

# **WORKPLAN**

**October 1, 1996 - September 30, 1997**

## **Contraceptive Technology and Family Planning Research Program**

**Cooperative Agreement**

**CCP-3079-A-00-5022-00**

**Submitted to:  
Office of Population, Research Division  
United States Agency for International Development**

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# TABLE OF CONTENTS

|  |  |
|--|--|
| ACRONYM LIST.....                                    | iii                                    |
| GLOSSARY.....  | v                                      |
| SECTION I - OVERVIEW.....                            | 1                                      |
| SECTION II - COOPERATIVE AGREEMENT .....             | 5                                      |
| SECTION III - ANNUAL WORKPLAN: FISCAL YEAR 1997..... | 11                                     |
| CLINICAL TRIALS.....                                 | 13                                     |
| BIOSTATISTICS .....                                  | 37                                     |
| CONTRACEPTIVE USE AND EPIDEMIOLOGY.....              | 41                                     |
| FIELD OPERATIONS.....                                | 75                                     |
| POLICY AND RESEARCH UTILIZATION.....                 | 83                                     |
| SERVICE DELIVERY RESEARCH .....                      | 107                                    |
| PRODUCT QUALITY & COMPLIANCE.....                    | 135                                    |
| SECTION IV - FINANCIAL INFORMATION .....             | 143                                    |
| APPENDICES   |  |
| Appendix A   | Results Framework                      |
| Appendix B   | Advisory Committee Rosters             |
| Appendix C   | Current Listing of FHI Paper Proposals |

## FCO INDEX

## ACRONYM LIST

|          |   |  |
|----------|---|--|
| ADS      | - | Asociación Demográfica Salvadoreña   |
| AIDSCAP  | - | AIDS Control and Prevention Project (FHI)                                      |
| AMH      | - | Asociación Médica Haitienne (Haiti)  |
| APROFAM  | - | Asociación Pro-Bienestar de la Familia (Guatemala)                             |
| ASTM     | - | American Society for Testing Materials   |
| AVSC     | - | Access to Voluntary and Safe Contraception (AVSC) International                |
| CA       | - | Cooperating Agency   |
| CBD      | - | Community Based Distribution   |
| CEFFEVA  | - | Comité d'Etude sur les Femmes, la Famille et l'Environnement en Afrique        |
| CEMOPLAF | - | Centros Médicos de Orientación y Planificación Familiar (Ecuador)              |
| CLM      | - | Contraceptive Logistics Management   |
| CME      | - | Continuing Medical Education   |
| COC      | - | Combined Oral Contraceptive  |
| CONRAD   | - | Contraceptive Research and Development Program                                 |
| CRO      | - | Contract Research Organization   |
| CTU      | - | Contraceptive Technology Update  |
| DHS      | - | Demographic and Health Survey  |
| DMPA     | - | Depot Medroxyprogesterone Acetate  |
| ECP      | - | Emergency Contraceptive Pills  |
| FAMPOP   | - | Family Planning Options Project (Guinea)                                       |
| FCO      | - | Final Cost Objective (equates to an FHI subproject number)                     |
| FEMAP    | - | Federación Mexicana de Asociaciones Privadas de Salud y Desarrollo Comunitario |
| FHI      | - | Family Health International  |
| FLASOG   | - | IX Latin American Congress of Gynecology and Obstetrics Organizing Committee   |
| FLE      | - | Family Life Education  |
| FPAK     | - | Family Planning Association of Kenya   |
| GMP      | - | Good Manufacturing Practices   |
| GON      | - | Government of Nepal  |
| GSMF     | - | Ghana Social Marketing Foundation  |
| HCTP     | - | Health Communication and Training Program                                      |
| HPV      | - | Human Papilloma Virus  |
| HRU      | - | Health Research Unit   |
| IEC      | - | Information, Education and Communication                                       |
| IMSS     | - | Instituto Mexicano de Seguro Social  |
| INHSAC   | - | Institut Haitien de Santé Communautaire  |
| INOPAL   | - | Investigación Operativa para América Latina                                    |
| INTRAH   | - | Program for International Training and Health                                  |
| IPPF     | - | International Planned Parenthood Federation                                    |
| IRB      | - | Institutional Review Board   |
| ISO      | - | International Standards Organization   |

|          |   |  |
|----------|---|--|
| JFPA     | - | Jamaican Family Planning Association                                     |
| JHPIEGO  | - | Johns Hopkins Program for International Education in Reproductive Health |
| LAM      | - | Lactational Amenorrhea Method  |
| MAJ      | - | Medical Association of Jamaica   |
| MAQ      | - | Maximizing Access and Quality  |
| MOH      | - | Ministry of Health   |
| MOPE     | - | Ministry of Population and Environment (Nepal)                           |
| N-9      | - | Nonoxynol-9  |
| NET      | - | Norethindrone  |
| NFPB     | - | National Family Planning Board (Jamaica)                                 |
| NGO      | - | Nongovernmental Organization   |
| NIAID    | - | National Institute of Allergy and Infectious Diseases                    |
| NICHD    | - | National Institute of Child Health and Human Development                 |
| OYB      | - | Operating Year Budget  |
| PAFMACH  | - | Pan African Federation of Maternal and Child Health                      |
| PATH     | - | Program for Appropriate Technology in Health                             |
| PHSC     | - | Protection of Human Subjects Committee                                   |
| PID      | - | Pelvic Inflammatory Disease  |
| PMA      | - | Premarket Approval Application   |
| PNPF     | - | Programme National de Planning Familiale (Senegal)                       |
| POC      | - | Progestin-only Oral Contraceptive  |
| POP III  | - | Population and Family Planning III Project (Egypt)                       |
| PQC      | - | Product Quality and Compliance (FHI Division)                            |
| PROSALUD | - | Protección a la Salud (Bolivia)  |
| PRU      | - | Policy and Research Utilization (FHI division)                           |
| RI       | - | Research International   |
| SDR      | - | Service Delivery Research (FHI division)                                 |
| TGWG     | - | Technical Guidance Working Group   |
| TOC      | - | Technical Oversight Committee  |
| UNC      | - | University of North Carolina   |
| UNFPA    | - | United Nations Population Fund   |
| USFDA    | - | United States Food and Drug Administration                               |
| USAID    | - | United States Agency for International Development                       |
| VCF®     | - | Vaginal Contraceptive Film   |
| VFT      | - | Vaginal Foaming Tablet   |
| WHO      | - | World Health Organization  |
| WSP      | - | Women's Studies Project (FHI)  |

