including OCs, IUDs and suppositories. Areas of quality assurance research include:

Condom Production Surveillance: This program verifies contractor compliance in the manufacture of USAID-supplied condoms for the international community, as a means to improve product use and storage potential. FHI visits manufacturing sites monthly for production lot sampling, and bi-monthly for comprehensive audits of GMP compliance, trend analysis, equipment performance and other internal operations.

Field Stock Evaluation/Complaints: The ability to assess the condition of contraceptive stocks in the field is critical to maintaining high quality distribution. In many countries this involves assessment of storage conditions and distribution programs, ad hoc testing of products to verify shelf life, and use acceptability. This project also promotes improved communication on product quality concerns and related technical issues among governmental and health care personnel.

Condom Prospective Aging Studies: Because condoms are stored under a variety of climatic conditions, it is necessary to understand and predict the effects of various conditions on product quality. This program area studies the effects of different heat and humidity conditions, and, combined with human use studies, evaluates their integrity and user acceptability.

Research and Test Method Development: Because the correlation of effective use with product test results is of primary interest, special emphasis must be placed on

contraceptive testing methodology. This research area identifies and develops new methods which are better related to contraceptive reliability.

Human Use Studies: In order to determine the impact of human behavior and physical factors on condom performance, FHI is conducting studies to evaluate the relationship of material properties (e.g., composition and stress/strain attributes) and actual use breakage rates.

Contraceptive Quality Surveillance: All other contraceptives that USAID procures for distribution are being added progressively to the FHI surveillance program. During FY'93, formal surveillance programs were established for oral contraceptives and IUDs, and preliminary work began on foaming tablets and injectables. FHI is establishing in-house testing capability for these products as well as conducting a series of research projects to improve product stability in adverse environments.

Accomplishments during this reporting period include:

- Sixteen visits for sampling and auditing were conducted at the manufacturing facilities of USAID condom suppliers, with a total of 126 condom lots evaluated. A total of six audits of OC and IUD manufacturers were conducted. In addition, production surveillance agreements were formalized with two new product contractors.
- Field evaluations of USAID-supplied condoms and other contraceptive products were conducted in the Philippines. Condom stock certification was conducted in Pakistan. In addition, product complaints were responded to in eight countries.
- Study sites in Mexico for the Condom Prospective Aging Study were monitored, and samples from the stock were evaluated. The second iteration of the human use component of this study was completed. There will be three more iterations before the study is complete.

2. Introducing Methods and Expanding Method Availability

FHI's contraceptive introduction activities focus on the 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 planning and implementation of activities aimed at increasing method use.

Much of FHI's work is related to the expansion of method acceptance and use, including activities and research concerned with the acceptability, quality of care, costing, and reducing barriers to access for specific methods. At present, FHI's contraceptive introduction efforts are focused on two methods, DMPA and Norplant, and on postpartum and postabortion contraception.

DMPA: In response to the U.S. FDA's approval of this method, FHI developed an introduction strategy for DMPA. The strategy is based on an innovative methodology which recognizes that countries wishing to introduce DMPA into the family planning program mix may be at different stages of readiness, and have different research and programming needs. FHI has disseminated the strategy to USAID Missions, and is providing assistance in the introduction of DMPA to countries according to specific needs.

Norplant: FHI has been involved in the introduction and/or expansion of Norplant services in 12 countries. FHI has worked with local investigators in 11 of these countries to conduct preintroductory clinical trials of Norplant. The purpose of these trials is to introduce the method into countries without previous implantable contraceptive experience, provide needed physician training, and determine product acceptability. Preintroductory clinical trials are ongoing in El Salvador and Senegal. Programmatic research and assistance for Norplant introduction are being provided or planned for in Senegal, Mali, El Salvador and Haiti.

Postpartum Contraception: FHI provided technical assistance to studies of the clinical and programmatic outcomes of both immediate postplacental IUD insertion (IPPI), and insertion of IUDs before hospital discharge in Kenya and Mali. An introductory study of postdelivery IUD insertion in Niger has been developed.

FHI is involved in investigation of the lactational amenorrhea method (LAM) as a contraceptive method; clinical trials conducted in Pakistan and the Philippines will provide data on the use of this method.

Accomplishments during this reporting period include:

- An interdisciplinary FHI team, working jointly with Pathfinder, assisted USAID/ Manila and the Department of Health (DOH) of the government of the Philippines to develop a strategy for the introduction of DMPA into the family planning program. The strategy was approved by the DOH.
- FHI and the Population Council INOPAL Project (Operations Research for Latin America) developed a memorandum of understanding detailing possible joint activities on DMPA in the Latin America/Caribbean region. The memorandum was sent to selected missions in the region.

- Norplant clinical trial sites were closed in Pakistan and Ghana; follow-up of 333 women at sites in Senegal and 401 in El Salvador is ongoing.
- In Senegal, programmatic research on the introduction of Norplant is underway. Data collection for a study of client perspective regarding satisfaction with Norplant and counseling techniques relative to other methods was completed; focus groups with discontinuers and husbands of Norplant acceptors continue.
- Data collection was completed and analysis begun for two studies evaluating immediate postpartum IUD insertion in Kenya and Mali. The Kenya study included a cost component analyzed separately at FHI; the results indicated that substantial savings could be made if more IUDs were inserted immediately postpartum as compared to insertions before discharge or interval insertions.
- Preliminary analyses of data from the clinical trial of LAM in the Philippines suggest that the method is as effective as predicted in the Bellagio Consensus, which states that this method is 98% effective for the first six months postpartum for fully-breastfeeding and amenorrheic women.
- FHI continues to participate in the WHO-led Working Group on Barrier Methods and in the development of studies of the diaphragm.
- FHI staff met with representatives of USAID/Amman, the Ministry of Health, Royal Medical Services, University of Jordan, and the private sector in Amman to discuss areas of collaboration; FHI has been requested to provide technical assistance in the introduction of new methods of birth spacing, particularly DMPA, Norplant and postpartum IUDs, into the Jordanian family planning program.

3. Improving Contraceptive Acceptance and Use

Many factors influence whether and how effectively contraceptive technologies are used by consumers. Aside from the biomedical issues of safety and efficacy, consumer characteristics, differences in needs or preferences for specific methods, and perceived benefits and risks of all methods influence whether individuals adopt and continue to use contraceptives successfully. In addition to pregnancy prevention, family planning methods have other potential health consequences for users, including possible reduction in risk of contracting sexually transmitted diseases (STDs), which may also influence decisions to use specific methods.

FHI's research in this area is broad based and involves the study of a variety of methods within diverse populations. At present, FHI has three strategic areas of acceptability and use research:

Acceptability and Use of Barrier Methods: FHI's research agenda includes a growing emphasis on contraceptive methods which may also provide protection against STDs. In accordance with this priority, acceptability and use research on a range of barrier methods, including male and female condoms and vaginal contraceptive film, is ongoing. The feasibility of dual contraceptive use is of increasing interest.

Contraceptive Compliance: Recent research has found that users of temporary contraceptive methods often lack knowledge about correct method use. Behavioral research has found that many users do not use methods as instructed. FHI's program reflects the belief the research leading to improving compliance for widely used methods such as pills and condoms could have a significant impact on user continuation and the reduction of unintended pregnancies. During this reporting period, compliance and use research focused on improving written instructions for oral contraceptives and gaining further insight into how users take OCs.

Postpartum Contraception: Many behavioral and programmatic factors affect the use of contraception in the year after the birth of a child. FHI continues to study breastfeeding as a contraceptive method, programmatic issues concerned in postpartum contraception, and the acceptability and appropriate use of methods including IUDs and progestin-only oral contraceptives during the postpartum period.

Accomplishments during the reporting period in this area include:

- Studies of condom use in the Dominican Republic, Mexico, and the Philippines yielded preliminary results suggesting that certain behaviors appear to be associated with condom failure, including: unrolling condoms before donning, having particularly intense or long intercourse, using instruments such as teeth or scissors to open condoms, and withdrawing after loss of erection. Across all three sites, individuals who have experienced past condom failure appear to be more likely to experience condom failure in the future.
- A study to determine consumer preference for the standard or smaller condom and to determine slippage and breakage rates for two condom sizes was completed in three sites in the Philippines (similar studies were completed in Nepal and Sri Lanka sites in 1992) and a final report issued. One hundred and fifty men tested 750 standard and 744 smaller condoms in the Philippines sites. None of the standard or smaller condoms was reported to have slipped off. Reported breakage rates for the standard and smaller condoms were 0.1% and 0.5% respectively. Both condoms were rated equally in terms of acceptability.
- Eighty-five women and 128 men completed a study of the acceptability of three nonoxynol-9 spermicides among STDs clinic attenders in Lusaka, Zambia. A

large proportion of participants did not continue product use throughout each two-week study period; discontinuation was most often attributed to personal reasons unrelated to acceptability. Despite limitations of the study, more participants identified positive rather than negative features of the spermicides and mean ratings of various product characteristics were favorable along a wide range of acceptability parameters. The data suggest that men found the spermicides to be at least as acceptable as the women did.

- The FHI-developed and U.S. FDA-approved instructions for OC use prepared for U.S. manufacturers for use in developing countries were modified after field testing by users and medical staff in Mexico. Contacts have been made for further testing in two additional countries.
- Enrollment of subjects was halted for a multi-country study of timing of initiation of progestin-only oral contraceptives among lactating women at eight sites in five countries (Kenya, Indonesia, Mexico, Philippines, and Zimbabwe).
- Two editions of the quarterly Acceptability Research Newsletter, with status reports of the acceptability research studies conducted by FHI, were published during this reporting period.

4. Improving Access to Contraception

At USAID's request, FHI is leading an international initiative to reduce unnecessary barriers to contraception, with a goal of increasing access to quality contraceptive services. FHI has been an active partner with USAID and other CAs in efforts at an international level, as well as in various developing countries.

FHI's programmatic efforts to increase access to contraception through reducing unnecessary barriers can be divided into three categories:

Education and Training: Dissemination of the latest contraceptive information is crucial to keeping the practices of providers current and improving access to contraception. FHI works with local organizations and other CAs to design and conduct activities at which current scientific information is discussed and reviewed with key members of family planning communities. FHI's recent activities in this area include the organization of contraceptive technology update (CTU) seminars in Pakistan and Egypt and assistance in development of seminars in Bangladesh and Indonesia.

In support of these and other educational and training initiatives, FHI is leading the development of a series of contraceptive update modules which address contraceptive specific issues.

Policy and Practice Revision: FHI uses various methods to influence policy and practice revision. These include working with key members of the local family planning community to build consensus during public conferences, and to assess and identify existing barriers to access to contraception. FHI also collaborates with other CAs as they encourage the revision of unnecessary restrictions in policy, standards, and protocols. During this reporting period FHI initiated a study to assess barriers in the practices of private physicians in Jamaica.

Research: FHI conducts research to identify which and how existing medical barriers to family planning service delivery can be removed without negative consequences for the health of clients. Recent FHI studies focus on excessive follow-up schedules for IUD users and the variation between service delivery guidelines and actual practices.

Accomplishments during this reporting period in this area include:

- Contributing to the general USAID initiative, FHI has:
 - participated in revisions of the Guides for Medical Practices for the IUD and Hormonal Methods;
 - co-authored a paper on access, quality of care, and medical barriers in family planning;
 - revised general analysis of the USAID Mission responses to the Country-Level Analysis Working Group Questionnaire;
 - proposed the first draft of the Cooperating Agencies Calendar of Organized Educational Events to Reduce Medical Barriers; and
 - organized and chaired two meetings of the Organized Educational Events Working Group and participated in the Steering Committee and the Guidelines and Country Level Analysis Working Groups.
- Two-day CTU seminars were conducted in Lahore and Karachi, Pakistan, with approximately 360 government policymakers, family planning officials and service providers participating. Barriers identified and discussed included: age and parity, provider bias toward certain methods, overly restrictive contraindication guidelines, and logistical difficulties.
- The fourth symposium in the series of Distinguished Lectures on Contraception in Egypt was held in collaboration with the National Population Council (NPC); approximately 150 attended. Outputs include recommendations for improving access to family planning in Egypt which will be distributed to policymakers for action.

- Production work on the CTU module on injectables was completed; development and production is at varying stages for modules on: postpartum contraception, IUDs, OCs, barrier methods, and the lactational amenorrhea method.
- Three slide sets on the reduction of unnecessarily restrictive services practices were developed for use by experts.
- Field work was completed and data analysis begun on a mapping study of all service delivery outlets in Jamaica and on an in-depth study of practices of private physicians who offer family planning. The study is being conducted by Jamaica's National Family Planning Board (through the University of the West Indies), the Futures Group's OPTIONS II Project and FHI. Preliminary analysis of the data indicates that there are barriers to family planning access in Jamaica.
- A study carried out in collaboration with CEMOPLAF, an Ecuadoran family planning PVO, and INOPAL, the USAID-supported operations research project in Latin America, evaluated IUD follow-up schedules. Results showed that reducing the number of recommended IUD revisits from four to one in the first year would result in 55 missed problems per 10,000 insertions, but would save CEMOPLAF approximately \$35,000 that could be applied to new users.
- A study in Mexico evaluating IUD follow-up visits is nearing completion; the cost of a routine IUD follow-up visit at the IMSS clinic has been estimated at \$7.81.

5. Improving Resource Allocation and Financial Sustainability

Family planning programs in developing countries receive funding from various sources, including governments, international donors, and client fees. While demand for family planning services has continued to grow rapidly, donor contributions have stagnated or even declined in recent years. Planners and providers are seeking ways to improve the use of existing resources, and to increase the financial resources generated locally. Issues of resource use and financial sustainability are increasingly important research areas for FHI.

Cost of Services: Family planning programs produce protection from unwanted pregnancy; the costs of producing this protection vary depending on methods and delivery systems employed. FHI helps programs estimate costs in order to identify opportunities to save resources, to project the total costs of producing a given amount of protection, and to establish cost recovery targets and pricing schedules.

Cost and Impact of Introducing New Contraceptive Technologies: New methods and new ways of distributing existing methods should be evaluated in terms of their impact on program costs and on contraceptive use. FHI conducts research to demonstrate to family

planning managers the additional contraceptive use achieved and the costs incurred by investing in a new delivery system. An FHI study is examining the impact of the introduction of DMPA on the family planning program in Ecuador (in collaboration with the Population Council). Development of a study of the impact of Norplant expansion in Haiti is underway, and will be implemented pending resolution of the present political situation.

Cost Recovery: FHI assists programs that want to establish or increase fees for family planning services to carry out research to quantify the impact of fees on use of services and on program income. FHI is working with an Ecuadoran PVO to examine program issues related to cost recovery and program sustainability.

Accomplishments during this reporting period include:

- A final report was completed for a study, carried out with the Population Development and Evaluation Unit, of costs and funding for the Family Planning Program in Bangladesh. Data from published sources were analyzed; results showed that family planning funding has grown substantially between 1987/88 and 1990/91. Donor funding and increased spending by the government of Bangladesh have contributed; however, since donor funding has grown more rapidly than the government contribution, the government's share of funding has decreased.
- Fieldwork has begun on a study of government and non-government family planning programs in Bangladesh to estimate the cost per couple year of protection (CYP) for various combinations of methods and delivery systems and to determine reasons for variations.
- A study of the impact of adding Norplant to the National Family Planning Program (NFPP) was completed involving 12 family planning clinics in 12 hospitals throughout Thailand. At these sites, nurses were trained to provide Norplant; 12 hospitals served as controls. Five hundred and fifty women were interviewed, almost all of whom had used contraception and would have used another method if Norplant had not been available. The cost per CYP for all durations of use is higher for Norplant than for the IUD or injectables; the IUD is the least costly for all durations of use. Thus, method switching would raise the costs to the NFPP. Some contraceptive users had obtained their previous method in the private sector, further increasing costs to the NFPP.
- FHI assisted ASHONPLAFA, the Honduran IPPF affiliate, with an economic analysis of their programs. The analysis showed that utilization of ASHONPLAFA's smaller clinics is very low, resulting in much higher average costs for clinic services. In terms of cost per CYP, female sterilization is the least

costly method, while the costliest methods are condoms distributed through the CBD program. Cost recovery is highest in the Social Marketing program, and lowest in the clinics; cost recovery for female sterilization is especially low, with clients paying US\$0.75 per year of protection. Recommendations were made to ASHONPLAFA on ways to improve cost recovery, to increase utilization of smaller clinics, and to track costs more effectively.

- FHI and the Population Council INOPAL II project are providing technical assistance to CEMOPLAF, an Ecuadoran family planning PVO, in sustainability. Training was provided to staff in costing, strategic planning, PC software packages and market segmentation techniques. Training courses involved from three to 25 CEMOPLAF staff, and varied in length from 1 to 5 days.
- A presentation on cost issues was made to the Service Delivery Working Group of the Evaluation Project.

6. Improving Quality Of Care

As family planning programs expand beyond a clinic-based approach to service delivery, the quality of care (QOC) provided to clients is becoming a key program focus. FHI is engaged in a range of research activities related to improving the quality of services. Two priority areas are described below.

Quality of Care Assessments: FHI uses an integrated methodology to study the quality of contraceptive services in family planning programs and the impact of changes in quality on family planning clients. Assessments draw on the indicators recently developed to measure quality (FHI participated on the working groups to develop the indicators). QOC studies can assess the quality of services at the program or service delivery site level, or can be used to assess the quality of care offered for individual services, such as the assessment of Norplant provision planned for the Haitian NGO family planning sector.

Service Quality Improvement: FHI has introduced a process for service quality improvement (SQI) in family planning, which synthesizes the Bruce framework and a Total Quality Management (TQM) methodology now used in domestic health care. SQI has been presented by FHI at a number of workshops held in collaboration with IPPF, UNFPA, PAHO, CEDPA and Pathfinder.

Accomplishments during this reporting period include:

- Following a meeting on quality of care held at FHI in late March, 1993 (with representatives from PAHO, USAID/W, IPAS, IPPF and FHI), an integrated model of quality of care in reproductive health was drafted in collaboration with PAHO

and IPAS and sent out for review. This is part of an effort to develop and field test an integrated framework for use by programs in Latin America to assess and improve reproductive health services, including family planning, maternal health and HIV/STDs.

- The research outline was developed for an assessment of the quality of Norplant clinical and counseling service provision with the Haitian NGO family planning sector. A planned trip late in FY'93 to discuss the objectives and refine the study protocol with in-country researchers and service providers was postponed due to political instability.
- "Quality of Care in Family Planning. A Catalog of Assessment and Improvement Tools," a 200-page document, was produced and 500 copies were distributed. A second printing is underway.
- A slide presentation on quality of care was developed and used in Pakistan, Egypt, and by Dr. Senanayake of IPPF.
- Information and materials on SQI were provided to several CAs, including SEATS for use in Morocco.
- An FHI paper on the SQI model to be published in International Family Planning Perspectives, was translated into Spanish for presentation at a workshop in Mexico (with MSH/FPMD and the Population Council).

C. Benefits and Risks of Contraceptive Methods

1. Long-term Effects of Contraceptive Use

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. FHI focuses on understanding the epidemiology of reproductive health problems and the relative benefits and risks of different contraceptive methods, including long-term effects. Two current areas of emphasis are described below.

Computer Life-Table Model: Using a computer life-table model (OCRISK), FHI is evaluating the effect of combined OCs and progestin-only methods in terms of longevity and deaths caused or averted among users and non-users of these methods. Information generated by this activity will inform policy concerning the use of various methods for particular subgroups of women or women in particular countries.

Contraception and Cancer: Associations between contraception and cancer form a second research focus in this area. In response to studies suggesting an association between vasectomy and prostate cancer published during the last year in the New England Journal of Medicine, FHI is studying this issue in the United States and Korea. FHI has also completed a case-control study in Jamaica examining the relationship between DMPA use and cervical cancer.

Accomplishments during this reporting period include:

- In preparation for analyses using the life-table model (OCRISK), data on OC prevalence, mortality and population have been compiled for several Latin American countries. The OCRISK software has been modified to enable new assumptions and risk factors to be added.
- A PROCITE data base has been developed to incorporate the cardiovascular and breast cancer literature which is the basis for the above analyses.
- FHI undertook a study of vasectomy and prostate cancer in a U.S. screening population. A questionnaire was administered to 1800 men, and blood and urine samples were collected from 350 men at 10 sites in the U.S. during National Prostate Cancer Awareness Week (September 20-30, 1993).
- FHI established a collaborative arrangement with WHO to participate in a multicountry, multicenter hospital-based case-control study of the relationship between prostate cancer and vasectomy in developing countries (China, India, Korea and Nepal) and one developed country (New Zealand). FHI has negotiated our role with an investigator in Seoul, Korea.
- A case-control study was completed using cases drawn from the Kingston-St. Andrew Corporate Area to determine whether use of DMPA is an independent risk factor for cervical cancer among women in Jamaica. Analysis results show no significant increases in risk among DMPA users according to duration, latency, or recency of use. Overall, these findings are reassuring for prospective, current and former users of DMPA who undergo regular screenings for cervical cancer. However, the moderate increase in risk of cervical cancer among women who used DMPA for five or more years warrants further consideration. This particularly rich data set will be used for additional analyses, with a number of papers planned.
- USAID funds are used for development of selected, important studies for which non-USAID support is being sought. Three such studies of contraceptive benefits and risk have been developed and submitted to potential donors for funding: (1)

2. Contraception and STDs

Use of different family planning methods affects the risk of contracting sexually transmitted diseases (STD); measuring the risk of STDs outcomes, including HIV infection, among users of specific family planning methods is a priority research area for FHI. Specific areas of study include spermicide use and HIV infection, cervical infections among women using condoms, barrier contraceptive use among couples at high risk of HIV infection, and the association between OC use and HIV infection.

Accomplishments during this reporting period include:

- USAID support was used to develop two studies for submission to NIH:
(1) a randomized controlled trial to assess the effect of N-9 use in preventing HIV infection among woman. The study was approved for funding by NIH.
(2) A study to examine the association between use of combined OCs and the incidence of HIV infection in women. The proposal was re-submitted to NIH for review September 1, 1993.
- The protocol for a randomized trial to assess the effectiveness of N-9 lubricated condoms for the prevention of gonorrhea and chlamydial infection compared with that of silicone condoms was translated into Spanish, reviewed by the local investigator, and approved by the local ethics review committee in the Dominican Republic.
- The final analysis was completed for a study of 110 HIV discordant couples in Zambia which measured the association between consistent spermicide use and HIV infection, and the association between consistent condom use and HIV infection. Comparing full-time condom users with other couples, the HIV rate ratio [RR] was 0.2 (0.0-1.9). Comparing full-time spermicide users with other couples, the HIV RR was 0.8 (0.2-2.9). Among couples with seronegative women, consistent use of either barrier method was associated with more substantial reductions in the HIV incidence. Proportional hazards regression confirmed the strong protective effect associated with consistent condom use, and the elevated incidence among male seronegatives. On the other hand, consistent spermicide use was invariably associated with a higher HIV incidence rate in these multivariable models. Self-reported genital irritation was associated with a substantially increased incidence of HIV infection.

- Data collection was initiated for a study of barrier contraceptive use (female and male condoms, vaginal contraceptive film) among couples at high risk of HIV infection in Zambia.

D. Research Utilization Activities

1. Publications/Information Dissemination

Research on contraception and reproductive health is useful only if the findings are shared with other researchers, with those who set policy and implement service programs, and with those who are users or potential users of contraceptive methods. FHI has developed and employs a number of mechanisms to reach a wide audience with important research findings and programmatic information.

Network: Through this quarterly bulletin, FHI distributes the latest scientific and programmatic information on reproductive health issues in a timely manner to readers around the world. Articles synthesize a broad range of information in an easy-to-understand format, involving international experts and overseas journalists as contributors. Network is published in English, French, and Spanish four times a year, with a combined distribution of more than 40,000 copies per issue. Issues are also published in other languages for special projects.

Special Publications: FHI develops and produces special publications on issues of interest to the family planning community. Such a publication on journalism training is ready for production and a publication on barrier methods is planned.

Information Dissemination: FHI provides a range of information dissemination services and materials on reproductive health, especially on controversial issues, new technologies, and new research findings on contraceptive safety. FHI is called on by colleagues in developing countries to assist with immediate and targeted response to specific issues arising locally.

Accomplishments during this reporting period include:

- 13,000 copies of the English "Quality of Care" issue (14:1) of Network were distributed in August; 25,000 were expected to be distributed in French and Spanish in October.
- Approximately 8,000 copies of French Network issue (8:4) on medical barriers were produced and distributed.

- 17,000 Spanish copies and 8,000 French copies of issue (8:3) of Network, focusing on women and AIDS, were distributed; this issue was funded by FHI's AIDSCAP Division.
- Translated and published Spanish and French Network issue (8:4) on Quality of Care; 25,000 Spanish copies and more than 8,500 French copies were printed for distribution in October.
- The number of individual subscribers increased by 64% for Spanish Network and 24% for the French version during this reporting period.
- Translation of the Reduction of Medical Barriers issue of Network into Russian was completed and printed, and a plan was developed for distribution to the Central Asian Republics, Russia, and the Transcaucasus.
- Developing Health Journalists: A Training Manual for Improving News Coverage of Reproductive Health was completed and sent for printing. This manual, based on journalists workshops implemented by FHI in Africa and Asia, is designed to provide trainers with the tools needed to train journalists in researching and reporting on population and health issues facing their nations.
- FHI responded to more than 2,000 requests for information on contraception and reproductive health issues from USAID Missions, health personnel, policymakers and other organizations.
- In response to a USAID/Honduras and PAHO request, FHI prepared and distributed 2,000 sets of materials in English and Spanish on the safety and use of progestin-only contraceptives (POCs) by breastfeeding women to researchers, providers and media in Latin America and to selected health agencies in the U.S. Also as part of this effort, an article on this subject was published in Network, reaching an estimated 40,000 readers in three languages.
- In response to a request from USAID/Kenya, FHI worked with members of the Kenyan media to counteract misinformation being spread that condoms supplied by USAID were contaminated with HIV.
- FHI distributed eight news releases on various contraceptive technology and reproductive health topics, resulting in extensive media coverage in the U.S. and developing countries, including Ecuador, Tanzania, the Philippines and Sri Lanka.
- As part of its annual series of French and Spanish-language translations of important scientific journal articles, FHI translated five articles in this reporting

period; 2,822 copies of the Spanish series were distributed in Latin America and 808 in French to Francophone Africa.

2. Conferences/Workshops

Sponsorship of conferences, workshops and seminars is part of FHI's strategy for improving utilization of reproductive health research. These events provide a mechanism for the dissemination of information and the discussion of health and family planning issues and their program implications.

Conferences and workshops during this reporting period include:

- *Interagency Meeting on Long-Acting Progestins: Management of Bleeding Disturbances:* With increasing use and availability of long-acting progestins, the need to address concerns relating to product side effects, particularly bleeding disturbances, has become apparent. FHI sponsored an interagency meeting to address this issue and to suggest potential courses of action. Research on counseling and medical treatments for bleeding problems were established as priorities. Based on the discussion, it is likely that a first line of study would be directed toward the evaluation of specific treatments when used in the first six months following Norplant insertion, with a recommended follow-up of bleeding patterns for up to 18 months. The treatments of interest would be: (1) combined OCs, (2) Ibuprofen, (3) combination of OCs and Ibuprofen, and (4) placebo.

A proposal was drafted for a three or four arm study comparing the effects of low dose OCs, Ibuprofen and placebo on bleeding disturbances.

- *Barrier Contraceptive Conference:* An international experts conference, held in the Dominican Republic, was sponsored jointly by FHI and CONRAD in March, 1993. A draft of the proceedings was edited and technical assistance on production was given by FHI during this reporting period.
- *Workshop on Postpartum and Postabortion Family Planning:* FHI and the Pan American Health Organization (PAHO), in collaboration with AVSC, IPPF, IPAS, JHPIEGO, Pathfinder International, the Population Council and UNFPA, conducted a Workshop on Postpartum and Postabortion Family Planning in Quito, Ecuador, July 12-15, 1993. The objective of the workshop was to assist in the integration of postpartum and postabortion family planning into the existing reproductive health services of nine Latin American countries (Bolivia, Ecuador, El Salvador, Guatemala, Honduras, Nicaragua, Paraguay, Peru and Venezuela). Eighty-eight public health/family planning leaders and resource persons from 134 Latin American countries and the U.S. participated in the workshop.

- *East and Southern African Editors Seminar:* A pre-workshop needs assessment was conducted and the workshop program was designed; a four-day workshop to improve news coverage of reproductive health in east and southern Africa by increasing editors' commitment to this type of coverage will be conducted early in FY'94. Thirty editors from the leading news dailies and agencies in 10 countries in east and southern Africa will participate.
- *Regional Experts Meetings on Reduction of Medical Barriers:* Planning and organization was begun for two regional workshops to improve access to contraceptive services through reduction of medical barriers. Workshops will be conducted in Manila (for the Asia Region) and Panama City (for the Latin America Region) in November, 1993, in collaboration with AVSC, JHPIEGO, WHO, The Population Council, Pathfinder International and IPPF.

3. Research Capacity Building

Over the years, FHI has provided long-term assistance to research centers in selected countries, in order to strengthen institutional capacities to conduct reproductive health research and utilize and disseminate findings to influence family planning policies and programs. Although the focus on long-term institutional development has decreased, the principles of local capacity building remain important in all FHI activities.

During this reporting period, FHI has provided technical assistance in the planning, design, implementation and dissemination of findings of contraceptive and reproductive health research to the following:

- University of Nairobi Department of Obstetrics and Gynaecology
- Mali Association for the Promotion and Protection of the Family (AMPPF)
- Government of Nepal: Population Division of the National Planning Commission and Family Health Division, Ministry of Health
- Government of Egypt: National Population Council
- Bangladesh Institute of Research for Promotion of Essential and Reproductive Health and Technologies (BIRPERHT)

III. Subproject Descriptions

A. Global Initiatives for Improvement in Contraception

FHI is engaged in a range of research activities, both in the U.S. and developing countries, which will contribute to the improvement of contraceptives worldwide. This includes initiatives in contraceptive technology development, contraceptive quality assurance, improving compliance, and understanding benefits and risks of contraceptive methods. Wherever the activity takes place, the primary objective of our work is to increase safe, effective and acceptable contraceptive options for use in developing countries.

The subproject descriptions in this section are for activities which are global in scope and therefore would not fall under the regional and country programs presented in Section III.B. Accomplishments in the last 6 months and plans for the next 6 months are given for ongoing subprojects. Results are given for studies completed during the reporting period.

1. Contraceptive Technology Development

FHI's work in contraceptive technology development is concerned primarily with providing sufficient data to the FDA and other regulatory agencies to secure marketing approval of new products. During this reporting period, research focused on the following products: nonlatex male condoms, the REALITY™ Female Condom, an iodine sclerosing formulation for nonsurgical female sterilization, the Filshie Clip for female sterilization, biodegradable NET pellets, norethindrone (NET) injectable microspheres and Lea's Shield.

Barrier Contraceptives and Spermicides

FHI has responded to the increasing rates of STDs, including HIV, in many parts of the world with intensified efforts to provide new and better barrier contraceptives which may offer protection from these diseases, as well as from pregnancy. A major effort is underway to develop a thermoplastic male condom with advantages over the latex condom in ease of use, acceptability, and prolonged shelf life. FHI is also evaluating other barrier contraceptives (the female condom and Lea's Shield™), as well as various spermicide products.

Thermoplastic Condoms: Roll-on/Slip-on (8030-8037)

The current AIDS pandemic is a major concern for the world community. Latex condoms have significant limitations in their mechanical and aesthetic properties. Natural latex rubber loses strength under adverse storage conditions or when used with certain lubricants. The Materials Technology Division (MTD) is employing new materials and unique manufacturing techniques to produce condoms that will overcome these limitations and has developed two viable product designs which differ in their retention component. The sheath design is common to all prototypes. The roll-on design uses a separate enclosed retaining ring; two prototypes have been developed which differ in the structure of the retention ring. The sheath design utilizes a flanged component that is constructed out of the sheath material and has apertures which allow the condom to be donned bidirectionally.

Objective: To develop one or more cost-competitive plastic condom(s) 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 and to obtain FDA clearance for each of these condoms.

Accomplishments related to the roll-on design:

Through March 1993

- Since the beginning of the project in 1991, a heat sealed thermoplastic condom has been developed that utilizes unique materials, designs, equipment and processing techniques. Studies to date indicate the product is stable with acceptable toxicological properties. Patents are pending on design and process features.
- In February, 1992, a 510(k) was submitted on an early condom design which used a soft gel ring retention component.
- There have been two rounds of FDA queries and responses regarding the 510(k), however, final clearance from the FDA is still pending.
- Novel pilot-scale manufacturing equipment has been designed, built and installed throughout the project.
- A unique leak detection methodology was developed.
- A clinical testing program to support a 510(k) filing on a second product which uses a knitted ring retention component has been initiated.
- An Investigational Device Exemption (IDE) was submitted to the FDA and a non-significant risk determination was received for a Phase IA safety study of the knitted ring roll-on condom.

During the last six months

- A computer systems validation audit was conducted April 12-13, 1993 at FHI by a consultant auditor (Clinarium, Inc.) to determine whether or not appropriate validation systems were in place for data handling and management at FHI prior to the start of the phase IA clinical study of the Plastic Condom.
- An audit report was issued by Clinarium on May 3, 1993. Copies of the report were distributed to appropriate FHI management on May 24, 1993.
- FHI's Clinical Trials Division initiated the Phase I trial in June.
- Notice was received in September from the U. S. Patent and Trademark Office that certain claims contained in the knitted ring patent application would be allowed. Minor revision is underway in anticipation of patent issuance.
- Sufficient dialogue was conducted during the reporting period with FDA to finalize a clinical protocol comparing the roll-on condom to a latex condom in terms of breakage and slippage rates. (Phase IB).
- In August, 6 month accelerated aging studies were completed, with no significant physical property loss observed.
- A contract laboratory audit was conducted at National Sanitation Foundation International on July 1, 1993 to determine their Good Laboratory Practices compliance capabilities prior to contracting with them to conduct the methylenedianiline (MDA) analysis on the plastic condom materials which was requested by the FDA.
- An audit report was distributed to appropriate management on August 5, 1993.
- Biocompatibility studies were completed in September. Acceptable outcomes were reported.
- A clinical study site audit was conducted September 2-16 at the University of North Carolina Hospital in Chapel Hill for the phase IA knitted ring plastic condom study.
- FHI's Regulatory Affairs and Quality Assurance Division (RA/QA) managed clinical supplies and monitored regulatory compliance for the Phase IA safety studies for the roll-on condom.
- Analytical studies designed to quantify the level of MDA in the product were initiated at the National Sanitation Foundation.
- There was no action on the 510(k) for the gel-ring roll-on condom, as we are awaiting results of MDA analysis. (see below)

Plans for the next six months for the roll-on/ring condom:

- The remainder of the semi-automatic processing equipment (ring welder and stress-softener) will be received.
- The roll-on manufacturing process will be validated.
- Manufacture of condoms will begin for a comparative clinical trial after the semi-automatic equipment is installed.
- In November, a three-year stability study will be initiated with the knitted ring version and latex condoms representing several manufacturers. Physical, chemical, and viral permeability properties will be assessed.
- MDA levels in the gel ring version of this product will be determined and provided to the FDA in response to queries.
- A contract laboratory audit is scheduled to be conducted at Nelson Labs during November 1993 to determine Good Laboratory Practices compliance capabilities prior to their conducting viral permeability studies on plastic condoms for FHI.
- A re-audit of FHI's pilot production facility, which is manufacturing investigational plastic condoms for clinical studies, is scheduled for January 1994. This re-audit will be conducted to assure that corrective actions have been taken to the findings of a quality assurance audit conducted in Jan.-Feb. 1993 of that facility.
- RA/QA will submit to the FDA the results of the methylenedianiline analysis which are expected in the fall of 1993, for the pending 510(k).
- RA/QA will continue to manage clinical supplies and monitor regulatory compliance for both the Phase IA and Phase IB clinical studies of the roll-on condom.

Accomplishments related to the slip-on design:

Through March 1993

- The initial version of the current slip-on was proposed in April of 1991 after the original flanged design was determined to be unacceptable.
- A small-scale acceptability study of the new design was completed in 1991 and indicated favorable acceptability.
- Fabrication equipment was designed, ordered, and received.

- A patent application for this condom and its manufacturing process was filed in March, 1992.

During the last six months

- The manufacturing equipment received for slip-on manufacture required significant redesign. It was reconfigured and is now functional.
- In August, candidate films for the sheath of this condom were narrowed to five formulations. These materials were submitted for biocompatibility testing sufficient to allow small scale acceptability testing.

Plans for the next six months:

- Biocompatibility screening will be completed.
- Product design and film selection will be finalized after the analysis of results from donning and use studies to be completed in March.
- A small-scale acceptability study has been initiated with the product and will be completed.
- The study protocols and manufacture of condoms to initiate a large scale slippage/breakage/acceptability study will be completed in March.
- Production process and product specifications will be finalized.
- Stability studies will be initiated and additional toxicology testing will be conducted.
- Final action from the Patent and Trademark Office is expected.

Safety Assessment of the Slip-On Thermoplastic Male Condom (Clinical Trial) (2212)

This study will evaluate the feasibility, acceptability and safety of FHI's slip-on thermoplastic male condom when used during vaginal intercourse. About fifty monogamous couples will be recruited at a single site. Safety will be evaluated through vaginal and colposcopic examination.

Objective: To evaluate the acceptability and safety of FHI's slip-on male condom.

Accomplishments:

During the last six months

- Development of a study outline for this Phase I trial was initiated.

Plans for the next six months:

- The protocol will be completed and the study site(s) selected.

Comparative Clinical Evaluation of the Slip-On Thermoplastic Condom and a Latex Condom (2207)

This comparative clinical trial will be designed to evaluate the contraceptive efficacy of the slip-on thermoplastic condom compared to a commercially available latex condom.

Objective: To determine if the contraceptive efficacy of the slip-on thermoplastic condom is substantially equivalent to that of a commercially marketed latex condom.

Accomplishments:

During the last six months

- Development of study outline was initiated.

Plans for the next six months:

- A study protocol will be completed.
- Site selection will be initiated.

Prototype Condom Evaluation: Donning (6386)

The intent of a series of studies to be conducted under this protocol is to "explore the suitability of various condom designs and different polyurethane materials." The shapes, sizes and methods of application of the prototype condoms which will be tested may vary considerably. A limited number of participants (up to 25) will be enrolled for each iteration (round) of the study. Condoms used in these studies will be donned only. Condoms will not be used for intercourse. The information gathered in this series of studies supports the development of the FHI thermoplastic condom.

Objective: To select the best materials (structural integrity) and designs (acceptability) for prototype thermoplastic condoms.

Accomplishments:

Through March 1993

- Several iterations of the plastic condom have been developed and evaluated in human testing.

- Clinical data for the knitted ring condom has been submitted to the FDA for approval.
- One study of the slip-on condom has been conducted.

During the last six months

- The protocol was developed and approved.
- The recruitment materials were developed and approved.
- First study design was approved on September 30, 1993.

Plans for the next six months:

- Study related documents (test instruments) will be developed.
- A study to determine the best aperture size for a slip-on condom will be initiated.
- Data (face-to-face interviews) will be collected.
- Data will be analyzed and a final report will be issued.
- The design of the next round of the study based on "aperture size" study results will be determined.

Prototype Condom Evaluation: Acceptability and Feasibility for Use During Intercourse (6386)

The intent of this series of studies to be conducted under this protocol is to "explore the suitability of various condom designs and different polyurethane materials." The shapes, sizes and methods of application of the prototype condoms may vary considerably. The number of participants in any given study (round of study) will not exceed 350. These studies will be conducted with couples who are protected by an effective form of non-barrier contraceptive and are not at risk for STD. Data from these studies will be used to support the FHI thermoplastic condom project.

Objective: To evaluate several different condoms to determine their feasibility for development into marketable products. These investigations will assess device acceptability and rates of breakage and slippage (device function).

Accomplishments:

Through March of 1993

- Several iterations of the plastic condom have been developed and evaluated in human testing.

- Clinical data for the knitted ring condom has been submitted to the FDA for approval.
- One study of the slip-on condom has been conducted.

During the last six months

- The protocol was developed and approved.
- The first study design to be utilized was approved on September 30, 1993.

Plans for the next six months:

- The study related documents will be developed.
- The study to determine best functioning/most acceptable prototype will be initiated
- Approval of the design for the next phase of study will be sought.

Functionality and Acceptability Study of Three Lubricated Tactylon™ Condoms and a Standard, Lubricated Latex Condom (6002)

The purpose of this study was to evaluate the acceptability and device function of three dipped polyurethane plastic condoms. The study was done at the request of USAID to evaluate another potential plastic condom product.

The study evaluated the functional aspects (breakage and slippage) and general acceptability of four different types of condoms. Three of the condoms were made of Tactylon™, a thermoplastic elastomer or special type of plastic. The Tactylon™ condoms were of three different designs as well. Tactylon A had dimensions and thickness similar to the latex condom. Tactylon B was constructed of softer (lower modulus material) and Tactylon C had a bulbous end. The fourth condom tested was the USAID distributed 52mm latex condom.

Objectives: The primary objective of the study was to evaluate the functionality (breakage and slippage) of three non-latex condoms compared to the latex condom. The secondary objective was to evaluate the acceptability of each of the non-latex condoms compared to the standard latex condom and to each other.

Accomplishments:

Through March 1993

- The protocol and related study instruments were developed.

- The study was initiated and monitored.
- The data were collected and analyzed (N = 284 couples).

During the last six months

- A final report was issued in July of 1993.

Results:

- The latex condom had the lowest clinical breakage rate (0.89%) while the remaining three types had rates at least twice as high (Tactylon C at 2.18%, Tactylon A at 3.44% and Tactylon B at 3.04%).
- Tactylon A condoms had the lowest slippage rate (0.72%) while Tactylon C had a slippage rate almost four times as high (2.72%).
- Latex condoms and Tactylon B had slippage rates in the middle of this range (1.60% and 1.25%, respectively).

Phase II Evaluation of the Safety, Contraceptive Efficacy and Clinical Acceptability of a Female Condom (2098)

This multicenter, contraceptive efficacy study was conducted at nine sites; six (four in collaboration with CONRAD) in the United States, one in the Dominican Republic, and two in Mexico. A total of 377 women were recruited to use the REALITY™ Female Condom as their sole means of contraception for a period of 6 months. Subjects were followed at 1, 3 and 6 months postadmission.

FHI research indicated that the REALITY™ Female Condom was a safe and reasonably effective contraceptive method. These clinical data were used as part of the pre-marketing application submitted by Wisconsin Pharmacal to the FDA that resulted in FDA approval for marketing this device.

Objective: To assess the contraceptive efficacy and safety of the female condom or vaginal pouch (REALITY™, Wisconsin Pharmacal, Jackson, WI), obtaining information necessary for Wisconsin Pharmacal to gain FDA approval of this device.

Accomplishments:

Through March 1993

- FHI's results were submitted to Wisconsin Pharmacal.
- Wisconsin Pharmacal prepared and submitted a pre-marketing application to the FDA.

During the last six months

- FHI responded to questions during the FDA review process.
- Two manuscripts detailing results of the clinical investigation are in review at *Family Planning Perspectives* and the *American Journal of Public Health*.
- The FDA announced its approval of the female condom on May 10, 1993.
- In August, FHI submitted its final report on this investigation to the FDA.
- In a letter dated September 10, 1993, the FDA acknowledged the receipt of our final report and the termination of this investigation.

Phase II Efficacy and Safety of Lea's Shield™ Used With and Without Spermicide (2658)

Lea's Shield™, a vaginal barrier device, is designed as an alternative to currently available vaginal barrier contraceptives and can be used for up to 48 hours after insertion. This contraceptive efficacy study is a six-month Phase II clinical trial conducted by CONRAD in collaboration with FHI. FHI has contributed to managing and monitoring the study and has served as the project's data manager. The study was initiated in 1991 and over 300 volunteers were recruited and randomly assigned to use Lea's Shield™ with or without spermicide. Research results will be used as part of the pre-marketing application to the FDA.

Objective: To develop a new barrier method, called Lea's Shield™, which has the potential of being used continuously for 48 hours, preferably without a spermicide.

Accomplishments:

Through March 1993

- FHI provided assistance to the CONRAD study monitor in performing data quality checks and verification.
- An interim analysis was generated for CONRAD at their request in the early spring of 1993.

During the last six months

- A progress report and a listing of current investigators was submitted to the FDA on April 16, 1993.

Plans for the next six months:

- Data verification and loading will be completed.
- Data analysis will be completed and a statistical report submitted to CONRAD.
- Case report forms will be filed for storage.
- A progress report and list of investigators will be submitted to the FDA in October.
- Preparations for the Phase III study will begin.

Clinical Evaluation of Vaginal Contraceptive Film™ (2211)

This international, multicenter contraceptive efficacy study will be conducted at four sites which have not yet been identified. A total of 500 women will be recruited to use Vaginal Contraceptive Film™ (VCF™) as their sole means of contraception. VCF™ is a barrier method commercially available in the United States which contains the spermicide nonoxynol-9. Subjects will be followed for a period of six months.

Data from this study will be used to assess the contraceptive effectiveness of vaginal contraceptive film when used under typical use conditions. Additional information on compliance and acceptability will also be collected. The study is expected to begin in early 1994.

Objective: To assess the efficacy of vaginal contraceptive film (VCF™, Apothecus, Inc.) in preventing unintended pregnancy as well as compliance and acceptability when used by women choosing VCF™ as their sole means of contraception as a possible substitution for vaginal tablets used in USAID programs.

Accomplishments:*During the last six months*

- FHI initiated recruitment of research sites in September of 1993.
- Development of study protocol and case report forms was initiated.

Plans for the next six months:

- Study protocol and case report form development will be completed and submitted to FHI's Protection of Human Subjects Committee for approval.
- Research sites will be identified and staff trained in study procedures.

- Recruitment of study subjects will be initiated.

Pilot Study of the Physical Characteristics of Spermicidal Preparations (2000)

While there are standard methods for the evaluation of many contraceptive methods (e.g. condom testing, hormonal assays, etc.), there is at least one major deficiency in current methodologies: there is no standardized method to measure the speed of disintegration or dissolution of vaginal preparations (e.g. vaginal tablets or vaginal film). Such a method would be useful in the evaluation and comparison of new and existing spermicidal products and formulations.

Objectives: To develop a method that can be used to compare the speed of dissolution of various spermicidal preparations under different conditions. A second objective is to assess the feasibility of developing an in-vitro system for spermicide evaluation which would mimic vaginal conditions.

Accomplishments:

Through March 1993

- It was indicated in an initial report six months ago that this project would be completed in six months' time. This has not occurred due to (1) competing priorities for the time of the personnel involved and (2) the length of time needed to obtain and set up the laboratory equipment that will be used in this study.

During the last six months

- The objective was modified from measuring "disintegration" to measuring "dissolution" of spermicide products.
- A test protocol was drafted.
- Some of the equipment needed for the work was ordered and obtained.

Plans for the next six months:

- A protocol to test the speed of dissolution of spermicides in wet and moist conditions will be finalized.
- The laboratory equipment to measure nonoxynol-9 (N-9) dissolution will be set up.
- Tests will be conducted on two N-9 formulations: foaming tablets and film.

Barrier Guidelines (2204)

Experience in designing clinical trials for the evaluation of barrier contraceptive methods has led to the recognition that there are a number of potential methodological problems associated with these clinical trials. Some of the criteria used in the design of barrier method clinical trials have been quite arbitrary, ill-defined and inconsistent across studies. In particular, the criteria used for the evaluation of contraceptive efficacy make the current knowledge of the efficacy of these methods inaccurate.

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

Accomplishments:

Through March 1993

- The main methodological problems in the clinical evaluation of efficacy and safety of physical and chemical barrier methods were identified.
- A priority list of issues was developed with participating CAs.
- A draft document discussing FHI's considerations of these issues was developed.

During the last six months

- Because of competing priorities for staff time, there was no activity on this project during the last six months.

Plans for the next six months:

- A manuscript is being finalized using a list of methodological issues in the barrier contraceptives study and will be approved by various USAID CAs.
- A manuscript detailing guidelines will be submitted for publication.

Long-Acting Steroids

FHI is conducting research for the development of new and improved long-acting steroids, specifically, norethindrone 90-day injectable microspheres, a biodegradable norethindrone pellet implant, and a sterile, single use pre-filled mechanism for use in delivering injectable contraceptives. In addition to increasing the contraceptive options available to women, these products would provide hormonal methods without the degree of user compliance required for oral contraceptive use.

Phase I, II, and III Evaluation of the Safety and Pharmacokinetics of Norethindrone 90-Day Injectable Microspheres (2031)

These studies were conducted at 23 sites in six countries: Phase II Clinical (1986-1987) - six sites in the US, Italy, Mexico and Chile; Phase II Endocrine (1986-1987) - two sites in the US; Phase III (1987-1989) - 15 sites in the US, Chile, Mexico, Singapore; and Phase I (1990-1991) - one site in the US. A final report for each of these studies has been initiated.

This research has been used to direct further development of norethindrone 90-day injectable microspheres, but problems related to formulation and scale-up of production of the microspheres have arisen. All future work regarding this product is pending negotiations between USAID, FHI and Ortho, to whom activities regarding this project will be transferred.

Objective: To develop a safe, FDA approvable, injectable contraceptive that will provide continuous efficacy over 90 days while utilizing less than the equivalent steroid dose in other available injectable contraceptives.

Accomplishments:

Through March 1993

- Medisorb, a company established by Stolle and Dupont to further develop microsphere technology, has reformulated the NET-90 (norethindrone) microspheres.
- In the winter of 1992, two solvent systems were identified for producing the product and non-GMP batches were made and tested in baboons.

During the last six months

- Further testing in baboons was funded by Medisorb using GMP batches of reformulated product. FHI has not received copies of the final results. If the results prove to be favorable, the product will move to clinical evaluation.
- Work was initiated on a final report of all previously completed studies.