## GLOSSARY

- Collaborating Agency:** A USAID cooperating agency, a private or governmental group, or a nongovernmental organization (NGO) with which FHI is working in partnership and which is providing additional financial or technical services to the subproject.
- Implementing Agency:** Institution(s) or organization(s) designated by FHI as responsible for executing the subproject under the FCO. A Subagreement or Letter of Agreement generally exists between FHI and the implementing agency.
- Final Cost Objective (FCO):** The accounting number created by FHI's Contracts and Grants Office and assigned to each discrete subproject. This is the key unit for all financial reports.
- FCO Approved:** The date that a subproject is first assigned its own unique identifying "final cost objective" number. Currently, in order for an FHI subproject to be assigned an FCO number, its purpose and a tentative budget must have been approved by both the relevant Division Director and Vice President. Providing that the FCO is not one being established solely for management or development purposes, its assignment directly precedes a Project Approval Letter (PAL) to request USAID approval to develop the subproject for final review and approval. For projects that preceded the current cooperative agreement and that are not tied to the conclusion of a specific deliverable, the FCO Approved date is given as <Aug 1995.
- Operating Year Budget (OYB):** This refers to an Operating Year Budget transfer that USAID Missions may use to direct funds to FHI. By this means, money that USAID/W originally designated as Mission money is routed back to Washington by the Mission and put into FHI's cooperative agreement. OYBs can also come from other federal agencies (i.e., NIH and CDC).
- Projected End Date:** While previously this term was often applied to the anticipated completion date of field activities, in this report we have tried to standardize its usage to reflect the anticipated date (month, year) that all subproject activities will be completed- including, for example, the writing of final reports and closing out of expenses.
- Subproject:** An activity within the Cooperative Agreement that has specific objectives and outputs. It usually is assigned one FCO, though multiple FCOs are possible if different funding sources need to be distinguished. Subprojects may include research studies, workshops, surveys, and major publications such as monographs, or *Network*.
- Total Budget:** The current anticipated total cost of a subproject. For an on-going subproject, the total budget is determined by adding together three figures: 1) previous fiscal year(s) expenditures, 2) the current fiscal year's budget, and 3) the anticipated budget needs for future fiscal years until the subproject is completed and the account (FCO) is closed. In cases where multiple sources of funding exist for a single subproject, a breakdown of the total budget by funding source is provided.

This document constitutes the second annual workplan for Cooperative Agreement No. CCP-3079-A-00-5022-00, entitled "Contraceptive Technology and Family Planning Research," implemented by Family Health International (FHI) with funds provided by the Office of Population, Research Division of the United States Agency for International Development (USAID). FHI is a private, nonprofit organization dedicated to improving the health of individuals worldwide, with an emphasis on developing countries. For twenty-five years, FHI has worked in more than 100 countries carrying out joint research programs and providing technical assistance to help solve problems identified by governments, clinical researchers and health-care providers in family planning, reproductive health and, for the past ten years, in AIDS prevention. FHI works closely with international health and development organizations, including USAID, its overseas Missions and cooperating agencies (CAs); the World Health Organization (WHO); the Pan American Health Organization (PAHO); the National Institutes of Health (NIH); the Centers for Disease Control and Prevention (CDC); the United Nations Population Fund (UNFPA) and a host of other agencies working in related areas.

The need to base contraceptive program decisions on sound research was recognized by USAID soon after the Office of Population was founded. FHI was established in 1971 to provide USAID with the data needed to make important decisions concerning the purchase and provision of contraceptives for its programs in developing countries. While the specific questions continue to evolve and change, program decisions still need to be based on well-conducted research. USAID has continued to rely on FHI and its other CAs to meet that need. FHI's role has included designing and implementing clinical trials to evaluate the safety and efficacy of different contraceptive types and brands in developing country settings. FHI has also conducted clinical trials and provided other types of support to introduce contraceptive methods and new technologies to developing countries. Examples include laparoscopic sterilization, minilaparotomy sterilization, no-scalpel vasectomy, combined and progestin-only oral contraceptives (COCs and POCs), intrauterine devices (IUDs), NORPLANT®<sup>1</sup> implants and the female condom.

Because many questions in contraceptive service provision cannot be addressed adequately through clinical research, FHI's role was expanded by USAID to include a "social science" or programmatic research component. Programmatic research at FHI provides additional insights on provider and consumer behavior that complement clinical studies and is responsive to the needs of service programs at the country level, including, for example, ways to improve compliance and enhance the acceptability of new methods. In recent years, FHI has formed closer linkages with other divisions in the Office of Population, including the Family Planning Services Division, the Commodities and Logistics Management (CLM) Division and the Information and Training Division.

Beginning with its previous contraceptive technology cooperative agreement, FHI worked closely with the Office of Population and other CAs to develop and implement a strategy aimed at maximizing access and improving the quality of family planning services.

FHI's role has continued to evolve to meet USAID's research needs. Throughout the 1980s, as U.S. pharmaceutical companies reduced their efforts to develop new contraceptives, the U.S. government (USAID and NIH) played an increasingly significant part in supporting new contraceptive research and development. In implementing its USAID-funded contraceptive development research program, FHI frequently works with small, private companies that have innovative leads to support the research necessary to achieve regulatory approval. In particular, this means providing data for the approval of

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<sup>1</sup> NORPLANT® is a registered trademark of The Population Council, Inc. for subdermal contraceptive implants. NORPLANT® implants (levonorgestrel subdermal contraceptive implants) are manufactured by Leiras Pharmaceuticals, Turku, Finland.

new methods by the United States Food and Drug Administration (USFDA)—a prerequisite for USAID purchase of commodities for its developing country service delivery programs. Data from FHI studies have also been used to support product approval by regulatory agencies in developing countries. Most recently, FHI's research on a thermoplastic male condom has led to the development of a new, innovative product that has recently been licensed to a manufacturer. FHI will complete the studies necessary for USFDA clearance.

In addition to initiatives with the private sector, FHI works with other USAID CAs and international organizations involved in contraceptive development. FHI is collaborating closely with the Contraceptive Research and Development Program (CONRAD) on the development of several products. FHI also participates in the Interagency Working Group on Vaginal Microbicides, an informal network organized by WHO to coordinate work on the development of new vaginal microbicides.

Responding to concerns of women's advocacy groups, as well as to the worldwide epidemic of human immunodeficiency virus (HIV) infection and other sexually transmitted diseases (STDs), FHI continues to focus increasing attention on developing and evaluating barrier methods and spermicides, which will protect against both pregnancy and STDs. For many years, condoms were not a major method provided by many family planning programs because their clients are usually women, many men dislike using condoms, and storage can be difficult in some climates. USAID has asked FHI to carry out a program of research and quality surveillance, including evaluation of the integrity of latex condoms stored under specified conditions, both in the laboratory and in actual use. Improved quality surveillance has the potential for significantly reducing wastage associated with poor storage conditions. The product quality surveillance program is expanding to include other types of contraceptives.