Plans for the next six months:

- FHI expects to complete the final report on the Phase I, II, and III clinical trials conducted on old formulations.
- The IND for this product will be transferred to Ortho, pending negotiations between USAID, FHI and Ortho.
- Any further activities with this product are dependent on negotiations between USAID, FHI and Ortho and on progress with the product formulation.

Phase II-A Pharmacokinetic Evaluation of Biodegradable Norethindrone Pellet Implants (NET Pellets) (2041)

This Phase II-A study was begun in October of 1991 and is being conducted at two sites in the United States (New York, NY and Norfolk, VA). Recruitment ended in April of 1992. A total of 39 subjects have been enrolled and assigned to either a four or five pellet treatment group. Blood levels of norethindrone (NET), the active ingredient, are being followed in these subjects from day 1 after insertion until levels reach the limit of detection of the assay or until subjects discontinue from the study. Participants are also being followed up in order to determine the product's efficacy (pregnancy rates) during the first 13 months in the study, and to assess safety including adverse events and bleeding patterns. Follow-up will continue at least through April of 1994 and possibly up to April of 1995.

Based on NET serum blood levels to date, the four pellet system may provide effective protection for at least 1 year and the five pellet system may be effective for up to 2 years or longer. There were no pregnancies during the first 13 months of this study, after which time subjects were asked to use alternative non-hormonal contraception. There have been no definite indications of any serious product related side effects.

Results from this study will provide information for the development of a Phase III protocol. Future work with this product is dependent upon negotiations between FHI and Endocon, the holder of the IND.

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

Accomplishments:

Through March 1993

- The IND for this product was transferred to Endocon on September 28, 1992. Future work with this product is dependent upon FHI negotiations with the manufacturer.

During the last six months

- There was one serious adverse event reported in May of 1993 for a subject hospitalized in April at the CONRAD site (Norfolk, VA). This subject had an extended history of chronic lupus erythematosus and experienced a lupus flare requiring hospitalization and maintenance steroid therapy. It was the investigator's opinion that since the subject had completed over 18 months of the study with no other adverse events, it was unlikely that this event was related to the study product.

- Work was initiated on a Progress Report which will describe the first 15 months of experience of subjects in this study. Meetings were held with Dr. S. Mitchell Harman, a clinical consultant to Endocon, to discuss the contents of the report. This report will be submitted to the FDA in early 1994.

Plans for the next six months:

- Subject follow-up for safety parameters and evaluation of serum NET levels will continue under a protocol amendment which extended follow-up past the original 24 months to 36 months. This will allow full evaluation of the tail of NET levels in all subjects.
- The Progress Report covering the first 15 months of experience will be completed in November.

Uniject Development (8019)

Injectable contraceptives such as DMPA are popular among many users. However, in many countries barriers exist to its safe use, including a shortage of sterile syringes, and the low educational level of some providers which may make administering proper dosages problematic. In collaboration with PATH, a sterile, single use, pre-filled mechanism is being devised for injecting the contraceptive.

Objective: To coordinate the development of the PATH single dose delivery system for DMPA.

Accomplishments:

Through March 1993

- A subagreement for the project was finalized and approved by USAID.
- A visit was made to the manufacturer of the injection mold UNIJECT mechanism.

During the last six months

- The design for the Uniject mechanism was virtually completed, and final tooling for preparation of a larger needle insert is in progress.

Plans for the next six months:

- Mechanism development will be completed and the larger needle component will be tested.
- A company to conduct the aseptic filling of the device will be identified.

- Planning of human trials of the device using other medicinals will be initiated. The device will be tested in one or more overseas sites.

Female Sterilization

FHI has a long history of research on female sterilization. Work begun in the 1980s on the Filshie Clip has resulted in a PMA to the FDA. At present, FHI's efforts focus on the development of a method for non-surgical female sterilization using iodine.

Filshie Clip Tubal Sterilization (2091)

The Filshie Clip is a small device that was developed by Dr. Marcus Filshie. It is similar in concept to the Falope-Ring Band and the Hulka Clip and is widely used in a number of countries outside the United States. It can be applied to the fallopian tube by surgeons doing laparoscopic surgery or mini-laparotomies, and has the advantage of potentially being more easily reversible than other surgical methods.

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

Accomplishments:

Through March 1993

- From 1983 through 1989, FHI conducted Phase III clinical trials in 21 countries: Haiti, Mexico, Venezuela, Guatemala, Malaysia, Dominican Republic, Panama, Indonesia, Thailand, Peru, Kenya, Brazil, Canada, England, Scotland, Taiwan, Philippines, Finland, Korea, Austria, Nigeria.
- In collaboration with the British manufacturer, FHI prepared a pre-marketing approval application (PMA), requesting approval to market the Filshie Clip in the United States.
- FHI submitted the 77-volume PMA to the FDA on September 9, 1992.

During the last six months

- Although the Filshie Clip PMA was submitted to the FDA on September 9, 1992, they had not formally responded by September 30 as to whether our submission had been filed. Recent informal communications suggest that the PMA will be filed and that we will receive a list of questions in October 1993.

Plans for the next six months:

- FHI's Regulatory Affairs, Biostatistics and Clinical Trials Divisions will interact with the FDA throughout the PMA review process.

- FHI will respond as effectively and as quickly as possible to the FDA's queries.

Evaluation of the Safety and Effects of Intratubal Administration of an Iodine Formulation on the Genital Tracts of Women Awaiting Hysterectomy (2087)

Used as a transcervically delivered sterilization method, iodine could be an inexpensive, less invasive alternative to surgical sterilization for women in the developing world. Based on prior research and most recent results of efficacy trials, FHI believes this to be a promising product for use in non-surgical female sterilization. Our goal in this study is to establish this compound's preclinical efficacy at iodine concentrations equal to or lower than the 4.14% concentration of the original formulation.

Based on favorable results seen in over 18 months of stability/viscosity testing of the formulation, FHI proceeded with initial efficacy testing in the pig model with very encouraging results. This has been followed by a dose-finding efficacy study in the pig and rabbit models. A full-scale toxicity and irritation study will be performed to address prior FDA concerns. All clinical testing of this formulation has been placed on clinical hold by the FDA pending further preclinical safety testing. FHI plans to complete the necessary preclinical efficacy and toxicity testing of the iodine formulation so that the FDA will lift its clinical hold.

Results from the efficacy and toxicity testing will help to guide the Phase I protocol which is currently under development. This will be followed by a Phase I study projected to be conducted at selected U.S. Clinical Research Centers to evaluate safety and effects of this compound in the 24 hours following intratubal installation.

Objective: To evaluate the safety and efficacy of the transcervical/intratubal delivery of an iodine compound as a nonsurgical method of tubal sterilization.

Accomplishments:

Through March 1993

- FHI has over 18 months of stability/viscosity data on the new formulation from research conducted between January 1991 and August 1992. The data show that the compound is able to maintain a fairly constant state under both room temperature and refrigerated 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.

During the last six months

- Pre-clinical dose-titration studies in the pig and rabbit models were begun and preliminary reports are expected by December 1993 - January 1994. The necessary preclinical toxicity studies are being evaluated and developed.
- The foundation for the next series of pre-clinical studies has been provided.
- A quality assurance audit was conducted at the Massachusetts College of Pharmacy on July 8, 1993 in the laboratory that is developing and testing the iodine sclerosing formulations for FHI.
- Audit findings were presented to appropriate management in a meeting on July 15, 1993.
- An audit report was distributed to appropriate management on August 6, 1993.

Plans for the next six months:

- FHI expects that preclinical studies in the pig and rabbit models will continue through 1993.
- The toxicity studies are to begin in the spring of 1994.
- A proposed Phase I clinical study will be developed.

Iodine Non-Surgical Sterilization (8039)

Although sterilization is an effective, and in many cases, preferred means of contraception, the need for a surgical operation makes it risky for some women, especially those living in developing countries. Non-surgical sterilization using chemical agents to sclerose the fallopian tubes is another possibility. This new project is working to improve a known iodine sclerosing compound and its delivery system to provide a safe, effective, storable, one-application means of sterilization.

Objective: To develop an iodine sclerosing solution with acceptable pH stability.

Accomplishments:

During the last six months

- Discussions have been held with the producer of the current sclerosing solution concerning alternate formulations.
- Samples of the present formulation containing different concentrations of iodine have been analyzed at an independent laboratory.

Plans for the next six months:

- Equipment for iodine formulation will be received and installed.
- Efforts will continue to analyze the present formulation, and experiments will begin with alternate formulations.

Male Sterilization

FHI is conducting two vasectomy studies. Progress on the comparative trial of the no-scalpel vasectomy versus the standard incision vasectomy is reported below. A summary of a pilot study of the time to infertility after vasectomy, to be initiated in January in Mexico, is presented as part of the Mexico Country Program.

No-Scalpel Versus Standard Incision Vasectomy (2006)

From 1986 to 1992 FHI conducted a comparative trial of the no-scalpel vasectomy versus the standard incision vasectomy in Indonesia, Brazil, Guatemala, Thailand and Sri Lanka. The basis for the study was a method of vasectomy developed by the Chinese that avoids the use of a scalpel through the use of a special vas-fixing clamp and a curved hemostat with sharpened points. The stated advantages of this method are that (a) it produces less bleeding and fewer hematomas, and (b) men may be less fearful of the procedure since it does not involve a scalpel.

Objectives: To (1) evaluate the safety and efficacy of two different techniques for performing percutaneous vasectomy (the no-scalpel puncture technique and the standard incision technique), and (2) introduce the no-scalpel technique into programs in participating countries.

Accomplishments:

Through March 1993

- Approximately 1,400 procedures were performed. Data collection has been completed and all study sites have been closed.
- Data were cleaned and the analysis plan finalized.

During the last six months

- Data analysis has been completed but a draft report has not yet been completed as planned.

Plans for the next six months:

- A multicenter report will be completed.

2. Contraceptive Quality Assurance

The primary purpose of the FHI contraceptive quality assurance program is to ensure that contraceptives, particularly condoms, distributed by USAID are of the highest practical quality. FHI is carrying out various contraceptive testing and research programs to fulfill this purpose.

Condom Production Surveillance Program (8015)

This program began in 1990 to provide closer scrutiny of condom production to ensure that product distributed to developing countries by USAID meet performance standards. After utilizing the services of two independent testing laboratories, FHI developed internal testing capability and has performed all condom compliance testing for USAID since 1991.

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

Accomplishments:

Through March 1993

- In 1993, state-of-the-art air inflation testing equipment and a fully computerized data maintenance system were installed.
- The program has been modified to satisfy new USAID requirements for closer adherence to contract compliance.
- A Technical Oversight Committee was established to provide technical expertise to ensure that the FHI production surveillance program remains competent and meets the requirements of USAID.
- Testing capability of condom stocks has been significantly enhanced with the addition of state-of-the-art air inflation testing equipment.

During the last six months

- Monthly sampling and evaluation were performed on condom lots produced by USAID contractors and product was dispositioned accordingly.
- Three compliance audits of USAID contractors were performed.
- Two meetings of the Technical Oversight Committee were held to review condom compliance testing and test results of the current manufacturers.

Plans for the next six months:

- Monthly sampling and evaluation of new production, and bimonthly compliance audits will continue.
- The Technical Oversight Committee will convene in October 1993, and March 1994.
- Interlaboratory condom testing studies will be conducted in October 1993 and March 1994.

Contraceptive Quality Surveillance (8017)

USAID distributes a wide range of contraceptives other than condoms, including IUDs, OCs, implants and injectables. In order to verify contractor compliance and to ensure and maintain product acceptance, FHI has initiated a production surveillance program for these commodities. Since 1992, quarterly audits of manufacturers have been conducted and representative lots selected for evaluation by independent analytical testing laboratories. In-house testing capabilities are presently being built in order to expand the program to include additional contractors and to increase the number of lots evaluated.

Objectives: To assure that contraceptive products distributed by USAID comply with the respective product specifications at the time of manufacture. In addition, proper storage and distribution procedures in the field are assessed to ensure each product's acceptability for use throughout its shelf life expectancy.

Accomplishments:

Through March 1993

- Technical expertise was acquired to establish and manage a pharmaceutical product testing and research program at FHI.
- Since 1992, auditing and testing has been conducted at Ayerst-Wyeth for OCs, and at Finishing Enterprises for IUDs.

During the last six months

- 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 both sites were evaluated.
- Production surveillance programs were initiated at Ortho Pharmaceutical, a foaming tablet manufacturer, and at Syntex Pharmaceutical, an oral contraceptive manufacturer, to initiate production surveillance programs.

- Contraceptive stocks in the Philippines were sampled for evaluation.

Plans for the next six months:

- The pharmaceutical testing laboratory will be made operational.
- Quarterly audits of Wyeth-Ayerst, Finishing Enterprises, Ortho Pharmaceuticals, and Sharp Packaging will be conducted.

PATH: Condom Research (8016)

PATH has significant expertise in condom evaluation, and is a valuable resource when condom technical issues arise which require investigation and recommendations to USAID's Commodities and Program Support Division (CPSD) and FHI controlled programs. Funding for this project is used to cover travel and lodging expenses for meeting attendance, subsequent reporting, and other ad hoc technical assignments. The level of participation and funding is determined by CPSD based on the recommendation of FHI.

Objective: To support PATH to conduct specific research projects and to sponsor participation in technical conferences/meetings as deemed appropriate by USAID/CPSD and FHI.

Accomplishments:

Through March 1993

- Since 1991, PATH personnel have participated in quarterly meetings of the ASTM (American Standard Testing Methods) Condom Task Force Committee, and at two ISO (International Standards Organization) meetings.

During the last six months

- PATH personnel participated in the June, 1993 ASTM meeting in Atlanta, Georgia.
- PATH hosted a technical meeting attended by FHI, PATH, USAID and other agencies in Seattle, Washington.

Plans for the next six months:

- PATH representatives will attend four ASTM meetings, one ISO meeting, and other meetings at the request of FHI and USAID.

PATH: Package Integrity Study (8028)

Because the long term strength of condoms depends on the packaging that protects them from the elements, this project is evaluating the effects of plastic packaging compared to foil packaging over a number of years. Condoms with both types of packaging are heat aged, and tested at 12 different intervals for dimensional changes, water leakage, weight of lubricant, air inflation and tensile strength.

Objective: To research the effect(s) of long term accelerated heat aging of latex condoms in different packaging materials over a period of 4 years.

Accomplishments:

Through March 1993

- A study protocol was finalized and test condoms were heat aged.

During the last six months

- The study, which began in August, 1992, completed year 1 of the testing for which a report has been issued. To date, no appreciable changes have been detected in the physical parameters of either type of package of condoms.

Plans for the next six months:

- A semiannual status report will be issued.

Field Evaluations (8011)

Condom users and potential users must perceive that the condoms they receive are of good quality; frequent breakage of condoms may discourage their use. This project helps to ensure that the integrity of USAID-provided condoms is adequately maintained during in-country storage.

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

Accomplishments:

Through March 1993

- Sixteen field stock evaluations has conducted in fourteen developing countries.
- Numerous field complaints involving contraceptive product quality were handled; technical assistance has been provided upon request to USAID Missions and

other cooperating agencies to resolve problems of product handling, storage and use.

During the last six months

- A quality evaluation of excess condom stocks in Pakistan was performed prior to redistribution.
- A field evaluation of condoms and other contraceptives was conducted in the Philippines.

Plans for the next six months:

- Two country contraceptive distribution programs will be evaluated for quality integrity, with representative samples evaluated at the FHI laboratories.
- Technical assistance will continue to be provided upon request.

Prospective Aging Study (8014)

Condoms must often be stored for long periods under differing climatic conditions, which may affect their quality. This study began in 1990 when five types of latex condoms were placed in storage sites with various climates in Mexico and North Carolina. Later the study was modified to include a study site in Niger. Samples have been retrieved from all study sites on a yearly basis and evaluated for effects of deterioration. Environmental conditions in the storage facilities have been monitored by temperature/humidity recorders. Representative samples from the most extreme sites have been placed in human use studies on an annual basis to study the effect of breakage with age.

Objective: To determine the effect(s) of adverse storage conditions on the stability of latex condoms over a five-year period.

Accomplishments:

Through March 1993

- Sampling and evaluation of the first through third years of the study have been completed.
- The first iteration of a human use study was completed.

During the last six months

- A second iteration of human use testing was completed.
- A third-year interval site monitoring and sampling was conducted.

Plans for the next six months:

- Samples retrieved in September 1993 will be evaluated, and a status report issued.
- A third human use iteration will be conducted.
- Study sites in both Mexico and Niger will be monitored and sampled.
- Newly manufactured condoms will be placed at study sites.

Human Use Studies (8013)

In conjunction with the Contraceptive Use and Epidemiology Division, the Materials Technology Division conducts human use studies to evaluate the relationship of the Condom Quality Index (CQI) with breakage in actual use.

Objective: To correlate latex condom breakage during human use with various behavioral and physical factors that affect functionality.

Accomplishments:*Through March 1993*

- A condom lubricant study was conducted comparing the adverse effects of various lubricants on use breakage.
- Two human use study iterations were conducted with condoms from the Prospective Aging Study.
- Studies to date have revealed that age alone correlates best with breakage and is the best predictor of condom breakage.

During the last six months

- The second human use iteration, using condoms from the Prospective Aging Study, was completed.

Plans for the next six months:

- A third human use iteration will be initiated, using condom samples from the Prospective Aging Study.

Condom Laboratory Monitoring (8029)

Because condom testing equipment and procedures and different testing locations may vary, data from condom lots tested at different facilities may be inconsistent. To resolve this issue, FHI is facilitating comparative air inflation testing at five different testing locations: FHI, Akron Rubber, Smithers, Aladan, and PATH. Samples from single condom production lots are tested at each location and test results examined for consistency. The project was initiated in June 1993, with testing conducted at 6 month intervals.

Objective: To determine the level of consistency and variability in the air inflation test results among the participating condom testing laboratories over a period of 2 years.

Accomplishments:

During the last six months

- Testing protocol and schedule was agreed upon by participating test sites, and subagreement finalized and approved.
- The first round of testing was completed, and test results were sent to PATH for compilation with others.

Plans for the next six months:

- A second round of testing will be conducted.
- Technicians from Aladan and Ansell will visit FHI to uniformly calibrate airburst testing equipment.
- Data collection and reporting software will be upgraded.

Research and Test Method Development (8012)

This program began in 1990 to address many of the unknowns in condom testing. For many years, condom manufacturers relied on results of tensile and water leakage tests to qualify the product for use. However, little was known or understood of how these tests related to actual use conditions or if these tests effectively identified substandard product. Although the air inflation test was gaining acceptance around the world, it was not embraced by United States manufacturers because of its perceived complexity and costs. In the last 3 years FHI has investigated many potential improvements to tensile and air inflation testing methodology and related equipment. It has collaborated with many research organizations (ASTM, WHO, PATH, HIMA, LIG in studying the effects of aging, breakage in use and packaging.

Objective: To investigate the utility of new and modified physical test methods in the evaluation of latex condoms; and to determine, through prospective and accelerated aging, the potential shelf life of oral contraceptives, IUDs, spermicides and injectables.

Accomplishments:

Through March 1993

- In 1991, a device for waterburst testing was designed and built to study the effects and performance on latex condoms in a moist environment, and has been adapted to evaluate non-latex condom prototypes.

During the last six months

- Air inflation test equipment was modified to eliminate excess condom stress during inflation.
- A doctoral level chemist was hired to develop FHI drug testing capability.
- Collaborations were arranged with two USAID drug contractors to research product stability under climatic extremes.
- A pilot stability study with OCs and IUDs was initiated.

Plans for the next six months:

- Correlation studies of the three FHI air inflation testing setups will be conducted.
- The new contraceptive testing laboratory will be equipped and a comprehensive stability research program will be initiated.
- In-house stability studies for OCs, IUDs, DMPA, and foaming tablets will be initiated.

3. Increasing Contraceptive Compliance

FHI has undertaken a series of projects which aim to increase compliance through improvement of labeling and instructions for oral contraceptives and the integration of new OC use instructions into training materials. The bulk of this work has taken place in the U.S. and Mexico. The subproject descriptions which follow detail U.S.-based activities. Additional descriptions are presented in the Mexico Country Program section. Projects carried out in Mexico include testing of new OC instructions (final report submitted to USAID) and research to determine OC knowledge, compliance and continuation among women who receive OCs from midwives in order to find ways to improve the training of rural midwives.

FHI is also conducting preliminary dual-method research in Bryan, Texas to compare compliance of OC users at increased risk of STDs who are also offered latex condoms vs. those offered a choice of latex condoms and nonoxynol-9 film.

OC Compliance (6380)

This project includes a variety of activities and specific tasks designed to explore relationships between compliance and effective use of OCs; improve OC use; inform, educate and provide technical assistance to USAID and the FDA, professional providers, and pharmaceutical companies about compliance and how to improve it. The emphasis is on providing better tools for increasing the use-effectiveness of OCs.

Objectives: 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 users and providers; and to better understand the relationship between problems with pill taking, compliance, and continuation of the method.

Accomplishments:

Through March 1993

- FHI developed standardized, simplified OC use instructions for the FDA which are now appearing in several brands of OCs, including Ortho's Tri-Cept and Ortho-Cept, Organon's Desogene; as well as in several clinical guides for reproductive health (e.g. Hatcher, et al., *Contraceptive Technology*, 1994, in press; Speroff & Darney, *Clinical Guide to Contraception*, 1992).
- FHI staff have participated in symposia, workshops and have presented papers on this work at American Public Health Association, Population Association of America, Association of Reproductive Health Professionals, Drug Information Association and other national meetings in several countries.
- Articles and interviews on new OC use instructions and compliance have been prepared for use in family planning and the lay press (*Contraceptive Technology Update*, *Family Planning World*, *Ob/Gyn News*; *Glamour*, *Working Woman*, *Self*, etc.).
- A Pro-Cite database for OC literature has been developed.

During the last six months

- Invited presentations on OC compliance were given at the following meetings: Association of Latin American Investigators in Reproductive Health (May 23, 1993) on comparison of OC use instructions; Kaiser Family Foundation Symposium on Over-the-Counter OCs (July 9-10, 1993), discussion for presentations on efficacy; Annual Conference of Nurse Practitioners in Reproductive Health Care (June 10, 1993) on new FDA OC use instructions.

- A resource guide on "Contraceptive Practice and Population Policy" was prepared for FHI use.
- The database was further expanded.
- Potential subproject development was explored in Haiti, Mexico, Brazil, Bangladesh, the Philippines and Brazil.

Plans for the next six months:

- FHI staff will present FHI's recommendations for simplifying full OC package labeling (patient package insert) at the FDA Advisory Meeting on October 29, 1993. Staff will work with pharmaceutical companies to develop the final labeling.
- Staff will continue to work with pharmaceutical companies and clinicians to improve the labeling instructions.
- A retrospective record review to study compliance/continuation of DMPA users will be conducted at a local health department.
- Assistance will be provided to other researchers at FHI to include compliance components in their research studies of non-permanent contraceptive methods, and to review projects that do have compliance components (e.g., Kenya OC Compliance, Condom/OC Dual Methods study).
- Other papers will be prepared on general issues of compliance across methods and will include lessons learned from FHI research and directions to take in the future.
- Project development, both international and domestic, will be pursued.

Further Testing of New OC Use Instructions (6018)

This project, an extension of an FHI study in Mexico which tested a set of OC use instructions for USAID to include in its pill packs, is to further test the instructions in different populations.

Objectives: To further test the USAID OC use instructions in at least two other countries, and in different populations with lower literacy and education levels.

Accomplishments:*Through March 1993*

- Development of a project with the Population Council in Egypt was begun. Project development was discontinued when USAID ceased distribution of OCs in that country.

During the last six months

- New contacts with other countries, especially Brazil, were initiated.

Plans for the next six months:

- Further contacts with USAID, Population Council, and SOMARC will be made to determine if/where the new OC instructions should be further tested in order to be included in USAID pill packs (Latin America, Africa, Asia). At least one of these projects will be developed.

**Revision of Package Labeling for Progestin-Only OC Pills (POPS)
(6472)**

A new package labeling will replace the combined OC (COC) labeling that is now the only labeling available for all OCs. The COC labeling is incorrect and inappropriate for POPS, causing much confusion (and even international incidents related to their use during breastfeeding), when found in POP pill packs.

Objectives: To develop package labeling and insert instructions appropriate to POPS, with simplified text for the patient information, and also to create an indexed POP bibliography/database.

Accomplishments:*During the last six months*

- A background paper was drafted and reviewed by international experts. Final revisions are now being made.
- A POPS database was completed and indexed and will be updated regularly.
- FHI worked with USAID to an information package for Honduras and other Latin American countries on the safety of POPS. This was in response to in-country claims that POPS are harmful if used by lactating women.

Plans for the next six months:

- The POPs background paper will be completed and submitted to the FDA and also for publication.
- Package insert labeling will be drafted and submitted to FDA for review.

Measuring OC Compliance Using the Medication Event Monitoring System (MEMS™) Device (6003)

The purpose of this pilot project is to measure OC use in two different types of populations; publicly-funded health clinic users and university health service users, using a computerized dialpak designed to record dispensing activity. Both study sites are in North Carolina, with the goal of 50 volunteers per site. Participants will be followed for 3 months. They will complete a questionnaire at each visit, and keep a daily diary card of OC use.

This study is also being piloted at two similar sites by the University of Michigan. This collaborative effort is intended to lead to a proposal to be submitted to NICHD for a multi-site study.

This study is a pilot for future compliance studies in the U.S. and in developing countries to measure OC use behavior more rigorously than has previously been possible. Results should provide guidance on how to improve compliance among all types of OC users.

Objective: 1) To validate a computerized pill dispenser (MEMS) as a tool for studying OC compliance; 2) and to examine compliance in the context of various personal and service system characteristics.

Accomplishments:

Through March 1993

- Study protocols, questionnaires, data management forms and other project materials were developed, and PHSC and site approvals were received.

During the last six months

- OCs and MEMS devices were donated by a private pharmaceutical company.
- The study was initiated at:

Site 1: Wake County Department of Health, Women's Health Clinic on July 19, 1993. Volunteer recruitment was halted seven weeks later due to slow recruitment. Only 12 women were recruited; with 9 continuing. The slow

recruitment was primarily due to potential volunteers opting to use DMPA or Norplant rather than OCs.

Site 2: The University of North Carolina-Chapel Hill, Student Health Service on August 31, 1993. Volunteer recruitment was complete on September 28. Fifty-five women were recruited, with 54 continuing.

Plans for the next six months:

- Three follow-up visits will be held with each study volunteer.
- Data entry and data analysis will be completed with donated assistance from the developers of MEMS technology.
- Site specific final reports will be prepared.
- A proposal will be drafted for an NICHD multi-site study.

Dual Method Acceptability: Latex Condoms vs. Choice of Latex Condoms and Nonoxynol-9 Film among Oral Contraceptive Users - Bryan, Texas (6010)

In the absence of an ideal method that provides maximum protection against both pregnancy and STDs, family planning providers must decide on what method, or combination of methods, to recommend to clients who are both at risk of pregnancy and STDs. One option is to provide clients with two methods: a barrier method to protect against STDs and a non-barrier method to provide maximum protection against pregnancy. Aside from the increased cost of this approach, there is a possibility that clients will use one, or possibly, both methods less effectively than if they were using a single method.

A cohort of current OC users who have been identified as being at increased risk for STDs will be randomized into two groups. The first group will be provided the standard counseling on the importance of using condoms to prevent STDs. This first group (**condom group**) will be provided condoms along with their OCs during the six-month study. The second group (**choice group**) will be provided the standard counseling on the importance of using condoms to prevent STDs. In addition, participants in the **choice group** will be told that for women who believe it difficult to convince their partners to use condoms, N-9 may provide barrier protection against STDs. The **choice group** will be provided both condoms and N-9 film during the first two months. At the two-month and four-month follow-up visit they will be asked with what barrier method(s) they want to be resupplied. Both groups will be provided with coital logs to record coital episodes and the barrier contraceptive method(s) used during the six month study. Pill compliance will be assessed with a series of questions on the follow-up questionnaires.

Objectives: The primary objective is to assess if OC clients at increased risk of STDs, who are provided a choice between condoms and nonoxynol-9 (N-9) film to protect themselves from STDs, use barrier methods more consistently than their counterparts who are only provided condoms to protect themselves from STDs. A secondary objective is to assess the impact of additional barrier method use on OC compliance.

Accomplishments:

During the last six months

- The study protocol was finalized in September 1993.
- Data collection instruments have been pretested and placed in final review.

Plans for the next six months:

- Data collection instruments will be finalized.
- The study will be initiated at the U.S. site.

Can Family Planning Clients at Increased Risk of STDs Be Identified? An Evaluation of a Risk Assessment Form (6010: Addendum)

The Dual Method study will use a risk assessment form to divide current oral contraceptive (OC) users into two groups. The first group is judged to be at increased risk for STDs, including HIV, while the second is judged at low risk for STDs, including HIV. The definitions for high and low risk are based on a recent article (J.A. Catania et al., Prevalence of AIDS-related risk factors and condom use in the United States, *Science*, 258:1101, 1992). As part of the Dual Method study, STDs prevalence data from 250 OC users at increased risk for STDs will be collected at the beginning of the study. In addition, STDs cumulative incidence data will be collected after six months. To validate the risk assessment form, we need to collect additional STDs prevalence and cumulative incidence data from a group of OC users at low risk for STDs. This additional data will enable us to compare the STDs data of the low and high risk groups.

Objectives: The primary objective of this study is to evaluate the three definitions for high/low risk outlined by Catania et al. by estimating the likelihood ratio (sensitivity/1-specificity) and predictive value. The secondary objective is to create definitions for high/low risk that have a higher likelihood ratio and predictive value than the definitions outlined by Catania et al.

Accomplishments:

During the last six months

- A protocol addendum was finalized in September 1993
- Data collection instruments were pretested and placed in final review.

Plans for the next six months:

- Data collection instruments will be finalized.
- The study will be initiated at the U.S. site.

4. Benefits and Risks of Contraceptive Methods

FHI has a long record of work in the examination of the benefits and risks of a range of contraceptive methods. Projects in this area are included in the country reports for Thailand, Korea, Jamaica, Chile, and Zambia. In addition to research being carried out in these countries, FHI is developing methods of analysis to evaluate the impact of various contraceptive choices on the risk of mortality. FHI is also conducting research in the U.S. to examine the possible relationship between vasectomy and prostate cancer.

Risks and Benefits of Contraceptive Methods (6216)

The purpose of this project is to develop methods of analysis to elucidate and update the impact of various contraceptive choices on the risk of mortality. The project encompasses several substudies, all of which assess the impact of the benefits and risks of contraceptive methods on mortality. The use of information generated by this activity will inform policy concerning the use of various methods for particular subgroups of women or women in particular countries. Substudies include: (1) Ongoing use and development of OCRISK software to assess the impact of risks and benefits of OC use on life expectancy in the United States and other countries. Users and nonusers of OCs are contrasted in this model. (2) Incorporation of U.S. data on smoking into the OCRISK model to compare mortality risk for groups characterized by different categories of OC use and smoking. (3) Development of a decision tree to compare mortality risks for a cohort of women who chose various contraceptive options. In this model, mortality risks of OC users, users of no method, users of barrier methods and users of sterilization will be contrasted. (4) Development of a decision tree which incorporates data on pre-existing conditions (smoking, diabetes, hypertension) to evaluate risk of mortality from various contraceptive methods compared to the risk of pregnancy among users of no method; this will be adapted for women in developing countries.

Objective: To evaluate the impact of known benefits and risks of OC use and other contraceptive methods on mortality.

Accomplishments:

Through March 1993

- An update of the epidemiologic literature on benefits and risks of oral contraceptives was completed.
- New staff were trained in the use and development of the OCRISK software, and the process of transferring software support from an out-of-house consultant/developer to the Scientific Support Services Division has been accomplished. 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.
- Conceptualization of a decision tree model was initiated.

During the last six months

- Data on OC prevalence, mortality and population have been compiled for several Latin American countries for use in the OCRISK substudy.
- OCRISK software has been modified for use to enable new assumptions to be added.
- An analysis of U.S. 1990 data was performed and made into a slide presentation for the FHI CTU conference in Pakistan in June 1993
- A draft paper is in process for two Central American countries.
- A PROCITE data base has been developed to incorporate the cardiovascular and breast cancer literature which is the basis for the analyses.

Plans for the next six months:

- A paper will be completed on the impact of oral contraceptive use on mortality in Latin America.
- Smoking will be incorporated into the OCRISK model for the United States.
- Development of a decision tree will begin.

Vasectomy and Prostate Cancer in a U.S. Screening Population (6206)

A positive relationship between vasectomy and prostate cancer has been noted in several U.S. studies. While there is no clear biologic mechanism for such a relationship, there is consensus that the small to modest elevation in risk groups among vasectomized men may be due to detection bias; that is, vasectomized men may be more likely to be detected since they may use urologic screening services more often and may be more medicalized. This phenomenon is likely to be confined to the peculiarities of the system in the U.S., since extensive screening for prostate cancer is common only here. However, the impact of this information has the potential to affect acceptance of vasectomy throughout the world. Our hypothesis is that a study of this relationship conducted among several populations in the U.S. will show no effect, since all men seeking screening may be "equally" likely to be medicalized. Should we see no effect, with sufficient numbers, these results would provide strong evidence for the existence of such a bias. This confirmation would help the scientific community interpret previous findings.

Objectives: To evaluate the putative association between vasectomy and subsequent prostate cancer by conducting a pilot case-control study within a population of men seeking screening for prostate cancer. This pilot will determine the feasibility of conducting a full case-control study within the prostate cancer screening population, and will be the basis for preliminary work in the submission of an NIH grant application.

Accomplishments:

During the last six months

- A research proposal and collaborative arrangement between FHI and the Prostate Cancer Education Council was developed.
- A questionnaire was administered to 1800 men during National Prostate Cancer Awareness Week (September 20 - 30, 1993) from 10 participating sites in the U.S., and blood and urine samples were collected from 350 men.

Plans for the next six months:

- The follow-up phase of the pilot study will be conducted and prostate cancer cases and controls will be ascertained.
- Pilot data from the baseline data collection will be coded, entered, and checked.
- Validation of vasectomy history on approximately 30 vasectomized men will be completed

- Analysis of the screening histories of vasectomized and non-vasectomized men will be completed
- Preliminary analysis of the question of vasectomy and prostate cancer will be performed.

Vasectomy and 5-Alpha-Reductase Metabolites (6206)

If vasectomy is related to prostate cancer, it is likely that the mechanism is a hormonal one. The specific, relevant hormones for prostate cancer are as yet undetermined; however, it is strongly suspected that 5-alpha-reduced metabolites are implicated in the etiology of prostate cancer. The measurement of these metabolites in urine and serum has been suggested by specialists in prostate cancer.

Objective: To evaluate whether vasectomized men have higher levels of 5-alpha-reductase metabolites.

Accomplishments:

Through March 1993

- A proposal was developed and a collaborator identified to conduct bioassays on serum and urine of vasectomized and non-vasectomized men.

During the last six months

- Urine and serum samples of 350 men participating in the National Prostate Cancer Awareness Week (September 20 - 30, 1993) were collected, frozen and stored. Many fewer samples than expected were collected due to the fact that most of the screenings were held in the evenings, when it was planned that blood samples should not be collected (due to the diurnal variation).

Plans for the next six months:

- A determination of the number of samples from vasectomized and non-vasectomized men will be made; and a decision about what to do with this smaller number of samples will be made.
- Funding for bioassays will be sought.

B. Regional/Country Programs

1. Africa

Africa continues to be the region with the highest fertility rates and the lowest use of contraception. DHS data show that prevalence for modern methods of contraception range

from below 10% in thirteen sub-Saharan African countries to 28% to 38% in Kenya, Botswana and Zimbabwe. Traditional African beliefs value high fertility, leading African women to want more children than women in other regions.

The following situational factors are relevant for family planning in Africa:

- A substantial number of married women desire to space births, even though they continue to desire large numbers of children.
- Rural-urban and educational differences in contraceptive prevalence are more pronounced in African countries where contraceptive use is low.
- Lengthy sexual abstinence after births, breastfeeding and postpartum amenorrhea partially compensates for the low use of contraception in Africa.
- Modern methods of contraception are not widely available, especially in rural areas.
- Most African governments have provided little support for family planning programs; yet government programs are the main source for contraception in most countries.

Africa is the continent most affected by the AIDS epidemic and high rates of other STDs. The STDs/HIV epidemic presents special challenges to family planning programs as service providers must strive to provide the most appropriate contraceptives for a growing proportion of clients at increased risk for HIV and other STDs and for clients who are already infected. The epidemic has posed a number of dilemmas for family planning programs including the potential risk of infection for providers and clients; the need to reorient family planning programs to promote condoms more aggressively; concerns about whether some family planning methods (IUDs, spermicides, OCs) may increase the risk of infection, and the difficulties of counseling HIV infected clients.

The major direction for FHI in Africa will be to determine how to increase acceptance and continuation of modern methods of contraception, increase access to contraception, improve program sustainability, and integrate STDs/HIV and family planning services appropriately.

FHI is working in 10 countries in sub-Saharan Africa (Cameroon, Ghana, Kenya, Malawi, Mali, Niger, Nigeria, Senegal, Zambia and Zimbabwe). In each country, FHI works within existing health infrastructures in accordance with USAID Mission priorities. Activities in the 10 countries are described in detail below.

Accomplishments in the last six months and plans for the next six months are given for ongoing projects. Lessons learned are detailed for projects completed during the reporting period.

Africa Regional Office for Population Activities (7494/7496)

In January 1992, FHI established an office in Nairobi, Kenya. The office is headed by FHI's Senior Representative for Population Activities and has on staff a Research Associate to provide prompt technical assistance to various research projects and related activities in the region.

Objective: To better meet the particular program needs of specific countries and to strengthen FHI's presence in the field.

Accomplishments:

Through March 1993

- FHI's Regional Office for Population Activities was legally registered as an NGO within Kenya in December 1992.
- Population activities with USAID Missions in the region were explored via correspondence and trips from Kenya to Tanzania, Malawi, Zimbabwe, Morocco, Niger, Uganda, Ethiopia, Madagascar, Côte d'Ivoire and Rwanda.

During the last six months

- Collaborative opportunities in the region were identified, including those related to addressing unmet need, reducing medical barriers to family planning, and targeting adolescents. The following agencies were involved in these discussions: Pathfinder, the Population Council, INTRAH, AVSC, CEDPA, the Rockefeller Foundation, and URC. Potential activities discussed included initiation of a postpartum IUD study in Zimbabwe in collaboration with SEATS, holding a Contraceptive Technology Update in Ethiopia in collaboration with INTRAH, and implementation of the national CBD strategy in Tanzania with Pathfinder.
- The protocol and data collection instruments for a pill compliance study in collaboration with researchers from the Family Planning Association of Kenya (FPAK) and IDP staff were developed and possible funding sources for the study were identified including the World Bank (through the Ministry of Health) and GTZ.

Plans for the next six months:

- FHI will continue to explore future population activities with USAID Missions and other CAs in the region, particularly in the areas of STDs and family planning and improving access to contraception by reducing medical barriers.
- FHI will continue to provide technical, administrative and logistical assistance to FHI staff travelling to the region and, upon request, to ongoing projects.

East and Southern African Editors Seminar (3201)

FHI and the African Council on Communication Education (ACCE) are organizing a four-day seminar for east and southern African editors on news coverage of reproductive health to be held November 9-12, 1993 in Naivasha, Kenya. Thirty participants, including assignment editors and sub-editors from Botswana, Eritrea, Ethiopia, Kenya, Malawi, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe will attend.

Objective: To improve news coverage of reproductive health in east and southern Africa by increasing editors' awareness of the importance of covering reproductive health and motivating them to make a commitment to improving and increasing this coverage.

Accomplishments:

Through March 1993

- This project is a result of the assessment by graduates of FHI's journalism skills training workshops in East Africa that the greatest obstacle that skilled reporters face in trying to cover reproductive health is a lack of interest in these issues on the part of their editors.

During the last six months

- Participants were identified and invited.
- A pre-workshop needs assessment was conducted.
- Workshop objectives and program were designed.

Plans for the next six months:

- A four-day workshop will be conducted for 30 editors from the leading news dailies and agencies in 10 countries in east and southern Africa.

Cameroon

Population: 10.5 million

Total Fertility Rate: 5.8

Growth Rate: 2.90%

Contraceptive Prevalence: 16% (Modern Methods: 4%)

Major Modern Methods: OCs (1%), Female Sterilization (1%)

Cameroon has a relatively high level of fertility. This is due in part to a cultural preference for large families and an unmet need for family planning estimated at 22%. The use of modern contraceptives remains low. The most common traditional contraceptive method is periodic abstinence.

The government has chosen to focus its family planning program on encouraging women to space their births rather than to decrease the number of children born. Family planning services are provided by both the private and public sector, though by the latter only recently. CBD programs which distribute condoms are run only through the private sector as part of a well established STDs/HIV prevention program.

FHI is currently working in Cameroon on a project to measure the impact of the introduction of a National Family Planning Policy and Standards Guidelines on reducing medical barriers that limit access to family planning. FHI also disseminates information about contraceptive technology.

Cameroon: Measuring Provider Adherence to National Family Planning Policy and Standards (9315)

Restrictive practices limit access to family planning in Cameroon. FHI and INTRAH are working together to reduce these restrictive practices through the development, introduction and evaluation of policies, standards and guidelines. INTRAH is mainly responsible for the development of guidelines and for training to implement them, while FHI has taken the lead in dissemination of information about contraceptive technology and in measuring the impact of guidelines in service delivery practices.

The impact of policies on service delivery practices will be evaluated using a number of different approaches. These include data currently obtained at participating clinics as well as interviews with service providers and with clients. The instruments focus on nine primary barriers including age and parity restrictions on provision of injectables and lab tests for hormonal methods.

Objective: To measure the impact of the introduction of National Family Planning Policy and Standards Guidelines on reducing medical barriers that limit access to family planning.

Accomplishments:

During the last six months

- The Subagreement was finalized.
- The study protocol was designed.
- Data collection instruments were developed and pre-tested.
- Study sites were selected.

Plans for the next six months:

- Data collection instruments will be finalized.

- Investigators will be trained to collect data.
- Data collection will begin.

Cameroon: Dissemination Seminars (3215)

FHI, in collaboration with INTRAH and the Ministry of Public Health (MOPH), will co-sponsor a 2-day national seminar to introduce policy makers and government officials to Cameroon's new Maternal and Child Health/Family Planning Policy and Standards document. In addition, five 3-day provincial-level seminars will be conducted to disseminate the Maternal and Child Health/Family Planning Medical Protocols document to service providers. These activities are scheduled to take place in FY'94 and are the principal intervention for a parallel FHI activity, a study of service provider adherence to national family planning policies.

Also, FHI is printing French and English versions of Cameroon's policy and standards document and medical protocols documents.

Objective: To improve client access to contraceptive services in Cameroon through the dissemination of newly developed national family planning policy and standards guidelines.

Accomplishments:

During the last six months:

- Production of maternal and child health/family planning documents in French and English was begun.
- Planning and design of upcoming dissemination seminars was initiated with INTRAH and the MOPH.

Plans for the next six months:

- Six dissemination activities will be conducted; one national level and five provincial level seminars.

Ghana

Population: 12.3 million

Total Fertility Rate: 6.4

Growth Rate: 2.6%

Contraceptive Prevalence: 13% (Modern Methods: 4%)

Major Modern Methods: OCs (1.8%), Foaming Tablets (1.3%)

Fertility continues to remain high in Ghana with the average woman giving birth to just over six children. The average ideal family size as stated by married women is 5.3. Forty-eight percent of married women want to postpone their next birth or are uncertain about having another child but are not using contraception.

While the vast majority of married women in Ghana know of at least one modern contraceptive method, only half of them know where to obtain that method. Family planning services are provided by both private and public sectors. Two percent of married women received their supplies through CBD programs.

Currently, FHI is working in Ghana on a Phase III clinical trial for Norplant introduction. Physicians have been trained in insertion and removal procedures as well as in patient counseling.

Ghana: Clinical Trial of the Norplant Contraceptive Implant System (2032)

FHI has been conducting studies of Norplant since 1984. During this time approximately 8650 subjects have been admitted to studies at 43 centers in 11 countries, including Ghana. The site in Ghana has been closed; however, a final report has not yet been completed.

FHI has used these studies to introduce Norplant into countries without previous implant experience and to provide physician training in the method. These studies have provided additional insight into the product's overall acceptability among various cultures while assisting these countries in their efforts to gain regulatory approval of this method. Much of the acceptability data, especially that relating to menstrual disturbances, is being used to develop additional studies to improve user satisfaction and increase continuation rates.

Objectives: To (1) use Norplant subdermal implants in Phase III pre-introductory clinical trials, introducing the method into countries without previous implantable contraceptive experience; (2) provide training to physicians in inserting and removing Norplant properly and also in patient counseling; and (3) determine the implant's overall acceptability in different populations.

Accomplishments:

Through March 1993:

- The study was initiated in June of 1987 with 100 women enrolled.

During last six months

- The site was closed in August 1993.

- Regulatory approval in Ghana of Norplant implants is being sought.
- FHI continues to coordinate area activities with Leiras.

Plans for the next six months:

- Complete the country report.

Kenya

Population: 27 million

Total Fertility Rate: 5.4

Growth Rate: 3.7%

Contraceptive Prevalence: 32% (Modern Methods: 28%)

Major Modern Methods: OCs (10%), Injectables (7%), IUDs (4%)

Kenya was one of the first sub-Saharan African countries with a population policy. The Government's policy of reducing the rate of fertility through family planning seeks to achieve a better balance between population growth and economic development. Family planning services are provided by both the public and private sectors. Community-based distribution programs are prevalent, although half the population is still more than one hour away from clinic services.

Like other countries in East and Southern Africa, Kenya is confronted with an ever-growing epidemic of HIV infection and high rates of STDs. Family planning programs are trying to determine the appropriate level of integration of family planning and STDs services at service delivery points.

FHI has worked with investigators in Kenya to increase acceptability of the IUD and Progestin-only oral contraceptives; to evaluate whether some family planning methods may increase the risk of HIV infection; and to strengthen the capacity of the University of Nairobi to manage a broad-based contraceptive and reproductive health research program.

Kenya: Evaluation of Immediate Postplacental IUD Insertion (9306)

A study to assess clinical and programmatic outcomes related to immediate postplacental IUD insertion and postpartum IUD insertion before hospital discharge was initiated in Nyeri, Kenya in 1992. Data were collected from two hundred twenty-four women who chose to have an IUD inserted after delivery. Similar samples of non-acceptors who delivered in the same hospital where the IUD insertions were performed were also interviewed to determine factors relevant to the acceptance of an IUD during this period. In a separate component to the project, the costs of delivering postpartum IUD services were compared to those for interval insertions.

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 IUD acceptability, development of informational and educational materials, and assessment of the costs of postpartum IUD programs. This project assesses the clinical and programmatic impact of immediate postplacental IUD insertion introduction on contraceptive use and service delivery costs.

Accomplishments:

Through March 1993

- Two hundred forty-four postpartum IUD acceptors and 185 non-acceptors were recruited into the study.
- Data for the cost component of this study were analyzed at FHI and results were presented at the APHA meeting in November 1992. The results indicated that substantial cost savings could be made if more IUDs were inserted immediately postpartum as compared to insertions before hospital discharge or interval insertions. More than 140 immediate insertion clients could receive services for the same cost of serving 100 interval clients.

During the last six months

- Follow-up visits for IUD acceptors were completed.
- IUD acceptor and non-acceptor data were entered and cleaned.
- Data analysis was begun.

Plans for the next six months:

- Data analysis will be completed and the final report (integrating the cost component and data on acceptors and non-acceptors) will be written.
- A paper to be submitted for publication will be written describing the experiences at this site and at a site in Mali.

Kenya: Reproductive Health Research/Institutional Development Project (IDP) (7793)

For the past 5 years, FHI has provided training and technical assistance to the University of Nairobi Department of Obstetrics and Gynecology in activities related to reproductive health research and family planning service delivery. The Department takes a lead role in updating Kenyan service providers and policymakers on

contraceptive technology and related reproductive health issues. This project has been supported by add-on funds.

Objectives: 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; and to develop a network of trained investigators throughout Kenya interested in all phases of family planning research.

Accomplishments:

Through March 1993

- Training seminars were conducted on research related topics including clinical trials methodology, data management and analysis, scientific writing and information dissemination to increase the research skills of the Ob/Gyn Department staff.
- Technical assistance was provided in the development, implementation, and analysis of four reproductive health research projects: a Physicians' KAP Survey, studies of Barriers to Contraceptive Use, Acceptability of Three Family Planning Methods, and Causes and Prevention of Maternal Mortality. The results of the first three of these studies were given in the last semiannual report.
- Computer hardware and software for research and information management were procured and training in their use provided.
- A computerized database was developed of all reproductive health research carried out in Kenya; this is now shared with other teaching institutions in Kenya and the region. The library in the Ob/Gyn Department was also upgraded.

During the last six months

- The second of a two-part workshop on increasing access to contraception by reducing medical barriers was conducted. The workshop was co-sponsored with the Population Council and the Ministry of Health and attended by approximately 75 representatives from the Kenya family planning community, government agencies and other CAs. Outputs included recommendations for service delivery guideline revisions and identification of means for implementing these changes.
- A Contraceptive Technology Update for 120 participants was held in August 1993 as a follow-up to the workshop on reducing medical barriers. It addressed many of the service delivery related issues discussed at the first meeting and identified needed changes in policies and procedures.

- Technical assistance was provided in the completion of final reports for each of the research projects conducted under the IDP and in the presentation of the results of the studies at the September 1993 end-of-project Information Dissemination Seminar attended by representatives of other CAs, local family planning agencies, the Ministry of Health, and the University. Results of the first three studies listed above were reported in the last semiannual report. The Maternal Mortality Study revealed that most maternal deaths occurred outside the hospital. Of the hospital deaths, over 70% occurred during the first 48 hours following admission. Of deaths leading to an interview with a surviving family member, less than 10% were to women who had ever used a modern family planning method.
- IDP staff, some of whom are trained social scientists, were successfully integrated into the Department to work with clinical staff in carrying out research of programmatic importance in Kenya.
- Strategic plans for securing funding for future research and information dissemination activities were developed.
- The first reproductive health newsletter was published by the Ob/Gyn Department and focused on findings from the Physicians' KAP Survey.

Plans for the next six months:

- The expansion of the OB/GYN Department which will house the Reproductive Health Research Unit will be monitored and carried out. The contract with the selected architectural firm has been finalized; work is scheduled to begin in October 1993.
- A limited number of activities will be undertaken as set forth in the new scope of work for expenditure of remaining project funds. These activities are likely to be related to STDs and family planning and/or to reducing barriers to access contraception.

Kenya: Time of Progestin-Only Oral Contraceptive Initiation Among Lactating Women (2096)

The goal of this study is to assess whether acceptability and efficacy can be affected by the time after delivery at which breastfeeding women begin taking the progestin-only contraceptive (POC). This study is being conducted at eight sites in the following countries: Kenya, Indonesia, Mexico, Philippines, and Zimbabwe. A total of approximately 1440 subjects were enrolled prior to the halt of enrollment in July 1993 due to slow recruitment. At that time, 5 of the sites (3 in Mexico and 2 in Kenya) had met recruitment goals. After enrollment into the study, the subjects were assigned to one of two groups to begin using the progestin-only contraceptive at either 6 weeks or 6 months postpartum. Subjects are being followed up at 6 weeks

and 6, 12 and 18 months. At these follow-up visits subjects are being evaluated for continuation rates and compliance with both this method and methods which they switch to while participating in the study. Also being evaluated are pregnancy and acceptability parameters.

Results of this study should provide insight into more effective distribution of the progestin-only contraceptive and its general acceptability in relation to methods switched-to among the breastfeeding population.

Objectives: (1) To compare the 12- and 18-month postpartum pregnancy rates, and the 12- and 18-month continuation rates from time of admission to study among breastfeeding women assigned to begin taking the progestin-only oral contraceptive (POC), norgestrel, 75 mcg at (a) 6 weeks postpartum, or (b) at 6 months postpartum or return of first menses, whichever comes first. (2) To evaluate acceptability by determining the reasons for pill discontinuation and any relationship to POC initiation time. (3) To evaluate safety by determining the frequency and types of adverse experiences.

Accomplishments:

Through March 1993

- The study was initiated and subject enrollment was begun in March 1992.

During the last six months

- Recruitment of 400 subjects at the two sites in Kenya was completed; and follow-up of enrolled subjects at these sites continued.

Plans for the next six months:

- Subject follow-up will continue at all sites in all five countries through the summer of 1994 at which time sites will be closed and a final analysis performed and reports completed.

Kenya: Oral Contraceptive Use and HIV Infection in Women (6000)

This study is designed to examine the association, if any exists, between use of combined OCs and the incidence of HIV infection. It will be conducted in several clinics in Nairobi. A large cohort of 10,000 women attending family planning and MCH clinics, both contraceptive users and non-users, will be created and followed at quarterly visits for up to one year. In the nested case-control study, women with incident HIV infection will become cases, and three matched controls will be selected for each. Cases and controls will have a detailed interview about sexual and other exposures relevant to HIV infection.

Objectives: To measure the association between use of combined OCs and the incidence of HIV infection in women.

Accomplishments:

Through March 1993

- A pilot study conducted in 1990-1992 and funded by USAID, NICHD, WHO and Ortho demonstrated the overall feasibility of the study design, but pointed out the need for improved follow-up and the addition of other clinics.

During the last six months

- A proposal submitted to NIH in May 1993 was not funded. The overall score was disappointing, in part reflecting the confusion of the primary reviewer. The proposal was re-written and re-submitted on September 1, 1993. The most important change is that DMPA and IUD users will not be studied, only oral contraceptive users, thereby simplifying control selection and reducing the size and cost of the study.

Plans for the next six months:

- The score and pink sheets from NIH will be reviewed. If the proposal score has improved substantially, the proposal may be re-submitted.

Malawi

Population: 10 million

Total Fertility Rate: 7.7

Growth Rate: 3.4%

Contraceptive Prevalence: 7% (Modern Methods: 1%)

Major Modern Methods: OCs (2.2%), Female Sterilization (1.7%), Injectables (1.5)

Due to the generally conservative nature of Malawian society and a strong Christian moral ethic, population issues and family planning have not been widely advocated or discussed in public. Until recently the Government of Malawi did not have an explicit population policy or family planning program. However, due to increasing economic difficulties, the Government has recognized the need to bring population growth in line with economic growth by promoting child spacing and reducing the total fertility rate. The general public seems to realize the importance of slowing population growth; and family planning is rapidly becoming a topic of public discourse.

Malawi suffers from one of the highest infant mortality rates in the region (137 per 1,000 live births) and reportedly has a high maternal mortality rate as well. There is also a high

incidence of sexually transmitted diseases, including HIV infection, and AIDS is a serious public health concern.

FHI is working with commercial sex workers and their partners through two hospitals in Malawi to gain behavioral information on female condom use.

Malawi: Acceptability of the Female Condom Among Commercial Sex Workers, Their Clients and Couples in the Nkhotakota and Salima Districts (6382)

The purpose of this study is to provide behavioral information on female condom use. Such information will assist health care providers, social workers, etc. in the provision of better interventions for the prevention of sexually transmitted disease, HIV and pregnancy. Approximately 120 women (60 commercial sex workers and 60 married women) will be enrolled in this study. For CSWs in Malawi, the choices available if a client refuses to wear a condom are to risk acquiring a sexually transmitted disease or lose business. Thus, it is important for these women to experience using a method that is under their control. It is equally important for couples trying to avoid pregnancy to assess the acceptability of the female condom. Acceptability measures will include an assessment of how well women and men liked using the device, whether the device caused any discomfort in use and how well the female condom performed.

Objectives: The primary objective of this study is to assess the acceptability of the REALITY™ female condom in two study populations: commercial sex workers and their clients and married or cohabiting couples. In addition, information will be gathered on male attitudes and opinions and the male's role in the decision to use/discontinue use of the device.

Accomplishments:

During the last six months

- The study protocol and related study documents were developed.
- The study was initiated.

Plans for the next six months:

- Data collection will be completed.
- The data will be cleaned and analyzed.
- A final report will be written and issued in early February 1994.

Mali

Population: 8.9 million

Total Fertility Rate: 7.3

Growth Rate: 3.0%

Contraceptive Prevalence: 5% (Modern Methods: 1%)

Major Modern Methods: OCs (.9%)

The Government of Mali currently has a family planning program which promotes birth spacing as a way to improve the general well-being of the family. Contraceptive prevalence remains low with the modern method rate of 1%, despite the fact that Mali has had a family planning program since 1980. Nearly one third of the women in union expressed a desire to space their children at least two years apart and one in five wanted no more children. Despite that, only 10% planned to use any form of contraception ever in her life.

When asked what was the ideal number of children for a family to have, one fourth of the women answered that "it was up to God." This feeling that planning families is out of their control may explain the low level of knowledge of any contraceptive method and the fact that the second most used form of birth control is the "Gris-Gris" (a small sack of herbs worn to protect against evil).

FHI is working in Mali to improve knowledge of contraception through a project with the AMPPF, and to introduce and evaluate new methods.

Mali: Technical Assistance to the Mali Association for the Promotion and Protection of the Family (AMPPF) (7581)

The AMPPF, created in 1971 as Mali's IPPF affiliate, has promoted and provided family planning services to both rural and urban populations in Mali since that time. The AMPPF also trains family planning providers and conducts research related to sexuality and family planning. Since 1983, FHI has assisted the AMPPF in its institutional development in order to increase the organization's effectiveness.

Objective: To strengthen the institutional capacity of the AMPPF to conduct family planning research in order to improve service provision.

Accomplishments:

Through March 1993

- A computerized client information system was developed through which service delivery data can be collected, analyzed, and reported.

- Three semiannual bulletins devoted to general issues of family planning, including updates on contraceptive methods and HIV/STDs prevention through the use of condoms, were prepared and disseminated.
- An evaluation of a pilot family planning IEC campaign in the Bagueda region was conducted in March 1993, revealing that local service providers and promoters need additional training in planning skills as well as additional material support.

During the last six months

- The fourth semiannual bulletin (highlighting female sterility) was prepared.
- Through the computerized client information system, critical January - March 1993 service delivery data were reported to USAID/Bamako and the Ministry of Health, Solidarity, and Aged Persons. The data included socio-demographic characteristics of the AMPPF clientele, factors influencing their decision to visit the AMPPF and their choice of contraceptive method.
- Future areas of collaboration between the AMPPF and FHI were prioritized; namely, improvement of the client information system, information-resource management, and contraceptive technology updates.

Plans for the next six months:

- The agreement between the AMPPF and FHI will be extended.
- The client information system will continue to be used.
- A fifth bulletin, this one on male sterility, will be prepared.
- Library services at the AMPPF will be improved through the development of an organized system of cataloging and display.

Mali: Evaluation Of Immediate Postplacental IUD Insertion (9311)

A study to assess clinical and programmatic outcomes related to immediate postplacental IUD insertion and postpartum IUD insertion before hospital discharge were initiated in Mali in 1992. Data were collected from 110 women in Mali who chose to have an IUD inserted after delivery. Similar samples of non-acceptors who delivered in the same hospital where the IUD insertions were performed were also interviewed to determine factors relevant to the acceptance of an IUD during this period.

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 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 postplacental IUD insertion introduction on contraceptive use.

Accomplishments:

Through March 1993

- One hundred and ten postpartum IUD acceptors and 273 non-acceptors were recruited into the study.

During the last six months

- Follow-up visits were completed.
- Data were entered on the computer and cleaned.
- Data analysis was begun.

Plans for the next six months:

- Data analysis will be completed and final reports will be written.
- A paper will be written describing this experience in Mali and be submitted for publication.

Mali: Programmatic Evaluation of Norplant Introduction (9714)

In February 1993, FHI began work with the Family and Community Health Division (DSF) of the Ministry of Health, Solidarity and Aged Persons (MSSPA) to develop a research study to evaluate programmatic and clinical outcomes associated with Norplant introduction into five family planning clinics in Bamako. The results obtained in this study will be used to improve the Norplant program and assist in developing the expansion phase. Outcomes to be examined include the factors which could influence a woman's decision to accept Norplant, the quality of counseling, client satisfaction, program costs, impact on contraceptive use, experience with side effects and requests for removal.

This study will interview all women who accept Norplant at the pilot clinics during a 6 month period. They will be interviewed at the time of insertion and again 6 months later. A similar number of women who accept another contraceptive method (i.e. pills, IUD or injectables) will be interviewed at the time of method acceptance in order to serve as a comparison group.

Objective: To evaluate the acceptability of Norplant as a long-term contraceptive method for Malian women.

Accomplishments:

During the last six months

- Research objectives were identified.
- Study protocol and data collection instruments were developed.

Plans for the next six months:

- A subagreement will be completed.
- Data collection instruments will be finalized.
- Interviewer training will take place in January 1994.
- Data collection will begin in February 1994.

Niger

Population: 8.5 million

Total Fertility Rate: 7.4

Growth Rate: 3.2

Contraceptive Prevalence: 4% (Modern Methods: 2%)

Major Modern Methods: OCs (1.5%)

Niger has one of the highest infant and maternal mortality rates in the world. This, coupled with an average age of marriage of 15 years, and a stated ideal number of children at 8.5 for women and 12.6 for men, has led to an extremely low rate of contraceptive use. Only 2% of women in union use a modern method of contraception and 68% plan never to use any form of contraception in their lives. Despite all this, there is an estimated unmet family planning need of 19%, most of which is attributed to the desire for birth spacing.

The first official family planning program in Niger was adopted in 1992 by the Government. Only recently implemented, it strives to improve the socio-economic and educational situation of its population as well as lowering infant and maternal mortality. There is no mention of decreasing the total fertility rate or increasing the contraceptive prevalence rate.

Currently, FHI is conducting an introductory study of postpartum IUD insertion in Niger. The objective of the study is to evaluate programmatic and clinical outcomes of introducing postpartum insertion of IUDs into an existing family planning program.

Niger: Introductory Study of Post-Delivery IUD Insertion (9718)

The insertion of an IUD in the post-delivery period (the time period between expulsion of the placenta and maternity discharge) represents an alternative approach to administering a widely available contraceptive technology. Potential advantages of this approach include 1) contraception with no known effects on breastfeeding performance, 2) the masking of early IUD side effects by normal puerperal bleeding and discomfort, and 3) fewer unwanted pregnancies due to women waiting for the return of menses following birth before seeking family planning. The primary disadvantage of post-delivery IUD insertions is the increased risk of expulsion. This study will follow 100 post-delivery IUD acceptors and 100 controls at Maternité Poudrière in Niamey to evaluate the introduction of this approach in Niger.

Objective: To evaluate programmatic and clinical outcomes of introducing post-delivery insertion of IUDs into an existing family planning program in Niger. Criteria for evaluating clinical outcomes include expulsion rates and insertion-related complications. Programmatic outcomes will be evaluated by considering user satisfaction and the effect of prenatal family planning counseling on acceptance of post-delivery IUD insertion.

Accomplishments:

During the last six months

- Counseling training was conducted for local midwives. Two 2-day counseling workshops were held; 37 local midwives were trained.
- A field visit to coordinate training and finalize study methodology and logistics was carried out.
- Subagreement was written and approved.
- A Mission buy-in was received.
- Two Nigerien midwives were sent to Mali for training in post-delivery insertions.

Plans for the next six months:

- Hire and train interviewers.
- Initiate study.
- Begin data collection and home visits.
- Write data entry programs, begin data entry.

Nigeria

Population: (est.) 119 million

Total Fertility Rate: 6.0 (1990 NDHS data)

Growth rate: 3.6%

Contraceptive Prevalence: 6% (Modern Methods: 4%)

Major Modern Method: OCs 5% (NDHS)

In the past decade, the Nigerian Government has adopted a national population policy and its family planning program has made dramatic progress. Health facilities offering family planning services and knowledge of family planning among potential users have both substantially increased. An estimated 1.5 million Nigerian women of reproductive age are currently estimated to be using modern family planning methods, more than in any other country in Africa. There is an almost even split between those who obtain family planning services from the private sector and those who obtained them from the public sector.

Despite, and in some respects *because* of this progress, there is currently a large unmet need for family planning services; more than three-fourths of the women who need family planning services are not getting them. Long-term methods are particularly important if this need is to be met. Logistics remain a weak link in the overall program with contraceptive pills and injectables often being in short supply. Cost comparisons between methods and service delivery models will become even more important as the program continues to expand.

FHI's role within the large USAID Family Health Services Project of Nigeria has been one of providing short- and long-term technical assistance. Most significantly, FHI has a subcontract with the International Science and Technology Institute for the services of John McWilliam who has served as the Administrator of the FHS Project since September 1991. In addition, FHI has responded to requests for an assessment of the Planned Parenthood Federation of Nigeria, a synopsis of research issues for the program, an evaluation of the impact of training conducted under the Project and a regional contraceptive technology meeting with the Association of General and Private Medical Practitioners of Nigeria.

Nigeria: Support to the Family Health Services Project (7801/7802)

The USAID-sponsored Family Health Services (FHS) Project was begun in 1988 with the purpose of making family planning information and services within Nigeria widely available. The original end-of-project goal was to reach a nationwide contraceptive prevalence of 12 percent, or approximately 2.5 million users. Four prime contractors were chosen to implement four distinct but interrelated components: private sector service delivery; public sector service delivery; information, education and communication; and policy implementation. An administrative and logistics component was added to support the other four. In 1991, following a management review of the FHS Project, it was recommended that the Project Administrator's role

be strengthened to improve coordination among the subcontractors. One suggestion for strengthening the role was to hire an Administrator through a buy-in to an S&T/POP centrally funded project to provide further backstopping capacity than is possible with a personal services contract.

FHI was subsequently selected for this role and, through an add-on to its Cooperative Agreement, both long- and short-term technical assistance are provided to the FHS Project. In this capacity FHI has subcontracted with the International Science and Technology Institute (ISTI) to place Mr. John McWilliam in the role of Project Administrator. In addition, FHI has responded to specific requests from the Mission for short-term technical assistance, provided interim support for the FHS Deputy Administrator, and has sought to develop complementary activities.

Objective: To support the Nigerian Family Health Services (FHS) Project through the provision of short- and long-term technical assistance, including support to the Project Administrator and, for a specified period, the Deputy Project Administrator. In addition, support is to be provided through the implementation of complementary FHI activities aimed at strengthening policy-relevant research and its utilization in Nigeria.

Accomplishments:

Through March 1993

- The FHS Project Administrator has been supported since September 1991 through a subagreement with ISTI. The FHS Deputy Administrator was also supported through this subagreement from January 1992 - February 1993.
- An institutional assessment of Planned Parenthood Federation of Nigeria (PPFN) was completed with recommendations for furthering the quality and expansion of services. Key points included the need for formulating and implementing written clinical quality standards, a plan for developing PPFN's institutional infrastructure to accommodate development initiatives, ways of expanding the use and development of IEC materials at the local levels, and further development of the family planning associations to expand country-wide the successful advocacy and community organization of the PPFN.
- The FHS Deputy Administrator was provided financial support to attend a Management Sciences for Health course on "Managing Skills for Health Professionals" held in Boston in May-June 1992. During this same trip, he visited AID/W and several Cooperating Agencies, including FHI.
- At the USAID Mission's request, an ISTI consultant was supported to facilitate two planning workshops in early 1993 at the FHS offices.

During the last six months

- FHI continued to support the FHS Project Administrator and, during a period of civil unrest in which he was required to remain in the U.S., the in-country Deputy Administrator assumed increasing responsibility for the direction of the project. This was in keeping with long-range goals for the project.
- A technical analysis for a research component for the Nigeria FHS II project was completed at FHI/North Carolina and submitted to FHS and USAID/Lagos. In addition to reviewing past research efforts within Nigeria, the report noted research questions pertaining to IEC, management, service delivery, and clinical/biomedical and costing issues within the national family planning program.
- An evaluation of the impact of major clinical, management and IEC training activities provided through the FHS project was completed by FHI and the Operations Research Unit of Obafemi Awolowo University. Trained interviewers collected information from 948 FHS trainees from four sample states. Findings were shared with USAID/Lagos and FHS for their use in planning future training. Key findings were that:
 - Respondents generally rated FHS training as effective in improving their abilities to provide services and otherwise interact with clients and staff. Still, nearly half of those involved in service delivery said their greatest need was for additional information and skills in the provision of methods.
 - The great majority of clinical service providers said they regularly used materials received during the course of their FHS training, principally as visual aids.
 - Though the unavailability of contraceptive supplies was reported as a persistent problem, trainees stated that a main impact of their training was an increase in both the demand for and provision of family planning services.
- Support was provided to the Association of General and Private Medical Practitioners of Nigeria (AGPMPN) for a regional meeting on contraceptive technology held in Ilorin in May 1993. Over 120 health professionals attended the meeting. FHI sent an international expert who spoke both at the meeting and to an FHS and MOH audience in Lagos on the topic of increasing access to modern contraception. The AGPMPN has subsequently explored the possibility of making bulk purchases of contraceptives for their members to distribute.

Plans for the next six months:

- Support of the FHS Administrator and the project in general will continue via our subcontract with ISTI.

- FHI collaboration with the AGPMPN in planning and organizing a March 1994 Annual Meeting on the topic of contraceptive technology will be further explored and, pending approval, carried out.
- Costing issues for the Nigerian family planning program, particularly those pertaining to Norplant, will be further defined and technical assistance will be provided.

Senegal

Population: 7.9 million

Total Fertility Rate: 6.3

Growth Rate: 2.7

Contraceptive Prevalence: 12% (Modern Methods: 2%)

Major Modern Methods: OCs (1.2%), IUDs (.7%), Female Sterilization (.2%)

As with many countries in Western Africa, Senegal is confronted with continued problems of high fertility and poor infant survival. Cultural norms have made the acceptance of family planning difficult. Over the last few years, however, there have been large strides in the program's development. Pronouncement of a new national population policy, structural reorganizations within the Ministry of Public Health and Social Action, including the creation of a permanent Office of Family Planning and an emphasis on decentralization of services, have coalesced to create a climate of challenge and opportunity. The Government of Senegal continues in its efforts to provide access to essential clinical services and improving the quality and quantity of clinic-based family planning services.

FHI has worked with investigators in Senegal to introduce Norplant, first through a clinical trial and second through a pilot service delivery project. These activities have provided additional insight into the overall acceptability of Norplant and assisted the Senegalese in their attempts to gain regulatory approval of this method. FHI has also worked to strengthen the research capacity of the University of Dakar to manage a "Client Perspective" study and to explore other contraceptive and reproductive health research topics.

Senegal: Introduction of Norplant (7753)

Through an add-on from USAID/Senegal, FHI is providing technical assistance to the Government of Senegal, Ministry of Health to facilitate the introduction of Norplant as an accepted method of contraception in the national program. This process began in 1986 as a pre-introductory clinical trial of Norplant with 50 women. Based on positive response, the trial was later expanded and a total of 333 women were enrolled through June 1991.

In 1991, following USFDA marketing approval of Norplant, FHI and JHPIEGO developed a joint strategy for Senegal to make the transition from research to routine

service delivery. Under the strategy, the "lead agencies" formed a Norplant Coordinating Committee, comprised of senior officials from the Ministry of Public Health and Social Action (MPA/SA), staff of Le Dantec Hospital and representatives of USAID and UNFPA sponsored family planning programs. FHI and JHPIEGO guided the Coordinating Committee in developing protocols for Norplant services, in selecting five clinics in Dakar to deliver services, in identifying physicians and midwives for JHPIEGO's medical training, and midwives and social workers for AVSC's counseling training, and in convening clinic-based information days sponsored by FHI.

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

Accomplishments:

Through March 1993

- Approximately 150 policymakers, clinicians and counselors received scientific and programmatic information about Norplant and its introduction into Senegal's national family planning program.
- A Norplant Information Day held in November 1992 provided media coverage throughout Senegal introducing Norplant as a new family planning option.
- Approximately 200 Senegalese women per month have selected Norplant as their method of contraception since services began in July 1992.
- Interviewer training for a client perspective study was conducted in February 1992. In March 1992, client interviews at the five pilot sites began collecting data on satisfaction rates and counseling techniques for Norplant relative to other methods.
- FHI provided technical assistance to the MPH/SA and HealthCom in developing a trilingual client brochure on Norplant.

During the last six months

- Data collection for the client perspective study was completed.
- Focus groups with Norplant discontinuers and the husbands of Norplant acceptors have been ongoing to gain complementary information on clients' experiences.
- Continued financial and technical support was provided to the Norplant Coordinating Committee for planning and monitoring the Norplant program and expansion activities.

- FHI continued to coordinate efforts with other USAID Cooperating Agencies (JHPIEGO, AVSC, the Population Council) in providing technical assistance to all aspects of the Norplant introduction program in Senegal.
- A draft Norplant service expansion plan was developed for the Norplant Committee to review.
- Opportunities for strengthening the IEC components were explored and a decision made to postpone further development work at this time. This was due to the fact the project was not ready to move into the expansion phase.

Plans for the next six months:

- Data analysis for the client perspective study will be completed.
- FHI will assist in the coordination of a dissemination meeting to share results of the client perspective study with personnel from the Ministry of Health, Office of Family Planning, Le Dantec Hospital, five clinic sites currently using Norplant and the Norplant Committee.
- Staff will assist in the coordination of a meeting for the Norplant Committee to plan for expansion activities.
- FHI will assist in the implementation of expansion activities in three designated areas: St. Louis, Koalack and Thies.

Senegal: Clinical Trial of the Norplant Contraceptive Implant System (2032)

FHI has been conducting studies of Norplant since 1984. During this time approximately 8650 subjects have been admitted to studies at 43 centers in 11 countries, including Senegal. Most of the sites have already been closed. Ongoing clinical work currently involves approximately 734 subjects at five centers in El Salvador and in Senegal. In Senegal, a pre-introductory clinical trial began in 1986 with 50 women. Based on positive responses, the study was expanded to include 333 women by 1991. Follow-up will continue for all enrolled subjects until the implants have been used 5 years or until they are removed.

FHI has used this multicountry study to introduce the Norplant system into countries without previous Norplant experience and to provide physician training with the method. These studies have provided additional insight into the product's overall acceptability among various cultures while assisting these countries in their efforts to gain regulatory approval of this method. Much of the acceptability data, especially that relating to menstrual disturbances, are being used to develop additional studies in order to improve user satisfaction and increase continuation rates.

Objectives: To (1) use Norplant subdermal implants in Phase III pre-introductory clinical trials, introducing the method into countries without previous implantable contraceptive experience; (2) provide training to physicians in proper insertion and removal of Norplant and also in patient counseling; and (3) determine the implant's overall acceptability in different populations.

Accomplishments:

- A pre-introductory clinical trial began in 1986 with 50 women. Based on positive responses, the study was expanded to include 333 women by 1991.
- Regulatory approval of Norplant is pending in Senegal.

Plans for the next six months:

- Follow-up will continue for all enrolled subjects until the implants have been used five years or until they are removed with maximum follow-up to March of 1996.

Zambia

Population: 8.6 million

Total Fertility Rate: 6.5

Growth Rate: 3.1%

Contraceptive Prevalence: 15% (Modern Methods: 9%)

Major Modern Methods: OCs (4.3%), Withdrawal (3%), Female Sterilization (2.1%), Condom (1.8%), IUD (.5%)

For the first fifteen years post-independence (which was in 1964), the high rate of population growth was not seen as a problem by the Government of Zambia in comparison to concerns about internal migration. In the early 1980s, the Government recognized the implied adverse effects the ever-increasing population would have on the overall national development and individual welfare. The Ministry of Planning and Development Corporation crafted a population policy which was to balance the population growth rate with that of Zambia's economic growth. In 1989, the National Population Policy was launched; its objective is to improve the standard of living and quality of life of all residents. The 1992 Health Reforms established the targets to be achieved by the year 2000 which include making family planning available, accessible and affordable to at least 30% of all adults in need and reducing maternal mortality (through the promotion of safe motherhood) by 50 percent. As in many countries in Africa, the spread of sexually transmitted diseases, including HIV, remains a concern.

FHI has worked with investigators in Zambia to evaluate the acceptability of long-term barrier contraceptive methods (vaginal contraceptive film, female condoms, and male condoms) among couples at high risk for HIV infection; to measure the association

between consistent spermicide use and HIV infection; and to evaluate the acceptability of spermicides (foam, tablets, suppositories) in couples at high risk of contracting an STDs.

Zambia: Spermicide and Condom Use and HIV Infection (6281)

This study evaluated the use of spermicides and non-spermicidal latex condoms in a cohort of stable couples that were discordant on HIV infection. Couples were advised to abstain from sexual intercourse. If they decided to continue having intercourse, they were advised to use both condoms and spermicides at every coitus. The three spermicide products tested, all of which contain nonoxynol-9, were Vaginal Contraceptive Film (VCF), Conceptrol gel, and Conceptrol suppositories. The couples made clinic visits every 3 months at which time both members received physical examinations, were tested for HIV and other STDs, and were interviewed about sexual activity, barrier contraceptive use and other relevant exposures.

Objectives: To measure the association between consistent spermicide use and HIV infection and to measure the association between consistent condom use and HIV infection.

Accomplishments:

Through March 1993

- 110 discordant couples were evaluated, of which 80 couples included a seronegative woman. The couples were followed for a mean of 17.6 months (median 15.3).

During the last six months

- The final analysis was completed. Couples remaining discordant and under observation have been recruited into the FHI study of long-term use of barrier methods including the female condom.

Results:

- Compliance with barrier method use was high, with 78% of coital episodes protected by condoms, 85% protected by spermicides, and 6.4% of coital acts unprotected by either barrier. Approximately one-third of couples used condoms for every act of intercourse, and over one-third used spermicides for every intercourse.
- There were a total of fourteen seroconversions among initially seronegative partners, an overall rate of 8.7 infections per 100 couple-years (19.1 per 100 c-y among seronegative men and 5.0 per 100 c-y among seronegative women; rate ratio[RR]=3.8, 95% CI 1.3-11.0).

- Comparing full-time condom users with other couples, the HIV RR was 0.2 (0.0-1.9). Comparing full-time spermicide users with other couples, the HIV RR was 0.8 (0.2-2.9). Among the couples with seronegative women, consistent use of either barrier method was associated with more substantial reductions in the HIV incidence.
- Proportional hazards regression confirmed the strong protective effect associated with consistent condom use, and the elevated incidence among male seronegatives. On the other hand, consistent spermicide use was invariably associated with a higher HIV incidence rate in these multivariable models. Self-reported genital irritation was associated with a substantially increased incidence of HIV infection.

Plans for the next six months:

- A manuscript will be submitted for publication in a refereed journal.

Zambia: Barrier Contraceptive Use Among Couples at High-Risk of HIV Infection (6305)

The goal of this study is to evaluate determinants and acceptability of long-term barrier contraceptive use among HIV-discordant couples, especially use of the female condom. Though there have been numerous short-term acceptability studies of the female condom, there have been no long-term acceptability studies among couples that should be well motivated to use a barrier method consistently. This study recruits 100 couples at high risk of HIV infection (HIV-discordant couples or couples with a partner with a diagnosed STDs), counsels them on use of the female and male condom and vaginal contraceptive film, and carefully measures long-term use of the methods (over 1 year period). In addition to behavioral variables, data on acceptability, psychosocial, and STDs variables are being collected.

Objectives: (1) To measure the long-term use of barrier contraceptives (female and male condoms, vaginal contraceptive film) among couples at high-risk for HIV infection; (2) to evaluate the acceptability of the female condom among women and men; (3) to identify factors predictive of long-term barrier contraceptive use.

Accomplishments:

During the last six months

- The study protocol was finalized and baseline and 3-month interview schedules were drafted and pretested.
- Study products were purchased and shipped to the field site.

- Training in interviewing techniques and counseling concerning the female condom was completed.
- Fifteen couples were recruited into the study and interviewed.

Plans for the next six months:

- We will complete recruitment and baseline interviews of 100 high-risk couples.
- 3- and 6-month follow-up interviews will be completed.
- FHI staff will create data entry programs and enter all baseline data.
- Preliminary analysis of baseline data will be done.

Zambia: Spermicide Acceptability Among STDs Clinic Attenders (6269)

Three spermicidal products containing nonoxynol-9 (N-9) were evaluated for acceptability by men and women at increased risk for acquiring STDs. Staff of the Dermato-Venereology Clinic of the University Teaching Hospital recruited participants and administered three follow-up interviews during this three month study. This study was intended to assist the Zambian National STDs Programme in their consideration of distributing spermicides.

Objectives: To evaluate the acceptability of three N-9 spermicides (Intercept Vaginal Suppositories, Conceptrol Vaginal Foaming Tablets and Delfen Contraceptive Foam) among men and women at high risk for acquiring STDs in Lusaka, Zambia.

Accomplishments:

Through March 1993

- Eighty-five women and 128 men completed the study and provided data acceptable for analysis.

During the last six months

- Data analysis was completed and a final report was written and disseminated.

Results:

- A large proportion of participants did not continue product use throughout each two-week study period (women: 41% to 47%, men: 20% to 22%).

Discontinuation was most often attributed to personal reasons unrelated to acceptability.

- Over three-fourths of both men and women reported continued spermicide use three months after the study, although these data are questionable.
- Despite limitations of the study, more participants identified positive rather than negative features of the spermicides and mean ratings of various product characteristics were favorable along a wide range of acceptability parameters.
- Notably, the data suggest that men found the spermicides to be at least as acceptable as the women did.

Zimbabwe

Population: 10.7 million

Total Fertility Rate: 5.3

Growth Rate: 3.0%

Contraceptive Prevalence: 45% (Modern Methods: 38%)

Major Modern Methods: OCs (31%)

Family planning information and services are provided by the Zimbabwe National Family Planning Council (ZNFPC), government hospitals and clinics, and by private sources such as doctors, hospitals and pharmacies. A hallmark of ZNFPC activities is a network of community-based distributors who supply contraceptives and information to couples in rural areas.

Contraceptive prevalence has been increasing steadily in Zimbabwe. There also has been a substantial shift from traditional to modern methods. One considerable unmet family planning need is for permanent methods. Almost one third of women in union reported wanting no more children; however, female sterilization accounts for only 5% of all contraceptives used.

FHI is currently involved in a study of progestin-only contraceptives, which evaluates whether acceptability and efficacy can be affected by the time after delivery at which breastfeeding women begin taking the progestin-only contraceptives.

Zimbabwe: Time of Progestin-Only Oral Contraceptive Initiation Among Lactating Women (2096)

The goal of this study is to assess whether acceptability and efficacy can be affected by the time after delivery at which breastfeeding women begin taking the progestin-only contraceptive (POC). This study is being conducted at eight sites in five countries. A total of approximately 1440 subjects were enrolled prior to the halt of enrollment in July 1993 due to slow recruitment. After enrollment into the study, the

subjects were assigned to one of two groups to begin using the progestin-only contraceptive at either 6 weeks or 6 months postpartum. Subjects are being followed up at 6 weeks and 6, 12 and 18 months. At these follow-up visits, subjects are being evaluated for continuation rates and compliance with both this method and methods which they switch to while participating in the study. Also being evaluated are pregnancy and acceptability parameters.

Results of this study should provide insight into more effective distribution of the progestin-only contraceptive and its general acceptability in relation to methods switched-to among the breastfeeding population.

Objectives: To compare the 12- and 18-month postpartum pregnancy rates, and the 12- and 18-month continuation rates from time of admission to study among breastfeeding women assigned to begin taking the progestin-only oral contraceptive (POC), norgestrel, 75 mcg (a) at 6 weeks postpartum, or (b) at 6 months postpartum or return of first menses, whichever comes first; to evaluate acceptability by determining the reasons for pill discontinuation and any relationship to POC initiation time; to evaluate safety by determining the frequency and types of adverse experiences.

Accomplishments:

Through March 1993

- The study was initiated and enrollment of subjects was begun in March 1992.

During the last six months

- Due to continued slow recruitment and enrollment, this study stopped enrolling subjects as of July 1, 1993. At the Zimbabwe site, 114 of 200 expected subjects were enrolled.

Plans for the next six months:

- Subject follow-up will continue at all sites in all five countries through the summer of 1994 at which time sites will be closed and a final analysis performed and reports completed.

2. Latin America and the Caribbean

In Latin America and the Caribbean as a whole, fertility averages between three and four children per woman and contraceptive prevalence is relatively high. DHS data show that prevalence for modern methods of contraception exceeds 50% in six countries and is below 10% in only one (Haiti). Although periodic abstinence is the only family planning method approved by the Catholic church, in many Latin American/Caribbean countries it is not the most popular method among Catholics.

The following situational factors are relevant for family planning in Latin America and the Caribbean:

- Even though contraceptive use is relatively high, nearly one-third of women already have more children than they say is ideal.
- The urban-rural gap in contraceptive prevalence has decreased for modern methods as family planning programs have been extended to rural areas.
- Length of breastfeeding and postpartum amenorrhea are shorter in Latin America than in other regions.
- Female voluntary sterilization is particularly prevalent throughout most of the region.
- Government serves a minority of users; non-governmental organizations and private, for-profit providers are important sources of contraceptives, especially those requiring resupply.

Few young people use contraception the first time they have premarital sexual intercourse. Contraceptive use increases for those who continue their sexual activity, however. Although HIV infection rates in most Latin American countries are still relatively low, other STDs pose a problem for many of those who are sexually active. Several Caribbean countries have experienced some of the world's highest STD infection rates. Increases in the acceptability and use of condoms, particularly by those at high risk of STDs, is essential.

The major directions for FHI in Latin America and the Caribbean are to improve compliance and acceptability for condoms and OCs, introduce long-acting steroidal methods, improve quality of care, and increase cost-effectiveness of family planning programs.

FHI is working in six countries in Latin America (Chile, Colombia, Ecuador, El Salvador, Honduras, and Mexico) and three in the Caribbean (Dominican Republic, Haiti and Jamaica). In each country, FHI works within existing health infrastructures in accordance with USAID Mission priorities. Activities in the nine countries are described in detail below.

Accomplishments in the last 6 months and plans for the next 6 months are given for ongoing projects. Lessons learned are detailed for projects completed during the reporting period.

PAHO/FHI Quality of Care Meeting (9302)

Quality of care was one of the areas designated for collaboration in a memorandum of understanding between the Pan American Health Organization (PAHO) and FHI.

PAHO requested the participation of FHI in developing a framework for an integrated model of quality of care in reproductive health. A workshop was held in March to

lay the foundation of the model. Participants at the meeting drew on FHI's and PAHO's substantial experience in family planning, maternal health and HIV/STDs. PAHO, FHI and IPAS have continued to expand on the meeting's output to further improve the integrated model of quality of care for reproductive health. The draft model is being widely reviewed at the country level in Latin America, and by experts in the field of quality of care and reproductive health. After one more revision, the framework will be presented at three country meetings (tentatively Honduras, Bolivia and Trinidad/Tobago). FHI will be represented in at least the first country meeting, and will likely remain involved in the country applications of the framework.

Objective: To develop and field test an integrated framework for assessing quality of care in reproductive health, including family planning, maternal health and HIV/STDs.

Accomplishments:

During the last six months

- A meeting on quality of care was held at FHI on March 25-27 and was attended by 25 participants. PAHO, IPAS, IPPF, USAID and FHI were represented.
- An integrated model of quality of care in reproductive health was drafted in collaboration with PAHO and IPAS and was sent out for review.

Plans for next six months:

- Three country meetings will be held.
- Technical assistance will be provided for in-country applications of the framework.

International Workshop on Postpartum and Postabortion Family Planning (3019)

FHI and the Pan American Health Organization (PAHO) in collaboration with AVSC, IPPF, IPAS, JHPIEGO, Pathfinder International, the Population Council and UNFPA conducted the International Workshop on Postpartum and Postabortion Family Planning in Quito, Ecuador, July 12-15, 1993. Eighty-eight public health/family planning leaders and resource persons from 13 Latin American countries and the United States participated in the four-day workshop.

Objective: To integrate postpartum and postabortion family planning in the existing reproductive health services of Bolivia, Ecuador, El Salvador, Guatemala, Honduras, Nicaragua, Paraguay, Peru and Venezuela -- nine Latin American countries identified by FHI and PAHO as having the greatest need for improving or increasing postpartum and postabortion family planning service delivery.

Accomplishments:

Through March 1993

- FHI worked with PAHO staff to develop plans for the workshop.

During the last six months

- Participating countries were identified by PAHO/FHI.
- Workshop participants were selected.
- Pre-workshop needs assessment was conducted.
- Workshop objectives and program were designed.
- Workshop was conducted.

Plans for the next six months:

- Technical assistance will be provided to one of the participating countries in the completion of the national strategies and implementation of certain of its components.
- A draft of the workshop publication will be written.

Chile

Population: 13.5 million

Total Fertility Rate: 2.6

Growth Rate: 1.6

Contraceptive Prevalence: No reliable data available

The first family planning program in Chile was started in 1938. Today's family planning activities fall under the newly created Maternal and Child Health Program which was designed to assure that all pregnancies would be desired and would occur under optimal conditions. Responsible parenthood has always been a cornerstone of all family planning programs. This combined with an extensive family planning education program in the clinics, has led to a high level of knowledge about the importance of birth spacing, well-child care and contraceptives.

Family planning services in Chile are provided by both the public and private sectors. One of the largest private organizations is the Chilean Association for Family Protection (APROFA), which has been offering family planning services since 1968.

FHI has provided funding for analysis of a Chilean data set to compare the growth rate of bottle-fed versus breastfed babies.

Chile: Secondary Analysis: Growth of Breastfed Babies (6405)

Good information on the growth rates of babies who are exclusively breastfed is scarce. FHI is providing Dr. Soledad Diaz of the Instituto Chileno de Medicina Reproductiva with funding to analyze such data from a Chilean data set.

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

Accomplishments:

Through March 1993

- Data have been abstracted from 1,217 medical records, entered into computerized data files, and verified.
- A preliminary analysis and manuscript were submitted by the subcontractor to FHI.
- After review, extensive revisions were made.

During the last six months

- A revised report has been submitted to FHI for review. Breast milk alone supported the growth of most infants for the first six months of life at rates comparable to international standards.

Plans for next six months:

- After in-house review has been completed, a final paper will be submitted by Dr. Diaz for journal publication.

Colombia

Population: 34.9 million

Total Fertility Rate: 2.8

Growth Rate: 2.1%

Contraceptive Prevalence: 66% (Modern Methods: 55%)

Major Modern Methods: Female Sterilization (20.9%), OCs (14.1%), IUD (12.4%)

Colombia has made great strides in reducing its total fertility rate, from one of the highest in Latin America to one of the lowest. There is no official family planning program run by the Government of Colombia. Instead a private organization, La Asociación Pro-

Bienestar de la Familia, PROFAMILIA, was started in 1965. Between its 56 clinics (8 of which are targeted for men), and its extensive community-based distribution program, PROFAMILIA provides about 65% of all family planning in Colombia. The rest is split between local pharmacies, which sell injectables, OCs and all barrier methods, and private doctors and clinics.

Condom use in Colombia has nearly doubled since 1986, reflecting an increased awareness of STDs, particularly HIV/AIDS. FHI recently completed a study of condom and spermicide use among women at high risk for STDs.

Colombia: Use of Condoms and Vaginal Spermicides by Women at High Risk of Contracting Sexually Transmitted Diseases (2202)

This study was initiated in 1990 and conducted at the Laboratorio de Investigaciones de Enfermedades Venéreas in Bogotá, Colombia.

Enrolled women were randomly assigned to one of three study groups. One group was to use condoms only. The second group was given condoms and spermicide to use concurrently. The third group was given condoms and spermicides, but instructed to use the latter only if the male partner refused to use a condom. A total of 200 women were recruited to participate for a period of 12 weeks.

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 also was to test whether or not providing condoms and spermicides encourages combined contraceptive use.

Accomplishments:

Through March 1993

- Due to travel restrictions, FHI staff could not monitor the study before its completion. After several attempts, case report forms remaining at the site were shipped to FHI for review, cleaning and data processing in May 1993.

Plans for the next six months:

- Review, cleaning and processing of case report forms will be completed.
- A final report will be completed.

Dominican Republic

Population: 7.6 million

Total Fertility Rate: 3.3

Growth Rate: 2.2%

Contraceptive Prevalence: 56% (Modern Methods: 52%)

Major Modern Methods: Female Sterilization (39%), OCs (10%)

The Dominican Republic has seen a significant decrease in its total fertility rate in the last decade, achieving its desired fertility rate (2.8) in urban areas. The problem remains at the rural level where education and literacy rates are much lower than in urban areas and the birth rate is double the urban rate.

Nearly one quarter of married women who desire to either space or to not have any more children do not have access to the family planning services they need. Thirty eight percent live at a distance greater than fifteen kilometers from a clinic or hospital which provides family planning services and twelve percent do not know where the closest hospital or clinic is located.

The Dominican Republic has an extensive community-based distribution program which gives out a variety of contraceptives. Nearly three-fourths of all married women live in communities which are served by either a CBD program or by community health workers.

FHI is currently involved in two studies in the Dominican Republic. One study is aimed at assessing different methods of identifying condom users who are at risk of condom failure. The other study is comparing condoms lubricated with N-9 versus silicone and their effectiveness at preventing gonorrhea and chlamydial infections.

Dominican Republic: Methods of Identifying Condom Users at Risk of Breakage and Slippage (6004)

Within any given condom breakage study, the majority of condom breaks occur among a small group of study participants. If these individuals and the reasons for condom breakage can be identified, better condom use instruction interventions can be developed for those using condoms as contraception or for disease prevention. Also, identification of individuals who tend to be "breakers" is useful as a screening process for product evaluation, to remove from the study population those individuals who are likely to have higher rates of breakage because of misuse practices.

In the D.R. (one of three international sites), this study was conducted in collaboration with the PROFAMILIA. Male condom users (130) were given a background interview and five condoms to be used for vaginal intercourse. After a three-week study period, participants were interviewed to determine condom breakage and slippage rates and to assess behaviors that may lead to condom failure (condom breaking or slipping off completely).

Objectives: To assess different methods of identifying condom users who are at risk of condom failure, and to assess behaviors that lead to condom failure.

Accomplishments:

During the last six months

- Field work was completed; 126 participants completed the study.
- Data have been cleaned and analysis is in progress.
- The data suggest that past condom failure predicts future condom failure (consistent across all three sites).
- Preliminary analysis has identified behaviors which appear to be associated with condom failure including: using instruments such as teeth, scissors or pencils to open condom packages, unrolling condoms before donning, and having particularly intense or long intercourse. Use of additional lubrication and re-use of condoms (behaviors identified in prior FHI research) were reported infrequently in this study.

Plans for next six months:

- Data analysis will be completed.
- A site specific report will be written and disseminated
- Study results will be presented in October at the APHA Meeting.
- An article will be prepared for publication.

Dominican Republic: Cervical Infection and Condom Use (6304)

Condoms are the foundation for programs and individuals attempting to prevent the spread of sexually transmitted infections (STI), including HIV. Several varieties of condoms are available and nonoxynol-9 (N-9) lubricated condoms have been promoted as providing extra protection because of the microbicidal activity of N-9. However, N-9 lubricated condoms are more expensive than condoms lubricated only with silicone. There are no human use data to determine if they afford more protection, or whether they are as non-irritating to women as silicone lubricated condoms. We will test the hypothesis that the addition of N-9 to silicone lubricant on latex male condoms can reduce the rate of gonorrheal and chlamydial cervicitis when compared with condoms lubricated only with silicone. We will also test the hypothesis that the N-9 lubricant has no increased effect on genital irritation in women who engage in frequent sexual intercourse when compared with silicone lubricant.

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

Accomplishments:

Through March 1993

- A protocol was developed, reviewed, and approved by FHI's Protection of Human Subjects Committee.

During the last six months

- The protocol was translated to Spanish, reviewed by the local investigator, and approved by the local ethics review committee.
- The subagreement was developed and submitted for approval.

Plans for the next six months:

- Final approvals will be obtained.
- Field materials will be developed, supplies ordered, final logistics arranged, and field staff trained.
- The study will be initiated.

Ecuador

Population: 10.3 million

Total Fertility Rate: 3.8

Growth Rate: 2.5%

Contraceptive Prevalence: 53% (Modern Methods: 42%)

Major Modern Methods: Sterilization (19%), IUD (12%), OCs (9%)

The Total Fertility Rate (TFR) has declined considerably in the period between the 1987 DHS Survey (4.3) and the 1989 CDC Survey (3.8). Fifty percent of women with no formal education had no knowledge of contraceptive methods, which underscores the need to develop educational materials and programs specifically for women with little or no education.

The most important suppliers of contraceptives in Ecuador are the MOH (27%) and private clinics (26%), followed by pharmacies (17%) and APROFE (12%), the local IPPF affiliate. The MOH is the principal source of sterilizations, while APROFE is the main supplier of IUDs, and pharmacies are the major suppliers of OCs, condoms and vaginal methods.

FHI has carried out a study with CEMOPLAF, an Ecuadoran family planning PVO, to compare the costs and effectiveness in terms of problem detection of various follow-up schedules for IUD users. Training and technical assistance are also being provided to CEMOPLAF in the areas of cost containment, cost recovery and income generation. Finally, FHI is providing CEMOPLAF with technical assistance to assess the clinical performance, acceptability and method continuation of DMPA, and to test the efficiency and cost-effectiveness of different systems of supply and resupply of DMPA.

Ecuador: Evaluation of IUD Follow-up Schedules (9305)

This study was carried out in collaboration with CEMOPLAF, an Ecuadoran Family Planning PVO, and INOPAL, the USAID-supported operations research project in Latin America. CEMOPLAF was concerned about clinic overcrowding, and was interested in finding ways to reduce congestion. Service statistics revealed that a large proportion of clinic visits were IUD follow-up visits. CEMOPLAF wanted to know what the impact would be of reducing the number of recommended IUD follow-up visits. The study used information from client interviews and clinic records to estimate the probability of an IUD acceptor returning to the clinic for a scheduled revisit, and the probability of an IUD-related problem being detected at the revisit.

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

Accomplishments:

Through March 1993

- A dissemination meeting was held in Quito in March 1993, at which project findings were presented to an audience including representatives of MOH, Social Security, USAID, other FP NGOs, and USAID Cooperating Agencies.

During the last six months

- The final report was completed
- Results showed that more than 80 percent of clients with side effects would have returned to the clinic for treatment without a scheduled visit; more than 70 percent of client questions and concerns about the IUD could be addressed through better counseling at the time of insertion; reducing from four to one the number of recommended IUD revisits in the first year would result in 55 missed problems per 10,000 insertions, but would save CEMOPLAF approximately \$35,000 that could be applied to new users.
- Based on these results, CEMOPLAF changed its follow-up norms to agree with the recommendation stated in the report, i.e., one visit at 30-45 days.

Ecuador: Technical Assistance in Sustainability (9309)

CEMOPLAF, an Ecuadoran family planning PVO, is interested in strengthening its ability to conduct programmatic research that will improve agency cost control, cost recovery, and income generation. USAID/Ecuador is helping CEMOPLAF achieve these aims, with the assistance of the Population Council INOPAL II project and FHI. Staff from INOPAL II and FHI will coordinate several training courses in research methodology for CEMOPLAF staff, and then will provide technical assistance to CEMOPLAF researchers as they apply their skills in a series of costing, pricing and market research studies.

Objective: To provide training and technical assistance to CEMOPLAF in the areas of cost containment, cost recovery and income generation.

Accomplishments:

During the last six months

- Training was provided to CEMOPLAF staff in costing, strategic planning, family planning terminology, PC software packages and market segmentation techniques. Training courses involved from three to twenty-five CEMOPLAF staff, and varied in length from one to five days.

Plans for the next six months:

- Training activities will be completed by January 1994
- Research studies will begin in early 1994. The start date was postponed from September 1993 because the pace of the training was slower than we had envisioned, due to difficulties in scheduling instructors from outside of CEMOPLAF.