Evaluating the safety of contraception includes studying long-term unanticipated consequences, as well as short-term effects. A significant part of FHI's USAID resources is dedicated to research concerned with the noncontraceptive benefits and risks of the contraceptive methods provided by USAID in developing countries.

FHI strives to have a balanced research portfolio and agenda that has a broad relevance to programs worldwide, as well as meeting particular program needs in specific countries. FHI recognizes the importance of country-level input, as well as central input, when setting global research and development priorities. To this end, FHI established a regional office in Nairobi, Kenya in January 1992 and placed a resident advisor to the Ministry of Public Health in Nepal in January 1993. FHI also maintains an office in Cairo, Egypt and established a country office in Bolivia during FY'96. FHI remains responsive, as resources permit, to requests from USAID Missions around the world but gives emphasis to those countries designated as priority by the Office of Population.

## **Organization of This Report**

The following report describes FHI's program and FY'97 planned activities under the Contraceptive Technology and Family Planning Research Cooperative Agreement. Following this Overview, Section II lays out the broad goal, program priorities and key interdivisional initiatives. The FHI divisions responsible for implementing the program are also described briefly.

Section III presents the detailed annual workplan for FY'97 by division. For each of the divisions, with the exception of the support divisions, an overview of planned activities for the current year is presented. Following this introduction, a detailed individual workplan for each subproject within a division is presented. The subprojects are listed in the order described within the introduction to each division (e.g. for the Clinical Trials Division, subprojects are grouped by method). Readers will note that each subproject report denotes the USAID Population, Health and Nutrition Center's Results to which the subproject activities and accomplishments most directly contribute. This reflects USAID's Results Framework, schematically depicted in Appendix A.

The budget for FY'97 is presented in Section IV. The budget is presented first in summary form with each Division's total budget specified. A more detailed budget is then provided by project, organized geographically first by regions and the, within regions, by country. Appendices and an FCO Index follow the body of the workplan. The latter will aid those wishing to locate a particular subproject report. Within the Index, each subproject is listed in chronological order by Division, along with the page number on which the subproject description can be found.

The broad goal of the Contraceptive Technology and Family Planning Research Cooperative Agreement No. CCP-3079-A-00-5022-00 is to enhance the freedom and abilities of individuals in the developing world to choose voluntarily the number and spacing of their children. The specific purpose of the work to be carried out 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.

## FHI DIVISIONS IMPLEMENTING THE COOPERATIVE AGREEMENT

Under FHI's organizational structure, the Contraceptive Technology and Family Planning Research Cooperative Agreement is implemented by the Research and Development Department (R&D), the Reproductive Health Programs Department and the Product Quality and Compliance (PQC) Division. The work of these groups is supported by the Information and Technology Office (ITO) and by the Administration and Finance Department.

The divisions comprising the Research and Development Department are Clinical Trials, Biostatistics, and Regulatory Affairs and Quality Assurance. Four Reproductive Health Programs Department divisions contribute to the work of the Cooperative Agreement: Contraceptive Use and Epidemiology, Field Operations, Policy and Research Utilization, and Service Delivery Research. A brief description of each division is given below.

**The Clinical Trials Division (CT)** conducts Phase I through Phase III clinical trials to evaluate new contraceptive technologies and to provide the data necessary to obtain U.S. and developing country regulatory agency approvals. CT also conducts studies on approved contraceptives, including Phase IV post-marketing surveillance studies, to obtain and provide information about the efficacy, safety and acceptability of these methods in different cultural settings to facilitate product introduction and use.

**The Biostatistics Division (BIOS)** is involved in all stages of clinical and programmatic research. Biostatisticians collaborate with clinicians and researchers to define research objectives and to determine appropriate study designs and sample sizes. Biostatisticians develop and carry out the data analysis plans for all clinical studies and provide statistical review and support on a consultative basis for programmatic and epidemiologic studies. FHI's biostatisticians evaluate recent developments in statistical applications and play a lead role in determining how these methods can be used to improve the quality of contraceptive research worldwide.

**The Contraceptive Use and Epidemiology Division (CUE)** carries out research to assist individuals and programs in improving the safety, acceptability and effective use of contraceptive methods. The research is broad-based and involves the study of a variety of methods used by diverse populations. CUE's present research focuses on acceptability of barrier methods, contraceptive use dynamics, contraceptive benefits and risks, and contraception and STDs/HIV.

**The Field Operations Division (FO)** serves as the principal coordinating point for FHI's country-specific programs and activities and provides support for FHI regional and country offices. It provides the geographic focus to FHI activities and promotes planning based on country and regional needs.

**The Policy and Research Utilization Division (PRU)** works to improve the dissemination and use of research findings. Family planning providers and planners are the primary audiences for dissemination efforts. The division's work falls under four categories: reproductive health information dissemination, health communication and training, activities to improve access to contraception, and technical assistance and training for family planning related policy development. Oversight of FHI's specialized reproductive health library, which serves the needs of the entire organization, is also the responsibility of this division.

**The Service Delivery Research Division (SDR)** carries out studies that aim to improve the delivery of family planning services, with the overall goal of increasing access to contraception. The emphasis of the division's work is to inform management and to guide policy decisions that can lead to increased access to program contraception. Divisional priorities are improving quality of care, reducing barriers that limit access to contraception, evaluating new combinations of methods and delivery systems, and improving resource allocation and financial sustainability.

**The Product Quality and Compliance Division (PQC)** coordinates and manages FHI's contraceptive quality assurance programs. PQC evaluates the quality of contraceptive products distributed by USAID, including condoms, oral contraceptives (OCs), injectables, suppositories and IUDs. These evaluations serve to ensure that all contraceptives procured by USAID for distribution to developing countries meet the quality expectations when manufactured, during shipping and storage, and when used in the field.

**The Regulatory Affairs and Quality Assurance Division (RA/QA)** provides regulatory support necessary for research and program divisions. In this capacity, RA/QA staff review all clinical trial protocols and reports, and they participate as regulatory advisors on interdivisional project working groups. The RA/QA staff maintain a current working knowledge of USFDA regulations and guidelines applicable to contraceptive drugs and medical devices. They are also responsible for the development, implementation and auditing of standard operating procedures for interdivisional activities and for the compliance auditing of Good Laboratory Practices, Good Manufacturing Practices (GMP) and Good Clinical Practices activities for FHI.

**The Information Technology Office (ITO)** provides computer systems and networks in support of FHI work on a worldwide basis. FHI uses a combination of Client/Server technologies, industry standard clinical trials methodologies and products, and state of the art networks to fulfill its mission. ITO is organized into four major sections: User Support, Information Systems Operations, Database Administration and Systems Development.

## **FY'97 PROGRAM PRIORITIES AND INTERDIVISIONAL INITIATIVES**

### **Program Priorities**

During the five-year period covered by the cooperative agreement (August 1995 - August 2000), FHI continues to build upon the work it has carried out for the past two decades with funding from the Office of Population. Although program priorities may change from year to year, the following activities are of continuing importance to FHI:

- research to develop and obtain regulatory approval of new, safe and effective contraceptive technologies;
- research and technical assistance for contraceptive introduction and evaluation;
- testing and surveillance to assure the quality of contraceptive products;
- studies to improve acceptability and correct use of contraceptive methods;

- research to improve access to contraception by improving family planning service delivery practices and quality of care;
- research to support family planning service delivery programs, including studies to improve cost-effectiveness for delivery of contraceptive methods;
- studies (unique among Office of Population CAs) to evaluate both long- and short-term benefits and risks of contraceptive use;
- dissemination of contraceptive research findings and information in formats that are useful to service providers, policymakers and family planning clients.

Workplan priorities for the current fiscal year, developed in consultation with staff in the Research Divisions and approved by FHI's Scientific Committee and the Technical Advisory Committee are:

- **Evaluation and Approval of New Contraceptives:** The need for safer, more effective and more acceptable methods drives the contraceptive development process. This process includes basic and preclinical research to develop new methods and Phase I, II and III clinical trials to evaluate the products and provide data for regulatory approval. During FY'97, FHI's activities will include research on various barrier methods (polyurethane slip-on male condoms, vaginal contraceptive films and Femcap<sup>®2</sup>), female sterilization (quinacrine retrospective cohort study), male sterilization (time to infertility after vasectomy), long-acting steroid delivery systems (Norplant and OCs (timing of initiation of progestin-only pills in lactating women).
- **Contraceptive Introduction and Evaluation:** FHI's activities also focus on post-approval introduction of methods into programs and the evaluation of interactions between users and the method. Research at this stage often influences further improvements in the method and guides the development of education and counseling materials and programs to enhance correct, consistent use. In FY'97, FHI's efforts in this area will focus on acceptability of barrier methods (dual method use, female condoms, diaphragm), and contraceptive use behavior and compliance.
- **Service Delivery Research:** FHI's research also studies interactions between providers, users, and the method, as program use of a method expands. In FY'97, FHI's service delivery research will address issues of accessibility, quality and affordability of products and services, and the cost of providing the methods. FHI's contraceptive quality assurance program will continue to evaluate the quality of contraceptive products distributed by USAID. FHI will continue to work closely with other CAs to carry out research that contributes to USAID's Maximizing Access and Quality (MAQ) Initiative. Research to expand and improve services, including the evaluation of family planning guidelines, will be undertaken. Improving family planning access to underserved groups, particularly young adults and women immediately following abortions, will be of particular interest. FHI will continue to respond to Missions' requests for research and technical assistance on costs of services and methods and on the best use of limited resources. The advantages and disadvantages of integrating family planning and STD services will also be studied.
- **Noncontraceptive Benefits and Risks:** FHI research includes aspects of safety and special considerations for use, which can be studied only when methods have been used by large numbers of people, often for long periods. This research seeks to improve understanding of noncontraceptive effects of a method on aspects of the user's health and well-being. FHI's FY'97 workplan includes continued investigation on the benefits and risks of OC use, the association between vasectomy and prostate cancer, and the link between copper IUD use and tubal infertility, as well as several studies to measure the risk of STDs, including HIV infection, among users of specific family planning methods. Because epidemiologic studies tend to be expensive,

<sup>2</sup> Femcap<sup>®</sup> is a registered trademark of FemCap, Inc. for a vaginal barrier device.

in many instances FHI has received USAID permission to use its funding to carry out basic study development work in order to seek funding from other agencies, such as NIH.

- **Improved Knowledge and Skills:** At each step of the contraceptive technology research process, FHI disseminates the information produced in order to enhance the knowledge and skills of providers, to improve the quality of services and to promote expanded choices for consumers. This information and knowledge also feed back into the research continuum to assure that the needs and concerns of users and providers regarding the safety, efficacy, acceptability and affordability of methods are understood and considered in efforts to improve existing methods and their use, as well as to develop new methods. During FY'97, FHI's quarterly bulletin, *Network*, will continue to be produced in three languages and distributed worldwide. Development, production and translation of several contraceptive technology update (CTU) modules are ongoing. In addition, FHI will respond to requests for information from individuals and organizations and carry out targeted dissemination activities, as needed, to respond to misinformation in the media about contraception.

## Major Interdivisional Initiatives

As described in the previous section, FHI is organized by departments and divisions, with each division having primary responsibility for major components of FHI's contraceptive technology and family planning research program, based on technical and methodologic skills within the division. However, collaborative work among divisions is mandated by the complexity of the issues FHI addresses in this program, and FHI has used various approaches to maintain collaboration among divisions in key program areas. During the past fiscal year, a number of program area interdivisional working groups were superseded by the establishment of three interdivisional 'strategic planning groups,' one dealing with new technologies, one focusing on research issues in existing technologies, and one on reproductive program issues. The roles of these groups include information gathering, priority setting, resource identification, implementation team identification, information sharing, and peer review. Among the tasks undertaken by the groups was the identification and development of research and program issues for consideration by the Technical Advisory Committee (TAC) for the Contraceptive Research Cooperative Agreement. Through a review and consensus process that incorporates recommendations of the strategic planning groups, the TAC, FHI's Scientific Committee, and staff in the Research Division of USAID's Office of Population, FHI has identified priority areas for FY '97, as described in the following paragraphs. These priority areas will continue to benefit from the broad range of skills and institutional capabilities of the various divisions of FHI.

### ■ Barriers and Spermicides

For the past several years, FHI's research agenda has emphasized contraceptive methods that may also provide protection against STDs, including HIV. In accordance with this priority, clinical, behavioral and programmatic studies on a range of barrier methods including male and female condoms, diaphragms and cervical caps, and vaginal spermicidal products are ongoing or planned for FY'97.

In FY'96, several years of interdivisional FHI efforts to develop a non-latex male condom culminated in a licensing agreement of the polyurethane condom to a commercial partner, Mayer Laboratories. Under this agreement, FHI plans to carry out a multicenter clinic-based contraceptive efficacy study as required by a new USFDA guidance for marketing of synthetic condoms. Completion of this study will involve the CT, BIOS, RA/QA and ITO divisions.