Ecuador: Introduction of an Injectable Contraceptive in an Ecuadoran Family Planning Program (9323)

FHI is collaborating with the Population Council to carry out a comprehensive analysis of DMPA introduction through three delivery channels: (1) physicians in clinics; (2) non-physicians in clinics; and (3) community outreach workers making home visits. The Population Council is training non-physicians and is coordinating the clinical and acceptability research activities. FHI is providing technical assistance in the design and implementation of the cost effectiveness analysis, and will participate in the analysis of acceptability and continuation data.

A total of approximately 1000 women will be recruited in clinics operated by CEMOPLAF, an Ecuadoran family planning PVO. Women will be assigned to one of three resupply groups: physician, non-physician, or community outreach worker. Acceptability, continuation, and costs of provision will be compared among the three

groups. The Ecuadoran Ministry of Health will use the results of this study to decide whether and how to introduce DMPA through its extensive network of health facilities.

Objective: To assess the clinical performance, acceptability and method continuation of DMPA, and to test the efficiency and cost effectiveness of different systems of supply and resupply of DMPA.

Accomplishments:

During the last six months:

- The study protocol and subagreement were approved.
- Data collection forms were designed and pretested
- Client recruitment began in June in six CEMOPLAF clinics

Plans for the next six months:

- Client recruitment will continue .
- Data collection forms and analysis plans will be developed to determine the costs of different resupply models.

El Salvador

Population: 5.2 million

Total Fertility Rate: 4.6

Growth Rate: 2.6%

Contraceptive Prevalence: 47% (Modern Methods: 44%)

Major Modern Methods: Female Sterilization (30%), OCs (8%)

Nearly half of the women of childbearing age currently in union use contraceptives in El Salvador. This is a significant increase compared with the 1978 rate of 34.4%. As is the case in most larger developing countries, rural areas are the most underserved and consequently have the lowest contraceptive prevalence.

Family planning services in El Salvador are provided by both the public and private sector. There is a fairly well established community based distribution program which serves most of the country, although "many women indicated their reservations about using this service due to a lack of confidence in non-medical personnel".

Sterilization is largely responsible for the increase in contraceptive users. Among women aged 15-24, however, hormonal methods account for nearly half of all contraceptives used.

Due to this high interest in hormonal methods, El Salvador was chosen as a site for FHI's Norplant Phase III pre-introductory clinical trials. Physicians were trained in insertion and removal, and the acceptability of Norplant in this population has been studied. A project for providing technical assistance on the widescale introduction of Norplant in El Salvador is under development.

El Salvador: Clinical Trial of the Norplant Contraceptive Implant System (2032)

FHI has been conducting studies of Norplant since 1984. During this time approximately 8650 subjects have been admitted to studies at 43 centers in 11 countries. Most of the sites have already been closed. Ongoing clinical work currently involves approximately 734 subjects at five centers in Senegal and in El Salvador. In 1988, FHI began pre-introductory clinical trials at four centers in El Salvador in collaboration with the Asociación Demográfica Salvadoreña (ADS), the IPPF affiliate. Follow-up is still continuing at all centers; however, discontinuation rates have been higher than seen in other studies of Norplant. This observation indicates the need for a careful patient selection process and good counseling.

FHI has used this multicenter, multicountry study to introduce the Norplant system method into countries without previous Norplant experience and to provide physician training with the method. These studies have provided additional insight into the product's overall acceptability among various cultures while assisting these countries in their efforts to gain regulatory approval of this method. Much of the acceptability data, especially that relating to menstrual disturbances, is being used to develop additional studies in order to improve user satisfaction and increase continuation rates.

Objective: To (1) evaluate Norplant subdermal implants through Phase III pre-introductory clinical trials, introducing the method into countries without previous implantable contraceptive experience; (2) provide training to physicians in proper insertion and removal of Norplant and also in patient counseling; and (3) determine the implant's overall acceptability in different populations.

Accomplishments:

Through March 1993

- 401 admissions were recorded at four centers in El Salvador.

During the last six months

- Monitoring of the four centers was conducted.

Plans for the next six months:

- Follow-up is expected to continue until September 1994.

El Salvador: Norplant Introduction (7704)

In 1988, through a USAID Mission add-on, FHI began pre-introductory clinical trials in El Salvador in collaboration with the Asociación Demográfica Salvadoreña (ADS), the IPPF affiliate. Follow-up is still continuing but high discontinuation rates have already indicated the need for a more careful patient selection process and good counseling. In considering an expansion of the method, the USAID Mission requested technical assistance to assure that Norplant's introduction into the national program is carefully monitored and that a high quality of service delivery is established. JHPIEGO will provide technical assistance in training for both clinical and counseling services. FHI will provide technical assistance with a management information system (MIS) and IEC materials.

Objective: To provide technical support to the Ministry of Health (MSP), Social Security Institute (ISSS), Asociación Demográfica Salvadoreña (ADS) and ANTEL (the health care agency serving communications workers) to ensure the coordinated introduction of Norplant as a contraceptive choice in El Salvador. FHI will assist in the design, training and implementation of standard reporting and management system as well as in the development of IEC materials.

Accomplishments:

Through March 1993

- In January 1993, FHI and JHPIEGO representatives reviewed the Norplant Introduction strategy with the member institutions of the National Norplant Introduction Committee (MSP, ISSS, ADS, ANTEL) and USAID/San Salvador.
- Training and information needs for the member organizations and program evaluation were discussed. The plan at that time was to implement Norplant introduction over a two-year period beginning June 1993 financed with USAID add-on funds.

During the last six months

- The PIO/T was developed from the workplans submitted by FHI and JHPIEGO. To date it has not been submitted to USAID/Washington by USAID/San Salvador; hence no further FHI-development action on this project has occurred.

Plans for the next six months (contingent on PIO/T approval):

- FHI will participate in the Norplant provider training course to promote utilization of the unified MIS by all institutions providing Norplant.
- FHI will initiate the development of Norplant IEC materials for acceptors, specifically the revision of the general family planning brochure for new family

planning clients to include information on Norplant and a new booklet for Norplant users to address method-specific issues.

Haiti

Population: 6.5 million

Total Fertility Rate: 6.0

Growth Rate: 2.8%

Contraceptive Prevalence: 10% (Modern Methods: 9%)

Major Modern Methods: OCs (3.7%), Condoms (3.4%)

Haiti's family planning program was begun in 1973 as a response to the high infant and maternal mortality rate. Only recently has it evolved to address the need for slowing population growth. Contraceptive prevalence is low and unmet family planning needs are high at 40%. Also of concern is the fact that instead of Haiti's contraceptive prevalence increasing, it is actually decreasing. This is presumably the reason for an increase of nearly 50% in the Total Fertility Rate over the last 10 years.

One positive aspect in the family planning program of Haiti is the involvement of men. Condoms are the second most used modern method of contraception and 80% of men surveyed knew of at least one modern method and where to obtain it.

FHI has been involved in an extensive Norplant introduction and expansion project in Haiti. Norplant has been available in Haiti since 1985 and has been widely accepted with both users and providers reporting high satisfaction with the method. Pending resolution of the current political situation in Haiti, FHI will continue to collaborate with several Haitian organizations to expand the provision of Norplant. Specifically, FHI will provide technical assistance in three areas: management logistics, IEC and training, and the impact of expansion on contraceptive use and service costs.

Haiti: Technical Assistance to the Family Planning Association of Haiti (PROFAMIL) in Norplant Logistics (7705)

One of the major problems experienced with Norplant service delivery to date in Haiti has been ensuring an adequate supply of the contraceptive implants at the various service delivery points. As a result, FHI will work with the leading Norplant provider to improve the logistics system for Norplant.

Objective: To improve PROFAMIL's system for supplies as well as the client tracking system for Norplant users.

Accomplishments:

During the last six months

- Discussions with PROFAMIL to develop the planned scope of work and budget were initiated.

Plans for the next six months (pending resolution of the current political crisis):

- PROFAMIL and FHI will finalize the scope of work and budget.
- Inventory and tracking systems will be designed.

Haiti: Norplant Information, Education, Communication and Training (3721)

Because of the initial success with Norplant introduction activities, and in response to increasing demand among potential family planning clients, the Institut Haitien de Santé Communautaire (INHSAC) and FHI will expand training and communication activities. Training activities will focus on expanding service provision by increasing the number of trained providers and improving the quality of services by expanding counseling training. Communication activities will focus on the development of education materials about Norplant.

Objectives: To (1) train 60 physicians, nurses and midwives in Norplant service provision; (2) establish a training of trainers (TOT) program that provides training in Norplant clinical and counseling services to approximately 21 nurses/midwives in each of seven geographic regions of Haiti; and (3) develop and distribute appropriate educational materials for selected target groups about Norplant.

Accomplishments:

During the last six months

- A local implementing agency, the INHSAC, was identified to conduct the training.

Plans for the next six months (pending resolution of the current political crisis)

- Client/partner educational materials will be designed and pre-tested.
- Training materials for service providers will be reviewed and modified.
- Physician and midwives clinical/counseling training will be conducted.

Haiti: The Impact of Norplant Expansion (9715)

New contraceptive methods should be evaluated in terms of their impact on program costs and on overall contraceptive use. FHI is developing a study that will evaluate the impact of Norplant expansion on incremental costs and contraceptive use in Haitian family planning programs. The study will assess the economic advantages and disadvantages of introducing this new method given the various environments in which services are delivered.

Objective: To measure the impact of expanding Norplant services on total contraceptive use and costs in Haitian family planning programs.

Accomplishments:

During the past six months

- A research outline was developed; data collection will include client interviews to determine contraceptive decision making, family planning statistical reviews to measure changes in contraceptive use, and cost estimates of Norplant expansion. A planned trip late in FY'93 to further refine the study was postponed due to political instability.

Plans for the next six months (pending resolution of the current political crisis):

- A local research organization to conduct the study will be identified.
- The research protocol will be finalized.

Honduras

Population: 5.6 million

Total Fertility Rate: 5.1

Growth Rate: 3.1%

Contraceptive prevalence: 47% (Modern Methods: 33%)

Major Modern methods: Female Sterilization (16%), OCs (10%)

The majority of family planning services in Honduras are provided by the private sector and the MOH. Twenty-four percent of female users obtain their contraceptives directly from ASHONPLAFA, the local IPPF affiliate. There is an estimated unmet family planning need of 16%, nearly three quarters of which is from rural areas.

Even though the prevalence of contraceptive use has increased from 41% to 47% within the last five years, this has been due primarily to the increase in the use of natural methods, namely rhythm and withdrawal (an increase from 7 to 12%). Women living in rural areas have, on average, three more children than those living in urban areas, and

women with no formal education on average have four more children than those who have received formal education.

FHI provided technical assistance to Honduras on the 1991/92 Epidemiology and Family Health Survey, which has provided important national estimates for key health indicators. Furthermore, a study has been conducted at ASHONPLAFA to provide them with information on how to control costs and establish a fee structure.

Honduras: 1991/92 Epidemiology and Family Health Survey (9719)

This is the third major cross-sectional survey in which FHI has provided technical assistance to Honduras; FHI's participation in this project is funded by USAID/Honduras. Over 8,000 women aged 15-49 were interviewed on a variety of family health topics, including fertility, mortality, pre- and post-natal care, breastfeeding, other feeding practices, family planning, child health (diarrhea, acute respiratory infections, vaccination status), and knowledge about AIDS. The 1991/92 survey provides important national and subnational estimates for key health indicators; when compared with results from the previous surveys (1984 and 1987), they can help identify strengths and weaknesses in the Honduran health care system.

Objective: To estimate key national and subnational fertility and health indicators, and compare these results with previous findings to better understand the national health picture.

Accomplishments:

Through March 1993

- The key findings from the survey are as follows:
 - The contraceptive prevalence rate increased to 47% (41% in 1987), but the rise is mostly due to an increase in the use of traditional methods.
 - Institutional prenatal care and births have increased since 1987.
 - Infant mortality and fertility rates continue to decline, and are currently estimated to be 50.0 and 5.1, respectively.

During the last six months

- The Spanish Summary Report was printed and distributed.
- The English Summary Report was translated from Spanish and revised and edited.
- Plans for secondary analysis were outlined and work has begun.

Plans for the next six months:

- The English Summary Report will be printed and distributed.
- One paper suitable for publication will be written to explore the rise in prevalence of traditional methods.
- FHI will provide additional technical assistance to support secondary analysis of other topics as requested.

Honduras: Economic Analysis of ASHONPLAFA Programs (9712)

This study was conducted at ASHONPLAFA, the Honduran IPPF affiliate, and was funded with an add-on from USAID/Honduras. ASHONPLAFA and USAID were interested in conducting this study to provide ASHONPLAFA with information to control costs and to establish a fee structure.

Objective: To use economic criteria to evaluate various aspects of ASHONPLAFA's family planning service delivery.

Accomplishments:*Through March 1993*

- ASHONPLAFA staff were trained in techniques for calculating costs.
- Data on program expenditures and donated resources for the clinical, CBD and social marketing programs were collected.
- More than 600 observations of staff time use for different types of visits were collected.

During the last six months

- Analysis of the cost data was completed.
- A report was drafted and sent to ASHONPLAFA and to USAID/Honduras for comment.
- Results and recommendations were presented to ASHONPLAFA senior management and to USAID/Honduras; The results showed that utilization of ASHONPLAFA's smaller clinics is very low, resulting in much higher average costs for clinic services. In terms of cost per CYP, female sterilization is the least costly method, while the costliest methods are condoms distributed through the CBD program. Cost recovery is highest in the Social Marketing program, and lowest in the clinics; cost recovery for female sterilization is especially low,

with clients paying US\$0.75 per year of protection. Recommendations were made to ASHONPLAFA senior management on ways to improve cost recovery, to increase utilization of smaller clinics, and to track costs more effectively.

- Arrangements were made for local translation of the report into Spanish.

Plans for next six months:

- Complete final report, submit to USAID/Honduras

Jamaica

Population: 2.4 million

Total Fertility Rate: 2.4

Growth Rate: 1.7%

Contraceptive Prevalence: 67% (Modern Methods: 63%)

Major Modern Methods: OCs (24%), Condoms (18%), Sterilization (13%)

The family planning program in Jamaica is relatively mature. Nonetheless, more than 75% of women in the 1993 CPS report that their most recent pregnancy was either unwanted or mistimed. Services are available in the public and private sectors, although the public sector predominates and is heavily dependent upon donor resources.

International donors are phasing out financial and commodity assistance; USAID will withdraw all assistance to family planning in Jamaica by 1998. Thus, family planning services and organizations are striving to improve their managerial and financial sustainability.

The projected decrease in donor support will require private sector services to assume greater prominence. FHI activities geared toward preparing the private sector for this role include revising medical guidelines for contraception and assessing medical barriers to family planning in the private sector.

FHI, in conjunction with the Futures Group, has been studying service delivery practices among private physicians in support of the shift to greater private sector participation. A workshop to disseminate the results of the study and a series of contraceptive technology updates are planned for 1994. A study of the relationship between DMPA use and the role of cervical cancer has been recently completed, and a final report will be written in 1994. FHI also is developing a study of quality of care in public sector family planning services to identify areas for improving services.

Jamaica: Addressing Medical Barriers Among Private Physicians (9314)

USAID, through its current bilateral Family Planning Initiatives Project (FPIP), is phasing out all assistance for family planning beginning in 1993 and ending in 1998. The two main thrusts of the FPIP are to promote a shift to greater private sector participation in service delivery and to shift method mix to more cost-effective long-term and permanent methods. To assist the government of Jamaica to prepare for USAID's withdrawal, the National Family Planning Board, through the University of the West Indies (UWI) and in collaboration with the Futures Group OPTIONS II project and FHI, is conducting a mapping study of all service delivery outlets in Jamaica and an in-depth study of the service delivery practices of private physicians who offer family planning.

As a result of the study, a pilot project will be developed to assist private doctors to expand their provision of family planning. The in-depth study is focusing on medical barriers related to service delivery practice. Results of the study will be used by FHI to prepare and conduct a series of contraceptive technology update seminars (CTUs) throughout Jamaica. Preliminary results from the study indicate that there are medical barriers to family planning access in Jamaica and that private physicians would welcome CTUs.

Objective: To assess medical barriers in the practices of private physicians who provide family planning counseling or services in order to help design a pilot project to involve private physicians in family planning.

Accomplishments:

During the last six months

- Interviewers and data entry staff were trained.
- Field work was conducted, with a total of 407 completed questionnaires.
- Data entry and cleaning were performed. Data analysis has begun.

Plans for the next six months:

- Complete the data analysis and prepare the final report.
- Participate in the dissemination seminar.
- Use the findings from the study to prepare a series of CTUs at the parish level.
- Use the findings to revise service delivery guidelines and training curricula.

Jamaica: Case Control Study of Cervical Cancer (6202)

Cervical cancer is a leading cause of cancer morbidity and mortality among women throughout the world. The worldwide incidence of cervical cancer ranks second only to breast cancer (Stanley et al. 1987). In countries where facilities for widespread screening and early treatment of pre-malignant lesions are unavailable or inadequate, a large percentage of cervical cancer cases are diagnosed at an advanced and incurable stage. Known risk factors include low social class, multiple sexual partners, history of sexually transmitted diseases (STDs), low frequency of Pap smears, and smoking. Use of injectable DMPA has been implicated as a possible risk factor for cervical cancer.

Objectives: To determine the relationship between use of DMPA and the risk of cervical cancer.

Accomplishments:

Through March 1993

- A case-control study was conducted using cases drawn from the Kingston-St. Andrew Corporate Area to determine whether use of DMPA is an independent risk factor for cervical cancer in situ (CIS) among women in Jamaica.
- To increase the comparability of cases and controls with respect to access and use of cervical cancer screening, three controls drawn from the Kingston-St Andrew Corporate Area were randomly selected for each case, matched on clinic and date of Pap smear.
- The matched analysis of DMPA use and CIS was completed.

During the last six months:

- A draft report "Use of DMPA and the Risk of Cervical Carcinoma In Situ" was submitted to USAID.
- Data for cases and controls, included an unmatched analysis of DMPA use and cervical cancer in situ, were cleaned and imputations made for missing data where appropriate.
- Unmatched analysis for DMPA and cervical cancer in situ was completed.
- Exposure variables (ever use, duration, recency, latency, and age at first use) were created for other contraceptives methods: condoms, diaphragm, spermicides, and IUD.

Results:

- From a total of 220 women identified as CIS cases, 147 were interviewed, and 129 had complete data for an unmatched analysis. From the 945 controls selected, 365 were interviewed and 337 were available for an unmatched analysis. When matched on category of Pap smear source and year, 117 cases and 302 controls were available for a matched analysis.
- Adjusted odds ratio were estimated using conditional logistic regression for the matched analysis and unconditional logistic regression for the unmatched analysis. Comparison of odds ratio estimates and confidence intervals from the matched and unmatched analyses showed inflated odds ratios and wider confidence intervals resulted from the unmatched analysis.
- Bivariate analyses showed that women who did not have an appropriate match were considerably different from women in the matched sample in terms of source of their Pap smear and exposure to DMPA. Since the women without an appropriate match were a likely source of bias, the results from the matched analysis (117 cases and 302 controls) are presented here.
- Among the variables considered to be potential confounders, only age at index date (date of the diagnostic Pap smear), first intercourse before age 18, and number of pregnancies were found to be confounders. After adjusting for these confounders, the odds ratio for ever use of DMPA fell from the crude estimate of 1.7 (95% CI: 1.1-2.7) to 1.1 (95% CI 0.6-1.9). However, the odds ratio for women who had used DMPA five years or more was elevated (OR=1.9, 95% CI: 0.7-4.8).
- No significant increase in risk for CIS was observed with ever use of DMPA, nor were significant increases in risk seen with duration, latency, or recency of use. Overall, these findings are reassuring for prospective, current and former users of DMPA who undergo regular screening for cervical cancer. However, the moderate increase in risk of CIS among women who used DMPA for five or more years warrants careful consideration.

Plans for the next six months:

- The final report and a paper for submission to a journal on DMPA use and cervical cancer will be written. Secondary analyses and corresponding papers will be completed.

Mexico

Population: 90 million

Total Fertility rate: 3.5

Growth Rate: 2.3%

Contraceptive Prevalence: 55% (Modern Methods: 46%)

Major Modern Methods: Female Sterilization (18%), IUDs (11%), OCs (11%)

In 1973 a new General Population Law was passed in Mexico, which in turn led to the need for new family planning programs. Based on the new law, the National Population Council was established in 1974, and a National Family Planning Plan was approved by the president of Mexico in 1977. In 1990 the General Population Law was amended, giving rise to the 1990-1994 National Family Planning Program, put together by the National Population Council. This family planning program has become the cornerstone for all agencies who are involved in family planning.

Despite the considerable declines in fertility rates, annual growth rates, and crude birth rates throughout the last couple of decades, there are still several segments of the population who remain underserved in terms of family planning services. Designing specific programs for adolescents, who comprise almost a quarter of the total population; expanding services to rural areas; and increasing male involvement are some of the main areas on which the new family planning program is focusing in an effort to increase access to family planning.

FHI has worked closely with both the public and private sectors in various studies. FHI's focus has been on increasing the acceptability and use-effectiveness of male and female condoms and OCs, increasing the efficiency of IUD services by eliminating unnecessary clinic visits and assessing the time to infertility after vasectomy.

Mexico: Acceptability of the REALITY™ Female Condom Among Selected Females and Males in Mexico City (6382)

The purpose of this study is to provide behavioral information on female condom use. Such information will assist health care providers, social workers, etc. in the provision of better interventions for the prevention of sexually transmitted diseases; HIV and pregnancy. The study will use interviews and focus groups to assess the acceptability of female condom use among mid-socioeconomic couples and among commercial sex workers (CSWs) and their clients in Mexico City. One hundred sixty participants will be enrolled in the study.

Objectives: The primary objective of the study is to assess the acceptability of the REALITY™ female condom among a group of sexually active, mid-socioeconomic level couples and among CSWs and their clients. A secondary objective is to examine male attitudes and opinions about use of the female condom in order to develop better interventions for women choosing to use the method.

Accomplishments:*During the last six months*

- The protocol and related study documents were developed.
- The subagreement was prepared for signoff.

Plans for the next six months:

- The study will be initiated in late January 1994.
- Data will be collected and the study monitored.
- Several focus groups will be conducted.

Mexico: Methods of Identifying Condom Users at Risk of Breakage and Slippage (6004)

Within any given condom breakage study, the majority of condom breaks occur among a small group of study participants. If these individuals and the reasons for condom breakage can be identified, better condom use instruction interventions can be developed for those using condoms as contraception or for disease prevention.

In Mexico (one of three international sites), this study was conducted in collaboration with the Instituto de Investigación Científica. Male condom users (130) were given a background interview and five condoms to be used for vaginal intercourse. After a three-week study period, participants were interviewed to determine condom breakage and slippage rates and to assess behaviors that may lead to condom failure (condom breaking or slipping off completely).

Objectives: To assess different methods of identifying condom users who are at risk of condom failure, and to assess behaviors that lead to condom failure.

Accomplishments:*During the last six months*

- Field work was completed; 130 participants completed the study.
- Data have been cleaned and analysis is in progress.
- The data suggest that past condom failure predicts future condom failure (consistent across all three sites).

- Preliminary analysis has identified behaviors which appear to be associated with condom failure including: using instruments such as teeth or scissors to open condom packages, unrolling condoms before donning, and having particularly intense or long intercourse. Use of additional lubrication and re-use of condoms (behaviors identified in prior FHI research) were reported infrequently.

Plans for the next six months:

- Data analysis will be completed.
- A site specific report will be written and disseminated.
- Study findings will be presented in October at the APHA Meeting.
- An article will be prepared for publication.

Mexico: OC Knowledge and Practices of Mexican Institute of Social Security (IMSS) Rural Midwives and Their Recent OC Acceptors (6008)

IMSS is the largest provider of OCs in Mexico and is seeking to expand its OC program. This project was initiated because of concern at IMSS about the high rates of clients of midwives who were discontinuing OCs, and to better understand the problems and approaches to correcting them.

Objectives: To determine OC knowledge, compliance and continuation among women who receive OCs from IMSS midwives and use that information to improve the training of these midwives.

Accomplishments:

Through March 1993

- Interviews were completed with 870 OC acceptors and 263 rural midwives in three northern and three southern states in September 1992.
- Data were edited, coded, and analyzed.

During the last six months

- The final report was completed, translated into English, and is now in final revisions.

Results:

- Nearly half of the OC users knew they should use a backup method when two or more pills are missed, but only 17% reported doing so.
- With regard to the midwife's knowledge of pill use, only one-quarter knew how long to wait between 28-day pill packs and half knew that they should recommend use of a backup method when two or more pills are missed.
- Knowledge of all OC use measures was lower than expected, and in some cases the users knew more than the providers.

Plans for the next six months:

- The final report will be submitted to USAID and IMSS.
- The midwife training materials will be revised in cooperation with IMSS to make them simpler.

Mexico: OC Use (Phase II) (6017)

Mexican midwives are one of the primary providers of oral contraceptives to rural users. Results from a previous FHI study of these midwives show their knowledge of OC compliance measures to be low. Phase II of this project seeks to incorporate new OC use instructions into the midwife training materials, and to then evaluate the new training using the revised materials.

Objectives: To revise training of rural midwives and clinicians, based on results of the rural midwives study and study of new OC instructions, and to evaluate the impact of that training on changes in OC knowledge and use among acceptors and knowledge of their providers.

Accomplishments:

During the last six months

- None. FHI has been unable to meet with the proposed Principal Investigator.

Plans for next six months:

- This project has been postponed until revised training materials and new OC use instructions are incorporated into the IMSS health care system so that changes in OC use can be measured against changes in training and educational materials.

Mexico: Testing of New OC Instructions (6009)

This project was initiated at the request of USAID in order to develop OC use instructions that can be included in the millions of pill packs that USAID provides to programs around the world.

Objectives: To test a modified version of the FHI-developed and U.S. FDA-approved instructions for OC use prepared for U.S. manufacturers to be used in developing countries.

During the last six months

- Two rounds of one-on-one interviewing (N=100) and one round of focus groups with Mexican Institute for Social Security (IMSS) patients were used to modify and simplify OC instructions, which were also tested with IMSS medical staff to the point that all parties were comfortable that these were clearly understandable, usable instructions.
- The final report was submitted to USAID and IMSS in April 1993.

Plans for the next six months:

- The new instructions will be used as the basis for modifying the training materials for IMSS midwives and medical providers, and will then be provided to patients.

Mexico: Time of Progestin-Only Oral Contraceptive Initiation Among Lactating Women (2096)

The goal of this study is to assess whether acceptability and efficacy can be affected by the time after delivery at which breastfeeding women begin taking the progestin-only contraceptive. This study is being conducted at eight sites in five countries. A total of approximately 1440 subjects were enrolled prior to the halt of enrollment in July, 1993 due to slow recruitment. At that time, five of the sites (three in Mexico and two in Kenya) had met recruitment goals. After enrollment into the study, the subjects were assigned to one of two groups to begin using the progestin-only contraceptive at either 6 weeks or 6 months postpartum. Subjects are being followed up at 6 weeks and 6, 12 and 18 months. At these follow-up visits, subjects are being evaluated for continuation rates and compliance with both this method and methods

which they switch to while participating in the study. Also being evaluated are pregnancy and acceptability parameters.

Results of this study should provide insight into more effective distribution of the progestin-only contraceptive and its general acceptability in relation to methods switched-to among the breastfeeding population.

Objective: (1) To compare the 12- and 18-month postpartum pregnancy rates, and the 12- and 18-month continuation rates from time of admission to study among breastfeeding women assigned to begin taking the progestin-only oral contraceptive (POC), norgestrel, 75 mcg (a) at 6 weeks postpartum, or (b) at 6 months postpartum or return of first menses, whichever comes first. (2) To evaluate acceptability by determining the reasons for pill discontinuation and any relationship to POC initiation time. (3) To evaluate safety by determining the frequency and types of adverse experiences.

Accomplishments:

Through March 1993

- The study was initiated and enrollment of subjects began in March 1992.

During the last six months

- Enrollment of the expected 700 subjects at the three Mexican sites was completed by July 1, 1993.

Plans for the next six months:

- Subject follow-up will continue at all sites in all five countries through the summer of 1994 at which time sites will be closed and a final analysis performed and reports completed.

Mexico: IUD Follow-up Visits (9301 and 1588)

The IUD is the most commonly used temporary contraceptive method in Mexico. Since many providers ask their clients to make four follow-up visits in the first year of use, a significant portion of clinic resources is spent on appointments for perfectly healthy and satisfied users; these resources might be better spent servicing those with greater needs. This is a prospective study designed to examine costs and benefits of frequent follow-up schedules and is being conducted in collaboration with the Instituto Mexicano de Seguro Social (IMSS). It will compare the incidence of medical problems among a study population of 1,713 new IUD users. 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. All recruits have now completed one full year of use, and the costs of providing follow-up care have been estimated.

Objective: To determine whether a follow-up regimen of two scheduled visits is as safe as the four-visit regimen, and to estimate the cost savings of adopting a two-visit scheme.

Accomplishments:

Through March 1993

- Data collection forms for the clinic were finalized and the study began recruiting new IUD acceptors

During the last six months

- The cost of a routine IUD follow-up visit at IMSS was estimated to be \$7.81.
- Data analysis plans for determining the health consequences of a two-visit scheme have been outlined.
- The follow-up portion of the study was completed.

Plans for the next six months:

- A sample of women lost to follow-up will be contacted and interviewed to determine whether they experienced side effects or adverse reactions.
- The dataset will be finalized and all primary analyses will be completed
- A first draft of the final report will be completed.

Mexico: Copper IUD Use and Tubal Infertility (6205)

Previous research has shown an association between IUD use and tubal infertility among nulliparous women. Though the studies are widely cited, design flaws could have introduced biases which in turn resulted in spurious associations. This case-control study will use controls with male-mediated causes of infertility, and will be conducted at a site where copper IUD use is common.

Objectives: To determine whether IUD use among nulliparous women increases their risk of developing tubal infertility.

Accomplishments:

During the last six months

- The National Perinatology Institute in Mexico has confirmed its interest in collaborating on the study with FHI. It has undertaken a preliminary survey

among infertility clients (at its own expense) to help estimate the prevalence of previous IUD use among nulliparous women.

- The Mexican Social Security Institute (IMSS) has been asked to participate, but has not yet decided.

Plans for the next six months:

- Before designing the study, we must await the decision by the IMSS.

Mexico: Pilot Study of the Time to Infertility After Vasectomy (2206)

This study is being conducted at one site in Mexico in collaboration with the Association of Voluntary Surgical Contraception (AVSC) and the Instituto Mexicano de Seguro Social (IMSS). Approximately 20 volunteers will undergo vasectomy and be evaluated by weekly semen analysis to determine the time and number of ejaculations needed to achieve infertility (two consecutive azoospermic samples) as well as the time to the loss of sperm motility and loss of eosin staining ability. It is anticipated that subject recruitment will take approximately 8 weeks and subjects will be followed for a maximum of 24 weeks (the first 16 weeks by weekly examinations and bi-weekly up to 24 weeks or azoospermia).

Results from this study will be used to design a larger study to better assess standard parameters for the timing to azoospermia and/or the number of ejaculations. It is hoped that information from these studies will be used to better define standard information guidelines for physicians and patients.

Objective: To determine the time and/or 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.

Accomplishments:

Through March 1993

- The original protocol was approved by the PHSC in August 1992.

During the last six months

- Amendments to the protocol were approved by PHSC in August 1993.
- AVSC is covering field costs for this study, and evaluated and selected an IMSS clinic site in Mexico. This site was approved on August 27, 1993.

- Semen analysis training of laboratory personnel is being handled by AVSC prior to study initiation and is in progress.

Plans for the next six months:

- Site training and study initiation will occur in late January 1994.

3. Asia / Near East

Asia/Near East is the region with the greatest successes in lowering fertility rates by increasing contraceptive use. DHS data show that prevalence for modern methods of contraception exceeds 65% in three countries and is below 10% in only one (Pakistan). At one time the emphasis on childbearing and male offspring on the Indian subcontinent and in the Near East discouraged family planning. This may still be true in some countries with continued high fertility and low contraceptive use.

The following situational factors are relevant for family planning in Asia and the Near East:

- The median age at marriage has risen most in Asia and the Near East. Asia has the greatest range in age at marriage of all the continents.
- In countries with high rates of contraceptive use, there is little difference in contraceptive prevalence by women's level of education.
- IUDs are an important component of many Asia/Near East family planning programs. Several Asian countries are unique in their heavy reliance on sterilization.
- In many countries, governments have invested heavily in rural family planning programs from the beginning so that urban-rural differences in use of modern methods of contraception are small.
- In Asia, the government programs are a main source for contraception; in the Near East, non-governmental organizations and private, for-profit providers also play a significant role.

In general, the Asian family planning programs are more mature than those in other regions. Services are more readily available in rural as well as urban areas and modern methods are widely available. Men have supported family planning to a greater degree and have often taken responsibility for becoming sterilized or using condoms.

The major direction for FHI in Asia and the Near East are to determine how to increase acceptance and continuation of modern methods of contraception, increase access to contraception, introduce long-acting steroidal methods, and assist family planning programs with resource allocation. This region also has a number of highly capable investigators who collaborate with FHI on a range of global research priorities.

FHI is working in eight countries in Asia (Bangladesh, India, Indonesia, Korea, Nepal, Pakistan, Philippines and Thailand) and two in the Near East (Egypt and Jordan). In each country, FHI works within existing health infrastructures in accordance with USAID Mission priorities. Activities in the ten countries are described in detail below.

Accomplishments in the last 6 months and plans for the next 6 months are given for ongoing projects. Lessons learned are detailed for projects completed during the reporting period.

Bangladesh

Population: 116.7 million

Total Fertility Rate: 4.9

Growth Rate: 2.4

Contraceptive Prevalence: 40% (Modern Methods: 39%)

Major Modern Methods: OCs (13.9%), Female Sterilization (9.1%)

Bangladesh is one of the world's poorest and most densely populated countries. Despite its low economic standing, Bangladesh has made great strides in the past 25 years in lowering its fertility and growth rates and increasing contraceptive prevalence. These rate changes have occurred as a result of an intensive family planning program which includes pluralistic delivery systems, IEC activities, training field workers, and an extensive commodity logistics system.

However, in the past few years concerns have been raised regarding donor dependency and Bangladesh's ability to meet increased costs of their family planning programs as the contraceptive prevalence rate continues to increase and as more women enter childbearing years. Therefore, FHI is currently working on a cost-of-services project in order to determine whether there are more cost effective ways of providing services.

In connection with program sustainability, a study concerning the expenditures on family planning in Bangladesh was recently completed by FHI. FHI has worked with BIRPERHT (Bangladesh Institute of Research for Promotion of Essential and Reproductive Health and Technologies) to strengthen its institutional ability to carry out research projects. FHI also completed a study on access to removal of Norplant in Bangladesh.

Bangladesh: Expenditures and Sources of Funding for the Family Planning Program in Bangladesh (9711)

Contraceptive use has increased dramatically over the last several years in Bangladesh. However, there is concern about how the country will meet the increased costs as the contraceptive prevalence rate continues to increase and as more women enter the childbearing years. In addition, there is concern that the country is

too dependent on donor funds to support family planning activities, and that meeting the increased demands for family planning will increase this dependency. This project, which was carried out at the request of USAID/Dhaka and funded by the Mission, had two purposes, which were to determine: (1) how much Bangladesh was spending on family planning and (2) what were the sources of funds for these activities.

Objective: To determine the sources and amount of funding and to determine how funds are utilized for the family planning program in Bangladesh.

Accomplishments:

Through March 1993

- FHI worked with the Population Development and Evaluation Unit (PDEU) in Dhaka to carry out a study of costs and funding. Data were obtained from published sources and analyzed. Research showed that funding for family planning has grown substantially over the period 1987-1991. Donor funding and greater spending on the part of the government of Bangladesh have contributed to this increase. Because donor funding has grown more rapidly than has the government contribution, the government's share of funding has decreased.

During the last six months

- A final report was prepared which detailed the findings of the study. Findings are discussed above. Copies have been sent to Bangladesh.

Plans for the next six months:

- A presentation will be given during the first week in December by the director of PDEU to leading government officials and to the donor community on the results of the study.
- A paper will be prepared and submitted for publication. It will highlight the conflict between the twin goals of increasing financial sustainability and increasing contraceptive prevalence.

Bangladesh: Bangladesh Institute of Research for Promotion of Essential and Reproductive Health and Technologies (BIRPERHT) (7576)

BIRPERHT, previously known as the Bangladesh Fertility Research Programme, was formed in 1976 with FHI assistance to coordinate and conduct contraceptive clinical trials. The goal of BIRPERHT, identified as an FHI Family Health Research Center (FHRC), was subsequently expanded to become one of the premier reproductive health research organizations in Bangladesh. FHI worked with BIRPERHT to expand

its institutional ability to manage and carry out its research program. FHI support has included technical assistance in research planning, management, analysis, and reporting; institutional support for salaries and overhead expenses; training in research methodology and contraceptive technology; and funding for research studies.

With BIRPERHT's enhanced capabilities, its transition to status as a governmental institute, and the prospect of receiving substantial funding from the World Bank, FHI and USAID/Dhaka decided in 1992 that phasing out of FHI's institutional support funding was indicated. Funding during FY'93 (through December 31, 1992) was provided to help BIRPERHT bridge the end of FHI support and the beginning of support from the World Bank.

Within the time period of this report, FHI's institutional strengthening support to BIRPERHT has been minimal. Future FHI collaboration with BIRPERHT will take the form of contractual relationships for specific projects and BIRPERHT will continue to be considered a part of FHI's network of collaborating centers.

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

Accomplishments:

Through March 1993

- With FHI technical and financial support, BIRPERHT developed its research and management skills to an international standard of competency.
- BIRPERHT has diversified its funding to include the Ford Foundation, World Bank, WHO, UNICEF, SIDA, Organon, Schering, and the Bangladesh government.
- BIRPERHT has become the family planning secretariat for the Ministry of Health and Social Welfare.
- A strong management and technical staff has been developed below the level of director.
- BIRPERHT played a leading role in the study and eventual introduction of Norplant in Bangladesh's family planning program.

During the last six months

- SPSS/PC+ software previously provided by FHI was upgraded so that BIRPERHT would have enhanced data processing capability and, specifically, so that it could process data from the Ford Foundation-supported Maternal Morbidity study conducted in collaboration with FHI.

Lessons Learned:

- Developing a sustainable research institution requires a long-term commitment; the process can take 10-20 years in a developing country and may see numerous setbacks.
- In order to grow and flourish, BIRPERHT needed a strong, full-time leader who was hard-working, a visionary, and who understood and could work effectively within the environment of donors, consumers, and competitors.
- One or two key professionals were insufficient to advance BIRPERHT as a sustainable organization; it required a larger core of trained staff for the organization to reach institutional sustainability.
- The institutional development process must allow the organization freedom to make its own decisions and, sometimes, its own mistakes, in order to learn, improve, and grow.

Bangladesh: Cost of Methods/Delivery Systems (9713)

This study (funded by USAID/Bangladesh) will estimate the cost of services for combinations of delivery systems and contraceptive methods. While Bangladesh has made impressive gains in raising the level of contraceptive use, there are concerns about the growing costs of maintaining and expanding family planning services. Therefore the rationale for the study is to determine whether there are more cost effective ways of providing services so that contraceptive use can be expanded at reasonable cost.

The project covers both government and non-government programs, including some innovative programs of both the government and of non-governmental organizations. Within the government program, the major emphasis is on the outreach program which employs approximately 23,000 outreach workers and 5,000 supervisors. NGOs also run outreach programs. What are the current inefficiencies in this delivery model? Should greater reliance be placed on some of the innovative attempts to substitute lower paid part-time workers for these full-time workers?

Objective: To estimate the cost per couple year of protection for various combinations of methods and delivery systems and to determine reasons for variations.

Accomplishments:

Through March 1993

- The project outline was written, the subagreement was signed, and funds were allocated from USAID/Bangladesh to begin the project activities.

During the last six months

- Data collection forms have been finalized for government services
- The sample of government workers has been drawn and fieldwork has begun
- NGO service delivery systems have been selected, including special innovative programs

Plans for the next six months:

- Data collection methodologies for other delivery systems will be finalized
- All data collection will be completed.
- Data analysis will begin.

Egypt

Population: 58.3 million

Total Fertility Rate: 4.6

Growth Rate: 2.3%

Contraceptive Prevalence: 38% (Modern Methods: 35%)

Major Modern Methods: IUD 16%, OC 15%

In recent years, Egypt has made remarkable progress in addressing the pressing issues stemming from the country's rapidly growing population. In the 1960s the Government of Egypt (GOE) first recognized rapid population growth as an impediment to economic and social development and in the 1980s it began to take effective steps to address the problem. As a result, contraceptive prevalence increased from 24% to 38% between 1980 and 1988 -- attributed mostly to the four-fold increase in IUD use during that period, and preliminary reports from the 1992 DHS indicate a continued rise in prevalence to 45%. Accompanying this increase is a growing favorable attitude towards family planning and an almost universal awareness of modern methods and where they can be obtained.

Despite clear progress in reducing fertility and increasing the use of family planning, a number of continuing challenges face Egypt's population program. There remains a significant level of unwanted births and nearly 60% of women who are not currently using contraception report that they would be unhappy if they became pregnant. Over half of births are the outcome of pregnancies defined as high-risk, i.e., mother's age <18 or >35, mother with five or more previous births, or births <2 years after the last birth. Underlying great fertility differentials by area of residence is the significant variation in contraceptive use by area of residence. Prevalence in urban areas is well over twice that of rural areas. Also, while acceptance of contraception has continually increased, long-term continued use has not been demonstrated and discontinuation rates among OC and

IUD users remain high. The choice of modern methods needs to be expanded and the distribution in both public and private sectors needs to be improved. Timely, accurate and complete data to promote more effective planning, management and evaluation are lacking. Obstacles to family planning use, including medical, regulatory, geographical, and cultural barriers are widespread.

Egypt: Technical Assistance to the Joint USAID/GOE National Population Council (NPC) Institutional Development Project (7788)

The National Population Council (NPC) takes a lead role in updating service providers and policymakers in Egypt on both contraceptive technology and related reproductive health issues and in setting research priorities. With an add-on to its Cooperative Agreement, FHI has provided technical assistance to the NPC on two initiatives. The first required establishing a Research Management Unit (RMU) at the NPC to set national research priorities, to coordinate family planning research supported by the Egyptian government, to ensure the quality of the research and to provide funding for studies on a competitive basis. The second initiative was to introduce the concept of operations research (OR) to family planning organizations in Egypt and to assist them in study design, protocol development, implementation, data management and analysis, and reporting.

In addition, through a subcontract with E. Petrich and Associates (EP&A), FHI provides technical assistance to the Central Office of the NPC and twenty governorate offices to implement management information systems, program planning and evaluation.

Objective: To strengthen the institutional capability of the NPC and its implementing agencies to plan and coordinate research and other activities which support the delivery of improved and expanded family planning services in Egypt.

Accomplishments:

Through March 1993

- From 1989-1992, FHI and the NPC carried out the first operations research (OR) project in Egypt, in which nearly all of the major family planning agencies in Egypt participated. Under this project, a curriculum was designed for training staff of family planning agencies in Egypt to design, conduct and evaluate operations research. Three workshops were conducted, which resulted in ten completed proposals, nine of which were awarded funding and implemented. An information dissemination workshop was conducted at the end of the project to present results of the studies.

- A Research Management Unit (RMU) was established to set national research priorities and to ensure that high quality biomedical and programmatic research is implemented. Guidance was provided in the recruiting and hiring of two key research positions at the RMU -- a biomedical research officer and a programmatic research officer. FHI provided training to these staff in various aspects of research and trained them as trainers to conduct workshops on research-related topics.
- In 1989 FHI established an office in Cairo, staffed by a resident research advisor and a program officer. This has served to enhance our dialogue with the Egyptian family planning community and strengthened our ability to provide timely and appropriate technical assistance to the family planning program in Egypt.
- Staff planned and helped prepare an NPC Operating Procedures Manual which includes RMU procedures for scientific and ethical review of research proposals, use of approved and investigational new drugs, disbursement of funds for approved studies and study monitoring.
- Three symposia in a series of Distinguished Lectures in Contraception have been sponsored in collaboration with the NPC. Over 450 family planning policymakers, trainers, clinicians and counselors were provided with the latest information and a variety of contraceptive methods. The series emphasizes increasing access and reducing obstacles to contraceptive services in Egypt.
- The establishment of the RMU's institutional review board was facilitated.
- Four biomedical and two programmatic research studies have been awarded funding through the RMU. FHI staff have provided technical assistance in the design, implementation and analysis of these studies.

During the last six months

- Approximately 150 persons attended the fourth symposium in the series of Distinguished Lectures on Contraception in Egypt, held in collaboration with the NPC; outputs include recommendations for improving access to family planning in Egypt which will be distributed to policymakers for action.
- The NPC Operating Procedures Manual was finalized based on comments by the Manual Development and Review Committee.
- The results of two operations research studies were published in the NPC's journal *Population Studies*. One study focused on promoting the role of Raidat Refeat, a level of community-based nurses, in family planning service delivery. The second article compared the cost-effectiveness of different teams implementing the Regional Center for Training (RCT) follow-up system in three governorates in upper Egypt.

- The final training evaluation report for the IDP was prepared. Workshops on management, planning, monitoring and evaluation, population dynamics, computer operation, contraceptive technology, and teambuilding carried out through the IDP for NPC central and governorate office staff and implementing agencies were found to be appropriate and useful. The desire and need for continued training in basic management, computer use, and contraceptive technology were emphasized.
- Development and management of a computerized Population Information System and training NPC staff in its use were continued.
- A paper entitled "Introducing Operations Research: The Case of Egypt" was presented at the annual meeting of the International Union for Scientific Study of Population. The presentation was made by the FHI Egypt Resident Advisor for Programmatic Research.

Plans for the next six months:

- An assessment of the maximum service delivery capacity of both physical and human resources within various public and private sector family planning clinics will be conducted. This assessment will establish standards for caseload capacity for physicians and nurses at the service delivery points and thereby determine clinical training needs.
- Technical assistance in the preparation of final reports for the biomedical and programmatic research projects that have been or will be completed during the last few months of the project will be provided.
- A monograph based on research findings from the completed research projects to be distributed at the International Population Conference to be held in Cairo in 1994 will be prepared.
- The research officers of the RMU will participate in intensive training in the United States in scientific writing and in clinical trials management and monitoring.
- A paper entitled "The Impact of Nurse Training on Family Planning Knowledge, Attitudes and Practice Among MOH Clinic Clients in Egypt," prepared by Egyptian collaborators and FHI staff, will be finalized and submitted for publication.

India

Population: 897.4 million

Total Fertility Rate: 3.9

Growth Rate: 2.1%

Contraceptive Prevalence: 45% (Modern Methods: 40%)

Major Modern Methods: Female and Male Sterilization (28.5%)

At current growth rates India is poised to overtake China as the world's most populous country by the year 2035. The Government of India has had a population policy since 1951 which strives to balance population growth with socio-economic development. Its population policy is an integrated one which tries to address not only fertility control but also general health, education, literacy, improvement of the socio-economic conditions of women, employment, and income generating projects. Its population programs are targeted to states which have the highest need, though this sometimes excludes the poorest districts and urban areas.

The government's contraceptive of choice for controlling population growth has always been sterilization, with nearly three-quarters of contraceptors being sterilized. India is realizing, however, the need for contraceptive choice. There is a significant need for birth spacing and the demand for more temporary methods to achieve this is great.

In response to this greater need for temporary contraceptive methods as well as to the increase of HIV/AIDS, FHI recently completed evaluation of a condom social marketing program in India. FHI is also examining the barriers to the acceptance and use of OCs in India.

India: Evaluation of the Condom Social Marketing Program (7892)

The social marketing program for condoms in India is a collaboration between the government and business sector, resulting in an expansion of both the types and number of outlets where condoms might be available. FHI was asked by USAID/New Delhi to provide technical assistance in evaluating the social marketing program in general and to evaluate the performance of PSI/I in particular. The comprehensive evaluation involved three different studies. One focused on the socio-economic and demographic profile of the users of price-subsidized condom brands; a second sought to understand the market-related issues from the perspective of the store retailers and a third study involved interviewing marketing companies and agencies to find out more about their operations and experiences.

Objective: To assess the impact of the social marketing program for condoms in India and to share results of the evaluation so that condom-providing agencies, and particularly social marketing agencies, could further strengthen the program.

Accomplishments:

Through March 1993

- The final report of the evaluation project was presented to the USAID/New Delhi Mission in February 1993.

During the last six months

- A formal presentation to the Ministry of Health took place in April 1993.
- Copies of the report were distributed to appropriate agencies.

Lessons Learned:

- The maturity of the program and the experience gained have not only laid a solid foundation for the continued role of the program in the country's family welfare program, but they also provide the potential and opportunity for change in order to expand the program and make it more effective.
- As a result of the condom social marketing program, annual sales have increased from fewer than 16 million condoms 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.
- Through this program, the name "Nirodh" became a generic name for condoms in India. Awareness of Nirodh is nearly universal, even in rural India.
- Advertisements for condoms in India have generally had serious messages. Advertisers should be given the freedom to design more creative advertising to further increase sales.

India: OC Use (3724)

This project consists of two parts: 1) the preparation of a background review paper on the perceptions of advertisers, manufacturers and distributors of oral contraceptives and 2) a consumer market research survey to assess the preferences and buying habits of OC users. The project was developed at the request of USAID/New Delhi with the goal of improving OC acceptance and use in Uttar Pradesh, India.

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

Accomplishments:

Through March 1993

- Despite delays caused by civil unrest, interviews were conducted with advertising agencies, pharmaceutical manufacturers, distributors of OCs in Uttar Pradesh and key policymakers in New Dehli concerning their perceptions of the potential of and barriers to OCs.
- A subcontract proposal was prepared, the questionnaire drafted, reviewed, and translated from English into Hindi.
- Several potential firms were identified for the market research component but the survey has been postponed.