Other ongoing and planned contraceptive efficacy research includes the Tactylon™<sup>3</sup> condom, Femcap and Lea's Shield™<sup>4</sup>. In addition to interdivisional collaboration at FHI, these studies also involve collaboration with CONRAD. During this fiscal year, FHI will complete analysis of the Tactylon

<sup>3</sup> Tactylon™ is the trademark of Tactyl Technologies, Inc. for a nonlatex condom.

<sup>4</sup> Lea's Shield™ is the trademark of YAMA, Inc. for a vaginal barrier device

condom and Femcap studies, and will continue to negotiate with the inventor of Lea's Shield to resolve issues regarding next steps with seeking regulatory approval for this device.

Staff from several FHI divisions continue to be involved, as part of an interagency group headed by WHO, in a prospective study of diaphragm use in selected developing countries. FHI is responsible for the implementation of a study of the acceptability, service delivery requirements, and use-effectiveness of the diaphragm in the Philippines.

FHI is continuing a comparative efficacy study of vaginal contraceptive film (VCF)<sup>5</sup> and Conceptrol<sup>6</sup> in four developing countries (Ghana, Guatemala, Ecuador, and Mexico) and at a U.S. site. Also during this year, FHI will continue research on the safety and programmatic aspects of reuse of the female condom, an effort which entails the collaboration of staff in CUE, BIOS, PQC and RA/QA.

As a major research utilization and planning project during FY'97, FHI will prepare and publish a "state of the art" monograph on latex condoms, synthesizing the extensive work done by FHI and other organizations over the past several years. The monograph was recommended by an expert group that convened at FHI in May 1996 to identify future needs for research on latex condoms, both on the physical product, as well as on use behaviors and the interaction of use behaviors and product performance. The monograph team is led by staff in CUE but involves PQC, PRU and CT, as well as several external advisors and contributors.

#### ■ Maximizing Access and Quality (MAQ)

FHI is one of several USAID cooperating agencies that have been involved for a number of years in an international initiative to maximize access to and quality of contraceptive services. MAQ will continue to be a major focus for FHI in FY'97 and involves the efforts of several divisions. The SDR division has several planned and ongoing studies to identify barriers that restrict access to family planning services that be removed without jeopardizing the health of clients. SDR is also implementing studies that attempt to measure quality of care, and to measure the impact on safety, quality of care, and costs when barriers to providing certain methods are removed. In a new initiative discussed at the 1996 TAC meeting, FHI is developing a project to determine the degree to which contraceptive continuation is influenced by whether or not the consumer receives their method of choice.

Education and training are important components of FHI's MAQ activities. Under the leadership of PRU, staff from several divisions are involved in a multi-year project to develop a series of teaching modules on contraceptive technology and reproductive health. New modules to be developed during FY'97 will address the topics of adolescent reproductive health and sterilization (both male and female). PRU, through its MAQ focus, also conducts contraceptive technology update seminars for providers and policymakers in a number of countries. The CTU modules series serve as a key tool in these seminars.

Staff from several FHI divisions are involved in the USAID Technical Guidance Working Group. During this fiscal year, FHI staff will update checklists for use of COCs and injectables in community-based distribution (CBD) programs and for STD screening in resource-poor settings. In addition, FHI will contribute chapters on Spermicides, the Lactational Amenorrhea Method (LAM), POCs and Emergency Contraception for Volume II of the Technical Guidance document.

#### ■ Contraception, Family Planning and STDs/HIV

During FY'97, FHI will continue its leadership role in carrying out research to determine the protection afforded against contracting STDs/HIV, as well as the risks involved, to individuals contracting STDs, including HIV. Data from a study of the short-term complications of IUD use in HIV-positive women will be analyzed and reported, and an attempt will be made to locate women who were enrolled in this study as much as two years ago to determine long-term outcomes. Also continuing is a study on

<sup>5</sup> VCF<sup>®</sup> is a registered trademark of Apothecus, Inc. for Vaginal Contraceptive Film.

<sup>6</sup> Conceptrol<sup>®</sup> is a registered trademark of Ortho/McNeil for vaginal foaming tablets.

hormonal contraceptive use and the incidence of cervical ectopy and cervical chlamydia. A new study will be developed to assess the impact on STD prevalence in the community when the female condom is introduced into the contraceptive method mix.

Behavioral studies continue to be important in this area as well, and FHI will continue its work on "dual methods," where a primary method is used for contraception and a second method is used to protect against STDs. Studies will also be developed to evaluate a variation of the dual method approach — where a barrier method is used as the primary method to prevent both pregnancy and STDs but with backup ECPs for use in the event of a barrier method failure.

One of the issues of *Network* this fiscal year will be devoted to contraception, family planning and STDs/HIV.

### ■ Adolescent Reproductive Health

FHI will continue its work, developed over the past several years, on adolescent reproductive health. A major initiative this year will be the development and publication of a CTU module on this topic, which will be done collaboratively with USAID's FOCUS Project. An issue of *Network* dealing with adolescent reproductive health will also be published.

During FY'97, building on a study completed last year that assessed access to family planning by young adults in Senegal, FHI will coordinate a workshop in Dakar to sensitize service providers to the reproductive health needs and special service delivery issues for this group. FHI staff will also attend and participate in the international conference in Addis Ababa, Ethiopia organized by UNFPA and CEDPA on adolescent reproductive health .

FHI's program under the cooperative agreement is complemented by interdivisional activities conducted with support of other Projects, particularly activities focused on improving the reproductive health of adolescents in refugee situations supported by UNFPA and UNHCR and on research being conducted as part of the USAID-sponsored Women's Studies Project.

In this section (Section III), FY'97 workplans are presented for ongoing and new subprojects under the Contraceptive Technology and Family Planning Research Cooperative Agreement for FY'97. Management and development subprojects are excluded as they serve a support function to other efforts. There were a number of subprojects that, as of October 1, 1996 had no defined FCO number. As this Workplan was under preparation, the assignment of FCOs progressed. Because the identification of a specific FCO number is useful in tracking projects, the "to be determined" FCO designations were updated whenever specific FCO numbers were assigned. With that exception, the Workplan reflects subproject status as of the start of the fiscal year.

Individual reports include subproject objectives, a brief description and planned activities for FY'97, and possible barriers to completion of planned work. In addition, the implementing agency (if other than FHI) and collaborating agencies are presented. Budget figures are given both for the current fiscal year and current estimated total budget of the subproject. Both figures include FHI in-house and field costs.