Plans for the next six months:

- FHI will determine with the Mission whether or not to go ahead with the market research component of the project.

Indonesia

Population: 180 million

Total Fertility Rate: 3.3

Growth Rate: 1.9

Contraceptive Prevalence: 50% (Modern Methods: 47%)

Major Modern Methods: OCs (15%), IUD (13%), Injectables (12%)

The Indonesian family planning program is widely considered an Asian success story for its achievements in dramatically improving key population indicators over the past two decades. The program is characterized by strong governmental support, a widespread network of clinics offering family planning as well as MCH services, and adequate funding. With both the private and public sectors making major contributions to the family planning program, Indonesia is seen by many countries in the region as a program to emulate.

In family planning, increased attention is being given to improving the quality of family planning services, and to promoting better maternal and child care. Services are provided via a large network of government-funded health care centers, a social marketing program and the private sector.

FHI has been working in Indonesia with private foundation funds on a study to identify the optimum time for initiating progestin-only contraceptive pills in breastfeeding women. Although not funded by USAID, the Indonesia component of the study is described here because it is part of the multicountry study.

Indonesia: Time of Progestin-Only Oral Contraceptive Initiation Among Lactating Women (1670)

The goal of this study is to assess whether acceptability and efficacy can be affected by the time after delivery at which breastfeeding women begin taking the progestin-only contraceptive. This study is being conducted at eight sites in five countries including Indonesia. A total of approximately 1440 subjects were enrolled prior to the halt of enrollment in July, 1993 due to slow recruitment. At that time, five of the sites (three in Mexico and two in Kenya) had met recruitment goals. After enrollment into the study, the subjects were assigned to one of two groups to begin using the progestin-only contraceptive at either 6 weeks or 6 months postpartum. Subjects are being followed up at six weeks and 6, 12 and 18 months. At these follow-up visits, subjects are being evaluated for continuation rates and compliance with both this method and methods which they switch to while participating in the study. Also being evaluated are pregnancy and acceptability parameters.

Results of this study should provide insight into more effective distribution of the progestin-only contraceptive and its general acceptability in relation to methods switched-to among the breastfeeding population.

Objective: (1) To compare the 12- and 18-month postpartum pregnancy rates, and the 12- and 18-month continuation rates from time of admission to study among breastfeeding women assigned to begin taking the progestin-only oral contraceptive (POC), norgestrel, 75 mcg, at (a) 6 weeks postpartum, or (b) 6 months postpartum or return of first menses, whichever comes first. (2) To evaluate acceptability by determining the reasons for pill discontinuation and any relationship to POC initiation time. (3) To evaluate safety by determining the frequency and types of adverse experiences.

Accomplishments:

Through March 1993

- The study was initiated and subject enrollment began in March 1992.

During the last six months

- Due to continued slow recruitment and enrollment, this study stopped enrolling subjects as of July 1, 1993. Only 61 of the expected 200 subjects were enrolled at the Indonesia site.

Plans for the next six months:

- Subject follow-up will continue at all sites in all five countries through the summer of 1994 at which time sites will be closed and a final analysis performed and reports completed.

Jordan

Population: 3.4 million

Total Fertility Rate: 5.6

Growth rate: 3.3%

Contraceptive Prevalence: 40% (Modern Methods: 27%)

Major Modern Methods: IUD (15%), Sterilization (6%), OCs (5%)

Jordan is an arid, desert country, of which only about 15% has been cultivated. The population is highly concentrated in the northwest and along the Jordan River Valley, with more than 80% of the population living on less than 10% of the land. With a wave of nearly 400,000 returning Jordanians from the Gulf states following the 1990 Iraqi occupation of Kuwait and a worsening economy, Jordanian policymakers have realized the importance of slowing population growth and improving family and reproductive health.

Although contraceptive prevalence of modern methods is 27%, total fertility and the rate of natural increase remain high, and nearly one-half of all deliveries are short-interval (<2 years) births. The strategy for curbing population growth, therefore, is aimed at advocating birth spacing and includes promoting effective breastfeeding practices and greater acceptance of modern contraceptive technologies.

FHI previously supported a series of seminars on birth spacing and family health; currently FHI is negotiating a project proposal to assess the feasibility of adding Norplant and DMPA to the range of options available to Jordanian women.

Jordan: Technical Assistance in Developing Strategies for Introducing New Birth Spacing Methods (7000)

The introduction and evaluation of new birth spacing methods in both public and private sector family planning programs in Jordan is critically needed. Current contraceptive prevalence is 27%, comprised of 15% IUDs and about 6% each using oral contraceptives and female sterilization. However, total fertility remains high (5.6), as does natural population increase (3.6%), and nearly half of all births are short-interval (< 2 years). Recently, Jordanian policymakers and providers have begun to recognize the importance of slowing population growth and improving reproductive health through the promotion of effective breastfeeding practices and acceptance of modern contraceptive technologies for achieving adequate birth spacing intervals. One of the strategies to this approach, supported by USAID/Amman, is to expand the existing method mix and increase accessibility to family planning methods by introducing new, safe and effective birth spacing technologies such as DMPA, Norplant and postpartum IUD insertion.

Objective: To provide technical assistance in the development and implementation of projects for introducing new methods of birth spacing, particularly DMPA, Norplant and postpartum IUDs, into the Jordanian family planning program.

Accomplishments:

Through March 1993

- FHI worked with USAID/Amman and Jordanian counterparts to identify program needs and levels of interest in birth spacing technologies.
- Two FHI staff traveled to Jordan to meet with representatives of the Ministry of Health, Royal Medical Services, University of Jordan and the private sector to explore potential areas of collaboration.

Plans for the next six months:

- FHI will develop proposals for specific introduction projects and obtain approval and funding for at least one project.
- Technical assistance will be provided in monitoring and evaluating at least one introduction project.

Nepal

Population: 21 million

Total Fertility Rate: 6.12

Growth Rate: 2.5%

Contraceptive Prevalence: 25% (Modern Methods: 24%)

Major Modern Method: Female Sterilization; Male Sterilization

Although the practice of family planning among Nepalese married women of childbearing age has increased from the 3% figure obtained in the 1976 Nepal Fertility Survey, the fertility rate remains among the highest in Asia. The family planning program continues to be characterized by an over-reliance on sterilization. The early age of marriage (16 years being typical for women), combined with the low prevalence of modern method use underscores the important role played by breastfeeding in the reduction of total fertility within Nepal.

The family planning program has embraced a variety of approaches, including mobile clinics, outreach programs and community-based programs. Services are provided by the government, by a semi-autonomous community health organization under the Ministry of Health, by PVOs and by the private sector. Increasing contraceptive prevalence remains the primary challenge. Efforts to increase the knowledge, promotion and availability of spacing methods will need to be carefully integrated with efforts to reduce unnecessary medical restrictions and the establishment of a good logistics system.

FHI's program in Nepal has been diverse, responding to the requests of both the USAID Mission and the Ministry of Health. Assisted by an in-country technical advisor, FHI has

helped in policy development as well as programmatic research formulation and data analysis issues. In the coming year, the program will focus on increasing access to contraception and improving a management information system.

Nepal: FHI Support to the Government of Nepal (7493)

FHI has been providing technical support to the Government of Nepal (GON) in family planning and population sectors for over a decade. FHI support began in 1981 with a month-long research methodology workshop for the National Planning Commission (NPC), Ministry of Health (MOH), Family Planning Association of Nepal (FPAN), Center for Development Administration, and Tribhuvan University. During the period 1985-1990, FHI supported pre-introductory clinical trials of the Norplant implant contraceptive. These trials paved the way for the inclusion of this new contraceptive option in Nepal's national family program. At the request of GON and with support of the USAID Mission, FHI has had a Technical Advisor attached to the Family Health Division (FHD) of the MOH and the Population Division of the NPC since 1991. Most recently, with funding obtained from the Asia Bureau, FHI has also employed a policy and management specialist to work part-time with the FHD. FHI is assisting the FHD in assessment of program performance, utilization of data for policy and program development, facilitating and investigation of implementation issues/problems, and providing research and training opportunities to local population and health professionals.

Objective: To strengthen the institutional capacity of the Government of Nepal to develop and implement policies and strategies to increase the availability of and access to quality family planning/child survival services.

Accomplishments:

Through March 1993

- A country strategy paper has been finalized.
- FHI's Technical Advisor in Nepal has provided assistance to program development activities as requested by the Family Planning/Maternal Child Health Division Planning Commission of the Ministry of Health and USAID.

During the last six months

- The Exploratory Study on High Risk Behavior for Women in Nepal was completed and results submitted to the GON and USAID. The results from this study have assisted the GON in formulating appropriate policies dealing with women at risk of unwanted pregnancy and contracting STDs.
- A part-time researcher was hired in August 1993 to assist the Technical Advisor in responding to technical assistance requests and conducting relevant research.

Plans for the next six months:

- A workshop will be held with the objective of developing a comprehensive management information system for MOH.
- Plans for a study tour program for selected host country nationals will be developed.
- The Research Triangle Institute and The Futures Group will be assisted in the preparation and presentation of the RAPID-type model to the parliamentarians in Nepal.
- Two in-country workshops will be planned with the objective of providing training opportunities in conceptualization of research issues, use of software programs, data analysis, and scientific writing.
- Technical support will continue to be provided to the Family Health Division, Ministry of Health and Population Division, National Planning Commission.
- The development of the Nepal Population and Health Data Bank will continue.
- The analysis of district level data on utilization of FP and MCH services will continue.
- A collection of papers on preventive health care issues will be compiled and edited.
- The office will assist health professionals to participate in short- and long-term training programs.

Pakistan

Population: 128 million

Total Fertility Rate: 5.4

Growth Rate: 2.84%

Contraceptive Prevalence: 12% (Modern Methods: 9%)

Major Modern Methods: Female Sterilization (3.5%), Condoms (2.7%)

Although in the past few years there has been an increase in the age at marriage and a nominal rise in contraceptive prevalence, Pakistan has yet to experience sustained declines in fertility. At its current growth rate, Pakistan could double its population in only 23 years. These problems persist despite a 30-year old national family planning program and longstanding government policies to reduce the birth rate.

Many of these problems with lowering fertility stem from the low status of women in Pakistani society. The educational levels attained by women remain very low: 79 percent of women have had no formal education. The traditional social structure of Pakistan supports a natural fertility pattern in which the majority of women do not use any means of fertility regulation. In addition to the social situation, infant mortality in Pakistan remains very high. Nearly one-tenth of children in Pakistan die before reaching their first birthday.

FHI has worked in Pakistan since 1988 on a pre-introductory study of Norplant which was completed in 1993. Also in 1993, FHI sponsored two-day contraceptive technology updates in both Karachi and Lahore. Special emphasis was placed on reduction of medical barriers and quality of care issues. Lastly, FHI is finishing a study to determine the efficacy of the Lactational Amenorrhea Method which included women from Pakistan. At this time no other activities have been planned in Pakistan due to restrictions on USAID support.

Pakistan: Clinical Trial of the Norplant Contraceptive Implant System (2032)

FHI has been conducting studies of Norplant since 1984. During this time approximately 8650 subjects have been admitted to studies at 43 centers in 11 countries.

FHI has used these studies to introduce Norplant implants into countries without previous implant experience and to provide physician training with the method. These studies have provided additional insight into the overall acceptability of the product among various cultures while assisting these countries in their efforts to gain regulatory approval of this method. Much of the acceptability data, especially that relating to menstrual disturbances, is being used to develop additional studies to improve user satisfaction and increase continuation rates.

Objective: To: (1) use Norplant subdermal implants in Phase III pre-introductory clinical trials, introducing the method into countries without previous implantable contraceptive experience; (2) provide training to physicians in inserting and removing Norplant properly and also in patient counseling; and (3) determine the implant's overall acceptability in different populations.

Accomplishments:

Through March 1993

- The study was initiated in April 1988.
- Five hundred and forty five women were enrolled at five sites.

During the last six months

- The Pakistan study was closed in June of 1993.
- Regulatory approval of Norplant implants is being sought in Pakistan.
- FHI continues to coordinate area activities with Leiras.

Plans for the next six months:

- The final country report will be completed.

Pakistan: Contraceptive Technology Updates (3720)

This project supported two two-day conferences, one in Karachi and one in Lahore, which provided information from noted family planning experts to Pakistani policy-makers and family planning providers.

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

Accomplishments:

During the last six months

- Two conferences were conducted in collaboration with the National Research Institute of Fertility Control (NRIFC). Conferences were held June 20-21 in Karachi and June 23-24 in Lahore. Approximately 180 government policy-makers, family planning officials and service providers attended each meeting.
- A number of medical barriers were identified and discussed, including age and parity, provider bias toward certain family planning methods, overly restrictive contraindication guidelines, and logistical difficulties.
- A report on the meetings containing the texts of presentations and discussion points was compiled and printing is pending.

Plans for the next six months:

- No follow-up activities are planned at this time, due to restrictions on USAID support for Pakistan programs.

Pakistan: Clinical Trial of the Lactational Amenorrhea Method (6389)

The Lactational Amenorrhea Method (LAM) was developed based on prospective research which showed that the probability of conception during full breastfeeding and amenorrhea was extremely small during the first six months postpartum. However, few attempts have been made to teach women to use this information as a contraceptive method. In this project, women volunteer to use LAM as a contraceptive. This study has been conducted at three centers in Karachi and one center in Multan, Pakistan. The same study was also conducted in Manila, Philippines.

Objective: To determine the efficacy of the Lactational Amenorrhea Method.

Accomplishments:

Through March 1993

- Four hundred women were recruited into the study and followed for one year. Follow-up ended in December 1992. Twenty women were lost to follow-up.

During the last six months

- All data have shipped to FHI and entered for computer analysis.
- The data set has been cleaned and most queries resolved.

Plans for the next six months:

- A few outstanding data queries will be addressed and analysis of the data will begin.

Philippines

Population: 66 million

Total Fertility Rate: 3.9

Growth rate: 2.48%

Contraceptive Prevalence: 34% (Modern Methods: 25%)

Major Modern Method: Sterilization (11%), OCs (6%)

The recently revitalized family planning program in the Philippines seeks to reduce the country's birth rate to 2.0 by the end of the decade. If the unmet need for family planning services could be met, this goal is obtainable. Fully 3.5 to 4.9 million Philippine women are said to have an unmet need for family planning services. Expansion of service providers, an increasing number of contraceptive choices, and increased access to

contraception will be key factors in meeting this need. Religious influences and restrictive medical practices add to the challenge.

The level of poverty is such in the Philippines (6 of 10 families fall below the poverty line) that the public program remains the primary vehicle for providing services to the majority of couples. Nonetheless, social marketing programs are getting underway both with USAID and private funding. An effort is also being made to expand low-cost services through NGOs.

Many Cooperating Agencies have Resident Advisors in the Philippines who are providing long-term technical assistance in areas such as logistics, information and education, social marketing and voluntary surgical contraception. To date FHI's population program in the country has been entirely centrally-funded and has focused primarily on contraceptive research, seeking to expand choices ultimately available and/or define the issues surrounding correct use of existing methods. In addition, FHI has been asked by the Mission to assist with the introduction of DMPA.

Philippines: Methods of Identifying Condom Users at Risk of Breakage and Slippage (6004)

Within any given condom breakage study, the majority of condom breaks occur among a small group of study participants. If these individuals and the reasons for condom breakage can be identified, better condom use instruction interventions can be developed for those using condoms as contraception or for disease prevention.

In the Philippines (one of three international sites), this study was conducted in collaboration with the Comprehensive Family Planning Center at the Dr. Jose Fabella Memorial Hospital in Manila. Male condom users (130) were given a background interview and five condoms to be used for vaginal intercourse. After a three-week study period, participants were interviewed to determine condom breakage and slippage rates and to assess behaviors that may lead to condom failure (condom breaking or slipping off completely).

Objectives: To assess different methods of identifying condom users who are at risk of condom failure, and to assess behaviors that lead to condom failure.

Accomplishments:

During the last six months

- Field work was completed; 130 participants completed the study.
- FHI staff traveled to the Philippines in June to enter data and provide Epi-Info training to the local research staff
- Data have been cleaned and analysis is in progress.

- Consistent with recent FHI research in this country, breakage and slippage rates were low (breakage 0.8%, slippage 1.2%).
- Despite low condom failure rates, the data suggest that past condom failure predicts future condom failure (consistent across all three sites).
- Preliminary analysis has identified behaviors which appear to be associated with condom failure including: unrolling condoms before donning, having particularly intense or long intercourse, and withdrawing after loss of erection. Use of additional lubrication and re-use of condoms (behaviors identified in prior FHI research) were reported infrequently.

Plans for the next six months:

- Data analysis will be completed.
- A site specific report will be written and disseminated.
- Study findings will be presented in October at the APHA Meeting.
- An article will be prepared for publication.

Philippines: Acceptability and Actual Use Breakage and Slippage Rates of Standard and Smaller Latex Condoms (6316)

The purpose of this study was to provide information to guide USAID condom procurement decisions with respect to supplying smaller condoms in Asia.

Objectives: To determine consumer preference for the standard or smaller condom and to determine slippage and breakage rates for the two condom sizes. This study was conducted at three sites in collaboration with the Olongapo City Health Department (Olongapo, Philippines); Family Planning Association of Sri Lanka (Colombo, Sri Lanka) and Valley Research Group (Kathmandu, Nepal). A total of 271 participants from Nepal and Sri Lanka tested 1347 standard (52mm) and 1350 smaller (49mm) condoms.

Accomplishments:

Through March 1993

- A final report was issued in September of 1992 for the Sri Lanka and Nepal study sites. Among Sri Lankan participants, slippage was reported almost twice as often with the smaller condoms than 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). There were no significant differences in the condom breakage rates of the two devices in Sri Lanka and

Nepal. Responses to questions concerning device acceptability did not indicate a clear user preference for one condom over the other.

- The Philippines site was initiated in October 1992.

During the last six months

- The study was monitored in June 1993 at the Olongapo, Philippines site.
- The Philippines data set was analyzed, and a final report was issued in August 1993.

Results:

- In the Philippines, 150 men were enrolled and completed the study. Seven hundred fifty (750) standard condoms and 744 smaller condoms were tested.
- None of the standard or smaller condoms was reported to have slipped off. Reported breakage rates for the standard and smaller condoms were 0.1% and 0.5%, respectively.
- In terms of acceptability, both condoms were rated equally (i.e., no significant differences in preference for one condom over another was reported).

Philippines: Introduction of DMPA (9310)

FHI convened an interdepartmental working group to develop a strategy highlighting the strengths and experience FHI can contribute to the introduction of DMPA. The strategy addresses such needs as establishing a data base of information on DMPA, country needs assessments, and country introduction plans. Components included in the country plans are regulatory issues, policy and administrative planning, information and training, research and evaluation. The strategy was approved by USAID and FHI's Technical Advisory Committee and sent to Population Officers in selected Missions. In August of this year, USAID/Manila and the Philippine government requested FHI's assistance in the development of a strategy to introduce DMPA in their country, following its anticipated approval by their Bureau of Food and Drug.

Objective: To develop a strategy for the introduction or expansion of DMPA use in the Philippines.

Accomplishments:*During the last six months*

- A team of three FHI staff traveled to the Philippines and worked with Pathfinder in the development of a strategy document which was subsequently adopted by the Department of Health.

Plans for the next six months:

- Staff from FHI will work with the Department of Health to continue monitoring the introduction process and initiate activities as appropriate. The first activity will be to develop education and communication materials for DMPA. Other activities may include initiation of monitoring and evaluation activities.

Philippines: Clinical Trial of the Lactational Amenorrhea Method (6389)

The Lactational Amenorrhea Method (LAM) was developed based on prospective research which showed that the probability of conception during full breastfeeding and amenorrhea was extremely small during the first six months postpartum. However, few attempts have been made to teach women to use this information as a contraceptive method. In this project, women volunteer to use LAM as a contraceptive. This study has been conducted at the Dr. Jose Fabella Memorial Hospital in Manila, Philippines. The same study was also conducted in Pakistan.

Objectives: To determine the efficacy of the Lactational Amenorrhea Method.

Accomplishments:*Through March 1993*

- Five hundred and nine women were recruited into the study and followed for 1 year. Follow-up ended in March 1993. Ninety-nine women were lost to follow-up.

During the last six months

- All data for the contracted official 12 months of the study have been shipped to FHI, entered into computer and cleaned.
- Follow-up has been extended for the women who were still amenorrheic at twelve months postpartum.
- Preliminary analyses were conducted and a paper prepared for presentation at the Asia-Oceanic Congress of Obstetrics and Gynecology (AOCOG) to be held in

Manila in November 1993. Preliminary findings show that LAM is as effective as predicted in the Bellagio Consensus.

Plans for the next six months:

- The paper, "The Introduction of LAM into Family Planning Programs," will be presented at the AOCOG.
- Follow-up collection will finish and forms will be sent to FHI. Any outstanding queries will be addressed.
- Data analysis of the final study results will begin.

Philippines: Time of Progestin-Only Oral Contraceptive Initiation Among Lactating Women (2096)

The goal of this study is to assess whether acceptability and efficacy can be affected by the time after delivery at which breastfeeding women begin taking the progestin-only contraceptive. This study is being conducted at eight sites in five countries. A total of approximately 1440 subjects were enrolled prior to the halt of enrollment on July, 1993 due to slow recruitment. After enrollment into the study, the subjects were assigned to one of two groups to begin using the progestin-only contraceptive at either six weeks or six months postpartum. Subjects are being followed up at 6 weeks and 6, 12 and 18 months. At these follow-up visits, subjects are being evaluated for continuation rates and compliance with both this method and methods which they switch to while participating in the study. Also being evaluated are pregnancy and acceptability parameters.

Results of this study should provide insight into more effective distribution of the progestin-only contraceptive and its general acceptability in relation to methods switched-to among the breastfeeding population.

Objective: (1) To compare the 12- and 18-month postpartum pregnancy rates, and the 12- and 18-month continuation rates from time of admission to study among breastfeeding women assigned to begin taking the progestin-only oral contraceptive (POC), norgestrel, 75 mcg, at (a) 6 weeks postpartum, or (b) 6 months postpartum or return of first menses, whichever comes first. (2) To evaluate acceptability by determining the reasons for pill discontinuation and any relationship to POC initiation time. (3) To evaluate safety by determining the frequency and types of adverse experiences.

Accomplishments:

Through March 1993

- The study was initiated and enrollment of subjects began in March 1992.

During the last six months

- Due to continued slow recruitment and enrollment, this study stopped enrolling subjects as of July 1, 1993. Prior to halt of enrollment, the Philippines site had enrolled 165 of 200 subjects.

Plans for the next six months:

- Subject follow-up will continue at all sites in all five countries through the summer of 1994 at which time sites will be closed, a final analysis performed and reports completed.

South Korea

Population: 44.6 million

Total Fertility Rate: 1.6

Growth Rate: 1%

Contraceptive Prevalence: 77% (Modern Methods: 76%)

Major Modern Methods: Sterilization (male and female)

South Korea's national family planning program was created in the late 1950s to combat the country's high population growth rates. Population policy supportive of fertility decline has been part of the government's 5-year plans since 1962. Regarded by many as having one of the most successful family planning programs in the world, South Korea has lowered its total fertility rate from 6.0 in 1965 to its current rate of 1.6.

Government programs have consistently targeted rural areas for innovative population programs including extensive community-based distribution programs in which field workers make motivational home visits in addition to distributing contraceptives. Another aspect of South Korea's fertility control program is to have private physicians provide free contraceptive services to clients. Universal health insurance has been available to all South Koreans since 1989.

The prevalence of sterilization is declining, as is the number of induced abortions. However, the induced abortion rate for married women age 20-44 remains high at 1.9, and abortions among unmarried women are increasing. Reversible methods are the fastest rising contraceptive method among married women.

Because of their heavy reliance on sterilization, South Korea provides an ideal location for FHI's study of the relationship, if any, between vasectomy and prostate cancer. Due to South Korea's "graduate" status, FHI's work there will be restricted to this study or others like it which address international questions regarding long-term contraceptive safety.

South Korea: Vasectomy and Prostate Cancer in Asia (6287)

Vasectomy is used for family planning by approximately 42 million couples worldwide, the majority of whom live in developing countries. It is a highly reliable and safe contraceptive method which has been extensively studied. Recently, renewed concerns have been raised about a possible increased risk of cancer of the prostate many years after the procedure. These observations are based on research conducted in the U.S. where there is a high and rising incidence of prostate cancer. Overall incidence rates of prostate cancer in some developed countries, such as the U.S., are fifty times higher than in some developing countries, such as the People's Republic of China. The majority of epidemiological studies on the relationship between vasectomy and prostate cancer have been based in the U.S.; the findings are inconsistent and the reported associations are weak. Therefore, although on the basis of currently available data it is concluded that no changes in family planning policies with regard to vasectomy are warranted, the concerns raised by these studies require that research into any possible association be undertaken in countries where vasectomy is widely practiced and, so far, accepted.

To address this research need, FHI will participate with WHO in a multicountry, multicenter hospital-based case-control study on the relationship between prostate cancer and vasectomy in developing countries (China, India, Korea and Nepal) and one developed country (New Zealand) where vasectomy has been extensively practiced for family planning.

Objective: To ascertain if there is a relationship between vasectomy and prostate cancer in a non-Western population.

Accomplishments:

During the last six months

- FHI established a collaborative arrangement with WHO to participate in a pilot study and Korea was determined to be a feasible site.
- Negotiation of our role in the Korean case-control study with Dr. Kwang-ho Meng, in Seoul, Korea was completed.

Plans for next six months:

- Initiate the pilot study in Korea in November 1993.
- Monitor the Korean site and ascertain with collaborators the feasibility of using this site in the multinational study. There is a question whether there will be enough men who were vasectomized at least 20 years ago who can contribute data to the multicountry study.

Thailand

Population: 59 million

Total Fertility Rate: 2.2

Growth Rate: 1.4%

Contraceptive Prevalence: 68% (Modern Methods: 66%)

Major Modern Methods: Female Sterilization (23%), OCs (20%)

Thailand has achieved the status of a "graduate" country in terms of its development status in the economic, health and population areas, contributing to USAID's decision to close its Mission in 1995. The national family planning program has enabled Thailand to reach one of the highest contraceptive prevalence rates (68%) in Asia. Quality family planning services are provided by the Ministry of Public Health (MOPH) throughout most of the country (tribal areas still contain substantial unmet need), and are largely financed by the Royal Thai Government.

The country now faces a serious threat from a rampant AIDS epidemic but is taking the policy and preventive actions necessary to bring the spread under control. Some of these steps include integrating family planning and AIDS prevention services through the MOPH, condom use promotion, and a strong educational program.

Given its status as a county in the development transition, Thailand offers a unique opportunity for examining issues of importance to both developed and developing countries, such as contraceptive safety and cost of services. FHI has been examining the risk of gestational hypertension among OC users and the impact of adding Norplant to the contraceptive mix in the country.

Thailand: Oral Contraceptive Use and Risk of Gestational Hypertension (6000)

Oral contraceptive use increases blood pressure. Concern has been raised about whether the use of OCs shortly before conception or during pregnancy may increase the risk of developing pregnancy-induced hypertension (PIH) or preeclampsia. However, little is known about the effect of OC use on PIH in subsequent pregnancy. FHI designed a hospital-based case-control study to examine the association between barrier contraceptive methods, OC use, and risk of PIH in subsequent pregnancy. A total of 900 newly diagnosed cases with PIH (including gestational hypertension and pre-eclampsia) and 1,800 normotensive controls will be selected from three hospitals in Bangkok, Thailand. The controls are the two women who deliver immediately after the case in the same labor/delivery room. The cases and controls will be interviewed in the hospitals after delivery to obtain information on contraceptive use and other characteristics. Information on prenatal care, obstetric experience, and the neonate will be abstracted from medical records.

Objectives: 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.

Accomplishments:

Through March 1993

- A site visit to Thailand was made to assess the feasibility of this study.
- A proposal has been developed. Funding is being sought from non-USAID sources.

During the last six months

- A budget was finalized with Thai investigators, and contacts were sought for funding.

Plans for the next six months:

- Further funding sources will be sought.

Thailand: The Impact of Adding the Contraceptive Implant to Methods Offered by the National Family Planning Program (9316)

The main purpose of this study was to determine the impact on contraceptive use of adding Norplant to the method mix, and to compare the costs of expanding contraceptive use through provision of different methods. Results would then be used to determine the extent of the role that the contraceptive implant should play in the method mix.

Objective: To determine the impact on contraceptive use and the costs of increasing the provision of Norplant by training nurses to provide it, and to compare the costs of providing Norplant with the costs of providing injectables and the IUD.

Accomplishments:

Through March 1993

- The study was carried out at 12 family planning clinics in 12 hospitals throughout Thailand. At these sites, nurses were trained to provide Norplant. Twelve hospitals served as controls. At each site information on distribution of contraceptives was obtained. In addition, at the experimental sites, acceptors of Norplant were interviewed to determine why they chose Norplant, their previous contraceptive method and source, and the method that they would have selected in the absence of Norplant. Data on the costs of provision of Norplant, IUDs and injectables were obtained using patient flow analysis and financial data.
- Five hundred and fifty women were interviewed. Almost all had used contraception and would have used another method if Norplant had not been

available. The cost per couple year of protection for all durations of use is higher for Norplant than for the IUD or for injectables; the IUD is the least costly method for all durations of use. Thus, method switching would raise the costs to the National Family Planning Program (NFPP). Some contraceptive users had obtained their previous method in the private sector, further increasing costs to the NFPP.

- A researcher from the Family Health Division of the Ministry of Health visited FHI to work on other aspects of the analysis. A final report has not yet been received.

During the last six months

- A paper entitled "The Impact of Introducing the Contraceptive Implant on Method Use and Costs in Thailand," was written and sent to *International Family Planning Perspectives*. The journal asked that revisions be made and that the paper be resubmitted. (Major study findings have been discussed above.)

Plans for the next six months:

- Reviewers' comments will be used to revise and resubmit the paper to the journal.
- A final report will be prepared.

IV. PROGRAM MANAGEMENT

North Carolina Headquarters

Under FHI'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 Program Planning, Research and Support Department. Both departments underwent reorganization early in Fiscal Year 1993.

The divisions comprising the Research and Development Department are: Biostatistics, Clinical Trials, Materials Technology, Regulatory Affairs and Quality Assurance, and Scientific Support Services. The divisions in this department, working together, are design, implementation and management of multi- and single-center studies to evaluate the safety and efficacy of contraceptive methods, the development of new contraceptives, and quality assurance.

The Population Programs Department consists of four divisions: Contraceptive Use and Evaluation, Field Operations, Policy Research and Utilization, and Service Delivery Research. These divisions work together to develop and implement programs of broad interest for FHI's population and family planning agenda, concentrating resources and efforts in a number of countries that are of major importance for FHI's current and future programs.

Interdivisional working groups provide a mechanism for collaboration across departments and among divisions in key program areas: Contraceptive Introduction, Improving Access to Contraception through the Reduction of Medical Barriers, Postpartum Contraception, Adolescent Reproductive Health, and Family Planning and STDs/HIV.

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 broader issues for setting global research and development priorities. To this end, FHI has strengthened its field presence with a regional office for Africa, located in Kenya, and the placement of advisors in selected countries.

The FHI Africa Regional office is headed by a Senior Representative from FHI's staff who, with assistance from a Research Associate, provides support to the regional and Kenya country program. The regional office facilitates 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.

Library and Information Services

FHI's specialized reproductive health library provides vital support to FHI staff in all aspects of the program, enabling staff and colleagues to remain abreast of the rapidly changing knowledge and information in the fields of reproductive health, family planning and population. The library houses 750 periodicals, 6,000 books, and provides access to three database networks and more than a dozen in-house data bases on topics such as AIDS, IUDs, and oral contraceptives.

V. FINANCIAL INFORMATION

A. Summary of Expenditures

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

Expenditures By Type

1 April 1993 - 30 September 1993

| | |
|--|-----------------|
| Salaries and Fringe Benefits | \$ 4,520 |
| Service Centers | 0 |
| Consultant, Professional Fees, Contracted Labor | 0 |
| Travel - Domestic | 0 |
| Travel - Foreign | 3,342 |
| Supplies/Office | 0 |
| Printing and Reprints | 7,585 |
| Office/Medical Equipment, Maintenance and Repair | 0 |
| Freight | 211 |
| Registration Fees, Training Grant | 0 |
| Other Purchased Services | 0 |
| Keypunching | 0 |
| Other Expenses and Bank Service Charge | <5,153> |
| Data Purchases | 0 |
| Subcontract | 0 |
| General and Administrative Costs | <139> |
| Total | \$10,366 |

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

Expenditures By Type

1 April 1993 - 30 September 1993

| | |
|--|--------------------|
| Salaries and Fringe Benefits | \$2,841,598 |
| Service Centers | 427,306 |
| Consultant, Professional Fees, Contracted Labor | 227,450 |
| Travel - Domestic | 181,460 |
| Travel - Foreign | 454,138 |
| Supplies - Office | 27,061 |
| Supplies - Medical | 59,532 |
| Printing and Reprints | 203,781 |
| Office/Medical Equipment, Maintenance and Repair | 29,830 |
| Freight | 23,514 |
| Registration Fees | 30,181 |
| Subscription, Publications | 54,988 |
| Other Purchased Services | 179,116 |
| Keypunching | 1,282 |
| Other Expenses and Bank Service Charges | 110,525 |
| Subcontracts | 1,091,674 |
| General and Administrative Costs | <u>\$1,144,081</u> |
| Total | \$7,087,517 |

B. Program Area Activities by Region

1. Contraceptive Technology Development & Approval a. Barrier Contraceptives & Spermicides By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|---|-----------------------------|-----------------------------|------------------------------|
| LATIN AMERICA/CARIBBEAN: | | | |
| Dominican Republic Reality Vaginal Pouch | 5,176 | (57) | 0 |
| Mexico Reality Vaginal Pouch | 10,352 | (115) | 0 |
| TOTAL LATIN AMERICA/CARIBBEAN | 15,528 | (172) | 0 |
| From Central Funds | 15,528 | (172) | 0 |
| From Add-On Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

1. Contraceptive Technology Development & Approval
 a. Barrier Contraceptives & Spermicide (Continued)
 By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|--------------------------------------|-----------------------------|-----------------------------|------------------------------|
| USA/EUROPE: | | | |
| England | | | |
| Vaginal Methods, Diaphragm | 6,326 | 8,355 | 0 |
| Barrier Guidelines | 3,364 | 32,568 | 0 |
| USA | | | |
| Plastic Condoms Materials R & D | 59,029 | 81,438 | 46,000 |
| Tests of Prototype Plastic Condoms | 33,267 | 51,970 | 41,040 |
| Plastic Condoms Process R & D | 43,794 | 52,415 | 65,300 |
| Functionality & Acceptability | 23,112 | 8,248 | 0 |
| Plastic Condom Testing & Eval. | 36,747 | 52,094 | 71,000 |
| FDA - Vaginal Barrier Device | 74,026 | 11,184 | 105,807 |
| Plastic Condom Safety | 26,461 | 33,613 | 97,000 |
| Phase IB Slip on Plastic Condom | 508 | | 27,000 |
| Plastic Condom Machine Design & Dev. | 42,185 | (15,689) | 0 |
| Plastic Condom Fabrication | 29,689 | 39,799 | 71,000 |
| Plastic Condom Test Devel. | 9,170 | 57,278 | 0 |
| C-film | 27,992 | | 39,137 |
| Reality Vaginal Pouch | 8,000 | (89) | 0 |
| TOTAL USA/EUROPE | 423,670 | 413,184 | 563,284 |
| From Central Funds | 423,670 | 413,184 | 563,284 |
| From Add-On Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

1. Contraceptive Technology Development & Approval
a. Barrier Contraceptives & Spermicide (Continued)
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|--|---|---|--|
| INTERREGIONAL: | | | |
| interregional | | | |
| Plastic Condoms | 104,582 | 66,470 | 57,000 |
| Data Management | 112,748 | 63,999 | 53,852 |
| Regulatory Affairs | 23,962 | 19,871 | 11,684 |
| Vaginal Methods/General | 18,768 | 16,318 | 21,100 |
| Scientific Writing | 64,034 | 87,844 | 122,976 |
| Interregional Contraceptive Research/Development | 5,139 | 1,766 | 5,250 |
| Development/Management | 204,463 | 126,905 | 197,945 |
| Population Biostat Activity | 17,425 | 18,095 | 28,476 |
| R & D Interdivisional SOPS | 7,855 | 7,011 | 10,000 |
| General Quality Assurance | 5,866 | 16,185 | 7,952 |
| Quality Assurance Auditing | 5,489 | 3,625 | 4,102 |
| TOTAL INTERREGIONAL | 570,331 | 428,088 | 520,337 |
| From Central Funds | 570,331 | 428,088 | 520,337 |
| From Add-On Funds | 0 | 0 | 0 |
| TOTAL ALL REGIONS | 1,009,529 | 841,100 | 1,083,621 |
| From Central Funds | 1,009,529 | 841,100 | 1,083,621 |
| From Add-on Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

1. Contraceptive Technology Development & Approval
b. Long-Acting Steroids
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|--|------------------------------------|------------------------------------|-------------------------------------|
| USA/EUROPE | | | |
| USA | | | |
| Phase IB Eval. of NET Implants | 166,039 | 79,738 | 90,000 |
| SYS - NET Microspheres | 22,163 | 9,168 | 10,000 |
| TOTAL USA/EUROPE | 188,202 | 88,906 | 100,000 |
| From Central Funds | 188,202 | 88,906 | 100,000 |
| From Add-On Funds | 0 | 0 | 0 |
| INTERREGIONAL: | | | |
| Interregional | | | |
| Unject Project | 27,513 | 0 | 33,000 |
| Development/Management | 113,591 | 70,503 | 109,970 |
| Population Biostat Activity | 17,425 | 18,095 | 28,476 |
| SYS - General | 4,805 | 1,538 | 2,250 |
| Regulatory Affairs | 23,962 | 19,871 | 11,684 |
| NORPLANT Worldwide Clinical Data Base | (26) | (934) | 0 |
| Data Management | 62,638 | 35,555 | 20,918 |
| Interregional Contraceptive Research/Development | 5,139 | 1,766 | 5,250 |
| Quality Assurance Auditing | 5,489 | 3,625 | 4,102 |
| General Quality Assurance | 5,866 | 16,185 | 7,952 |
| TOTAL INTERREGIONAL | 266,402 | 166,203 | 232,601 |
| From Central Funds | 266,402 | 166,203 | 232,601 |
| From Add-On Funds | 0 | 0 | 0 |
| TOTAL ALL REGIONS | 454,604 | 255,109 | 332,601 |
| From Central Funds | 454,604 | 255,109 | 332,601 |
| From Add-on Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

**1. Contraceptive Technology Development & Approval
c. Female Sterilization
By Region and Funding Source**

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|--|-------------------------------------|-------------------------------------|--------------------------------------|
| USA/EUROPE: | | | |
| USA | | | |
| Filshie Clip PMA | 60,331 | 23,702 | 45,000 |
| FS - Nonsurgical/Iodine | 60,366 | 198,223 | 65,000 |
| TOTAL USA/EUROPE | 120,697 | 221,925 | 110,000 |
| From Central Funds | 120,697 | 221,925 | 110,000 |
| From Add-On Funds | 0 | 0 | 0 |
| INTERREGIONAL: | | | |
| Interregional | | | |
| Population Biostat Activity | 17,425 | 18,095 | 28,476 |
| Regulatory Affairs | 23,962 | 19,871 | 11,684 |
| Data Management | 37,583 | 21,333 | 17,951 |
| Interregional Contraceptive Research/Development | 5,139 | 1,766 | 5,250 |
| Development/Management | 68,154 | 42,302 | 65,982 |
| General Quality Assurance | 5,866 | 16,185 | 7,952 |
| Quality Assurance Auditing | 5,489 | 3,625 | 4,102 |
| TOTAL INTERREGIONAL | 163,618 | 123,176 | 141,396 |
| From Central Funds | 163,618 | 123,176 | 141,396 |
| From Add-On Funds | 0 | 0 | 0 |
| TOTAL ALL REGIONS | 284,315 | 345,101 | 251,396 |
| From Central Funds | 284,315 | 345,101 | 251,396 |
| From Add-on Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

B. Program Area Activities by Region

**1. Contraceptive Technology Development & Approval
d. Male Sterilization
By Region and Funding Source:**

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|---|-------------------------------------|-------------------------------------|--------------------------------------|
| LATIN AMERICA/CARIBBEAN: | | | |
| Mexico | | | |
| Infer. Vasectomy | 37,667 | 64,752 | 54,697 |
| TOTAL LATIN AMERICA/CARIBBEAN | 37,667 | 64,752 | 54,697 |
| From Central Funds | 37,667 | 64,752 | 54,697 |
| From Add-On Funds | 0 | 0 | 0 |
| INTERREGIONAL: | | | |
| Interregional: | | | |
| Regulatory Affairs | 23,962 | 19,871 | 11,684 |
| Data Management | 37,583 | 21,333 | 17,951 |
| Interregional Contraceptive Research/Development/Management | 5,139 | 1,766 | 5,250 |
| Male Sterilization | 58,154 | 42,302 | 65,982 |
| Population Biostat Activity | 57,302 | 14,824 | 14,640 |
| General Quality Assurance | 17,425 | 18,095 | 28,476 |
| Quality Assurance Auditing | 5,866 | 16,185 | 7,952 |
| | 5,489 | 3,625 | 4,102 |
| TOTAL INTERREGIONAL | 220,920 | 138,000 | 156,036 |
| From Central Funds | 220,920 | 138,000 | 156,036 |
| From Add-On Funds | 0 | 0 | 0 |
| TOTAL ALL REGIONS | 258,587 | 202,752 | 210,733 |
| From Central Funds | 258,587 | 202,752 | 210,733 |
| From Add-on Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

2. Improved Service Delivery
a. Quality Assurance of Contraceptives
By Region and Funding Source

| | ACTUAL FY'83 4/83 - 9/83 | BUDGET FY'83 4/83 - 9/83 | BUDGET FY'84 10/83 - 3/84 |
|--------------------------------|---|---|--|
| USA/EUROPE: | | | |
| USA | | | |
| PATH: Condom Research | 43,581 | 148,861 | 16,000 |
| Condom Research & Test Devel. | 14,891 | 32,506 | 23,000 |
| Special Condom Testing | 101,078 | 34,204 | 0 |
| TOTAL USA/EUROPE | 159,550 | 215,571 | 39,000 |
| From Central Funds | 159,550 | 215,571 | 39,000 |
| From Add-On Funds | 0 | 0 | 0 |
| INTERREGIONAL: | | | |
| Interregional | | | |
| Development & Management | 86,838 | 26,196 | 65,000 |
| Condom Prospective Aging | 17,368 | 12,520 | 17,000 |
| Condom Production Surveillance | 154,392 | (99,820) | 180,000 |
| Condom Field Evaluations | 20,651 | 99,890 | 101,000 |
| Condom Functionality Trials | 11,898 | 64,949 | 26,000 |
| Condom Quality Testing | 32,435 | 73,177 | 122,000 |
| Contraceptive Evaluation | 56,218 | 89,286 | 300,000 |
| TOTAL INTERREGIONAL | 379,800 | 265,998 | 811,000 |
| From Central Funds | 379,800 | 265,998 | 811,000 |
| From Add-On Funds | 0 | 0 | 0 |
| TOTAL ALL REGIONS | 539,350 | 481,569 | 850,000 |
| From Central Funds | 539,350 | 481,569 | 850,000 |
| From Add-on Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

2. Improved Service Delivery
b. Introducing and Expanding Methods
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|-------------------------|------------------------------------|------------------------------------|-------------------------------------|
| AFRICA: | | | |
| Ghana | | | |
| SYS - NORPLANT | 11,640 | 2,937 | 5,219 |
| Kenya | | | |
| IUD Introduction | 10,677 | 19,259 | 1,351 |
| Mali | | | |
| Mali Postpartum IUD | 28,098 | 39,453 | 4,329 |
| NORPLANT Introduction | 4,661 * | 0 * | 65,927 * |
| Niger | | | |
| IPPI Introduction Study | 31,491 * | 52,957 * | 15,000 * |
| Nigeria | | | |
| SYS - NORPLANT | 44,234 | 11,161 | 19,832 |
| Senegal | | | |
| NORPLANT Clinical Trial | 2,463 * | 11,419 * | 9,000 * |
| NORPLANT Management | 45,602 * | (16,370) * | 31,000 * |
| NORPLANT Management | 8,564 | 44,577 | 8,300 |
| TOTAL AFRICA | 187,430 | 185,393 | 198,958 |
| From Central Funds | 103,213 | 117,387 | 39,031 |
| From Add-On Funds | 84,217 | 48,006 | 120,927 |

* Denotes Mission or Bureau Add-On Funds

2. Improved Service Delivery
b. Introducing and Expanding Methods (Continued)
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|--------------------------------------|---|---|--|
| LATIN AMERICA/CARIBBEAN: | | | |
| El Salvador | | | |
| NORPLANT Introduction | (114)* | 25,280 * | 6,000 * |
| NORPLANT Clinical Trial | 70,210 * | 88,755 * | 14,000 * |
| Haiti | | | |
| NORPLANT Introduction | 6,921 * | 11,064 * | 0 * |
| NORPLANT Logistics | 102 * | 2,633 * | 15,000 * |
| NORPLANT Clinical Trial | (324)* | 846 * | 0 * |
| NORPLANT Training/IEC | 756 * | * | 37,000 * |
| TOTAL LATIN AMERICA/CARIBBEAN | 77,551 | 128,578 | 72,000 |
| From Central Funds | 0 | 0 | 0 |
| From Add-On Funds | 77,551 | 128,578 | 72,000 |

* Denotes Mission or Bureau Add-On Funds

2. Improved Service Delivery
b. Introducing and Expanding Methods (Continued)
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|-----------------------------|------------------------------------|------------------------------------|-------------------------------------|
| ASIA/NEAR EAST: | | | |
| Bangladesh | | | |
| SYS - NORPLANT | 19,789 | 4,993 | 8,872 |
| NORPLANT* | 0* | 46* | 0* |
| India | | | |
| Social Marketing Evaluation | (1,790)* | (4,317)* | 0* |
| Nepal | | | |
| SYS - NORPLANT | 698 | 176 | 313 |
| Pakistan | | | |
| NORPLANT Clinical Trials | 21,266* | 19,529* | 0* |
| LAM Trials | 10,307 | 11,469 | 0 |
| Philippines | | | |
| LAM Trials | 15,460 | 17,203 | 31,482 |
| SYS - NORPLANT | 26,773 | 6,755 | 12,004 |
| Sri Lanka | | | |
| SYS - NORPLANT | 13,270 | 3,348 | 5,950 |
| Egypt | | | |
| NORPLANT Support | 1,189* | 36,028* | 0* |
| TOTAL ASIA/NEAR EAST | 106,962 | 95,231 | 58,621 |
| From Central Funds | 86,297 | 79,973 | 58,621 |
| From Add-On Funds | 20,665 | 15,258 | 0 |

* Denotes Mission or Bureau Add-On Funds

2. Improved Service Delivery
b. Introducing and Expanding Methods (Continued)
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|--|---|---|--|
| INTERREGIONAL | | | |
| <i>Interregional</i> | | | |
| IUD - TCU 380A | 33,436 | 16,246 | 11,050 |
| BF & NFP Paper Preparation | 42,098 | 30,848 | 29,053 |
| Timing Distribution of POCs | 2,847 | 105 | 0 |
| Contractiv. Intro.: Prgm Devel. & Mgrmt. | 20,240 | (1,308) | 12,522 |
| Depo Introduction | 35,172 | (6,103) | 29,593 |
| TOTAL INTERREGIONAL | 133,793 | 39,788 | 82,218 |
| From Central Funds | 133,793 | 39,788 | 82,218 |
| From Add-On Funds | 0 | 0 | 0 |
| TOTAL ALL REGIONS | 505,736 | 428,990 | 372,796 |
| From Central Funds | 323,303 | 237,148 | 179,869 |
| From Add-on Funds | 182,433 | 191,842 | 192,927 |

* Denotes Mission or Bureau Add-On Funds

2. Improved Service Delivery
c. Improving Contraceptive Acceptance and Use
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|--------------------------------------|---|---|--|
| AFRICA: | | | |
| Kenya | | | |
| Vaginal Contraceptive Film | 118 | 2,888 | 0 |
| SYS - POC in Breastfeeding Women | 33,546 | 34,507 | 21,883 |
| Malawi | | | |
| Acceptability of Female Condom | 10,416 | 6,246 | 26,315 |
| Zambia | | | |
| Spermicide Accep.: in STD Clinics | 3,381 | (6,118) | 0 |
| Zimbabwe | | | |
| SYS - POC in Breastfeeding Women | 9,867 | 10,149 | 6,436 |
| TOTAL AFRICA | 57,328 | 47,672 | 54,634 |
| From Central Funds | 57,328 | 47,672 | 54,634 |
| From Add-On Funds | 0 | 0 | 0 |
| LATIN AMERICA/CARIBBEAN: | | | |
| Colombia | | | |
| Use of Condoms/Spermicides and STDs | 72,448 | 95,831 | 44,604 |
| Dominican Republic | | | |
| Vaginal Contraceptive Film | 276 | 6,739 | 0 |
| Multi-Site: Condom Use/Misuse | 24,091 | 22,001 | 3,582 |
| Mexico | | | |
| Study of OC Knowledge and Practices | 14,692 | 11,751 | 0 |
| Revise OC Use Instructions | 137 | 3,339 | 0 |
| Oral Contraceptive Use Instruc. Test | 2,551 | 4,545 | 0 |
| Test OC Instructions | 2,209 | 23,647 | 20,644 |
| Multi-Site: Condom Use/Misuse | 5,288 | 4,829 | 3,582 |
| Acceptability of Female Condom | 24,303 | 14,573 | 61,402 |
| Vaginal Contraceptive Film | 263 | 6,418 | 0 |
| SYS - POC in Breastfeeding Women | 136,132 | 142,086 | 90,105 |
| TOTAL LATIN AMERICA/CARIBBEAN | 284,590 | 335,820 | 223,917 |
| From Central Funds | 284,590 | 335,820 | 223,917 |
| From Add-On Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