The subproject report are grouped by Division, presented in the following order:

***Research and Development Department***

- Clinical Trials Division
- Biostatistics Division

***Reproductive Health Programs Department***

- Contraceptive Use and Epidemiology Division
- Field Operations Division
- Policy and Research Utilization Division
- Service Delivery Research Division

**Product Quality and Compliance Division**



## ■ Clinical Trials to Provide Information on Available Contraceptive Methods

The main purpose of these trials is to produce information for family planning providers and programs on contraceptive methods already in use and to provide data for policy decisions on the methods to be offered in a country program. Studies to date have included clinical trials of POCs and COCs, Norplant implants, IUDs, male and female sterilization techniques, and various barrier methods. Research is currently supported or planned on POCs (completion of a final report), Norplant implants, a monthly injectable (Cyclofem), emergency contraceptives and male sterilization.

### *Clinical Trials Division's FY'97 Program*

During FY'97, FHI's contraceptive development program will continue to emphasize research on barrier methods of contraception. A multicenter clinical trial will be initiated to compare the breakage and slippage rates, as well as the contraceptive effectiveness and acceptability, of our twin-aperture, slip-on plastic condom with a marketed latex condom. The multicenter clinical trial to compare the efficacy of VCF with vaginal foaming tablets (CONCEPTROL<sup>®</sup>) will be completed. FHI will continue its role in handling the data management and statistical analysis for a CONRAD-sponsored Phase II/III clinical trial of the Femcap. The FHI statistical report will be completed this fiscal year, and staff will continue to work closely with CONRAD staff into early next fiscal year in completing the overall final report. FHI staff will assist YAMA, Inc. during the FDA review of a premarket approval application (PMA) for Lea's Shield and will possibly become involved in any subsequent clinical trial that might be necessary for regulatory approval.

A subproject, conducted in cooperation with AVSC International, to better understand the timing of effectiveness of male sterilization will be completed with a final report written. Several papers for publication using the data from this and the earlier pilot study will be prepared.

Research on hormonal contraceptive methods will continue with the clinical trial of Norplant implants in Senegal being completed and a final report will be prepared. Completion of this study will end more than a decade of clinical trials on Norplant implants. Several secondary analyses using our full Norplant dataset will be conducted and papers for publication will be written. Final reports will be completed from the studies to help better understand the timing of the contraceptive effect of Norplant implants and the timing of initiation of the POP in lactating women. Several papers for publication will also be written related to these studies. Activities will be initiated to design and possibly implement a study to better understand the timing of effect of Cyclofem, a monthly injectable. This study will be a follow-on to the Norplant study mentioned above and a similar study (funded by the Mellon Foundation) using DMPA. Finally, assuming cofunding is obtained, we plan to conduct a clinical trial to evaluate whether an antiemetic drug will prevent nausea associated with the Yuzpe regimen of emergency contraceptive pills.

Details of CT subprojects are contained in individual workplans, presented by type of method, as listed below. Subprojects marked with an asterisk are new and expected to get underway in FY'97.

## ■ Barrier Contraceptives and Spermicides

- Lea's Shield PMA Panel Support (2059)
- Lea's Shield Development (2232)\*
- Vaginal Methods - General Development (2070)
- A Comparative Clinical Evaluation of VCF<sup>®</sup> and Conceptrol<sup>®</sup> (2211)
- Safety and Efficacy Study of Femcap Used With Spermicide vs the Ortho All-Flex<sup>®</sup> Diaphragm Used With Spermicide (2218)
- Collaboration with WHO on Spermicide and Microbicide Development (2220)
- Developing a Vaginal Microbicide to Prevent HPV Transmission (2227)
- Plastic Male Condom Development and Management (2224)

- Comparative Contraceptive Effectiveness Assessment of the Twin-Aperture Slip-On Male Condom and Latex Condoms (2229)
- Comparative Assessment of the Twin-Aperture Slip-On Condom and a Latex Condom: Breakage and Slippage (2233)\*

■ **Female Sterilization**

- Identification of New Methods of Nonsurgical Sterilization (2226)

■ **Male Sterilization**

- Expanded Study of the Time to Infertility After Vasectomy (2217)
- Sterilization Paper Writing (2231)

■ **Long-Acting Steroid Delivery Systems**

- Senegal: Pre-Introductory Clinical Trial of Norplant (Final Report) (2080)
- Timing of Onset of Contraceptive Effectiveness in Norplant Implant Users (2213)
- Extending the Initial Injection Window in Cyclofem Users (FCO TBD)\*

■ **Intrauterine Devices**

- TCu 380A IUD Clinical Research (2051)

■ **Oral Contraceptives**

- Timing of POC Initiation Among Lactating Women (final report: see 2030)
- General Systemics (2030)

■ **Emergency Contraception**

- Antiemetics to Prevent Nausea Associated with Emergency Contraceptive Pills (2230) \*

Individual descriptions of each of these subprojects follow in the order presented above.

**USA:           Lea's Shield PMA Panel Support (FCO 2059)**

**Technical Monitor:** Julie Omohundro

**Objective(s):** To assist Yama Inc. during FDA review of a premarket approval application (PMA) for Lea's Shield.

Note: The original objective of this subproject was to conduct a Phase III clinical trial for the Lea's Shield device. This study was canceled pending negotiations with the product developer, and the objective and title subsequently changed to reflect the developer's decision to proceed directly to product approval.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Lea's Shield, a vaginal barrier device, is designed as an alternative to currently available vaginal barrier contraceptives and is intended for use with spermicide for up to 48 hours after insertion. A randomized, multicenter, comparative Phase III study was planned to compare the contraceptive efficacy of Lea's Shield and a diaphragm when both devices were used with spermicide. The results of this clinical trial were to be used to seek product approval from the USFDA; however, the manufacturer chose to submit a premarket approval application to the FDA without conducting a Phase III study. This subproject subsequently is to provide technical services to Yama, Inc. in their PMA effort. New work on Lea's Shield, subsequent to this PMA effort, will be conducted under the newly established FCO 2232.

**Collaborating Agency(s):** CONRAD

**FY' 97 Planned Activities:**

- One of FHI's biostatisticians will present the results of the historical control analysis to an FDA advisory panel in October 1996.
- FHI's involvement with Lea's Shield development after the panel meeting is as yet undefined. This subproject will be closed once all residual work stemming from the FDA advisory panel meeting is completed.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Jul 1996 |
| <b>FY '97 Budget:</b>     | \$ 22,349  | <b>Projected End Date:</b> | Dec 1996 |
| <b>Total Budget:</b>      | \$ 86,300  |                            |          |

## Worldwide: Lea's Shield Development (FCO 2232)

**Technical Monitor:** Julie Omohundro

**Objective(s):** To determine whether FHI will play a role in the future clinical development of Lea's Shield and, if so, to define FHI's role and the source of funding.

Note: This subproject follows after FCO 2059, Lea's Shield Panel Support.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** On October 21, 1996, an FDA advisory panel is to recommend whether or not the FDA should approve Lea's Shield based only on the data that had been submitted to the FDA by Yama Inc., the product manufacturer. This subproject will be defined more fully once the future development needs for Lea's Shield are known.

### FY' 97 Planned Activities:

- Discussions with USAID, NIH, CONRAD, and Yama will continue regarding plans for a future development study of Lea's Shield.
- A signed agreement specifying the parties that will be involved in further study or development of Lea's Shield, their roles, and the source of funding will be obtained.

### Possible Problems, Barriers to Completion:

- Adequate funding might not be available.
- An agreement concerning FHI's role that is acceptable to all parties might not be reached.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Dec 1996 |
| <b>FY '97 Budget:</b>     | \$ 23,432  | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 23,432  |                            |          |

## Worldwide: Vaginal Methods - General Development (FCO 2070)

**Technical Monitor:** David Sokal

**Objective(s):** To support in-house activities related to barrier contraceptive research development, manuscript writing, data and file management, and staff support.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** General development activities for barrier contraceptives clinical research, including data file management and manuscript preparation, are supported under this subproject. Past activities have included a review of patent literature regarding vaginal barrier devices and assessments of the potential for collaborative development of specific vaginal methods.

**Collaborating Agency(s):** CONRAD

**FY' 97 Planned Activities:**

- FHI staff will discuss with CONRAD issues related to the potential pursuit of the development of a low-cost sponge.
- A paper analyzing acceptability issues from the FHI/CONRAD REALITY™ clinical trial will be prepared.
- An article is planned regarding the correlation of diaphragm sizes with height, weight, parity and other variables.

**Possible Problems, Barriers to Completion:**

- None foreseen.

**Funding Source(s):** USAID/Core  
**FY '97 Budget:** \$ 31,808  
**Total Budget:** N/A-Annual

**FCO Approved:** <Aug 1995  
**Projected End Date:** Sep 2000

# Worldwide: A Comparative Clinical Evaluation of VCF<sup>®</sup> and Conceptrol<sup>®</sup> (FCO 2211)

**Technical Monitor:** Elizabeth Raymond

**Objective(s):** To assess the contraceptive effectiveness, safety and acceptability of vaginal contraceptive film (VCF) in comparison to Conceptrol<sup>®</sup>.

## Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** VCF is a barrier method commercially available in the United States that contains the spermicide nonoxynol-9 (N-9). Conceptrol is a commercially marketed vaginal foaming tablet also containing N-9 that is currently supplied by USAID to developing countries. This randomized clinical trial compares the contraceptive effectiveness, safety and acceptability of these two spermicide products. Participants are being recruited at eight centers in Mexico, Ecuador, Guatemala, Ghana and the United States and followed-up for six months. The outcome of this project is expected to increase knowledge of contraceptive effectiveness and user dynamics of these two spermicides. Data from this study will be used by USAID officials to help decide whether to include VCF in their commodities programs. If USFDA issues new regulations requiring contraceptive effectiveness data for spermicide products, the results of the study may eventually be submitted to USFDA to support continued U.S. marketing of VCF and Conceptrol.

## Implementing Agency(s):

Guatemala: Asociacion Pro-Bienestar de la Familia (APROFAM); Ecuador: Family Planning Medical Centers (CEMOPLAF); Mexico: Ciudad Juarez (FEMAP), Durango (Instituto de Investigación), and Torreón (Escuela de Medicina); Ghana: Kamfo Anokye Teaching Hospital Family Planning Center; USA: Arizona Clinical Research Center, Tucson, AZ.

## FY' 97 Planned Activities:

- Recruitment will end in November 1996.
- Monitoring visits will continue to take place every 3-4 months.
- A planned interim analysis is scheduled for October/November 1996.
- It is expected that all participants will complete follow-up by June 1997.
- Monitoring visits will continue to take place every 3-4 months. Study close-out is scheduled for all sites between April and August 1997.
- Data analysis is expected to begin.

## Possible Problems, Barriers to Completion:

- None foreseen.

|                           |              |                            |          |
|---------------------------|--------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core   | <b>FCO Approved:</b>       | Sep 1995 |
| <b>FY '97 Budget:</b>     | \$ 375,252   | <b>Projected End Date:</b> | Dec 1997 |
| <b>Total Budget:</b>      | \$ 1,267,631 |                            |          |

<sup>8</sup> CONCEPTROL<sup>®</sup> is a registered trademark of Ortho/McNeil for vaginal foaming tablets.

**Worldwide: Safety and Efficacy Study of Femcap Used with Spermicide vs the Ortho All-Flex Diaphragm Used with Spermicide (FCO 2218)**

**Technical Monitor:** Sheri Spivey

**Objective(s):** 1) To evaluate and compare the safety and contraceptive efficacy of Femcap<sup>®</sup> used with 2% N-9 and Ortho All-Flex<sup>®9</sup> contraceptive diaphragm used with 2% N-9; and 2) to follow colposcopic changes, if any, occurring in the two groups and to describe the differences.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Femcap is a vaginal barrier device designed as an alternative to currently available vaginal barrier contraceptives. This contraceptive efficacy study involves 800 participants from 10 sites the USA and 80 participants from Chile. Women are randomly allocated to either Femcap or a diaphragm and are followed for 6 months. An additional small study involving 42 participants from the USA is being conducted in conjunction with the larger Femcap project. This study will follow colposcopic changes, if any, occurring in the participants. The procedures to be followed by these women will be exactly the same as those in the efficacy study, except that the women in the colposcopy study will undergo colposcopy on four occasions. CONRAD is conducting both studies in collaboration with FHI. FHI has reviewed the protocol and case report forms, is responsible for all data management and analysis activities, and is monitoring five of the ten domestic sites as well as the site in Chile. (Monitoring activities are contracted with CONRAD under a separate FCO.)

The outcome of the Femcap project is expected to lead to the approval of a new barrier method and to increase our knowledge of contraceptive effectiveness and user dynamics of these two female barrier contraceptives. Data collected from a questionnaire given to male partners of participants will enhance our understanding of the influence of male attitudes and male supportive behavior on the use of these methods.

**Implementing Agency(s):** **USA:** Norfolk: Eastern Virginia Medical School; Pittsburgh: Magee-Women's Hospital; Sacramento: Sutter Medical Group; Chicago: U. of Illinois; Baltimore: Francis Scott Key Medical Center, Johns Hopkins Medical Service Center; Houston: Baylor College of Medicine; Phoenix: Good Samaritan Regional Medical Center; Tucson: U. of Arizona Health Sciences Center; **Chile:** Instituto Chileno de Medicina Reproductiva (ICMER), Santiago.