2. Improved Service Delivery
 c. Improving Contraceptive Acceptance and Use (Continued)
 By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|----------------------------------|-----------------------------|-----------------------------|------------------------------|
| ASIA/NEAR EAST: | | | |
| Nepal | | | |
| Smaller Condoms | 6,471 | 9,303 | 0 |
| India | | | |
| OC Studies | 6,584 * | 38,046 * | 0 * |
| Malaysia | | | |
| SYS - POC in Breastfeeding Women | 9,867 | 10,149 | 0 |
| Philippines | | | |
| SYS - POC in Breastfeeding Women | 5,920 | 6,089 | 7,080 |
| TOTAL ASIA/NEAR EAST | | | |
| From Central Funds | 28,842 | 63,567 | 7,080 |
| From Add-On Funds | 22,258 | 25,541 | 7,080 |
| | 6,584 | 38,046 | 0 |

* Denotes Mission or Bureau Add-On Funds

2. Improved Service Delivery
c. Improving Contraceptive Acceptance and Use (Continued)
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|---------------------------------------|------------------------------------|------------------------------------|-------------------------------------|
| USA/EUROPE: | | | |
| USA | | | |
| Dual Method Acceptability Study | 32,176 | 29,270 | 52,712 |
| Breastfeeding & Women's Status | 2,990 | 3,554 | 0 |
| POC Labeling Instructions | 38,669 | 22,259 | 19,768 |
| TOTAL USA/EUROPE | 73,835 | 55,083 | 72,480 |
| From Central Funds | 73,835 | 55,083 | 72,480 |
| From Add-On Funds | 0 | 0 | 0 |
| INTERREGIONAL: | | | |
| Interregional | | | |
| Task Force on Accept. of New Methods | 411 | 1,350 | 3,730 |
| Acceptability Paper Writing | 12,802 | 37,889 | 16,899 |
| Measuring OC Compliance MEMS Device | 50,626 | 60,381 | 58,076 |
| OC Compliance | 40,332 | 22,641 | 39,231 |
| RH Paper Prep. for Completed Projects | 45,001 | 36,190 | 88,881 |
| OR Informed Choice | 2,581* | 24,100* | 0* |
| Development and Management | 226,030 | 441,038 | 210,004 |
| TOTAL INTERREGIONAL | 377,783 | 683,589 | 416,821 |
| From Central Funds | 375,202 | 659,489 | 416,821 |
| From Add-On Funds | 2,581 | 24,100 | 0 |
| TOTAL ALL REGIONS | 822,378 | 1,185,751 | 774,833 |
| From Central Funds | 813,213 | 1,123,605 | 774,833 |
| From Add-on Funds | 9,165 | 62,146 | 0 |

* Denotes Mission or Bureau Add-On Funds

2. Improved Service Delivery
 d. Reducing Medical Barriers
 By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|--|-----------------------------|-----------------------------|------------------------------|
| AFRICA: | | | |
| Cameroon | | | |
| Impact of Trng. Svc. Prov. on Guidelines | 70,482 | 60,700 | 54,000 |
| TOTAL AFRICA | 70,482 | 60,700 | 54,000 |
| From Central Funds | 70,482 | 60,700 | 54,000 |
| From Add-On Funds | 0 | 0 | 0 |
| LATIN AMERICA/CARIBBEAN | | | |
| Ecuador | | | |
| Flexible Schedules for IUD FU Visits | 4,028 | 12,625 | 0 |
| Jamaica | | | |
| Medical Barriers | 40,915 | 22,634 | 13,092 |
| Mexico | | | |
| Flexible IUD Revisit | 13,429 | 28,453 | 17,000 |
| TOTAL LATIN AMERICA/CARIBBEAN | 58,372 | 63,712 | 30,092 |
| From Central Funds | 58,372 | 63,712 | 30,092 |
| From Add-On Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

2. Improved Service Delivery
 d. Reducing Medical Barriers (Continued)
 By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|--|-----------------------------|-----------------------------|------------------------------|
| ASIA/NEAR EAST: | | | |
| Bangladesh | | | |
| Access to Removal of NORPLANT | 0 | 3,890 | 0 |
| Pakistan | | | |
| CTU Conference | 42,294 * | 59,886 * | 0 |
| Multi National | | | |
| ALMA ATA MCH Conference | (623) | (251) | 0 |
| TOTAL ASIA/NEAR EAST | 41,671 | 63,325 | 0 |
| From Central Funds | (623) | 3,439 | 0 |
| From Add-On Funds | 42,294 | 63,576 | 0 |
| INTERREGIONAL: | | | |
| Interregional | | | |
| Paper Writing for Cost Projects | 11,385 | 47,844 | 30,000 |
| CTU Modules | 127,769 | 191,379 | 34,000 |
| Med. Barriers: Mtg. on Serv. Delivery | (441) | (11,268) | 0 |
| CTUs for Reduction of Medical Barriers | 50,807 | 244,413 | 15,000 |
| WHO TA Medical Barriers | (1,080) | 503 | 0 |
| Medical Barriers to Contraception | 77,402 | 60,644 | 28,000 |
| Medical Barriers Research Support | 10,503 | 88,931 | 40,000 |
| TOTAL INTERREGIONAL | 276,345 | 622,446 | 147,000 |
| From Central Funds | 276,345 | 622,446 | 147,000 |
| From Add-On Funds | 0 | 0 | 0 |
| TOTAL ALL REGIONS | 446,070 | 810,183 | 231,092 |
| From Central Funds | 404,576 | 750,297 | 231,092 |
| From Add-on Funds | 42,294 | 63,576 | 0 |

* Denotes Mission or Bureau Add-On Funds

2. Improved Service Delivery
e. Improving Resource Allocation
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|--------------------------------------|---|---|--|
| AFRICA: | | | |
| Kenya | | | |
| FPAK Cost of Family Planning | 0 | 23,567 | 0 |
| TOTAL AFRICA | 0 | 23,567 | 0 |
| From Central Funds | 0 | 23,567 | 0 |
| From Add-On Funds | 0 | 0 | 0 |
| LATIN AMERICA/CARIBBEAN: | | | |
| Ecuador | | | |
| Technical Assistance Sustainability | 10,434 | 721 | 14,000 |
| Depo. Intro. & Resupply | 5,434 | 22,988 | 18,000 |
| Haiti | | | |
| NORPLANT Impact | 159 * | 1,300 * | 7,421 * |
| Honduras | | | |
| Cost of FP ASHONPLAFA | 4,225 * | 5,640 * | 1,800 * |
| 1992 Family Health Survey | 22,355 * | 36,975 * | 8,000 * |
| TOTAL LATIN AMERICA/CARIBBEAN | 42,007 | 67,624 | 49,221 |
| From Central Funds | 15,838 | 23,709 | 32,000 |
| From Add-On Funds | 26,739 | 43,915 | 17,221 |

* Denotes Mission or Bureau Add-On Funds

2. Improved Service Delivery
e. Improving Resource Allocation (Continued)
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|---|---|---|--|
| ASIA/NEAR EAST: | | | |
| Bangladesh | | | |
| Cost of Family Planning | 0 * | 32,846 * | 0 * |
| Cost of Methods | 38,410 * | 157,871 * | 100,000 * |
| Thailand | | | |
| NORPLANT Delivery by Nurses | 6,653 | 18,097 | 0 |
| TOTAL ASIA/NEAR EAST | 45,063 | 208,814 | 100,000 |
| From Central Funds | 6,653 | 50,943 | 0 |
| From Add-On Funds | 38,410 | 157,871 | 100,000 |
| INTERREGIONAL: | | | |
| Interregional | | | |
| Service Delivery Research Devel. & Management | 149,649 | 107,993 | 137,000 |
| TOTAL INTERREGIONAL | 149,649 | 107,993 | 137,000 |
| From Central Funds | 149,649 | 107,993 | 137,000 |
| From Add-On Funds | 0 | 0 | 0 |
| TOTAL ALL REGIONS | 237,319 | 407,798 | 286,221 |
| From Central Funds | 172,170 | 208,212 | 189,000 |
| From Add-on Funds | 65,149 | 201,586 | 117,221 |

* Denotes Mission or Bureau Add-On Funds

2. Improved Service Delivery
f. - Improving Quality of Care
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|--------------------------------------|---|---|--|
| LATIN AMERICA/CARIBBEAN: | | | |
| Haiti | | | |
| Quality of Care | 159 * | 1,435 * | 7,421 * |
| TOTAL LATIN AMERICA/CARIBBEAN | 159 | 1,435 | 7,421 |
| From Central Funds | 0 | 0 | 0 |
| From Add-On Funds | 159 | 1,435 | 7,421 |
| INTERREGIONAL: | | | |
| Interregional | | | |
| Quality of Care in Serv. Deliv. | 41,167 | 58,846 | 17,741 |
| Quality of Care Workshop/PAHO | 16,259 | (2,463) | 15,381 |
| TOTAL INTERREGIONAL | 57,426 | 56,383 | 33,122 |
| From Central Funds | 57,426 | 56,383 | 33,122 |
| From Add-On Funds | 0 | 0 | 0 |
| TOTAL ALL REGIONS | 57,585 | 57,818 | 40,543 |
| From Central Funds | 57,426 | 56,383 | 33,122 |
| From Add-on Funds | 159 | 1,435 | 7,421 |

* Denotes Mission or Bureau Add-On Funds

3. Benefits and Risks of Contraceptive Methods
a. Long-Term Effects of Contraceptive Use
By Region and Funding Source

| | ACTUAL FY'83 4/83 - 3/83 | BUDGET FY'83 4/83 - 3/83 | BUDGET FY'84 10/83 - 3/84 |
|--------------------------------------|------------------------------------|------------------------------------|-------------------------------------|
| LATIN AMERICA/CARIBBEAN: | | | |
| Jamaica | | | |
| Case Control Study of CXCA | 27,096 | 29,901 | 0 |
| TOTAL LATIN AMERICA/CARIBBEAN | 27,096 | 29,901 | 0 |
| From Central Funds | 27,096 | 29,901 | 0 |
| From Add-on Funds | 0 | 0 | 0 |
| ASIA/NEAR EAST: | | | |
| S. Korea | | | |
| Vasectomy & Prostate Cancer | 4,592 | 11,106 | 48,702 |
| TOTAL ASIA/NEAR EAST | 4,592 | 11,106 | 48,702 |
| From Central Funds | 4,592 | 11,106 | 48,702 |
| From Add-on Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

3. Benefits and Risks of Contraceptive Methods
a. Long-Term Effects of Contraceptive Use (Continued)
By Region and Funding Source

| | ACTUAL FY'83 4/93 - 9/93 | BUDGET FY'83 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|--------------------------------|------------------------------------|------------------------------------|-------------------------------------|
| USA/EUROPE: | | | |
| USA | | | |
| Low Dose OCs for Older Women | (18) | 6,620 | 0 |
| Risks and Benefits of OCs | 27,308 | 100,722 | 51,733 |
| TOTAL USA/EUROPE | 27,290 | 107,342 | 51,733 |
| From Central Funds | 27,290 | 107,342 | 51,733 |
| From Add-on Funds | 0 | 0 | 0 |
| INTERREGIONAL: | | | |
| Interregional | | | |
| Vasectomy Technical Assistance | 84,375 | 8,666 | 54,027 |
| TOTAL INTERREGIONAL | 84,375 | 8,666 | 54,027 |
| From Central Funds | 84,375 | 8,666 | 54,027 |
| From Add-on Funds | 0 | 0 | 0 |
| TOTAL ALL REGIONS | 143,353 | 157,015 | 154,461 |
| From Central Funds | 143,353 | 157,015 | 154,461 |
| From Add-on Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

3. Benefits and Risks of Contraceptive Methods
b. Contraception and STDs
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|---------------------------------------|---|---|--|
| AFRICA: | | | |
| Kenya | | | |
| Reversible Contraception and HIV | (207)* | (207)* | 0* |
| Zambia | | | |
| Spermicide Use and HIV Infection | 11,794 | 7,895 | 0 |
| Female Condom: & HIV | 49,183 | 55,760 | 41,172 |
| TOTAL AFRICA | 60,770 | 63,448 | 41,172 |
| From Central Funds | 60,977 | 63,655 | 41,172 |
| From Add-on Funds | (207) | (207) | 0 |
| LATIN AMERICA/CARIBBEAN: | | | |
| Dominican Republic | | | |
| Condoms & Cervical Infection | 16,828 | 11,515 | 72,776 |
| Honduras | | | |
| Spermicides & HIV | 18,559 | 12,251 | 40,408 |
| TOTAL LATIN AMERICAN/CARIBBEAN | 35,387 | 23,766 | 113,184 |
| From Central Funds | 35,387 | 23,766 | 113,184 |
| From Add-on Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

3. Benefits and Risks of Contraceptive Methods
b. Contraception and STDs (Continued)
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|---------------------------------------|------------------------------------|------------------------------------|-------------------------------------|
| INTERREGIONAL: | | | |
| Interregional HIV/BF Paper Writing | 3,762 | 4,255 | 0 |
| TOTAL INTERREGIONAL | 3,762 | 4,255 | 0 |
| From Central Funds | 3,762 | 4,255 | 0 |
| From Add-on Funds | 0 | 0 | 0 |
| TOTAL ALL REGIONS | 98,919 | 91,489 | 154,356 |
| From Central Funds | 100,126 | 91,676 | 154,356 |
| From Add-on Funds | (207) | (207) | 0 |

* Denotes Mission or Bureau Add-On Funds

4. Research Utilization Activities
a. Publications/Information Dissemination
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|--------------------------------------|---|---|--|
| AFRICA: | | | |
| Multi-National Network in French | 49,551 | 43,864 | 77,000 |
| TOTAL AFRICA | 49,551 | 43,864 | 77,000 |
| From Central Funds | 49,551 | 43,864 | 77,000 |
| From Add-on Funds | 0 | 0 | 0 |
| LATIN AMERICA/CARIBBEAN: | | | |
| Multi-national Network in Spanish | 80,035 | 60,498 | 108,000 |
| TOTAL LATIN AMERICA/CARIBBEAN | 80,035 | 60,498 | 108,000 |
| From Central Funds | 80,035 | 60,498 | 108,000 |
| From Add-on Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

4. Research Utilization: Activities
a. Publications/Information Dissemination (Continued)
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|---|---|---|--|
| USA/EUROPE: | | | |
| Former Soviet Union Network in Russian | 25,411 | | 29,500 |
| TOTAL USA/EUROPE | 25,411 | 0 | 29,500 |
| From Central Funds | 25,411 | 0 | 29,500 |
| From Add-on Funds | 0 | 0 | 0 |
| INTERREGIONAL: | | | |
| Interregional | | | |
| Publications Catalogue | 7,598 | 11,523 | 2,000 |
| Information Dissemination | 84,843 | 32,184 | 104,000 |
| Slides/Cataloguing | 1,132 | | 18,500 |
| NETWORK | 159,054 | 121,686 | 150,000 |
| Translations | 38,978 | 41,581 | 20,000 |
| Development & Management | (74,476) | (127,835) | 87,000 |
| Health Journalists Training Guidebook | 39,131 | | 0 |
| TOTAL INTERREGIONAL | 256,260 | 79,139 | 381,500 |
| From Central Funds | 256,260 | 79,139 | 381,500 |
| From Add-on Funds | 0 | 0 | 0 |
| TOTAL ALL REGIONS | 411,257 | 183,501 | 596,000 |
| From Central Funds | 411,257 | 183,501 | 596,000 |
| From Add-on Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

4. Research Utilization Activities
b. Conferences/Workshops
By Region and Funding Source

| | ACTUAL FY'83 4/83 - 9/83 | BUDGET FY'83 4/83 - 9/83 | BUDGET FY'84 10/83 - 3/84 |
|--------------------------------------|---|---|--|
| AFRICA: | | | |
| Multi-National | | | |
| East/So. African Editors Workshop | 29,078 | 62,490 | 45,000 |
| TOTAL AFRICA | 29,078 | 62,490 | 45,000 |
| From Central Funds | 29,078 | 62,490 | 45,000 |
| From Add-on Funds | 0 | 0 | 0 |
| LATIN AMERICA/CARIBBEAN: | | | |
| Mexico | | | |
| LA Symposium on Family Planning | 1,325 | 1,272 | 0 |
| Multi-National | | | |
| International Postpartum Workshop | 36,983 | 24,279 | 13,000 |
| RMB Panama Workshop | 13,056 | | 99,290 |
| TOTAL LATIN AMERICA/CARIBBEAN | 51,364 | 25,551 | 112,290 |
| From Central Funds | 51,364 | 25,551 | 112,290 |
| From Add-on Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

4. Research Utilization Activities
b. Conferences/Workshops (Continued)
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|-----------------------------------|---|---|--|
| ASIA: | | | |
| Bangladesh | | | |
| PP Contraception | (8) | 204 | 0 |
| Multi-National | | | |
| RMB Manila Workshop | 44,114 | 42,999 | 111,768 |
| Philippines | | | |
| POGS Meeting | (546) | 0 | 0 |
| TOTAL ASIA | 43,560 | 43,203 | 111,768 |
| From Central Funds | 43,560 | 43,203 | 111,768 |
| From Add-on Funds | 0 | 0 | 0 |
| INTERREGIONAL: | | | |
| Interregional | | | |
| NORPLANT Bleeding | 44,663 | 135,064 | 23,667 |
| Conference Travel (Non FHI Staff) | 2,376 | 31,680 | 0 |
| Bellagio II Conference | 0 | 8,824 | 95 |
| Barrier Conference | 28,162 | 34,665 | 0 |
| TOTAL INTERREGIONAL | 75,201 | 210,233 | 23,762 |
| From Central Funds | 75,201 | 210,233 | 23,762 |
| From Add-on Funds | 0 | 0 | 0 |
| TOTAL ALL REGIONS | 199,203 | 341,477 | 292,820 |
| From Central Funds | 199,203 | 341,477 | 292,820 |
| From Add-on Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

4. Research Utilization Activities
c. Research Capacity Building
By Region and Funding Source

| | ACTUAL FY'83 4/83 - 9/83 | BUDGET FY'83 4/83 - 9/83 | BUDGET FY'84 10/83 - 3/84 |
|--------------------------------------|---|---|--|
| AFRICA: | | | |
| Kenya | | | |
| Reprod. Health/Res. Inst. Dev. Proj. | 16,529 | 16,961 | 10,000 |
| Reprod. Health/Res. Inst. Dev. Proj. | 72,852 * | (20,261) * | 125,000 * |
| Mali | | | |
| TA to Malien Family Planning Assoc. | 25,867 | 30,646 | 10,500 |
| Niger | | | |
| Technical Assistance to CNSF | (167) | (1,614) | 0 |
| TOTAL AFRICA | 115,081 | 25,732 | 145,500 |
| From Central Funds | 42,229 | 45,993 | 23,500 |
| From Add-on Funds | 72,852 | (20,261) | 125,000 |
| ASIA/NEAR EAST | | | |
| Bangladesh | | | |
| BIRPERHT Support | (273) | 6,583 | 0 |
| Nepal | | | |
| FP Strategy Development | 27 * | 9,550 * | 0 * |
| Egypt | | | |
| Inst. Devel. Project of the NPC | 717,221 * | 952,390 * | 206,000 * |
| Multi-National | | | |
| Policy Implementation/Thaps | 2,339 | | 11,000 |
| TOTAL ASIA/NEAR EAST | 719,314 | 968,523 | 217,000 |
| From Central Funds | 2,066 | 6,583 | 11,000 |
| From Add-on Funds | 717,248 | 961,940 | 206,000 |

* Denotes Mission or Bureau Add-On Funds

4. Research Utilization Activities
c. Research Capacity Building (Continued)
By Region and Funding Source

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|--|---|---|--|
| INTERREGIONAL: | | | |
| Interregional Institutional Development | (6,046) | (21,669) | 0 |
| TOTAL INTERREGIONAL | (6,046) | (21,669) | 0 |
| From Central Funds | (6,046) | (21,669) | 0 |
| From Add-on Funds | 0 | 0 | 0 |
| TOTAL ALL REGIONS | 828,349 | 972,586 | 362,500 |
| From Central Funds | 38,249 | 30,907 | 31,500 |
| From Add-on Funds | 790,100 | 941,679 | 331,000 |

* Denotes Mission or Bureau Add-On Funds

**5. Other Activities
By Region and Funding Source**

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 1Q/93 - 3/94 |
|---|-------------------------------------|-------------------------------------|--------------------------------------|
| AFRICA: | | | |
| Ghana | | | |
| Impact of TBA Training | 197 * | 0 * | 75,000 * |
| Kenya | | | |
| Office Support | 60,431 | 13,282 | 55,000 |
| FHI Nairobi Office | 25,579 | 48,480 | 26,500 |
| Nigeria | | | |
| Devel. & Management of Comp. Activities | 17,298 * | 276,803 * | 10,000 * |
| Family Health Serv. Project | 159,439 * | 177,945 * | 220,000 * |
| Multi-national | | | |
| Africa: Regional Program Development | 35,742 | 86,724 | 50,000 |
| Africa Devel. & Management | 1,947 | 28,867 | 12,300 |
| TOTAL AFRICA | 300,633 | 632,101 | 448,800 |
| From Central Funds | 123,699 | 177,353 | 143,800 |
| From Add-on Funds | 176,934 | 454,748 | 305,000 |
| LATIN AMERICA/CARIBBEAN: | | | |
| Multi-national | | | |
| Latin America Devel. & Management | 2,070 | 13,900 | 8,500 |
| TOTAL LATIN AMERICA/CARIBBEAN | 2,070 | 13,900 | 8,500 |
| From Central Funds | 2,070 | 13,900 | 8,500 |
| From Add-on Funds | 0 | 0 | 0 |

* Denotes Mission or Bureau Add-On Funds

**5. Other Activities (Continued)
By Region and Funding Source**

| | ACTUAL FY'93 4/93 - 9/93 | BUDGET FY'93 4/93 - 9/93 | BUDGET FY'94 10/93 - 3/94 |
|--|-------------------------------------|-------------------------------------|--------------------------------------|
| ASIA: | | | |
| Multi-national | | | |
| Asia/NE Devel. & Management | 1,442 | 30,621 | 16,200 |
| Nepal | | | |
| Nepal Country Office | 50,723 | 24,534 | 10,000 |
| Nepal Country Office | 29,779* | 97,223* | 135,538* |
| TOTAL ASIA | 81,944 | 152,378 | 161,738 |
| From Central Funds | 52,165 | 85,155 | 26,200 |
| From Add-on Funds | 29,779 | 97,223 | 135,538 |
| INTERREGIONAL: | | | |
| Interregional | | | |
| Spain: Society Advance Contraception | 35,429 | 11,678 | 0 |
| Health Communication/Training Development | 36,114 | 31,202 | 41,500 |
| Interregional Population Coop. Agr. Mgt. | 75,392 | 44,278 | 76,632 |
| Development and Management | 195,099 | 225,705 | 235,000 |
| FHI Library | 142,731 | 136,642 | 137,000 |
| Medical Review | 54,113 | 17,053 | 38,183 |
| TOTAL INTERREGIONAL | 538,878 | 466,558 | 528,315 |
| From Central Funds | 538,878 | 466,558 | 528,315 |
| From Add-on Funds | 0 | 0 | 0 |
| TOTAL ALL REGIONS | 923,325 | 1,264,937 | 1,147,353 |
| From Central Funds | 716,812 | 712,908 | 706,615 |
| From Add-on Funds | 206,713 | 551,971 | 440,538 |
| Staff Travel Time Allocated to Projects | (123,995) | (123,995) | NA |
| GRAND TOTAL ALL ACTIVITIES | 7,097,883 | 7,903,161 | 7,141,425 |
| From Central Funds | 5,926,072 | 6,016,818 | 6,052,319 |
| From Add-On Funds | 1,295,808 | 2,014,028 | 1,089,108 |

* Denotes Mission or Bureau Add-On Funds

APPENDICES

APPENDIX A

FHI Staff and Consultant Travel Undertaken

FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|---|
| USA | AL | 21-APR-1993 | 22-APR-1993 | CARTER TO PERFORM PRODUCTION SURVEILLANCE SAMPLING AT ALADAN, INC. |
| USA | AL | 27-APR-1993 | 02-MAY-1993 | PRICE TO ATTEND THE 19TH ANNUAL MEETING OF THE SOCIETY FOR BIOMATERIALS AND THE 25TH INTERNATIONAL BIOMATERIALS SYMPOSIUM. |
| USA | AL | 10-MAY-1993 | 10-MAY-1993 | BROWN TO PERFORM PRODUCTION SURVEILLANCE SAMPLING AT ALADAN, INC. |
| USA | AL | 07-JUN-1993 | 08-JUN-1993 | CARTER TO PERFORM A PRODUCTION SURVEILLANCE AUDIT OF ALADAN, INC. PRODUCTION FACILITIES. |
| USA | AL | 07-JUN-1993 | 08-JUN-1993 | BROWN TO PERFORM PRODUCTION SURVEILLANCE SAMPLING AT ALADAN CORPORATION. |
| USA | AL | 12-JUL-1993 | 12-JUL-1993 | BROWN TO VISIT ALADAN CORPORATION TO PERFORM PRODUCTION SURVEILLANCE SAMPLING. |
| USA | AL | 10-AUG-1993 | 11-AUG-1993 | BROWN TO PERFORM PRODUCTION SURVEILLANCE SAMPLING AND TO PERFORM COMPLIANCE AUDIT. |
| USA | AL | 09-SEP-1993 | 09-SEP-1993 | BROWN TO ALADAN TO PERFORM PRODUCTION SURVEILLANCE SAMPLING. |
| USA | AR | 19-SEP-1993 | 30-SEP-1993 | WILLIAMSON TO MONITOR THE VASECTOMY AND PROSTATE CANCER STUDY IN FORT SMITH, AR. |

FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|---|
| USA | CA | 01-MAY-1993 | 06-MAY-1993 | HARRIS TO ATTEND THE SOCIETY OF RESEARCH ADMINISTRATORS SECTION MEETING. |
| USA | CA | 07-JUL-1993 | 09-JUL-1993 | POTTER TO ATTEND KAISER FAMILY FOUNDATION FORUM ON OVER-THE-COUNTER ORAL CONTRACEPTIVES AND ALSO TO VISIT APREX CORPORATION HEADQUARTERS. |
| USA | CA | 18-JUL-1993 | 26-JUL-1993 | ROGERS TO ATTEND DYNAMIC GRAPHICS WORKSHOP "PUBLICATIONS DESIGN". |
| USA | CA | 28-JUL-1993 | 29-JUL-1993 | SCHWINGL TO MEET WITH ENDOCRINOLOGIST (DR. RONALD SWERDLOFF) ABOUT TEST FOR 5 REDUCTASE ACTIVITY IN URINE AND BLOOD TO BE INCLUDED IN THE PROPOSAL TO HYBRITECH WITH PROSTATE CANCER EDUCATION COUNCIL AND IN A LATER STUDY FOLLOWING VASECTOMIZED AND NON-VASECTOMIZED MEN. |
| USA | CA | 31-AUG-1993 | 02-SEP-1993 | CARTER TO ACCOMPANY MARK RILLING TO SYNTEX TO DISCUSS PROCUREMENT ISSUES. |
| USA | CA | 20-SEP-1993 | 29-SEP-1993 | KING TO MONITOR THE VASECTOMY AND PROSTATE CANCER STUDY. |
| USA | CO | 12-JUN-1993 | 18-JUN-1993 | SCHWINGL ATTEND THE SOCIETY FOR EPIDEMIOLOGIC RESEARCH 26TH ANNUAL MEETING. |
| USA | CO | 14-JUN-1993 | 20-JUN-1993 | ZHANG TO ATTEND THE SOCIETY FOR EPIDEMIOLOGIC RESEARCH ANNUAL MEETING. |

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FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|---|
| USA | DC | 01-APR-1993 | 01-APR-1993 | OMOHUNDRO TO ATTEND A MEETING IN THE MORNING WITH FEMCARE, FHI AND GYNAPARMA REPRESENTATIVES; AND TO ATTEND A MEETING IN THE AFTERNOON WITH CONRAD. |
| USA | DC | 01-APR-1993 | 01-APR-1993 | DORFLINGER TO ATTEND A MEETING WITH FEMCARE, FHI AND GYNAPARMA REPRESENTATIVES. |
| USA | DC | 05-APR-1993 | 06-APR-1993 | PALMORE TO MEET WITH THE REDUCTION OF MEDICAL BARRIERS STEERING COMMITTEE; AND TO MEET WITH STAFF AT AID RE: QUALITY OF SERVICES. |
| USA | DC | 06-APR-1993 | 08-APR-1993 | JANOWITZ TO ATTEND THE SERVICE DELIVERY WORKING GROUP MEETING WITH THE EVALUATION PROJECT. |
| USA | DC | 14-APR-1993 | 14-APR-1993 | VILLINSKI TO MEET WITH THE COUNTRY ANALYSIS WORKING GROUP OF THE MEDICAL BARRIERS COMMITTEE TO DISCUSS ANALYSIS OF QUESTIONNAIRE DATA. |
| USA | DC | 16-APR-1993 | 16-APR-1993 | HARDEE TO MEET WITH MAUREEN CLYDE OF THE FUTURES GROUP, AND RUTH LEVINE OF THE URBAN INSTITUTE TO DISCUSS A MEDICAL BARRIERS ASSESSMENT FOR JAMAICA. |
| USA | DC | 21-APR-1993 | 21-APR-1993 | HARDEE TO ATTEND THE COUNTRY ANALYSIS GROUP STEERING COMMITTEE MEETINGS AT USAID. |
| USA | DC | 21-APR-1993 | 21-APR-1993 | RIVERA TO ATTEND THE MEETING ON QUALITY OF CARE AND MEDICAL BARRIERS, HELD BY THE SERVICE DELIVERY WORKING GROUP. |

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FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|---|
| USA | DC | 21-APR-1993 | 21-APR-1993 | ADRIAN TO ATTEND THE REDUCTION OF MEDICAL BARRIERS MEETINGS HELD AT THE POPTech OFFICES; AND TO MEET WITH THE FUTURES GROUP REGARDING TECHNICAL ASSISTANCE FOR JAMAICA. |
| USA | DC | 21-APR-1993 | 22-APR-1993 | PALMORE TO ATTEND THE COUNTRY ANALYSIS MEETING AND THE MEDICAL BARRIERS STEERING COMMITTEE MEETING IN WASHINGTON, DC. ALSO TO ATTEND CONGRESSIONAL MEETINGS ON APRIL 23RD AT THE REQUEST OF ANNE HARRIS CLARKE, ASSOCIATION OF POPULATION CENTERS. |
| USA | DC | 03-MAY-1993 | 03-MAY-1993 | LEWIS TO MEET WITH JEFF SPIELER, JIM SHELTON AND CELIA WOODFILL OF THE USAID OFFICE OF POPULATION TO REVIEW AND DISCUSS THE 1994 BUDGETS. |
| USA | DC | 05-MAY-1993 | 06-MAY-1993 | HARDEE TO ATTEND A WORKING GROUP MEETING ON THE EVALUATION PROJECT ON ACCESS; AND TO CONTINUE WORKING WITH THE FUTURES GROUP ON THE JAMAICA RMB QUESTIONNAIRE. |
| USA | DC | 05-MAY-1993 | 05-MAY-1993 | RIVERA TO ATTEND A MEETING OF THE ACCESSIBILITY SUB-COMMITTEE OF THE SERVICE DELIVERY WORKING GROUP. |
| USA | DC | 05-MAY-1993 | 05-MAY-1993 | CONNELL TO MEET WITH MS. CATHERINE CAMERON AND STAFF OF POPULATION ACTION INTERNATIONAL TO DISCUSS POSSIBLE COLLABORATIONS ON PROGRAMS. |
| USA | DC | 18-MAY-1993 | 18-MAY-1993 | CONNELL TO ATTEND A MEETING AT AVSC, ALONG WITH AXCAN. |

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FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|--|
| USA | DC | 19-MAY-1993 | 20-MAY-1993 | CANAMAR TO ATTEND THE FDA ADVISORY COMMITTEE MEETING OF THE FERTILITY AND MATERNAL HEALTH DRUGS. |
| USA | DC | 28-MAY-1993 | 28-MAY-1993 | HARDEE TO WORK WITH PAHO ON QOC MODEL, AND TO ATTEND BIDDERS MEETING FOR GENDER RFA. |
| USA | DC | 03-JUN-1993 | 03-JUN-1993 | RIVERA TO ATTEND THE MEDICAL BARRIERS GUIDELINES WORKING GROUP AT USAID. |
| USA | DC | 03-JUN-1993 | 04-JUN-1993 | PALMORE TO CHAIR THE ORGANIZED EDUCATIONAL EVENTS MEETING AND ALSO ATTEND THE MEDICAL BARRIERS STEERING COMMITTEE MEETING AT USAID. |
| USA | DC | 13-JUN-1993 | 16-JUN-1993 | CONNELL TO ATTEND THE TECHNICAL ADVISORY COMMITTEE MEETING FOR CONRAD AND TO ATTEND AN FDA MEETING WITH H. MILLER AND L. DORFLINGER. |
| USA | DC | 17-JUN-1993 | 18-JUN-1993 | HARDEE TO ATTEND EVALUATION PROJECT MEETING WITH THE POLICY WORKING GROUP. |
| USA | DC | 18-JUN-1993 | 19-JUN-1993 | BARNETT TO ASSIST CONRAD WITH THE PROCEEDINGS FROM AN INTERNATIONAL WORKSHOP HELD IN THE DOMINICAN REPUBLIC, "BARRIER CONTRACEPTIVES: CURRENT STATUS AND FUTURE PROSPECTS." |
| USA | DC | 18-JUN-1993 | 23-JUN-1993 | JASINSKI TO ATTEND THE 20TH INTERNATIONAL HEALTH CONFERENCE "HEALTH AND THE ENVIRONMENT". |

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FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|--|
| USA | DC | 23-JUN-1993 | 24-JUN-1993 | HERNDON TO ATTEND AN INTER-AGENCY MEETING OF INFORMATION PEOPLE; AND TO ASSIST CONRAD WITH THE PROCEEDINGS OF A MEETING HELD IN THE DOMINICAN REPUBLIC. |
| USA | DC | 23-JUN-1993 | 23-JUN-1993 | NICHOLS TO ATTEND A STRATEGY SESSION AT POPULATION ACTION INTERNATIONAL. |
| USA | DC | 07-JUL-1993 | 07-JUL-1993 | LEWIS TO VISIT USAID OFFICE OF POPULATION TO REVIEW AND DISCUSS 1994 WORKPLAN AND PROGRAMS. |
| USA | DC | 14-JUL-1993 | 15-JUL-1993 | ADRIAN TO ATTEND THE ANNUAL JAMAICA COOPERATING AGENCIES COORDINATION MEETING. |
| USA | DC | 14-JUL-1993 | 14-JUL-1993 | PHILLIPS TO ATTEND THE SEMI-ANNUAL MEETING OF THE TRAINING MATERIALS WORKING GROUP AT DEVELOPMENT ASSOCIATES. |
| USA | DC | 15-JUL-1993 | 15-JUL-1993 | LEWIS TO MEET WITH THE NEW ADMINISTRATOR OF THE UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT ON POPULATION PRIORITIES. |
| USA | DC | 28-JUL-1993 | 01-AUG-1993 | PALMORE TO VISIT THE AGENCY FOR INTERNATIONAL DEVELOPMENT AND MEET WITH DR. JAMES SHELTON AND MS. JENNIFER SMITH TO DISCUSS THE STATUS OF THE CONTRACEPTIVE TECHNOLOGY UPDATE MODULES. |
| USA | DC | 30-JUL-1993 | 30-JUL-1993 | JANOWITZ TO MEET WITH JIM FOREIT OF THE INOPAL PROJECT AND BARBARA O'HANLON OF OPTIONS TO DISCUSS POSSIBLE COLLABORATION ON PROJECTS ON DEPO PROVERA INTRODUCTION AND MEDICAL BARRIERS. |

FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|--|
| USA | DC | 03-AUG-1993 | 03-AUG-1993 | HARDEE TO WORK WITH THE EVALUATION PROJECT POLICY WORKING GROUP ON DEFINING A FRAMEWORK FOR POLICY ANALYSIS. |
| USA | DC | 04-AUG-1993 | 04-AUG-1993 | RIVERA TO ATTEND A MEETING WITH JIM SHELTON TO DISCUSS MEDICAL BARRIERS ISSUES. |
| USA | DC | 04-AUG-1993 | 04-AUG-1993 | FLICK TO ATTEND A MEETING WITH USAID REGARDING THE U TECHNIQUE FOR REMOVAL OF NORPLANT. |
| USA | DC | 04-AUG-1993 | 04-AUG-1993 | DOMINIK TO MEET WITH A CONSULTANT AT AIDSCAP REGARDING A BENEFITS ISSUE AT THE REQUEST OF DR. T. KING. |
| USA | DC | 11-AUG-1993 | 11-AUG-1993 | PALMORE TRAVEL TO THE AGENCY FOR INTERNATIONAL DEVELOPMENT TO MEET WITH MARIA BUSQUETS-MOURA TO DISCUSS THE UPCOMING OFFICE OF POPULATION'S COOPERATING AGENCIES MEETING. |
| USA | DC | 19-AUG-1993 | 20-AUG-1993 | NICHOLS TO ATTEND THE TWO-DAY CONFERENCE ENTITLED "POPULATION DYNAMICS OF SUB-SAHARAN AFRICA" TO BE HELD AT THE NATIONAL ACADEMY OF SCIENCES. |
| USA | DC | 25-AUG-1993 | 25-AUG-1993 | PALMORE ATTEND THE POPULATION CONFERENCE MEETING IN WASHINGTON, DC. |
| USA | DC | 25-AUG-1993 | 25-AUG-1993 | ROBINSON TO ATTEND USAID MEETING AT FUTURES GROUP ON PLANNING FOR CAIRO ICPD. |

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FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|---|
| USA | DC | 30-AUG-1993 | 02-SEP-1993 | KING INTRODUCE COMPUTER NETWORK SET UP TO USERS IN DC. |
| USA | DC | 30-AUG-1993 | 02-SEP-1993 | SAYLOR TO CONDUCT TRAINING FOR THE DC OFFICE AND ASSIST IN THE INTRODUCTION OF THE COMPUTER NETWORK. |
| USA | DC | 07-SEP-1993 | 10-SEP-1993 | POTTS TO ATTEND THE MEDICAL BARRIERS MEETING AT USAID. |
| USA | DC | 08-SEP-1993 | 09-SEP-1993 | RIVERA TO ATTEND THE MEDICAL BARRIERS GUIDELINES WORKING GROUP. |
| USA | DC | 08-SEP-1993 | 09-SEP-1993 | DORFLINGER TO MEET WITH INSTITUTE OF MEDICINE, CONRAD AND USAID. |
| USA | DC | 09-SEP-1993 | 10-SEP-1993 | PALMORE TO ATTEND THE MEDICAL BARRIERS STEERING COMMITTEE MEETING. ALSO TO CHAIR THE ORGANIZED EDUCATIONAL EVENTS MEETING. |
| USA | DC | 11-SEP-1993 | 21-SEP-1993 | RAMOS TO ATTEND A CONFERENCE AT GEORGETOWN UNIVERSITY ENTITLED, "BREASTFEEDING AS A WOMEN'S ISSUE". DR. RAMOS WILL MODERATE AN AUDIENCE DISCUSSION ON THE TOPIC OF BREASTFEEDING, WOMEN'S HEALTH AND FAMILY PLANNING. (TRAVELLER FROM THE PHILIPPINES) |
| USA | DC | 12-SEP-1993 | 13-SEP-1993 | BISGROVE TO ATTEND THE MEETING ON "BREASTFEEDING AS A WOMEN'S ISSUE" HOSTED BY THE GEORGETOWN INSTITUTE FOR REPRODUCTIVE HEALTH. |
| USA | DC | 12-SEP-1993 | 13-SEP-1993 | VISNESS TO ATTEND A CONFERENCE AT GEORGETOWN UNIVERSITY ENTITLED "BREASTFEEDING AS A WOMEN'S ISSUE". |

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FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|--|
| USA | DC | 12-SEP-1993 | 14-SEP-1993 | DIAZ TO ATTEND A CONFERENCE AT GEORGETOWN UNIVERSITY ENTITLED "BREASTFEEDING AS A WOMEN'S ISSUE." DR. DIAZ WILL MODERATE THE CONCLUDING AUDIENCE DISCUSSION. (TRAVELLER FROM CHILE) |
| USA | DC | 13-SEP-1993 | 13-SEP-1993 | BRATT TO PARTICIPATE IN A MEETING OF THE EVALUATION PROJECT ON COSTS ANALYSIS. |
| USA | DC | 14-SEP-1993 | 14-SEP-1993 | HARDEE TO PARTICIPATE IN THE SERVICE DELIVERY WORKING GROUP OF THE EVALUATION PROJECT. |
| USA | DC | 15-SEP-1993 | 15-SEP-1993 | FINGER TO ATTEND THE MEETING OF POPULATION REPORT TOPICS AT USAID. |
| USA | DC | 20-SEP-1993 | 20-SEP-1993 | VILLINSKI TO PARTICIPATE IN THE CA COORDINATING COMMITTEE MEETING FOR JAMAICA. |
| USA | DC | 26-SEP-1993 | 27-SEP-1993 | HARDEE TO PARTICIPATE IN THE POLICY WORKING GROUP OF THE EVALUATION PROJECT. |
| USA | DC | 26-SEP-1993 | 28-SEP-1993 | OMOHUNDRO TO ATTEND THE FDA DEVICE CLINICAL TRIALS WORKSHOP. |
| USA | DC | 26-SEP-1993 | 27-SEP-1993 | SCHWINGL TO ATTEND THE NATIONAL CANCER INSTITUTE'S PROSTATE CANCER WORKSHOP TO BE HELD IN BETHESDA, MD. |

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FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|--|
| USA | DC | 26-SEP-1993 | 28-SEP-1993 | SOKAL TO ATTEND THE FDA DEVICE CLINICAL TRIALS WORKSHOP GIVEN BY THE FDA CENTER FOR DEVICES & RADIOLOGICAL HEALTH. |
| USA | DC | 26-SEP-1993 | 28-SEP-1993 | DOMINICK TO ATTEND FDA DEVICE CLINICAL TRIALS WORKSHOP. |
| USA | GA | 03-MAY-1993 | 04-MAY-1993 | HAWLEY TO ATTEND THE 1993 SOUTHPACK "UNIVERSITY OF PACKAGING" CONFERENCE. |
| USA | GA | 21-JUN-1993 | 22-JUN-1993 | CARTER TO ATTEND ASTM REGIONAL MEETING. |
| USA | GA | 27-SEP-1993 | 30-SEP-1993 | DISANTOSTEFANO TO ATTEND SPC CONFERENCE FOR MANUFACTURING PROCESSES. |
| USA | IL | 15-APR-1993 | 18-APR-1993 | BEAN TO ATTEND A TRAINING COURSE IN GRAPHIC DESIGN AT THE UNIVERSITY OF CHICAGO ENTITLED, "ESSENTIALS OF DESIGN FOR THE EDITOR." |
| USA | IL | 16-APR-1993 | 18-APR-1993 | CAMERON TO ATTEND A GRAPHIC DESIGN COURSE HELD BY THE UNIVERSITY OF CHICAGO PUBLISHING PROGRAM. |
| USA | IL | 15-MAY-1993 | 19-MAY-1993 | KHALAF TO ATTEND THE DYNAMIC GRAPHICS EDUCATIONAL FOUNDATION TRAINING COURSE, ENTITLED "DESIGN METHODS II." |
| USA | IL | 10-JUL-1993 | 15-JUL-1993 | MAYETTE TO ATTEND THE 29TH ANNUAL MEETING: DRUG INFORMATION ASSOCIATION "GLOBAL DRUG DEVELOPMENT: FOCUS ON THE AMERICAS". |

FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|--|
| USA | IL | 10-JUL-1993 | 17-JUL-1993 | DOMINIK TO ATTEND 29TH ANNUAL MEETING: DRUG INFORMATION ASSOCIATION "GLOBAL DRUG DEVELOPMENT: FOCUS ON THE AMERICAS". |
| USA | IL | 11-JUL-1993 | 15-JUL-1993 | DUNSON TO ATTEND THE DIA 29TH MEETING: "GLOBAL DRUG DEVELOPMENT: FOCUS ON THE AMERICAS". |
| USA | IL | 11-JUL-1993 | 15-JUL-1993 | DUNSON TO SERVE AS PERSONAL CARE ATTENDANT FOR RANDY DUNSON DURING HIS TRIP TO CHICAGO, IL IN ORDER TO ATTEND THE DIA 29TH MEETING: "GLOBAL DRUG DEVELOPMENT: FOCUS ON THE AMERICAS". |
| USA | IL | 17-AUG-1993 | 18-AUG-1993 | HEDGPETH TO ATTEND MANAGEMENT BRIEFING ON KEY ISSUES IN PREPRODUCTION QUALITY ASSURANCE AND CURRENT CHANGES TO GOOD MANUFACTURING PRACTICES FOR THE MEDICAL DEVICE INDUSTRY. |
| USA | IL | 18-AUG-1993 | 25-AUG-1993 | WILSON TO ATTEND THE 26TH ACS NATIONAL MEETING. |
| USA | IN | 18-MAY-1993 | 23-MAY-1993 | COLE TO ATTEND THE 16TH ANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICAL WORKSHOP. |
| USA | KS | 02-JUN-1993 | 02-JUN-1993 | WILSON TO VISIT MIDWEST RESEARCH INSTITUTE TO REVIEW MDA ANALYSIS APPLICATION. |
| USA | KY | 20-SEP-1993 | 24-SEP-1993 | JASINKI TO MONITOR THE VASECTOMY AND PROSTATE CANCER STUDY. |

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FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| Country | State | Start Date | End Date | Traveler |
|---------|-------|-------------|-------------|---|
| USA | MA | 08-JUL-1993 | 08-JUL-1993 | HOVIS TO PERFORM AUDIT/INSPECTION OF MASSACHUSETTS COLLEGE OF PHARMACY AND ALLIED HEALTH SCIENCES LABORATORY. |
| USA | MA | 08-JUL-1993 | 08-JUL-1993 | WILSON TO PERFORM AUDIT/INSPECTION OF MASSACHUSETTS COLLEGE OF PHARMACY AND ALLIED HEALTH SCIENCES LABORATORY. |
| USA | MA | 12-AUG-1993 | 12-AUG-1993 | JOHNSON TO OBSERVE IODINE PROCESSING TECHNIQUES AT MASSACHUSETTS COLLEGE OF PHARMACY AND ALLIED HEALTH SCIENCE. |
| USA | MA | 12-AUG-1993 | 12-AUG-1993 | WILSON TO OBSERVE IODINE PROCESSING TECHNIQUES AT MASSACHUSETTS COLLEGE OF PHARMACY AND ALLIED HEALTH SCIENCES. |
| USA | MA | 23-AUG-1993 | 24-AUG-1993 | GOULD TO ATTEND A PLANNING MEETING IN NEWTON, MA AT MANAGEMENT SCIENCES FOR HEALTH FOR A QUALITY OF CARE WORKSHOP IN GUADALAJARA, MEXICO WITH REPRESENTATIVES OF FAMILY PLANNING MANAGEMENT DEVELOPMENT PROJECT, POPULATION COUNCIL/INOPAL AND MEXFAM. |
| USA | MD | 13-APR-1993 | 15-APR-1993 | OMOHUNDRO TO ATTEND ASQC SEMINAR, "BIOMEDICAL TECHNIQUES AND TOOLS FOR FDA REGULATORY SUBMISSIONS." |
| USA | MD | 10-MAY-1993 | 12-MAY-1993 | MORRISON TO ATTEND THE NIH CONFERENCE, "BEHAVIORIAL RESEARCH ON THE ROLE OF CONDOMS IN REPRODUCTIVE HEALTH". |
| USA | MD | 10-MAY-1993 | 12-MAY-1993 | STEINER TO ATTEND THE NIH CONFERENCE, "BEHAVIORIAL RESEARCH ON THE ROLE OF CONDOMS IN REPRODUCTIVE HEALTH". |

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FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| Country | State | Start Date | End Date | Traveler |
|---------|-------|-------------|-------------|--|
| USA | MD | 01-JUN-1993 | 01-JUN-1993 | CARTER TO ATTEND FDA CONDOM RESEARCH MEETINGS. |
| USA | MD | 19-JUN-1993 | 09-JUL-1993 | KIGONDU TO ATTEND DATA ANALYSIS COURSE AT JOEN HOPKINS UNIVERSITY. (TRAVELLER FROM KENYA) |
| USA | MI | 02-JUN-1993 | 04-JUN-1993 | WILSON TO VISIT NATIONAL SANITATION FOUNDATION TO REVIEW MDA ANALYSIS APPLICATION; AND TO VISIT DOW CHEMICAL TO DISCUSS TOXICOLOGICAL ISSUES. |
| USA | MI | 01-JUL-1993 | 01-JUL-1993 | HOVIS TO CONDUCT CONTRACT LAB AUDIT OF NSF. |
| USA | MI | 01-JUL-1993 | 01-JUL-1993 | WILSON TO VISIT NSF WITH VALERIE PALUMBO TO PERFORM AUDIT. |
| USA | MN | 20-JUL-1993 | 26-JUL-1993 | CUMMINGS TO ATTEND COURSE TITLED "CLINICAL STUDIES FOR MEDICAL DEVICES" HELD BY THE CENTER FOR PROFESSIONAL ADVANCEMENT. |
| USA | NC | 12-APR-1993 | 13-APR-1993 | PAVLOFF TO PERFORM A SYSTEMS OPERATIONS REVIEW OF FHI. |
| USA | NC | 22-APR-1993 | 22-APR-1993 | JEIVEN TO PRESENT TO FHI STAFF AN OVERVIEW OF THE MEMS DEVICE, AND TO TRAIN BOTH FHI STAFF AND PROJECT SITE STAFF IN THE USE OF THIS DEVICE. |
| USA | NC | 23-APR-1993 | 25-APR-1993 | HARDESTY TO ATTEND THE 7TH ANNUAL CONFERENCE OF THE CAROLINA ASSOCIATION OF TRANSLATORS AND INTERPRETERS. |

FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|---|
| USA | NC | 26-APR-1993 | 26-APR-1993 | PRICE TO VISIT SOUTHERN TESTING, INC. TO DISCUSS POTENTIAL FOR EXTRACTION ANALYSIS OF POLYURETHANE FOR THE PLASTIC CONDOM. |
| USA | NC | 27-APR-1993 | 27-APR-1993 | HEDGPETH TO VISIT DUNSIRN INDUSTRIES TO HAVE PLASTIC FILM FOR LCS SLIT. |
| USA | NC | 01-MAY-1993 | 15-MAY-1993 | OMONDI-ODHIAMBO THE SCOPE OF WORK FOR DR. ODHIAMBO INCLUDED MEETING WITH FHI/NC STAFF TO BECOME FAMILIAR WITH FHI RESEARCH POLICIES, PROCEDURES, AND PRIORITIES; TO FINALIZE PLANS FOR THE PILL COMPLIANCE STUDY TO BE CONDUCTED UNDER THE INSTITUTIONAL DEVELOPMENT PROJECT, AND TO DEVELOP THE PROPOSED STUDY TO DETERMINE THE IMPACT OF REMOVING THE CLINIC VISIT FROM THE CBD PROGRAM TO BE CONDUCTED WITH THE FAMILY PLANNING ASSOCIATION OF KENYA (FPAK). (TRAVELLER FROM KENYA) |
| USA | NC | 12-MAY-1993 | 15-MAY-1993 | FLICK TO ATTEND THE CLINICAL TRIALS MANAGEMENT WORKSHOP I. |
| USA | NC | 12-MAY-1993 | 14-MAY-1993 | DELGADO TO MEET WITH FHI STAFF AND GAIN A BETTER UNDERSTANDING OF OUR CAPABILITIES IN FAMILY PLANNING RESEARCH AND TECHNICAL ASSISTANCE; COLLABORATIVE OPPORTUNITIES WILL BE DISCUSSED. TO FINALIZE THE DESIGN OF A NEW STUDY OF INJECTABLE USERS. (TRAVELLER FROM MEXICO) |
| USA | NC | 29-MAY-1993 | 15-JUN-1993 | STANG TO ASSIST IN THE PRODUCTION OF THE POSTPARTUM AND LAM MODULES. |
| USA | NC | 04-JUN-1993 | 04-JUN-1993 | HAWLEY TO ACCOMPANY HOWARD PRICE AND DAVE JOHNSON TO DIXIE MACHINE TOOL COMPANY TO DISCUSS FABRICATION OF COMPONENTS FOR THE STRESS-SOFTENER MACHINE. |

FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3893,6000-999

| Country | State | Start Date | End Date | Traveler |
|---------|-------|-------------|-------------|---|
| USA | NC | 08-JUN-1993 | 10-JUL-1993 | JESENCKY TO MEET WITH FHI/NC STAFF TO DISCUSS FHI INITIATIVES SUCH AS MEDICAL BARRIERS AND PLAN FOR UPCOMING ACTIVITIES IN EAST AND SOUTHERN AFRICA |
| USA | NC | 08-JUN-1993 | 12-JUN-1993 | PIYA-ANANT TO ATTEND THE MEETING ON LONG ACTING PROGESTINS: MANAGEMENT OF BLEEDING DISTURBANCES BEING HELD BY FHI. (TRAVELLER FROM THAILAND) |
| USA | NC | 08-JUN-1993 | 12-JUN-1993 | MASSAI TO ATTEND THE MEETING ON LONG ACTING PROGESTINS: MANAGEMENT OF BLEEDING DISTURBANCES BEING HELD BY FHI. (TRAVELLER FROM CHILE) |
| USA | NC | 08-JUN-1993 | 11-JUN-1993 | D'ARCANGUES TO ATTEND THE MEETING ON LONG ACTING PROGESTINS: MANAGEMENT OF BLEEDING DISTURBANCES IN RTP, NC. (TRAVELLER FROM SWITZERLAND) |
| USA | NC | 09-JUN-1993 | 11-JUN-1993 | SMITH TO WORK WITH LUCY HARBER ON THE REVISION OF THE PAKISTAN CUE AND DEPO SLIDES FOR THE PAKISTAN MEETING; TO MEET WITH ROBERTO RIVERA AND OTHER MEMBERS OF THE MEDICAL BARRIERS WORKING GROUP ON THEIR GUIDELINES; AND TO ATTEND THE MEETING ON BLEEDING DISTURBANCES OF LONG-ACTING PROGESTINS TO BE HELD AT THE GUEST QUARTERS HOTEL ON JUNE 10-11. |
| USA | NC | 09-JUN-1993 | 11-JUN-1993 | DIAZ TO ATTEND THE MEETING ON LONG ACTING PROGESTINS: MANAGEMENT OF BLEEDING DISTURBANCES BEING HELD BY FHI. (TRAVELLER FROM CHILE). |
| USA | NC | 09-JUN-1993 | 11-JUN-1993 | ALVAREZ TO ATTEND THE MEETING ON THE LONG ACTING PROGESTINS: MANAGEMENT OF BLEEDING DISTURBANCES BEING HELD BY FHI. (TRAVELLER FROM DOMINICAN REPUBLIC) |

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FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|--|
| USA | NC | 11-JUN-1993 | 11-JUN-1993 | GENTILE TO BE BRIEFED ON MEDICAL ISSUES IN PAKISTAN IN PREPARATION FOR CTU CONFERENCE IN PAKISTAN, JUNE 21-25, 1993. |
| USA | NC | 25-JUN-1993 | 19-JUL-1993 | MCMULLEN TO BE UPDATED ON QUINACRINE RETROSPECTIVE STUDY AND TO PARTICIPATE IN BRIEFING ON CURRENT AND FUTURE QUINACRINE PROJECTS. ALSO, WILL BRIEF IN-HOUSE STAFF ON FIELD EXPERIENCES WITH THE POC STUDY AND TRAINING MANUALS THAT MS. MCMULLEN HAS BEEN DEVELOPING IN THE FIELD. |
| USA | NC | 28-JUN-1993 | 02-JUL-1993 | LAPIDO TO ATTEND THE ANNUAL TAC MEETING. (TRAVELLER FROM MEXICO) |
| USA | NC | 29-JUN-1993 | 01-JUL-1993 | HARPER TO ATTEND THE ANNUAL TAC MEETING. |
| USA | NC | 29-JUN-1993 | 02-JUL-1993 | AGUILLAME TO ATTEND THE ANNUAL TAC MEETING. |
| USA | NC | 30-JUN-1993 | 02-JUL-1993 | MANAUTOU TO ATTEND THE ANNUAL TAC MEETING. (TRAVELLER FROM BRAZIL) |
| USA | NC | 30-JUN-1993 | 01-JUL-1993 | ROOKS TO ATTEND THE ANNUAL TAC MEETING. |
| USA | NC | 30-JUN-1993 | 01-JUL-1993 | BROWN TO ATTEND THE ANNUAL TAC MEETING. |
| USA | NC | 30-JUN-1993 | 02-JUL-1993 | SENANAYAKE TO ATTEND THE ANNUAL TAC MEETING. |
| USA | NC | 30-JUN-1993 | 01-JUL-1993 | ANDERSON TO ATTEND THE ANNUAL TAC MEETING. |

FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|---|
| USA | NC | 30-JUN-1993 | 01-JUL-1993 | SHAIN TO ATTEND THE ANNUAL TAC MEETING. |
| USA | NC | 30-JUN-1993 | 03-JUL-1993 | KHANNA TO ATTEND THE ANNUAL TAC MEETING. |
| USA | NC | 30-JUN-1993 | 01-JUL-1993 | ATKINSON TO ATTEND THE ANNUAL TAC MEETING. |
| USA | NC | 30-JUN-1993 | 01-JUL-1993 | ROBBINS TO ATTEND THE ANNUAL TAC MEETING. |
| USA | NC | 01-JUL-1993 | 01-JUL-1993 | CATES TO ATTEND THE ANNUAL TAC MEETING. |
| USA | NC | 15-JUL-1993 | 15-JUL-1993 | JASS TO CONDUCT INTERVIEW FOR THE POSITION OF POTENTIAL CONSULTANT. |
| USA | NC | 21-JUL-1993 | 29-JUL-1993 | KIGONDU TO MEET WITH FHI-NC STAFF AND DISCUSS POSSIBLE FUTURE COLLABORATION. (TRAVELLER FROM KENYA) |
| USA | NC | 26-JUL-1993 | 27-JUL-1993 | NKWI TO WORK WITH ANDY THOMPSON ON THE STUDY FOR THE REDUCTION OF MEDICAL BARRIERS IN CAMEROON. |
| USA | NC | 05-AUG-1993 | 17-AUG-1993 | DIABATE TO COLLABORATE ON WORK RELATED TO THE MALI POSTPARTUM IUD STUDY AND TO PROVIDE INPUT INTO THE RESEARCH DESIGN FOR THE UPCOMING OPERATIONS RESEARCH PROJECT RELATED TO NORPLANT INTRODUCTION IN MALI. (TRAVELLER FROM MALI) |

FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPUIATION FUNDS 2000-3895,6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|---|
| USA | NC | 26-AUG-1993 | 29-AUG-1993 | FLICK TO ATTEND A CLINICAL TRIALS MANAGEMENT WORKSHOP II IN WINSTON-SALEM, NC. |
| USA | NC | 30-AUG-1993 | 31-AUG-1993 | SHERMAN TO MEET WITH FHI STAFF TO CONSIDER FAMILY PLANNING, MCH AND AIDS ACTIVITIES IN LIBERIA AND THROUGHOUT THE REGION. |
| USA | NC | 03-SEP-1993 | 03-SEP-1993 | KAFABI TO BE UPDATED ON FHI'S LATEST RESEARCH AND DISCUSS POSSIBLE RESEARCH ACTIVITIES FOR EUROPE. (TRAVELLER FROM EGYPT) |
| USA | NC | 06-SEP-1993 | 11-SEP-1993 | RAMOS TO MEET WITH THE STAFF OF FHI TO DISCUSS PROGRESS OF ONGOING FHI WORK IN THE PHILIPPINES; TO PLAN FOR FUTURE FHI ACTIVITIES; AND TO WORK ON THE PREPARATION OF LAM RESULTS FOR THE ASIA/OCEANIC CONGRESS OF OB/GYN IN NOVEMBER. (TRAVELLER FROM THE PHILIPPINES) |
| USA | NC | 09-SEP-1993 | 09-SEP-1993 | MCWILLIAM TO DISCUSS POSSIBLE ISTI/FHI COLLABORATION ON MALAWI RFP. TO WORK WITH SUSAN MCINTYRE ON FHS PROJECT IN NIGERIA. |
| USA | NC | 15-SEP-1993 | 18-SEP-1993 | PIEDRAHITA TO WORK WITH MARKUS STEINER TO FINALIZE DUAL METHOD DATA COLLECTION INSTRUMENTS FOR A STUDY INITIATION. |
| USA | NC | 15-SEP-1993 | 16-SEP-1993 | SMITH TO WORK WITH LUCY HARBER ON THE IUD AND COMBINED ORAL CONTRACEPTIVE SLIDES FOR DR. SHELTON AND TO WORK ON BARRIER METHODS SLIDES WITH SUSAN PALMORE. |

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FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|---|
| USA | NC | 20-SEP-1993 | 22-SEP-1993 | CARTER TO PERFORM PRODUCTION SURVEILLANCE AUDITS AT SHARP PACKAGING AND FINISHING ENTERPRISES. |
| USA | NJ | 20-JUL-1993 | 23-JUL-1993 | PALUMBO TO ATTEND A 3-DAY INTENSIVE TRAINING COURSE "SAFETY EVALUATION ON MEDICAL DEVICES". |
| USA | NJ | 08-AUG-1993 | 11-AUG-1993 | MARTINEZ TO ATTEND THE ADVERSE DRUG EVENT MONITORING AND REPORTING COURSE. |
| USA | NJ | 16-AUG-1993 | 17-AUG-1993 | CARTER TO ACCOMPANY JESSE MABELLOS OF FHI AND MARK RILLING OF AID TO ORTHO PHARMACEUTICALS TO DISCUSS PROCUREMENT ISSUES. |
| USA | NJ | 16-AUG-1993 | 17-AUG-1993 | MABELLOS TO ACCOMPANY ELI CARTER OF FHI AND MARK RILLING OF A.I.D TO ORTHO PHARMACEUTICALS TO DISCUSS PROCUREMENT ISSUES. |
| USA | NY | 28-APR-1993 | 29-APR-1993 | FINGER TO ATTEND A MEDIA COORDINATION MEETING, SPONSORED BY THE APHA COMMUNICATIONS TASK FORCE; AND TO MEET WITH VARIOUS CA'S AND UNFPA RE: FUTURE NETWORK ISSUES. |
| USA | NY | 29-APR-1993 | 30-APR-1993 | MONTZITH TO MONITOR NET PELLETS STUDY #890 (CENTER #952). |
| USA | NY | 08-MAY-1993 | 12-MAY-1993 | MONTGOMERY TO ATTEND ANNUAL S.U.G.I. WORKSHOP. |
| USA | NY | 16-JUN-1993 | 17-JUN-1993 | CARTER TO CONDUCT PRODUCTION SURVEILLANCE AUDIT OF FINISHING ENTERPRISES COPPER-T 380A IUD MANUFACTURING AND DISTRIBUTION OPERATIONS. |

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FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-999

| Country | State | Start Date | End Date | Traveler |
|---------|-------|-------------|-------------|--|
| USA | NY | 22-JUN-1993 | 22-JUN-1993 | ROMOCKI TO VISIT THE POPULATION COUNCIL STAFF, MS. MARTHA BRADY, DR. JUAN DIAZ, AND DR. DAVY CHIKAMATA TO DISCUSS FEMALE BARRIER METHODS AND SET DESIGN FOR INFORMATION, EDUCATION, AND COMMUNICATION MATERIALS. |
| USA | NY | 23-JUN-1993 | 23-JUN-1993 | PALMORE TO VISIT THE POPULATION COUNCIL STAFF, MS. MARTHA BRADY, DR. JUAN DIAZ, AND DR. DAVY CHIKAMATA TO DISCUSS FEMALE BARRIER METHODS AND SET DESIGN FOR INFORMATION, EDUCATION, AND COMMUNICATION MATERIALS. |
| USA | NY | 30-JUN-1993 | 05-JUL-1993 | MONTEITH TO MONITOR THE NET PELLET STUDY (CENTER #890). |
| USA | NY | 21-JUL-1993 | 21-JUL-1993 | MONTEITH TO MONITOR THE NET PELLET STUDY AND TO INTRODUCE DAPHNE MARTINEZ AS THE NEW MONITOR FOR THIS STUDY. |
| USA | NY | 21-JUL-1993 | 21-JUL-1993 | MARTINEZ TO MONITOR THE NET PELLETS STUDY AND TO BE INTRODUCED AS THE NEW MONITOR FOR THIS STUDY. |
| USA | NY | 05-AUG-1993 | 09-AUG-1993 | PALMORE TO MEET WITH STAFF AT THE POPULATION COUNCIL AND THE THE ASSOCIATION FOR VOLUNTARY SURGICAL CONTRACEPTION TO DISCUSS MEDICAL BARRIERS AND EXPLORE OPPORTUNITIES FOR COLLABORATIVE PROJECTS. |
| USA | NY | 30-AUG-1993 | 06-SEP-1993 | PALMORE TO PARTICIPATE IN A MEETING WITH THE POPULATION COUNCIL AND IWEC TO DISCUSS THE ACCEPTABILITY COMPONENT OF THE DIAPHRAGM STUDY. ALSO TO DISCUSS THE MANILA AND PANAMA CITY REGIONAL MEETING SHOPS WITH AVSC AND THE POPULATION COUNCIL. |

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FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| Country | State | Start Date | End Date | Traveler |
|---------|-------|-------------|-------------|---|
| USA | NY | 31-AUG-1993 | 01-SEP-1993 | ADRIAN TO PARTICIPATE IN A MEETING WITH THE POPULATION COUNCIL AND IWEC TO DISCUSS THE ACCEPTABILITY COMPONENT OF THE DIAPHRAGM STUDY AND TO DISCUSS THE MANILA AND PANAMA CITY REGIONAL WORKSHOPS WITH THE AVSC AND THE POPULATION COUNCIL. |
| USA | NY | 01-SEP-1993 | 01-SEP-1993 | JOANIS TO MEET WITH THE POPULATION COUNCIL REGARDING FUTURE DIAPHRAGM ACCEPTABILITY STUDY. |
| USA | NY | 09-SEP-1993 | 10-SEP-1993 | MARTINEZ TO MONITOR THE NET PELLETT STUDY. |
| USA | NY | 10-SEP-1993 | 12-SEP-1993 | JANOWITZ TO PARTICIPATE IN A MEETING OF THE EVALUATION PROJECT ON COSTS ANALYSIS AND TO ATTEND THE REGULARLY SCHEDULED MEETING. |
| USA | NY | 18-SEP-1993 | 26-SEP-1993 | ROBINSON TO ATTEND ADDRESS ON POPULATION AND DEVELOPMENT AT THE UNITED NATIONS, SPONSORED BY THE EMINENT CITIZEN'S COMMITTEE FOR CAIRO 1994 AND TO ATTEND COMMUNICATION'S TASK FORCE COMMITTEE AT AVSC. |
| USA | NY | 21-SEP-1993 | 22-SEP-1993 | CARTER TO PERFORM PRODUCTION SURVEILLANCE AUDITS AT SHARP PACKAGING AND FINISHING ENTERPRISES. |
| USA | PA | 05-APR-1993 | 05-APR-1993 | FARR TO MEET WITH REPRESENTATIVES OF BIOSYN, INC. TO DISCUSS POTENTIAL COLLABORATION ON A FUTURE CONTRACEPTIVE DEVELOPMENT PROJECT. |

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FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|--|
| USA | PA | 05-APR-1993 | 05-APR-1993 | SOKAL TO MEET WITH REPRESENTATIVES OF BIOSYN, INC. TO DISCUSS POTENTIAL COLLABORATION ON A FUTURE CONTRACEPTIVE DEVELOPMENT PROJECT. |
| USA | PA | 20-SEP-1993 | 21-SEP-1993 | CARTER TO PERFORM PRODUCTION SURVEILLANCE AUDITS AT SHARP PACKAGING AND FINISHING ENTERPRISES. |
| USA | SC | 04-JUL-1993 | 10-JUL-1993 | FLICK TO ATTEND THE NCAFP CONFERENCE. |
| USA | SC | 25-JUL-1993 | 28-JUL-1993 | KEWNEDY TO ATTEND THE ANNUAL PHYSICIAN'S SEMINAR OF LALECHE LEAGUE, INTERNATIONAL FEATURING A SESSION ON THE ROLE OF BREASTFEEDING IN DEVELOPING COUNTRIES. |
| USA | TN | 19-SEP-1993 | 24-SEP-1993 | GRIFFITH TO MONITOR THE VASECTOMY AND PROSTATE CANCER STUDY. |
| USA | TN | 19-SEP-1993 | 24-SEP-1993 | THOMPSON TO MONITOR VASECTOMY AND PROSTATE CANCER STUDY. |
| USA | TN | 26-SEP-1993 | 30-SEP-1993 | VISNESS TO MONITOR THE VASECTOMY AND PROSTATE CANCER STUDY. |
| USA | TX | 05-JUN-1993 | 09-JUN-1993 | NOWELL TO ATTEND THE 40TH ANNUAL CONFERENCE OF THE SOCIETY FOR TECHNICAL COMMUNICATION. |

FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|--|
| USA | VA | 06-APR-1993 | 06-APR-1993 | RIVERA TO ATTEND THE SERVICE DELIVERY WORKING GROUP MEETING ON QUALITY OF CARE AND MEDICAL BARRIERS. |
| USA | VA | 07-APR-1993 | 07-APR-1993 | CARTER TO CONDUCT PRODUCTION SURVEILLANCE SAMPLING AT SAFETEX CORP. |
| USA | VA | 01-MAY-1993 | 07-MAY-1993 | HARDESTY TO ATTEND THE CERTIFIED INTERPRETER'S EXAMINATION SPANISH TRANSLATION WORKSHOP. |
| USA | VA | 02-MAY-1993 | 06-MAY-1993 | WILSON TO ATTEND THE ANNUAL REGULATOR AFFAIRS PROFESSIONAL SOCIETY'S REGULATORY WORKSHOP AND EXHIBIT SEMINAR. |
| USA | VA | 02-MAY-1993 | 05-MAY-1993 | BLEVINS TO ATTEND THE REGULATORY AFFAIRS PROFESSIONAL SOCIETY REGULATORY WORKSHOP AND EXHIBIT SEMINAR. |
| USA | VA | 12-MAY-1993 | 12-MAY-1993 | CARTER TO MEET WITH THE STAFF OF SAFETEX REGARDING THE PRODUCTION SURVEILLANCE PROGRAM. |
| USA | VA | 20-MAY-1993 | 20-MAY-1993 | CARTER TO PERFORM PRODUCTION SURVEILLANCE SAMPLING AT SAFETEX, INC. |
| USA | VA | 01-JUN-1993 | 01-JUN-1993 | BROWN TO PERFORM PRODUCTION SURVEILLANCE SAMPLING AT SAFETEX, INC. |
| USA | VA | 02-JUN-1993 | 03-JUN-1993 | CARTER TO INSPECT USAID COMMODITY WAREHOUSE AND MEET WITH STAFF THERE, AND TO MEET WITH USAID/CPSD STAFF. |

FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|---|
| USA | VA | 03-JUN-1993 | 03-JUN-1993 | ADRIAN TO ATTEND THE ORGANIZED EDUCATIONAL EVENTS WORKING GROUP MEETING AT THE POPTECH OFFICE. |
| USA | VA | 20-JUN-1993 | 23-JUN-1993 | BLANEY TO ATTEND THE 20TH ANNUAL INTERNATIONAL HEALTH CONFERENCE. |
| USA | VA | 27-JUN-1993 | 30-JUN-1993 | MONTEITH TO MONITOR THE NET PELLETT STUDY (CENTER #908). |
| USA | VA | 08-JUL-1993 | 09-JUL-1993 | CARTER TO PERFORM AUDIT AND SAMPLING AT SAFTEX FOR THE PRODUCTION SURVEILLANCE PROGRAM. |
| USA | VA | 19-JUL-1993 | 19-JUL-1993 | MONTEITH TO MONITOR THE NET PELLETT STUDY AND TO INTRODUCE DAPHNE MARTINEZ AS THE NEW MONITOR FOR THE STUDY. |
| USA | VA | 19-JUL-1993 | 19-JUL-1993 | MARTINEZ TO MONITOR THE NET PELLETT STUDY AND TO BE INTRODUCED AS THE NEW MONITOR FOR THIS STUDY. |
| USA | VA | 20-JUL-1993 | 23-JUL-1993 | CARTER TO SAMPLE PANALPINA'S WAREHOUSE AND PREPARE TEST SHIPMENTS TO THE PHILIPPINES AND TO MEET WITH MARK RILLING (CPSD). |
| USA | VA | 12-AUG-1993 | 13-AUG-1993 | CARTER TO MEET WITH RON DAVIS OF SAFETEX TO PERFORM PRODUCTION SURVEILLANCE SAMPLING AND AUDIT. |
| USA | VA | 12-SEP-1993 | 14-SEP-1993 | MARTINEZ TO MONITOR THE NET PELLETT STUDY. |

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FAMILY HEALTH INTERNATIONAL
 DOMESTIC TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-999

| <u>Country</u> | <u>State</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|----------------|--------------|-------------------|-----------------|--|
| USA | VT | 20-SEP-1993 | 28-SEP-1993 | GOULD TO MONITOR THE VASECTOMY AND PROSTATE CANCER STUDY. |
| USA | WA | 29-AUG-1993 | 02-SEP-1993 | BROWN TO MEET WITH REPRESENTATIVES AT PATH TO DISCUSS CONDOM TESTING AND THE UNIJECT PROJECT. |
| USA | WA | 29-AUG-1993 | 31-AUG-1993 | CARTER TO MEET WITH REPRESENTATIVES AT PATH TO DISCUSS CONDOM TESTING AND THE UNIJECT PROJECT. |
| USA | WA | 29-AUG-1993 | 30-AUG-1993 | PRICE TO MEET WITH REPRESENTATIVES AT PATH TO DISCUSS CONDOM TESTING AND THE UNIJECT PROJECT. |
| USA | WA | 15-SEP-1993 | 16-SEP-1993 | RODDY TO MEET WITH DR. MILTON TAM AT PATH TO DISCUSS TESTING NEW STF DIAGNOSTICS AND EQUIPMENT IN THE CONDOMS AND CERVICAL INFECTION STUDY AND THE HIV AND M-9 STUDY. THESE TESTS WOULD BE VALIDATED BY THE GOLD STANDARDS USED IN THE STUDIES. |

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FAMILY HEALTH INTERNATIONAL
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Region</u> | <u>Country</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|---------------|----------------|-------------------|-----------------|---|
| AFR | CAMEROON | 28-JUN-1993 | 18-JUL-1993 | ADRIAN TO DEVELOP DATA COLLECTION INSTRUMENTS AND SELECT STUDY SITES FOR STUDY TO MEASURE SERVICE PROVIDER ADHERENCE FOR THE NATIONAL FAMILY PLANNING "POLICIES AND STANDARDS" DOCUMENT". |
| AFR | CAMEROON | 02-JUL-1993 | 18-JUL-1993 | THOMPSON TO DEVELOP DATA COLLECTION INSTRUMENTS AND SELECT STUDY SITES FOR STUDY TO MEASURE SERVICE PROVIDER ADHERENCE FOR THE NATIONAL FAMILY PLANNING "POLICIES AND STANDARDS" DOCUMENT. |
| AFR | ETHIOPIA | 17-JUL-1993 | 24-JUL-1993 | JESECKY TO DISCUSS PROJECT DEVELOPMENT POSSIBILITIES WITH THE USAID MISSION AND ETHIOPIAN FAMILY PLANNING AUTHORITIES. |
| AFR | GHANA | 21-AUG-1993 | 01-SEP-1993 | COLE ACCRA--TO MEET WITH USAID MISSION, FP SERVICE DELIVERY ORGANIZATIONS AND SOCIAL MARKETING PROGRAM PERSONNEL. KUMASI--TO CLOSE OUT NORPLANT STUDY WITH PROFESSOR MARTEY AND CLINIC STAFF. |
| AFR | KENYA | 01-APR-1993 | 02-APR-1993 | HUBER TO ASSIST IN THE FACILITATION OF TWO FHI/POPULATION COUNCIL/IDP SPONSORED MEETING IN NAIROBI TO ADDRESS THE ISSUE OF IMPROVING ACCESS CONTRACEPTIVE SERVICES IN KENYA. |
| AFR | KENYA | 05-APR-1993 | 06-APR-1993 | HUBER TO ASSIST IN THE FACILITATION OF TWO FHI/POPULATION COUNCIL/IDP SPONSORED MEETINGS IN NAIROBI TO ADDRESS THE ISSUE OF IMPROVING ACCESS CONTRACEPTIVE SERVICES IN KENYA. |
| AFR | KENYA | 05-APR-1993 | 06-APR-1993 | OMONDI-ODHIAMBO TO PARTICIPATE IN MEDICAL BARRIERS WORKSHOP TO DISCUSS IN DETAIL SPECIFIC MEDICAL BARRIERS IN KENYA AND DEVELOP STRATEGIES TO ADDRESS THEM. |

FAMILY HEALTH INTERNATIONAL
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-999

| <u>Region</u> | <u>Country</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|---------------|----------------|-------------------|-----------------|---|
| AFR | KENYA | 05-APR-1993 | 06-APR-1993 | JESENCKY TO PARTICIPATE IN THE MEDICAL BARRIERS WORKSHOP IN NAIVASBA TO DISCUSS IN DETAIL SPECIFIC MEDICAL BARRIERS IN KENYA AND DEVELOP STRATEGIES TO ADDRESS THEM. |
| AFR | KENYA | 14-APR-1993 | 15-APR-1993 | JESENCKY TO MONITOR THE PROGRESS OF IMMEDIATE POST-PLACENTAL IUD INSERTION AS WELL AS TO COLLECT THE FINAL FORMS FOR THE PROJECT FROM NYERI PROVINCIAL HOSPITAL. |
| AFR | KENYA | 14-APR-1993 | 15-APR-1993 | ODIEMO TO DRIVE KATHY JESENCKY TO NYERI. JESENCKY IS GOING TO MONITOR PROGRESS OF IPPI INSERTION PROJECT AND TO COLLECT THE FINAL PROJECT FORMS FROM NYERI PROVINCIAL HOSPITAL. |
| AFR | KENYA | 01-MAY-1993 | 15-MAY-1993 | OMONDI-ODHIAMBO TRAVELLED TO RTP FROM KENYA TO BECOME FAMILIAR WITH FHI RESEARCH POLICIES, PROCEDURES, AND PRIORITIES; TO FINALIZE PLANS FOR THE PILL COMPLIANCE STUDY TO BE CONDUCTED UNDER THE INSTITUTIONAL DEVELOPMENT PROJECT, AND TO DEVELOP THE PROPOSED STUDY TO DETERMINE THE IMPACT OF REMOVING THE CLINIC VISIT FROM THE CBD PROGRAM TO BE CONDUCTED WITH THE FAMILY PLANNING ASSOCIATION OF KENYA (FPAK). (TRAVELLER FROM KENYA) |
| AFR | KENYA | 05-JUN-1993 | 12-JUN-1993 | WANJALA TO PARTICIPATE IN THE ADVANCED COURSE FOR OBSTETRICIANS AND GYNECOLOGISTS IN LONDON, ENGLAND. (TRAVELLER FROM KENYA) |
| AFR | KENYA | 19-JUN-1993 | 09-JUL-1993 | KIGONDU TO ATTEND THE DATA ANALYSIS COURSE AT JOHN HOPKINS UNIVERSITY IN BALTIMORE, MD. (TRAVELLER FROM KENYA) |

FAMILY HEALTH INTERNATIONAL
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Region</u> | <u>Country</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|---------------|----------------|-------------------|-----------------|--|
| AFR | KENYA | 21-JUL-1993 | 29-JUL-1993 | KIGONDU TO ATTEND DATA ANALYSIS COURSE AT JOHN HOPKINS UNIVERSITY AND MEET WITH FHI-NC STAFF AND DISCUSS POSSIBLE FUTURE COLLABORATION. (TRAVELLER FROM KENYA) |
| AFR | KENYA | 10-AUG-1993 | 22-AUG-1993 | LEWIS AT THE REQUEST OF USAID/KENYA, TO ACCOMPANY FHI CTO JUDITH MANNING TO REVIEW FHI ACTIVITIES/PROGRAM IN KENYA, AND DISCUSS STATUS OF FHI REGIONAL OFFICE. |
| AFR | KENYA | 05-SEP-1993 | 18-SEP-1993 | NICHOLS TO FINALIZE INSTITUTIONAL DEVELOPMENT PROJECT REPORT WITH IDP AND FHI STAFF, IN PREPARATION FOR THE INFORMATION DISSEMINATION WORKSHOP AND TO PRESENT THE RESULTS OF THE IDP RESEARCH ACTIVITIES TO KENYAN RESEARCHERS, SERVICE PROVIDERS AND HEALTH POLICYMAKERS; AND TO PROVIDE ADDITIONAL TECHNICAL ASSISTANCE TO THE IDP CORE STAFF RELATED TO THE COMPLETION OF THE PROJECT, PUBLICATION OF RESEARCH FINDINGS AND IDP ACTIVITIES AFTER FY93. |
| AFR | KENYA | 11-SEP-1993 | 18-SEP-1993 | MCMULLEN TO MONITOR THE CLINICAL TRIAL "TIMING OF PROGESTIN-ONLY ORAL CONTRACEPTIVES IN BREASTFEEDING WOMEN" IN NAIROBI AND ELDORET. |
| AFR | MALI | 17-MAY-1993 | 24-MAY-1993 | KATZ TO MEET WITH SAVE THE CHILDREN TO MAKE PLANS FOR POST-TEST KAP SURVEY TO BE CONDUCTED IN THE FALL OF '93. MEET WITH DIRECTION SANTE FAMILIALE TO DISCUSS OPTIONS FOR RESEARCH PROJECTS ON NORPLANT INTRODUCTION. |
| AFR | MALI | 09-JUL-1993 | 24-JUL-1993 | FRANCOISE TO ATTEND IUD POSTPARTUM INSERTION TRAINING. |
| AFR | MALI | 09-JUL-1993 | 24-JUL-1993 | MARIAMA TO ATTEND IUD POSTPARTUM INSERTION TRAINING. |

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FAMILY HEALTH INTERNATIONAL
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Region</u> | <u>Country</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|---------------|----------------|-------------------|-----------------|---|
| AFR | MALI | 05-AUG-1993 | 17-AUG-1993 | DIABATE TO COLLABORATE ON WORK RELATED TO THE MALI POSTPARTUM IUD STUDY AND TO PROVIDE INPUT INTO THE RESEARCH DESIGN FOR THE UPCOMING OPERATIONS RESEARCH PROJECT RELATED TO NORPLANT INTRODUCTION IN MALI. (TRAVELLER FROM MALI) |
| AFR | NIGER | 23-JUN-1993 | 09-JUL-1993 | KATZ TO INITIATE POST-DELIVERY IUD INSERTION PROJECT INCLUDING TRAINING OF INTERVIEWERS AND STUDY COORDINATOR, FINALIZING AND PRETESTING OF STUDY FORMS, ASSISTING IN TRAINING OF MIDWIVES IN FAMILY PLANNING COUNSELING AND WORKING WITH DATA ENTRY STAFF; ALSO WILL WORK WITH THE MATERNITE POUDDRIERE URC AND THE DIRECTORATE OF FAMILY PLANNING. |
| AFR | NIGERIA | 11-MAY-1993 | 20-MAY-1993 | CHRISTAKOS TO SPEAK WITH REPRESENTATIVES OF THE MINISTRY OF HEALTH/FHS AND USAID/LAGOS. TO PRESENT AT MAY 15 MEETING OF THE ASSOCIATION OF GENERAL AND PRIVATE MEDICAL PRACTITIONERS OF NIGERIA IN ILORIN ON QUALITY OF CARE AND INCREASING ACCESS TO CONTRACEPTION. |
| AFR | SENEGAL | 24-MAY-1993 | 30-MAY-1993 | KATZ TO MONITOR CLIENT PERSPECTIVE STUDY OF NORPLANT INTRODUCTION IN SENEGAL BEING CONDUCTED AT 5 PILOT CLINICS IN DAKAR IN CONJUNCTION WITH LE DANTEC HOSPITAL. |
| AFR | SENEGAL | 17-AUG-1993 | 30-AUG-1993 | ISRAEL TO PROVIDE TECHNICAL ASSISTANCE TO THE NORPLANT COMMITTEE IN DEVELOPING A DOCUMENT THAT DESCRIBES THE STRATEGY FOR EXPANDING SERVICES IN SENEGAL; AND TO MONITOR NORPLANT CLINICAL TRIAL AND DETERMINE NEEDS FOR RE-SUPPLY OF NORPLANT-RELATED MATERIALS AT THE PILOT CLINICS. |

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FAMILY HEALTH INTERNATIONAL
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| Region ----- | Country ----- | Start Date ----- | End Date ----- | Traveler ----- |
|-----------------|------------------|---------------------|-------------------|--|
| AFR | ZAMBIA | 12-JUN-1993 | 23-JUN-1993 | JOANIS TO TRAIN INVESTIGATORS AT UNIVERSITY TEACHING HOSPITAL, LUSAKA, ZAMBIA, AND TO TRAIN STUDY PARTICIPANTS IN THE USE OF THE FEMALE CONDOMS. FURTHER, THE PROTOCOL WILL BE REVIEWED AND INTERVIEWERS WILL BE TRAINED IN THE USE OF STUDY INSTRUMENTS. |
| AFR | ZAMBIA | 13-JUN-1993 | 29-JUN-1993 | MORRISON TO INITIATE A STUDY TO EVALUATE DETERMINANTS AND ACCEPTABILITY OF LONG-TERM BARRIER USE AMONG HIV-DISCORDANT COUPLES. |
| AFR | ZIMBABWE | 04-SEP-1993 | 10-SEP-1993 | MCMULLEN TO MONITOR THE CLINICAL TRIAL "TIMING OF PROGESTIN-ONLY ORAL CONTRACEPTIVES IN BREASTFEEDING WOMEN". |
| ASI | BANGLADESH | 22-APR-1993 | 18-MAY-1993 | HUBACHER TO WORK WITH PDEU AND ACPR ON THE DESIGN OF A PROTOCOL AND DATA COLLECTION INSTRUMENTS FOR STUDY OF THE COSTS OF FAMILY PLANNING METHODS AND DELIVERY SYSTEMS. |
| ASI | BANGLADESH | 24-APR-1993 | 04-MAY-1993 | JANOWITZ TO WORK WITH PDEU AND ACPR ON THE DESIGN OF A PROTOCOL AND DATA COLLECTION INSTRUMENTS FOR STUDY OF THE COSTS OF FAMILY PLANNING METHODS AND DELIVERY SYSTEMS. TO PRESENT FINDINGS OF THE EXPENDITURE STUDY TO DONORS AND TO THE GOVERNMENT. |
| ASI | BANGLADESH | 08-JUL-1993 | 23-JUL-1993 | HUBACHER TO FURTHER DEVELOP THE DATA COLLECTION FORMS AND SAMPLING PLAN FOR THE VARIOUS SERVICE DELIVERY POINTS IN THE DIFFERENT PROGRAMS. IN ADDITION, THE SAMPLE OF GOVERNMENT PROVIDERS WILL BE SELECTED. |
| ASI | INDONESIA | 10-MAY-1993 | 15-MAY-1993 | MONTEITH TO MONITOR THE POC TRIAL AT JOSE FABELLA MEMORIAL HOSPITAL. |

FAMILY HEALTH INTERNATIONAL
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Region</u> | <u>Country</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|---------------|----------------|-------------------|-----------------|---|
| ASI | INDONESIA | 28-MAY-1993 | 06-JUN-1993 | BASNAYAKE TO PARTICIPATE ON BEHALF OF FHI IN A MEETING ORGANIZED BY JHPIEGO TO ASSESS A NEW SURGICAL TECHNIQUE FOR NORPLANT REMOVALS DEVELOPED BY AN INDONESIAN PHYSICIAN. |
| ASI | PAKISTAN | 24-APR-1993 | 03-MAY-1993 | CARTER TO VERIFY THE QUALITY STATUS OF EXISTING CONDOM STOCKS. |
| ASI | PAKISTAN | 01-MAY-1993 | 08-MAY-1993 | TUCKER TO CLOSE OUT NORPLANT PRE-INTRODUCTORY CLINICAL TRIAL IN KARACHI, ISLAMABAD, LAHORE, AND MULTAN; TO WORK WITH NRIFC AND ASSIST WITH PLANNING OF PAKISTAN CTU IN KARACHI, ISLAMABAD, AND LAHORE. |
| ASI | PAKISTAN | 13-JUN-1993 | 30-JUN-1993 | KLIESEN TO MEET WITH USAID PERSONNEL AND BRIEF ON CTU CONFERENCE PREPARATIONS AND UPCOMING FUNDING INITIATIVES AND ATTEND CTU CONFERENCE. |
| ASI | PAKISTAN | 16-JUN-1993 | 18-JUL-1993 | SMITH TO PARTICIPATE IN THE CTU WORKSHOP IN KARACHI AND LAHORE; AND TO HELP WITH THE PRODUCTION OF THE FINAL REPORT. |
| ASI | PAKISTAN | 17-JUN-1993 | 25-JUN-1993 | GENTILE TO ATTEND THE CTU CONFERENCE IN KARACHI AND LAHORE. |
| ASI | PAKISTAN | 19-JUN-1993 | 25-JUN-1993 | KOETSAWANG TO ATTEND CTU CONFERENCE IN KARACHI AND LAHORE. (TRAVELLER FROM THAILAND) |

FAMILY HEALTH INTERNATIONAL
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-999

| <u>Region</u> | <u>Country</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|---------------|----------------|-------------------|-----------------|--|
| ASI | PHILIPPINES | 29-MAY-1993 | 10-JUN-1993 | SPRUYT TO PROVIDE STATISTICAL SOFTWARE TRAINING (EPI INFO) TO STAFF OF THE DR. JOSE FABELLA MEMORIAL HOSPITAL COMPREHENSIVE FAMILY PLANNING CENTER IN MANILA; AND TO COMPLETE DATA ENTRY AND PRELIMINARY ANALYSIS FOR STUDY TO ASSESS METHODS OF IDENTIFYING CONDOM USERS AT RISK FOR BREAKAGE AND SLIPPAGE. TO REVIEW DRAFT REPORT OF COMPARATIVE STUDY OF ACCEPTABILITY RATES OF STANDARD AND SMALLER CONDOMS WITH PRINCIPAL INVESTIGATOR AND ACTUAL USE BREAKAGE RATES OF STANDARD AND SMALLER CONDOMS WITH PRINCIPAL INVESTIGATOR IN OLONGAPO AND EVALUATE THE POTENTIAL OF CONDUCTING FUTURE STUDIES WITH THE CITY HEALTH DEPARTMENT. |
| ASI | PHILIPPINES | 20-AUG-1993 | 09-SEP-1993 | HARDEE TO PARTICIPATE ON A TEAM TO ASSIST THE MISSION AND THE PHILIPPINE FAMILY PLANNING PROGRAM TO PLAN FOR THE INTRODUCTION OF DMPA INTO THE FAMILY PLANNING PROGRAM. |
| ASI | PHILIPPINES | 20-AUG-1993 | 31-AUG-1993 | MCINTYRE TO ASSIST THE MISSION AND THE PHILIPPINE FAMILY PLANNING PROGRAM IN THE DEVELOPMENT OF A PLAN FOR THE INTRODUCTION OF DMPA AND TO ASSIST THE PROGRAMMATIC ISSUES. |
| ASI | PHILIPPINES | 20-AUG-1993 | 03-SEP-1993 | PHILLIPS TO ASSIST THE ASSISTANT SECRETARY FOR SPECIAL CONCERNS WITH THE DEVELOPMENT OF A PLAN OF ACTION FOR THE INTRODUCTION OF DMPA. |
| ASI | PHILIPPINES | 06-SEP-1993 | 21-SEP-1993 | RAMOS TO ATTEND A CONFERENCE AT GEORGETOWN UNIVERSITY ENTITLED "BREASTFEEDING AS A WOMENS' ISSUE" AND TO MEET WITH THE STAFF OF FHI TO DISCUSS PRGRESS ON ONGOING FHI WORK IN THE PHILIPPINES. (TRAVELER FROM THE PHILIPPINES) |

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FAMILY HEALTH INTERNATIONAL
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-999

| <u>Region</u> | <u>Country</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|---------------|----------------|-------------------|-----------------|--|
| ASI | PHILIPPINES | 23-JUL-1993 | 31-JUL-1993 | FARR TO MONITOR THE POC TRIAL AT JOSE FABELLA MEMORIAL HOSPITAL. |
| ASI | THAILAND | 21-APR-1993 | 23-APR-1993 | JANOWITZ TO WORK WITH DR. KANCHANA AND MS. PORNSINEE ON FINALIZING THE REPORT ON THE NORPLANT STUDY. TO DISCUSS UNFPA RESEARCH SUPPORT FOR STUDY ON COST RECOVERY FOR THE NATIONAL FAMILY PLANNING PROGRAM AND TO DISCUSS THE PROJECT WITH MS. PATAMA OF THE FHD. TO DISCUSS PROFIT ACTIVITIES WITH DR. CHULONGPOB OF TDRI. |
| ASI | THAILAND | 08-JUN-1993 | 12-JUN-1993 | PIYA-ANANT TO ATTEND THE MEETING ON LONG ACTING PROGESTINS: MANAGEMENT OF BLEEDING DISTURBANCES BEING HELD BY FHI. (TRAVELLER FROM THAILAND) |
| ASI | THAILAND | 19-JUN-1993 | 25-JUN-1993 | KOETSAWANG TO ATTEND CTU CONFERENCE IN PAKISTAN. (TRAVELLER FROM THAILAND) |
| CAD | CANADA | 23-AUG-1993 | 31-AUG-1993 | KAFABI TO PRESENT A PAPER ON "INTRODUCING OPERATIONS RESEARCH: THE CASE IN EGYPT" AT THE INTERNATIONAL UNION FOR SCIENTIFIC STUDY OF POPULATION, GENERAL CONFERENCE. (TRAVELLER FROM EGYPT) |
| EUR | FINLAND | 24-AUG-1993 | 03-SEP-1993 | METCALF-WHITTAKER TO ATTEND THE TENTH INTERNATIONAL MEETING OF THE INTERNATIONAL SOCIETY FOR STD RESEARCH IN HELSINKI. |
| EUR | FINLAND | 26-AUG-1993 | 02-SEP-1993 | FELDELMUM TO ATTEND THE TENTH INTERNATIONAL MEETING OF THE INTERNATIONAL SOCIETY FOR STD RESEARCH. |

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FAMILY HEALTH INTERNATIONAL
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Region</u> | <u>Country</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|---------------|----------------|-------------------|-----------------|---|
| EUR | FINLAND | 26-AUG-1993 | 03-SEP-1993 | RODDY TO ATTEND THE 10TH INTERNATIONAL MEETING OF THE INTERNATIONAL SOCIETY OF STD RESEARCH. |
| EUR | FRANCE | 26-SEP-1993 | 29-SEP-1993 | MCMULLEN TO ATTEND DIA WORKSHOP "FRAUD AND MISCONDUCT IN CLINICAL RESEARCH: THE IMPACT ON THE DEVELOPMENT OF MEDICINAL PRODUCTS". |
| EUR | SWITZERLAND | 08-JUN-1993 | 11-JUN-1993 | D'ARCANGUES TO ATTEND THE MEETING ON LONG ACTING PROGESTINS: MANAGEMENT OF BLEEDING DISTURBANCES IN RTP, NC. (TRAVELLER FROM SWITZERLAND) |
| EUR | SWITZERLAND | 28-AUG-1993 | 04-SEP-1993 | KENNEDY TO SERVE AS A TEMPORARY CONSULTANT TO WHO ON THE TASK FORCE ON NATURAL METHODS OF FERTILITY REGULATION AND A SUBCOMMITTEE OF THAT TASK FORCE TO RECOMMEND DATA ANALYSES AND PUBLICATIONS FROM THE DATA COLLECTED IN THE WHO MULTICENTER STUDY OF BREASTFEEDING PATTERNS AND THE RETURN OF MENSES. USAID PAYS SALARY ONLY . |
| EUR | UK | 05-JUN-1993 | 12-JUN-1993 | WANJALA TO PARTICIPATE IN THE ADVANCED COURSE FOR OBSTETRICIANS AND GYNECOLOGISTS. (TRAVELLER FROM KENYA) |
| LAT | ARGENTINA | 18-MAY-1993 | 28-MAY-1993 | RIVERA TO ATTEND THE FLACIRH WORKSHOP ON REPRODUCTIVE HEALTH; AND TO ATTEND THE XIII ALIRH MEETING ON CONTRACEPTIVE TECHNOLOGY. |
| LAT | ARGENTINA | 18-MAY-1993 | 27-MAY-1993 | ULLOA TO ATTEND THE XIII ALIRH MEETING ON CONTRACEPTIVE TECHNOLOGY. (TRAVELLER FROM MEXICO) |

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FAMILY HEALTH INTERNATIONAL
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-999

| <u>Region</u> | <u>Country</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|---------------|----------------|-------------------|-----------------|--|
| LAT | ARGENTINA | 21-MAY-1993 | 26-MAY-1993 | POTTER TO PRESENT A PAPER ON "OC COMPLIANCE AND INSTRUCTIONS" AT THE 13TH ANNUAL MEETING OF THE XIII ALIRH MEETING ON CONTRACEPTIVE TECHNOLOGY. |
| LAT | ARGENTINA | 22-MAY-1993 | 27-MAY-1993 | DIAZ TO ATTEND THE XIII ALIRH MEETING ON CONTRACEPTIVE TECHNOLOGY. (TRAVELLER FROM BRAZIL) |
| LAT | ARGENTINA | 22-MAY-1993 | 31-MAY-1993 | HUBACHER TO GIVE AN ORAL PRESENTATION AT THE XIII ALIRH MEETING ON CONTRACEPTIVE TECHNOLOGY. |
| LAT | ARGENTINA | 22-MAY-1993 | 28-MAY-1993 | AZNAR TO ATTEND THE XIII ALIRH MEETING ON CONTRACEPTIVE TECENOLOGY. (TRAVELLER FROM MEXICO) |
| LAT | ARGENTINA | 22-MAY-1993 | 28-MAY-1993 | CRAVIOTO TO ATTEND THE XIII ALIRH MEETING ON CONTRACEPTIVE TECHNOLOGY. (TRAVELLER FROM MEXICO) |
| LAT | BRAZIL | 22-MAY-1993 | 27-MAY-1993 | DIAZ TO ATTEND THE XIII ALIRH MEETING ON CONTRACEPTIVE TECHNOLOGY. (TRAVELLER FROM BRAZIL) |
| LAT | BRAZIL | 30-JUN-1993 | 02-JUL-1993 | MANAUTOU TO ATTEND ANNUAL TAC MEETING IN RTP, NC. (TRAVELLER FROM BRAZIL) |
| LAT | CHILE | 08-JUN-1993 | 12-JUN-1993 | MASSAI TO ATTEND THE MEETING ON LONG ACTING PROGESTINS: MANAGEMENT OF BLEEDING DISTURBANCES BEING HELD BY FHI. (TRAVELLER FROM CHILE) |

FAMILY HEALTH INTERNATIONAL
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Region</u> | <u>Country</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|---------------|--------------------|-------------------|-----------------|--|
| LAT | CHILE | 09-JUN-1993 | 11-JUN-1993 | DIAZ TO ATTEND THE MEETING ON LONG ACTING PROGESTINS: MANAGEMENT OF BLEEDING DISTURBANCES BEING HELD BY FHI. (TRAVELLER FROM CHILE) |
| LAT | CHILE | 12-SEP-1993 | 14-SEP-1993 | DIAZ TO ATTEND A CONFERENCE AT GEORGETOWN UNIVERSITY ENTITLED "BREASTFEEDING AS A WOMEN'S ISSUE." DR. DIAZ WILL MODERATE THE CONCLUDING AUDIENCE DISCUSSION. (TRAVELLER FROM CHILE) |
| LAT | DOMINICAN REPUBLIC | 09-JUN-1993 | 11-JUN-1993 | ALVAREZ TO ATTEND THE MEETING ON LONG ACTING PROGESTINS: MANAGEMENT OF BLEEDING DISTURBANCES BEING HELD BY FHI. (TRAVELLER FROM DOMINICAN REPUBLIC) |
| LAT | ECUADOR | 09-JUL-1993 | 16-JUL-1993 | ROMERO TO PARTICIPATE IN THE FHI/PAHO WORKSHOP ON INTEGRATION OF POSTPARTUM AND POSTABORTION FAMILY PLANNING IN REPRODUCTIVE HEALTH SERVICES OF LATIN AMERICAN COUNTRIES HELD IN ECUADOR (TRAVELLER FROM PARAGUAY) |
| LAT | ECUADOR | 10-JUL-1993 | 19-JUL-1993 | BEAMISH TO HELP FACILITATE AND GIVE A PRESENTATION AT THE FHI/PAHO WORKSHOP ON INTEGRATION OF POSTPARTUM AND POSTABORTION FAMILY PLANNING IN THE REPRODUCTIVE HEALTH SERVICES OF LATIN AMERICAN COUNTRIES. |
| LAT | ECUADOR | 10-JUL-1993 | 16-JUL-1993 | ALVARADO TO GIVE A PRESENTATION AND PARTICIPATE IN THE FHI/PAHO WORKSHOP ON THE INTEGRATION OF POSTPARTUM AND POSTABORTION FAMILY PLANNING IN THE REPRODUCTIVE HEALTH SERVICES OF LATIN AMERICAN COUNTRIES. (TRAVELLER FROM MEXICO) |

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FAMILY HEALTH INTERNATIONAL
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Region</u> | <u>Country</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|---------------|----------------|-------------------|-----------------|--|
| LAT | ECUADOR | 10-JUL-1993 | 16-JUL-1993 | ORTIZ TO PARTICIPATE IN THE FHI/PAHO WORKSHOP ON THE INTEGRATION OF POSTPARTUM AND POSTABORTION FAMILY PLANNING IN REPRODUCTIVE HEALTH SERVICES OF LATIN AMERICAN COUNTRIES. (TRAVELLER FROM PARAGUAY) |
| LAT | ECUADOR | 10-JUL-1993 | 15-JUL-1993 | DE BENITEZ TO PARTICIPATE IN THE FHI/PAHO WORKSHOP ON THE INTEGRATION OF POSTPARTUM AND POSTABORTION FAMILY PLANNING IN REPRODUCTIVE HEALTH SERVICES OF LATIN AMERICAN COUNTRIES. (TRAVELLER FROM PARAGUAY) |
| LAT | ECUADOR | 10-JUL-1993 | 14-JUL-1993 | RIVERA TO HELP FACILITATE AND GIVE PRESENTATIONS AT THE FHI/PAHO WKSHOP ON INTEGRATION OF POSTPARTUM AND POSTABORTION FAMILY PLANNING IN THE REPRODUCTIVE HEALTH SERVICES OF LATIN AMERICAN COUNTRIES. |
| LAT | EL SALVADOR | 23-AUG-1993 | 03-SEP-1993 | OLGUIN TO MONIOR 100% QUALITY DATA ON NORPLANT STUDY CRFS. |
| LAT | HONDURAS | 26-APR-1993 | 04-MAY-1993 | MARTINEZ TO ASSIST THE MINISTRY OF EDUCATION (BY PERSONAL INVITATION FROM STAN TERRELL) IN TRAINING STAFF TO USE THE MACINTOSH AND TO TEACH LAYOUT AND PRODUCTION OF FINAL REPORTS USING MAC SOFTWARE. |
| LAT | HONDURAS | 02-JUN-1993 | 05-JUN-1993 | BRATT TO PRESENT THE RESULTS OF THE ASHONPLAFA COSTING STUDY TO SENIOR STAFF OF ASHONPLAFA AND USAID/HONDURAS; TO DISCUSS OTHER OPPORTUNITIES FOR ASHONPLAFA AND FHI TO COLLABORATE ON SERVICE DELIVERY PROJECTS. |

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FAMILY HEALTH INTERNATIONAL
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Region</u> | <u>Country</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|---------------|----------------|-------------------|-----------------|---|
| LAT | HONDURAS | 14-JUN-1993 | 23-JUN-1993 | HUBACHER TO DO SECONDARY ANALYSIS OF FAMILY PLANNING DATA IN COLLABORATION WITH USAID, MOPH AND ASHONPLAFA STAFF. A DRAFT PAPER WILL BE WRITTEN AND MODIFIED OVER SUBSEQUENT MONTHS TO SUBMIT TO A JOURNAL FOR PUBLICATION. |
| LAT | HONDURAS | 15-SEP-1993 | 25-SEP-1993 | BRATT TO PARTICIPATE IN AN ASSESSMENT OF THE SUSTAINABILITY OF FOUR NON-PROFIT FAMILY PLANNING PROVIDERS IN THE DOMINICAN REPUBLIC. |
| LAT | JAMAICA | 22-JUN-1993 | 27-JUN-1993 | HARDEE TO WORK WITH TP4 FUTURES GROUP AND THE NATIONAL FAMILY PLANNING BOARD ON A JOINT STUDY OF PRIVATE PRACTITIONERS IN JAMAICA (INCLUDING MEDICAL BARRIERS). |
| LAT | JAMAICA | 21-JUL-1993 | 30-JUL-1993 | HARDEE TO WORK WITH THE NATIONAL FAMILY PLANNING BOARD (NFPB) AND UNIVERSITY OF WEST INDIES (UWI) ON CODING CATEGORIES FOR THE PRIVATE PHYSICIAN'S SURVEY; TO PREPARE A DATA ANALYSIS PLAN; AND TO OUTLINE THE FINAL REPORT ON MEDICAL BARRIERS. |
| LAT | JAMAICA | 23-JUL-1993 | 06-AUG-1993 | VILLINSKI TO WORK WITH THE NATIONAL FAMILY PLANNING BOARD (NFPB) AND UNIVERSITY OF WEST INDIES (UWI) ON CODING CATEGORIES FOR THE PRIVATE PHYSICIAN'S SURVEY, TO PREPARE A DATA ANALYSIS PLAN AND TO OUTLINE THE FINAL REPORT ON MEDICAL BARRIERS. |
| LAT | JAMAICA | 15-AUG-1993 | 03-SEP-1993 | VILLINSKI TO CONTINUE WORKING WITH THE UNIVERSITY OF THE WEST INDIES AND THE NATIONAL FAMILY PLANNING BOARD ON THE SURVEY OF PRIVATE PHYSICIANS AND TO CONTINUE CODING QUESTIONNAIRES AND DATA ENTRY. |
| LAT | MEXICO | 02-MAY-1993 | 23-MAY-1993 | IRSULA TO MONITOR THE POC STUDY. |

FAMILY HEALTH INTERNATIONAL
 INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
 FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Region</u> | <u>Country</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|---------------|----------------|-------------------|-----------------|---|
| LAT | MEXICO | 12-MAY-1993 | 14-MAY-1993 | DELGADO TO MEET WITH THE FHI STAFF AND GAIN A BETTER UNDERSTANDING OF FHI'S CAPABILITIES IN FAMILY PLANNING RESEARCH AND TECHNICAL ASSISTANCE; TO FINALIZE THE DESIGN OF A NEW STUDY OF INJECTABLE USERS. (TRAVELLER FROM MEXICO) |
| LAT | MEXICO | 16-MAY-1993 | 25-MAY-1993 | MARTINEZ TO PERFORM A 100% DATA QUALITY CHECK ON THE CASE REPORT FORMS FOR THE POC STUDY. |
| LAT | MEXICO | 18-MAY-1993 | 27-MAY-1993 | ULLOA TO ATTEND THE XIII ALIRH MEETING ON CONTRACEPTIVE TECHNOLOGY. IN ARGENTINA. (TRAVELLER FROM MEXICO) |
| LAT | MEXICO | 22-MAY-1993 | 28-MAY-1993 | AZNAR TO ATTEND THE XIII ALIRH MEETING ON CONTRACEPTIVE TECHNOLOGY. (TRAVELLER FROM MEXICO) |
| LAT | MEXICO | 22-MAY-1993 | 28-MAY-1993 | CRAVIOTO TO ATTEND THE XIII ALIRH MEETING ON CONTRACEPTIVE TECHNOLOGY IN ARGENTINA. (TRAVELLER FROM MEXICO) |
| LAT | MEXICO | 28-JUN-1993 | 02-JUL-1993 | LAPIDO TO ATTEND THE ANNUAL TAC MEETING. (TRAVELLER FROM MEXICO) |
| LAT | MEXICO | 10-JUL-1993 | 16-JUL-1993 | ALVARADO TO GIVE A PRESENTATION AND PARTICIPATE IN THE FHI/PAHO WORKSHOP ON THE INTEGRATION OF POSTPARTUM AND POSTABORTION OF FAMILY PLANNING IN THE REPRODUCTIVE HEALTH SERVICES OF LATIN AMERICAN COUNTRIES HELD IN ECUADOR. (TRAVELLER FROM MEXICO) |
| LAT | MEXICO | 21-AUG-1993 | 03-SEP-1993 | IRSULA TO MONITOR THE POC STUDY IN DURANGO AND TORREON. |

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FAMILY HEALTH INTERNATIONAL
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
FUNDING SOURCE: POPULATION FUNDS 2000-3895, 6000-999

| <u>Region</u> | <u>Country</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|---------------|----------------|-------------------|-----------------|---|
| LAT | MEXICO | 01-SEP-1993 | 10-SEP-1993 | HUBACHER TO WORK WITH IMSS STAFF ON THE STUDY WHICH COMPARES TWO IUD FOLLOW-UP SCHEMES. SPECIFICALLY THE FOLLOWING WILL BE ACCOMPLISHED: ANALYSIS OF SIX-MONTH DATA, COMPLETE COST ESTIMATIONS, AND DEVELOP LOST-TO-FOLLOW UP FORMS. |
| LAT | MEXICO | 12-SEP-1993 | 15-SEP-1993 | CARTER TO MONITOR PROSPECTIVE AGING STUDY SITE. |
| LAT | MEXICO | 12-SEP-1993 | 15-SEP-1993 | BROWN TO MONITOR PROSPECTIVE AGING STUDY SITES (JUAREZ, MERIDA AND MEXICO CITY). |
| LAT | MEXICO | 19-SEP-1993 | 28-SEP-1993 | MARTINEZ TO MONITOR THE POC STUDIES IN VERACRUZ AND MEET WITH USAID MISSION. |
| LAT | PANAMA | 16-AUG-1993 | 21-AUG-1993 | IRSULA TO BEGIN LOCAL COORDINATION OF THE MEDICAL BARRIER WORKSHOP TO BE HELD IN PANAMA NOVEMBER 26 AND 27. |
| LAT | PARAGUAY | 09-JUL-1993 | 16-JUL-1993 | ROMERO TO PARTICIPATE IN THE FHI/PAHO WORKSHOP ON THE INTEGRATION OF POSTPARTUM AND POSTABORTION FAMILY PLANNING IN REPRODUCTIVE HEALTH SERVICE OF LATIN AMERICAN COUNTRIES. (TRAVELLER FROM PARAGUAY) |
| LAT | PARAGUAY | 10-JUL-1993 | 16-JUL-1993 | ORTIZ TO PARTICIPATE IN THE FHI/PAHO WORKSHOP ON THE INTEGRATION OF POSTPARTUM AND POSTABORTION FAMILY PLANNING IN REPRODUCTIVE HEALTH SERVICES OF LATIN AMERICAN COUNTRIES HELD IN ECUADOR. (TRAVELLER FROM PARAGUAY) |

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FAMILY HEALTH INTERNATIONAL
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
FUNDING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Region</u> | <u>Country</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|---------------|----------------|-------------------|-----------------|---|
| LAT | PARAGUAY | 10-JUL-1993 | 15-JUL-1993 | DE BENITEZ TO PARTICIPATE IN THE FHI/PAHO WORKSHOP ON THE INTEGRATION OF POSTPARTUM AND POSTABORTION FAMILY PLANNING IN REPRODUCTIVE HEALTH SERVICES OF LATIN AMERICAN COUNTRIES IN ECUADOR. (TRAVELLER FROM PARAGUAY) |
| LAT | PERU | 15-JUL-1993 | 17-JUL-1993 | RIVERA TO ATTEND THE 1ST INTERNATIONAL COURSE ON FAMILY PLANNING. |
| LAT | PUERTO RICO | 13-JUN-1993 | 15-JUN-1993 | CARTER TO CONDUCT PRODUCTION SURVEILLANCE AUDITS OF WYETH-AYERST LO-FEMENAL AND OVRETTE MANUFACTURING AND DISTRIBUTION OPERATIONS. |
| LAT | PUERTO RICO | 07-SEP-1993 | 09-SEP-1993 | MABELLOS TO PERFORM PRODUCTION SURVEILLANCE AUDIT OF OCS AT WYETH AYERST MANUFACTURING FACILITY IN GUAYAMA, PUERTO RICO. |
| LAT | PUERTO RICO | 07-SEP-1993 | 09-SEP-1993 | CARTER TO PERFORM PRODUCTION SURVEILLANCE SAMPLING AT WYETH-AYERST ALONG WITH JESSE MABELLOS. |
| NRE | EGYPT | 20-JUN-1993 | 02-JUL-1993 | WASZAK CAIRO--TO PROVIDE TECHNICAL ASSISTANCE, INCLUDING MONITORING STUDIES, TO THE RESEARCH MANAGEMENT UNIT. ALEXANDRIA--TO ATTEND A CONTRACEPTIVE UPDATE MEETING. |
| NRE | EGYPT | 22-JUN-1993 | 05-JUL-1993 | BHIMANDIWALLA TO ATTEND A CONTRACEPTIVE UPDATE MEETING. |

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FAMILY HEALTH INTERNATIONAL
INTERNATIONAL TRAVEL FOR PERIOD BETWEEN 01-APR-1993 THROUGH 30-SEP-1993
FUNLING SOURCE: POPULATION FUNDS 2000-3895,6000-999

| <u>Region</u> | <u>Country</u> | <u>Start Date</u> | <u>End Date</u> | <u>Traveler</u> |
|---------------|----------------|-------------------|-----------------|-----------------|
| NRE | EGYPT | 23-AUG-1993 | 03-SEP-1993 | KAFABI |

TO PRESENT A PAPER ON "INTRODUCING OPERATIONS RESEARCH: THE CASE IN EGYPT" AT THE INTERNATIONAL UNION FOR SCIENTIFIC STUDY OF POPULATION, GENERAL CONFERENCE IN MONTREAL, CANADA AND TO BE UPDATED ON FHI'S LATEST RSEARCH AND TO DISCUSS POSSIBLE RESEARCH ACTIVITIES FOR EUROPE. (TRAVELLER FROM EGYPT)

APPENDIX B

FHI Staff and Consultant Projected Travel

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FAMILY HEALTH INTERNATIONAL

INTERNATIONAL/DOMESTIC TRAVEL PLAN: OCTOBER 1, 1993 - MARCH 31, 1994

| <u>SITE</u> | <u>TRAVELER</u> | <u>DATES</u> | <u>FUNDING CODE</u> 1) USAID/POP 2) USAID/H 3) OTHER (code # only) | <u>PRIMARY PURPOSE</u> |
|------------------|---------------------|----------------|--|---|
| <u>AFRICA</u> | | | | |
| Cameroon | Thompson | Oct 15-30 | 1 | Train the data collectors |
| Cameroon | Janowitz | Oct 20-24 | 1 | Develop new projects |
| Cameroon | Thompson | Mar 1-15 | 1 | Monitor RMB study |
| Ghana | Janowitz | Oct 25-29 | 1 | Develop medical barriers project |
| Guyana | Sokal | Feb | 3 | Discussion of proposal to NIH |
| Kenya | Smith, J | Oct 1-8 | 3 | Regional OR meeting |
| Kenya | Allen | Jan (2 wks) | 3 | Plan initiation of CUE contraception/HIV studies, pending NIH & AMFAR funding |
| Kenya (or Ghana) | Spruyt | Mar 19-27 | 1 | Initiate risk assessment study |
| Malawi | Joanis | Oct/Nov (1 wk) | 1 | Initiate female condom study |
| Mali | Katz | Oct 1-30 | 1 | Protocol and review for Norplant introduction project |
| Mali | French Prog Officer | Dec (10 days) | 1 | Monitor implementation of the AMPPF subagreement |
| Mali | Katz | Jan 1 | 1 | Initiate Norplant introduction study; Save the Children post-test survey |

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AFRICA - continued

| | | | | |
|-----------|----------|----------------|---|---|
| Niger | Stanback | Jan 15-30 | 1 | Initiate IPPI study |
| Niger | Carter | Jan 13-16 | 1 | Prospective Aging Study |
| Senegal | Israel | Oct 17-31 | 1 | Provide TA to Norplant introduction project |
| Senegal | Katz | Oct 1-30 | 1 | Analyze data and report writing |
| Senegal | Katz | Nov (2 wks) | 1 | Conduct follow-up to research project |
| Senegal | Israel | Dec (1 wk) | 1 | Information dissemination for FHI's research results; next steps for Norplant expansion |
| Senegal | Israel | Mar (2 wks) | 1 | Monitor Norplant expansion activities |
| S. Africa | Carter | Jan 10-12 | 3 | ISO TC 157 meeting |
| Tanzania | Fortney | Mar 1-7 | 3 | WHO/UNDP maternal health mission |
| Zambia | Joanis | Oct/Nov (1 wk) | 1 | Monitor female condom study |
| Zambia | Morrison | Jan (2 wks) | 1 | Monitor female condom study |

ASIA/NEAR EAST

| | | | | |
|------------|-----------------------|-----|---|--------------------|
| Bangladesh | Hubacher/ Janowitz | Jan | 1 | Monitor cost study |
|------------|-----------------------|-----|---|--------------------|

ASIA/NEAR EAST - continued

| | | | | |
|---------------------------|----------------------------------|---------------|-----|---|
| Central Asian Republics | Tucker | Oct 14/Nov 2 | 3 | Accompany UNFPA to identify regions of mutual interest and potential collaboration |
| Kyrgyzstan/ Uzbekistan | Barry | Nov 4/Dec 5 | 3 | Participate in joint UNFPA/FHI training of trainers |
| Egypt | Waszak/ Allen | Nov 8-18 | 1 | Participate in Population Council workshop on report writing; discuss Women's Studies Project with mission; introduce Missie Allen to FHI work in Egypt |
| Egypt | Waszak | Jan | 1 | Develop project transition plan |
| Egypt | Allen | Feb (10 days) | 3 | Work on transition activities for POP II |
| Georgia/ Armenia | Tucker/ Barry | Jan (2 wks) | 1,3 | Initiate discussion of planned evaluation |
| Indonesia | Farr | Nov | 1 | Monitor POC study |
| Jordan | Balogh/ King, TM/ Stanback | Oct 29/Nov 12 | 1 | Plan for TA to projects on DMPA, Norplant and postpartum IUD introduction |
| Jordan | Balogh | Jan (2 wks) | 1 | Plan for responding to projected Postpartum Care RFP |
| Kazakhstan | Bailey | Oct 18-29 | 3 | Meet with USAID staff to discuss FHI TA to the MOH |

ASIA/NEAR EAST - continued

| | | | | |
|------------------------------|---|---|---|---|
| Korea | Zhang | Sep 26/Oct 3 | 1 | Develop vasectomy pilot study |
| Korea | Zhang | Feb (2 wks) | 1 | Initiate vasectomy study |
| Kyrgyzstan | Bailey | Oct 19-28 | 3 | Assist evaluation of MOH health worker program |
| Nepal/ Thailand/ India | Palmore | Dec 1-14 | 1 | Assess FY'93 work & develop workplans for FY'94; talk with Dr. Suporn Koetsawang re medical barriers and November Regional Meeting |
| Philippines | Carter | Sep 28/Oct 9 | 3 | Field production survey |
| Philippines | Allen/ Roddy | Oct 13-23 | 3 | Investigate possible sites for HIV & N-9 study |
| Philippines | Palmore/ McIntyre/ Phillips Rivera/ Spivey/ Adrian/ Barnett/ Martin, A/ Smith, J (from Wash.DC) (from Vietnam) (from Vietnam) (from Pakistan) (from Pakistan) (from Thailand) (from Thailand) (from Sri Lanka) (from Bangladesh) | Nov 4-22 Nov 9-20 Nov 5-19 Nov 10-19 Nov 5-17 Nov 5-16 Nov 6-15 Nov 5-19 Nov 8-15 Nov 11-15 Nov 11-15 Nov 10-15 Nov 11-15 Nov 10-20 Nov 10-20 Nov 10-22 Nov 10-20 | 1 | Attend regional IAC meeting; follow-up DMPA introduction; Regional Experts Medical Barriers and ACOG meeting; preparation for diaphragm study; attend 14th Oceanic Congress of Ob/Gyn |

ASIA/NEAR EAST - continued

Philippines - continued

| | | | | |
|-------------------|--------|-----------|--|--|
| (from Nepal) | Thapa | Nov 10-15 | | |
| (from Nepal) | Amatya | Nov 10-15 | | |
| (from Bangladesh) | Akhter | Nov 10-20 | | |

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|-------------|----------|-------------|---|--------------------------------|
| Philippines | McIntyre | Mar (2 wks) | 1 | Follow-up on DMPA introduction |
|-------------|----------|-------------|---|--------------------------------|

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|---|--------------------|----------------------|-----|--|
| Russia | Waszak | Jan | 3 | Monitor RFPA clinic evaluation project |
| Vietnam | Waszak/ Connell | Oct | 3 | Initiate retrospective Quinacrine study |
| Vietnam | Waszak | Mar | 3 | Monitor Quinacrine study |
| <u>AUSTRALIA</u> | | | | |
| Sydney/Adelaide | Bisgrove | Sep 17/Oct 2 | 1 | Attend international nutrition meetings |
| <u>CANADA/EUROPE</u> | | | | |
| Canada | Jones, D | Nov 7-10 | 1 | Attend Covey Leadership Workshop |
| Copenhagen | Tucker/ Barry | Nov/Dec (10 days) | 3 | Attend WHO coordinated donor meeting |
| Hungary | King, TM/ Cole | Oct 23-28 | 3 | Assessment of Research and Service Needs in Reproductive Health; its needs and priorities. |
| Switzerland | Fortney | Nov 8-13 | 3 | Safe Motherhood working group |
| Switzerland | Flick | Jan | 1 | Attend sterilization meeting at WHO |
| <u>CANADA/EUROPE - continued</u> | | | | |
| Switzerland | Rivera | Mar 3-11 | 1 | Scientific Research Meeting |
| United Kingdom | Dunson | Oct 10-13 | 1 | Attend DIA Europe meeting |
| <u>LATIN AMERICA/CARIBBEAN</u> | | | | |
| Brazil | Trottier | Oct/Nov (2 wks) | 1 | Develop USAID OC instruction study |
| Brazil | Bailey | Nov 14-23 | 3,1 | Plan maternal morbidity survey; meet with USAID staff to introduce Women's Studies |

| | | | | Project |
|---|----------------------|----------------|---|--|
| Brazil | Rivera | Jan 18-23 | 3 | WHO consultant |
| Dominican Republic | Roddy/Irsula | Oct 18-19 | 1 | Initiate condom/cervical infection study |
| Dominican Republic | Roddy/Irsula | Jan 11-15 | 1 | Monitor Condom/Cervical Infection study |
| Dominican Republic | Spruyt | Jan 15-23 | 1 | Initiate dual method acceptability study |
| El Salvador | Spanish Prog Officer | Jan (10 days) | 1 | Initiate and monitor Norplant introduction program |
| El Salvador | Olguin | Feb | 1 | Monitor Norplant study |
| Ecuador/Brazil | Bratt | Nov 7-17 | 1 | Monitor DMPA introduction study |
| <u>LATIN AMERICA/CARIBBEAN - continued</u> | | | | |
| Ecuador | Bratt | Mar | 1 | Monitor sustainability study |
| Haiti | French Prog Officer | Nov (20 days) | 3 | Work with IPPF and PROFAMIL on mgnt mechanisms for Norplant introduction; identify research collaborator |
| Haiti | French Prog Officer | Feb (10 days) | 3 | Follow-up to Norplant introduction |
| Haiti | Trottier | Feb/Mar (1 wk) | 1 | Develop OC compliance study |
| Honduras | Bratt | Jan | 1 | Develop IUD follow-up project |
| Jamaica | Hardee/Villinski | Oct | 1 | Monitor private physicians survey--RMB study |
| Jamaica | Spivey | Dec/Jan | 1 | RMB Conference |
| Mexico | Gould | Oct | 1 | Attend CQI workshop |

| | | | | |
|--------|----------------------|-----------------|---|------------------------------------|
| Mexico | Hubacher | Dec 1-10 | 1 | Write final report for IUD project |
| Mexico | Joanis | Jan (2 wks) | 1 | Monitor female condom study |
| Mexico | Spanish Prog Officer | Jan (10 days) | 1 | Development activities |
| Mexico | Martinez | Jan 16-25 | 1 | Monitor POC |
| Mexico | Canamar | Jan/Feb (2 wks) | 1 | Develop OC compliance study |
| Mexico | Hubacher | Mar | 1 | Write final report for IUD project |

LATIN AMERICA/CARIBBEAN - continued

| | | | | |
|-------------|--|---|---|---|
| Mexico | Flick/ Irsula | Sep 27/Oct 4 | 1 | Initiate TIV study |
| Mexico | Martinez | Jan 16-25 | 1 | Monitor POC study |
| Mexico | Irsula | Oct 27/Nov 4 | 1 | Monitor TIV |
| Panama | Irsula/ Oronoz/ Rivera/ Tenorio/ Doerfer | Nov 17/Dec 5 Nov 17/Dec 5 Nov 24/Dec 2 Nov 21-29 Nov 25/Dec 3 | 1 | To coordinate RMB Workshop; attend workshop |
| Paraguay | Bratt | Jan/Feb | 1 | Develop cost of FP project |
| Peru | Carter | Dec 13-24 | 3 | Field product survey |
| Puerto Rico | Carter/ Mabellos | Dec 8-12 | 3 | Product surveillance audit |
| Venezuela | Olguin | Oct 3-9 | 3 | Monitor Wyeth-Ayerst |
| Venezuela | Olguin | Jan | 3 | Monitor Wyeth-Ayerst |
| Venezuela | Olguin | Mar | 3 | Monitor Wyeth-Ayerst |

UNITED STATES OF AMERICA

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|---------|--------|-------|---|-------------------------|
| Alabama | Carter | Oct 2 | 3 | Production surveillance |
|---------|--------|-------|---|-------------------------|

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|--|---|---|---|---|
| Alabama | Brown, M | Nov 2 | 3 | Production surveillance |
| Alabama | Brown, M | Dec 2 | 3 | Production surveillance |
| Alabama | Carter | Jan 2 | 3 | Production surveillance |
| <u>UNITED STATES OF AMERICA - continued</u> | | | | |
| Alabama | Brown, M | Feb 2 | 3 | Production surveillance |
| Alabama | Carter | Mar 2 | 3 | Production surveillance |
| California | Schwingl | Oct (5 days) | 1 | Meet with Dr. Swerdloff at UCLA for vasectomy and prostate cancer study |
| California | Lewis, JC | Oct 1-3 | 1 | Attend DIA meeting |
| California | Palmore/ Terwey | Oct 14-17 Oct 15-16 | 1 | Attend meeting of Association of Population |
| California | Welsh | Oct 23-26 | 1 | Attend NCIH AIDS Task Force meeting |
| California | Palmore/ Beamish/ Finger/ Spruyt/ Bisgrove/ Potter/ Waszak/ Hardee/ Gould/ Krueger/ Chi/ Smith | Oct 25-29 Oct 24/Nov 1 Oct 24-30 Oct 23-28 Oct 23-28 Oct 23-28 Oct 24-28 Oct 24-28 Oct 24-28 Oct 26-30 Oct 26-30 Oct 19-30 | 1 | Attend APHA |
| California | Farr/ Sokal | Nov 5-8 | 1 | Attend ARHP conference |
| California | Trottier | Nov 10-13 | 1 | Presentation to N. American Primary Care Research Group |
| California | 3 SSS staff | Dec | 1 | Attend DECUS Fall '93 |

UNITED STATES OF AMERICA - continued

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|-------------|-----------------------------------|--------------|---|--|
| California | Collins | Dec 1-3 | 1 | Attend DIA Document Mgmt. Conference |
| California | Fortney | Feb 13-16 | 3 | PAA preparatory seminar |
| Colorado | Schwingl | Oct (5 days) | 1 | Meet with Ed D'Antoni on vasectomy & prostate cancer study |
| Connecticut | Wilson | Nov 16 | 1 | Perkin-Elmer training |
| Florida | Romocki | Oct 11-15 | 3 | Provide TA/IEC activities (Belle Glade) |
| Florida | Rich | Oct 24-27 | 1 | Computer training and support conference |
| Florida | Omohundro | Oct 27-29 | 1 | International Conference on Harmonization |
| Florida | Bisgrove/ Metcalf-Whittaker | Nov 19-21 | 1 | Attend adolescent reproductive health conference |
| Florida | Hardee/ Janowitz/ Villinski | Mar 3-7 | 1 | Attend Psychosocial/PAA |
| Georgia | Reusche/ Cummings/ Krueger | Oct 28-30 | 1 | Attend AMWA conference |
| Georgia | Glover | Jan 7-9 | 1 | American Statistical Association |
| Illinois | Hedgpeth | Oct 1-2 | 1 | LAT GMP meeting |
| Illinois | Bean/ McCune | Nov 15-16 | 3 | Attend publishers training course |

UNITED STATES OF AMERICA - continued

| | | | | |
|---------------|-----------------------------------|--------------------|---|--|
| Louisiana | Harris | Oct 1-6 | 3 | Attend Society of Research Administrators annual meeting |
| Maryland | Bolotin | As requested | 1 | Set-up SAS/PH Clinical for users at AVCS |
| Maryland | Potter/ Dorflinger | Oct 28-29 | 1 | FDA Advisory Committee meeting on OCs issues |
| Maryland | Dorflinger | Nov 11-12 | 1 | Set-up SAS/PH-Clinical for users at AVCS |
| Maryland | Potter/ McCann | Feb/Mar (2 wks) | 1 | Visit FDA to discuss further POPS labelling |
| Massachusetts | Johnson, D | Oct 15 | 1 | Meeting re: iodine |
| Massachusetts | Blevins | Oct 25-27 | 1 | Advances on medical plastics |
| Massachusetts | Bolotin | Nov 7-9 | 1 | Attend the SUGI Regional Conference |
| Massachusetts | Wilson | Nov 14 | 1 | Brookfield training |
| Massachusetts | Wilson | Nov 15 | 1 | Technical discussions |
| Massachusetts | Johnson, D | Dec 1 | 1 | Meeting re: iodine |
| Massachusetts | Palmore | Jan 26-27 | 1 | Visit Pathfinder & MSH |
| Massachusetts | Johnson, D | Feb 15 | 1 | Meeting re: iodine |
| Michigan | Wilson/ Johnson, D/ Palumbo | Nov 1 | 1 | MDA analysis closeout |

UNITED STATES OF AMERICA - continued

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|------------|----------|-----------|---|---------------------------|
| New Jersey | Palumbo | Oct 4-6 | 1 | Auditing clinical trials |
| New Jersey | Palumbo | Oct/Nov | 1 | Audit Nelson Laboratories |
| New Jersey | Dominik/ | Dec 13-15 | 1 | Applied Statistics |

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|--|------------------|-------------|---|---|--|
| | Cole | | | | |
| New York | Barrows | Oct 7-8 | 1 | Attend APLIC Board of Directors meeting | |
| New York | Palmore | Oct 18-19 | 1 | Meet with Population Council on joint diaphragm study | |
| New York | Rivera | Oct 19-22 | 1 | Attend Int'l Committee for Contraceptive Research, PopCouncil | |
| New York | Martinez | Oct 28-29 | 1 | Monitor NET Pellets | |
| New York | Joanis | Dec (1 day) | 1 | Diaphragm acceptability study development | |
| New York | Palmore | Dec 1-2 | 1 | Meet with Population Council on joint diaphragm study | |
| New York | Carter | Dec 4 | 3 | Production surveillance | |
| New York | Palmore | Jan 24-25 | 1 | Meet with Population Council on joint diaphragm study | |
| New York | Martinez | Feb 1-2 | 1 | Monitor NET Pellets | |
| New York | Martinez | Mar | 1 | Monitor NET Pellets | |
| <u>UNITED STATES OF AMERICA - continued</u> | | | | | |
| New York | Carter | Mar 6 | 3 | Production surveillance | |
| North Carolina | Kennedy | Oct (1 wk) | 1 | Direct ongoing BF and postpartum activities | |
| North Carolina (from Mexico) | Zuniga, Elena | Oct (1 wk) | 1 | To work on Mexico midwives paper | |
| North Carolina | Flick | Nov | 1 | Attend NCAFP meeting | |
| North Carolina (from Mexico) | Juarez, Consuelo | Nov 8-11 | 1 | To work on Mexico midwives OC training materials | |

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|----------------|---|---------------|---|---|
| North Carolina | 3 Vietnamese officials (to be named) | Nov 25/Dec 15 | 3 | Study tour of US population organizations |
| North Carolina | Kennedy | Mar (1 wk) | 1 | Direct ongoing BF and postpartum activities |
| Pennsylvania | Oronoz/ | Oct 5-10 | 1 | Attend ATA Conference |
| Pennsylvania | Palumbo | Jan 20-21 | 1 | Drug development and RDA regulations |
| Pennsylvania | Carter | Mar 10 | 3 | Attend ASTM meeting |
| South Carolina | Amatya | Mar | 1 | Drug Information Association Annual Biostatistics Meeting |
| South Carolina | Sturgen | Mar 29-31 | 1 | DIA statistical meeting |
| Texas | Carter | Dec 7 | 3 | Production surveillance |

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UNITED STATES OF AMERICA - continued

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|----------|-------------|---------------|---|---|
| Texas | Steiner | Mar 1-7 | 1 | Monitor dual method study |
| Utah | Palumbo | Oct/Nov | 1 | Audit Nelson Labaoratories |
| Virginia | Saylor | Every 8 weeks | 3 | Staff training, computers |
| Virginia | Terwey | As requested | 3 | Management and support |
| Virginia | King, M | As requested | 3 | Network/PC support |
| Virginia | Phillips, R | As requested | 3 | AIDSCAP MIS |
| Virginia | James | Oct | 3 | VMS upgrade |
| Virginia | Brown, M | Oct 5 | 3 | Production surveillance |
| Virginia | Martinez | Oct 21-22 | 1 | Monitor NET Pellets |
| Virginia | Brown, M | Nov 5 | 1 | Production surveillance |
| Virginia | Jasinski | Nov 15-16 | 1 | Attend "Issues & Case Report Form Design Preparation and Use" |
| Virginia | Martinez | Nov 29-30 | 1 | Monitor NET Pellets |
| Virginia | Brown, M | Dec 5 | 3 | Production surveillance |
| Virginia | Beamish | Dec 6-11 | 1 | Participate in advanced TOT |
| Virginia | Carter | Jan 5 | 3 | Production surveillance |

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UNITED STATES OF AMERICA - continued

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|----------------|--------------------------------------|-------------|---|--|
| Virginia | Beamish | Feb | 1 | Participate in LogFrame training |
| Virginia | Martinez | Feb 3-4 | 1 | Monitor NET Pellets |
| Virginia | Brown, M | Feb 5 | 3 | Production surveillance |
| Virginia | Carter | Mar 5 | 3 | Production surveillance |
| Washington | Price | Jan 17 | 1 | PATH program review |
| Washington, DC | Carter | Oct 1 | 3 | Meet with CPSD to review projects |
| Washington, DC | Johnson, D/ Blevins/ Omohundro | Oct 4-6 | 1 | RAPS conference |
| Washington, DC | Palmore | Oct 12 | 1 | Meet with Shelton on RMB activities, visit JSI |
| Washington, DC | Potter | Oct 28-29 | 3 | Combined OC Advisory Meeting/FDA |
| Washington, DC | Joanis | Nov (1 day) | 1 | Diaphragm acceptability study development |
| Washington, DC | Price | Nov 1 | 1 | USAID program review |
| Washington, DC | Carter | Nov 1-4 | 3 | FPLM retreat |
| Washington, DC | Cole | Nov 3-4 | 1 | Attend TAG meeting |
| Washington, DC | Omohundro | Nov 6 | 1 | RAPS certification exam |

UNITED STATES OF AMERICA - continued

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|----------------|---|--------------|---|---|
| Washington, DC | Nichols | Nov 11-12 | 3 | NIH Adolescent Family Life Review Panel |
| Washington, DC | Carter | Dec 1 | 3 | Meet with CPSD to review projects |
| Washington, DC | Palmore | Dec 20 | 1 | Chair OEE working group |
| Washington, DC | Carter | Jan 3 | 3 | Meet with CPSD to review projects |
| Washington, DC | Potter/ McCann | Jan (2 days) | 1 | FDA POP labeling meeting |
| Washington, DC | Palmore | Jan 6 | 1 | Planning mtg & CAs meeting; visit Futures |
| Washington, DC | Rivera | Jan 9-12 | 1 | TAC Meeting |
| Washington, DC | Rivera | 23-25 | 1 | Steering Committee Meeting |
| Washington, DC | Palmore | Feb (2 days) | 1 | Attend CAs meeting |
| Washington, DC | Price | Feb 1 | 1 | USAID program review |
| Washington, DC | Carter | Feb 1 | 3 | Meet with CPSD to review projects |
| Washington, DC | Carter | Mar 1 | 3 | Meet with CPSD to review projects |
| Washington, DC | Palmore | Mar 24 | 1 | OEE working group |
| Washington, DC | Palmore/ Spivey/ Barry/ Bridger/ Israel | Mar 24-26 | 1 | CTU training conference |

APPENDIX C

Publication List

PUBLICATIONS LIST APR 1 - SEPT 30, 1993*

- 93-06 Kane TT, De Buyscher R, Taylor-Thomas T, Smith T, Jeng M. Sexual activity, family life education and contraceptive practice among young adults in Banjul, The Gambia. *Stud Fam Plann.* 1993;24(1):50-61.
- 93-07 Fox L, Bailey PE, Clarke-Martinez K, Coello M, Ordonez FN, Barahona F. Condom use among high-risk women in Honduras: evaluation of an AIDS prevention program. *AIDS Educ Prev.* 1993;5(1):1-10.
- 93-08 Williams-Deane M, Potter L. Standardizing the instructions for oral contraceptive use. *Female Patient.* 1993;18(4):77-84.
- 93-09 Rivera R. Study and introduction of family planning methods in developing countries. *Ann Med.* 1993;25(1):57-60.
- 93-10 Ladipo OA, Falusi AG, Feldblum PJ, Osotimehin BO, Otolorin EO, Ojengbode OA. Norplant use by women with sickle cell disease. *Int J Gynecol Obstet.* 1993;41(1):85-87.
- 93-11 Chi IC. The TCU-380A(AG), MLCu-375 and Nova-T IUDs and the IUD daily releasing 20mcg levonorgestrel: four pillars of IUD contraception for the nineties and beyond? *Contraception.* 1993;47(4):325-347.
- 93-13 Kennedy KI, Visness CM, Bathija H, Williamson NE. Rejoinder to Bracher. Bellagio revisited. *Health Transit Rev.* 1993;3(1):107-8.
- 93-14 Roddy RE, Cordero M, Cordero C, Fortney JA. A dosing study of nonoxynol-9 and genital irritation. *Int J STD AIDS.* 1993;4(3):165-170.
- 93-15 Hubacher D, Potter L. Adherence to oral contraceptive regimens in four countries. *Int Fam Plann Perspect.* 1993;19(2):49-53.
- 93-16 Zhang J, Feldblum PJ, Fortney JA. The validity of self-reported height and weight in perimenopausal women. *Am J Public Health.* 1993;83(7):1052.
- 93-17 Dunson TR, McLaurin VL, Aguayo EL, de Silva P, Calventi V, Gerais AS, Serani RG. A multicenter comparative trial of triphasic and monophasic, low-dose combined oral contraceptives. *Contraception.* 1993;47(6):515-525.
- 93-18 Akhter H, Dunson TR, Amatya RN, Begum K, Chowdhury T, Dighe N, Krueger SL, Rahman S. A five-year clinical evaluation of Norplant contraceptive subdermal implants in Bangladeshi acceptors. *Contraception.* 1993;47(6):569-582.

93-20 Farr G. The IUD: will its future always be crippled by its past? *Fam Plann World*. 1993;3(4):5,26.

93-22 Chi I. Some methodological considerations of progestin-only oral contraceptive study from a programmatic perspective. *Adv Contracept*. 1993;9(3):205-213.

93-23 Zhang J. Factors associated with copper T IUD removal for bleeding/pain: a multivariate analysis. *Contraception*. 1993;48(1):13-21.

*Supported with funds provided under Cooperative Agreement
#DPE-3041-A-00-0043-00

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APPENDIX D

Summary - Clinical Trials

FAMILY HEALTH INTERNATIONAL

Summary - Clinical Trials April 1, 1993 - September 30, 1993

Country Reports

1. Expanded Clinical Trial of Norplant Cont. Subdermal Implants: Final Report on the Experience of Four Family Planning Clinics in Nepal (3/93)
2. A Comparative Study of Intrauterine Devices, Copper T380A vs Copper T200 in San Jose, Costa Rica (3/93)
3. A Comparative Study of the Diaphragm Only, Diaphragm with Spermicide and Spermicide Only in London, England (3/19/93)
4. Comparative Study of IUDs TCU380A vs TCU 200 in Ouagadougou, Burkina Faso (4/93)
5. Pre-Introductory Clinical Trial of Norplant Contraceptive Subdermal Implants: Final Report on the Experience at Five Family Planning Clinics in Pakistan (7/93)
6. A Comparative Study of Intrauterine Devices TCU 380A vs TCU200 in Medellin, Colombia (9/93)

APPENDIX E

Regulatory and Quality Assurance Activities

FAMILY HEALTH INTERNATIONAL

REGULATORY AND QUALITY ASSURANCE ACTIVITIES

During this reporting period, FHI's Division of Regulatory Affairs and Quality Affairs (RA/QA) provided regulatory and/or quality assurance support to seven contraceptive research and development projects:

- Iodine Formulation (IND 29,626)
- NET 90-Day Microspheres (IND 18,592)
- NET Subdermal Pellets (IND 17,452)
- Lea's Shield (IDE G860182)
- WFC-333 Vaginal Pouch (IDE G890203)
- Filshie Clip (PMA 920046)
- Polyurethane Condom (510k 920440)

RA/QA accomplishments and objectives for these projects are described in the project descriptions presented elsewhere in this report. The Division's general regulatory and quality assurance program activities are summarized below.

Regulatory Program

FHI's general regulatory program consists of 1) continually acquiring up-to-date information on evolving FDA requirements 2) communicating FDA requirements in a timely manner to all staff who are involved in the development of new contraceptives, and 3) developing procedures for complying with FDA requirements. RA/QA also manages, in compliance with FDA regulations, all investigational supplies of drugs and medical devices at FHI.

The past year has seen dramatic changes in the device regulations and in the management and policies of FDA's Center for Devices and Radiological Health. In April, an RA/QA staff member attended a three-day briefing on these changes. In October, an RA/QA staff member will attend an FDA-sponsored seminar on the design of device clinical trials and another seminar on FDA's ongoing efforts to harmonize its regulations with those of Europe and Japan. The information obtained in these seminars will be extremely important to FHI in its device development programs.

During the past reporting period, RA/QA developed two regulatory training programs and presented them to FHI staff. The first described the responsibilities of sponsors, IRBs, monitors, and investigators under the investigational new drug (IND) and investigational device exemption (IDE) regulations. The second described the types of documentation available at clinical sites and their importance from the perspectives of regulatory compliance, site selection, and study management. This fall, RA/QA plans to present these two training programs to several CONRAD staff. Last May, RA/QA implemented an online regulatory newsletter, which is distributed to staff on a monthly basis and summarizes new FDA regulations, product approvals, enforcement actions, and other FDA-related news of relevance to FHI. In the upcoming reporting period, RA/OA will expand distribution of this newsletter to include key staff at CONRAD and USAID.

Quality Assurance Program

Standard Operating Procedures. During the reporting period, RA/QA took the lead in developing six standard operating procedures (SOPs) describing range of interdivisional research and development activities: the review and approval of research and development documentation, the review and approval of SOPs and related forms, the preparation and submission of IND/IDE progress reports, and the conduct of planned and unplanned interim data analyses. Because of an anticipated increase in project-specific regulatory and QA activities over the next six months, RA/QA's involvement in SOP development will be limited to SOPs for QA auditing and participating in an interdivisional effort to expand the guidance document that is used to develop clinical protocols.

SOP Training. Over the past six months, RA/QA began to provide staff with training on each new or significantly revised SOP prior to its implementation. Over the next six months, RA/QA plans to provide training on the new SOPs for QA auditing, as soon as these SOPs are finalized.

QA Audits. During the reporting period, RA/QA began to develop policies and procedures for conducting QA audits of clinical study sites and contract laboratories. Over the next reporting period, RA/QA plans to issue written SOPs on these two types of audits.

APPENDIX F
Advisory Committees

ADVISORY COMMITTEES

Technical Advisory Committee (TAC)

The Technical Advisory Committee (TAC), composed of eight distinguished scientists in reproductive science and related fields, convenes annually to provide guidance on FHI's research activities and directions. The 1993 annual meeting was held on July 1, 1993. The 1992-1993 TAC roster is appended.

Protection of Human Subjects Committee (PHSC)

The Protection of Human Subjects Committee (PHSC) is established to ensure that FHI's research studies and informed consent documents comply with the Codes of Federal Regulations which govern the protection of human subjects. The Committee composition exceeds the minimal regulatory criteria. The PHSC is composed of eight voting members representing a diverse range of scientific and non-scientific disciplines and two institutional non-voting members. The Committee convenes at least three times per year to review and approve/disapprove study proposals. The frequency of review is determined by the committee at the time an initial or an amended proposal is approved. Within the past six months, an extensive review of the Committee's Operating Guidelines was conducted to ensure compliance with the Codes of Federal Regulations. The review resulted in the Committee's adoption of a number of amendments, which has yielded a resourceful tool not only to the committee, but staff as well. The Committee Chair has conducted two in-service staff presentations on "The Role of the Protection of Human Subjects Committee, an Institutional Review Board". One meeting of the PHSC has been held at FHI during this reporting period: August 27, 1993. The 1993 PHSC roster is appended.

Expert Meetings

An interagency meeting was convened, June 10/11, 1993, on the subject, Long-Acting Progestins: Management of Bleeding Disturbances.

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 27708-0968
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
738 Braniff Drive
Cary, NC 27513
919/319-1011 (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)

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)

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, Inc.
Research Triangle Park, NC 27709
919/460-9005 (B)

* Nonvoting member

Family Health International

Technical Advisory Committee

1992 - 1993 Roster

| | Physiology | | Reproductive Biology |
|------|--|------|---|
| 1995 | Linda E. Atkinson, PhD (Chair) Senior Scientist Product Registration Manager Alza Corporation 950 Page Mill Road Palo Alto, CA 94303-0802 415/494-5689 | 1994 | Michael John Kennedy Harper, PhD, ScD Department of Ob/Gyn Baylor College of Medicine 6550 Fanning Street, Suite 821A Houston, TX 77030 713/790-3640 (B) FAX: 713/798-7564 |
| | Obstetrics-Gynecology/ Reproductive Biology | | Endocrinology/Reproductive Biology |
| 1993 | Deborah J. Anderson, PhD Associate Professor Obstetrics, Gynecology & Reproductive Biology Harvard Medical School Director, Fearing Research Laboratory 250 Longwood Avenue-SGMB 204 Boston, MA 02115 617/432-0841; 617/432-2190 FAX: 617/432-0359 | 1993 | Jorge Martínez Manautou, MD President, Academia Mexicana de Investigación en Demografía Médica, A.C. Bajío No. 203-1er. Piso Col. Roma Sur Deleg. Cuauhtémoc 06760 México, D.F., México 264/11-60; 564/54-48 FAX: 564/5448 |
| | Epidemiology/Internal & Preventive Medicine | | Epidemiology |
| 1995 | Willard Cates, Jr., MD, MPH Director, Division of Training Centers for Disease Control (C08) Atlanta, GA 30333 404/639-3071; FAX: 404/639-2222 | 1994 | Judith P. Rooks, CNM, MS, MPH Independent Consultant 2706 SW English Court Portland, OR 97201 503/243-2253 (R) |
| | Obstetrics-Gynecology | | Social Science |
| 1995 | William Droegemueller, MD Chairman, Department of Ob/Gyn University of North Carolina School of Medicine CB# 7570, MacNider Bldg. Chapel Hill, NC 27599-7570 919/966-5281 | 1994 | Rochelle N. Shain, PhD Professor, Department of Ob/Gyn The University of Texas Health Science Center 7703 Floyd Curl Drive San Antonio, TX 78284 210/567-5051 |