**Collaborating Agency(s):** CONRAD

**FY' 97 Planned Activities:**

- To ensure a high level of data quality for this subproject, a data audit is planned for November 11-21, 1996.
- Participant follow-up in the USA will end in February 1997, and it is expected that site close-out visits will take place in March 1997.
- Recruitment and monitoring will continue at the Chile site.
- Femcap data for the ten domestic sites will be cleaned and analyzed. It is expected that a draft statistical report will be forwarded to CONRAD in July 1997.

<sup>9</sup> Ortho All-Flex<sup>®</sup> is a registered trademark of Ortho Pharmaceutical for a diaphragm.

- Enrollment is anticipated to continue in Chile at least through June 1997.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Oct 1994 |
| <b>FY '97 Budget:</b>     | \$ 123,739 | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 508,829 |                            |          |

## Worldwide: Collaboration With WHO on Vaginal Microbicide Development (FCO 2220)

**Technical Monitor:** David Sokal

**Objective(s):** To collaborate with researchers who are developing new vaginal microbicide products.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- 4.1 Effective interventions to reduce sexual transmission of HIV/STD identified strengthened, implemented and evaluated.

**Description:** The World Health Organization (WHO) proposed the formation of an informal network to coordinate work on the development of new vaginal microbicides for HIV prevention. The other organizations involved are NIH and CONRAD, The Population Council and the British Medical Research Council. In particular, FHI continues to explore the feasibility of developing a spermicidal virucide and/or a compound that would also be effective against human papillomavirus (HPV).

### FY' 97 Planned Activities:

- FHI will send a representative to the Fall 1996 collaborative group meeting in Europe.
- FHI will continue to explore possibilities for collaboration with WHO, CONRAD, CDC and others, as appropriate.
- FHI will send a representative to the Spring 1997 collaborative group meeting in the U.S.

### Possible Problems, Barriers to Completion:

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Nov 1994 |
| <b>FY '97 Budget:</b>     | \$ 29,225  | <b>Projected End Date:</b> | Sep 2000 |
| <b>Total Budget:</b>      | N/A-Annual |                            |          |

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| <b>USA: Developing a Vaginal Microbicide to Prevent HPV Infection (FCO 2227)</b> |
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**Technical Monitor:** David Sokal

**Objective(s):** To identify an effective agent that could be used as a vaginal microbicide against papillomavirus.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Infection with human papillomavirus (HPV) causes cervical cancer. A vaginal microbicide that could prevent sexual transmission of HPV as well as HIV would be a major advance in providing women with a method to protect themselves from serious illness. The goal of this project is to perform *in vitro* and animal testing of vaginal microbicide products that are in the pipeline. Based on *in vitro* and animal testing, a product may be chosen for further development. FHI's role is to coordinate the implementation of the lab research to demonstrate efficacy and to choose compounds for testing. FHI's only role in funding the pre-clinical work will be to pay a researcher at the University of Arkansas, Medical Sciences to screen four compounds *in-vitro*. If a suitable product is identified, an unsolicited proposal will be prepared for submission to the National Institute of Allergy and Infectious Diseases (NIAID) for a clinical trial. This is a collaborative effort with multiple funding sources. USAID is covering the costs of FHI staff time in contributing to the effort.

**FY' 97 Planned Activities:**

- FHI and JHU will continue to explore possibilities for collaboration with NIH, WHO, CONRAD, CDC and others as appropriate.
- FHI will draft an article to report the most recent results from *in vitro* testing of agents.

**Possible Problems, Barriers to Completion:**

- Limited time and staffing may reduce FHI's continued participation in this project.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Mar 1996 |
| <b>FY '97 Budget:</b>     | \$ 56,960  | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 75,824  |                            |          |

## Worldwide: Plastic Male Condom Development and Management (FCO 2224)

**Technical Monitor:** Gaston Farr

**Objective(s):** To develop polyurethane condoms functionally equivalent to condoms made of latex and to continue a working relationship with a corporate partner.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- 4.1 Effective interventions to reduce sexual transmission of HIV/STD identified, strengthened, implemented and evaluated in emphasis countries.

**Description:** Activities related to the development of new condoms made from polyurethanes have been ongoing since 1987. Activities specific to the development of the twin-aperture slip-on polyurethane condom have been ongoing since 1991. Initial efforts focused on the use of stress-softened Plaitlon<sup>®</sup> film. Processing and stability concerns resulted in a suspension of this effort in September 1994. The current focus is on the use of a film made from a Dow Chemical resin. A licensing agreement with a commercial partner, Mayer Laboratories, was signed in late 1995, and the technology subsequently transferred. Activities that were overseen by the Materials Technology Division and conducted under FCOs 8030-8037 were then either closed or transferred to the Clinical Trials Division under this FCO. FHI continues to assist Mayer Laboratories in this development effort.

### FY' 97 Planned Activities:

- Interactions with the corporate partner are expected to continue regarding patent research and filing issues for the slip-on condom.
- Meetings with Mayer Laboratories are expected to take place as needed.

### Possible Problems, Barriers to Completion:

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Jul 1995 |
| <b>FY '97 Budget:</b>     | \$ 43,861  | <b>Projected End Date:</b> | Sep 1999 |
| <b>Total Budget:</b>      | \$ 280,000 |                            |          |

|             |  |
|-------------|--|
| <b>USA:</b> | <b>Comparative Contraceptive Effectiveness<br/>Assessment of the Twin-Aperture Slip-On Condom and<br/>Latex Condoms (FCO 2229)</b> |
|-------------|--|

**Technical Monitor:** Gaston Farr

**Objective(s):** To assess the contraceptive effectiveness, safety, acceptability, and rate of breakage and slippage of the twin-aperture slip-on polyurethane condoms when compared to a marketed latex condom.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- 4.1 Effective interventions to reduce sexual transmission of HIV/STD identified, strengthened, implemented and evaluated.

**Description:** As part of a new guidance issued by the USFDA in June 1995, data from a clinic-based contraceptive efficacy study are required before unrestricted labeling will be granted for synthetic condoms. This randomized, multicenter comparative trial is designed to compare the contraceptive effectiveness of the twin-aperture slip-on polyurethane condom with a marketed latex condom. (In November 1995, FHI executed a licensing agreement with Mayer Laboratories for the twin-aperture condom.) Approximately 900 couples will be recruited and followed for a period not to exceed 30 weeks of product use. The couples will use the condoms as their sole means of birth control. Field work is expected to last approximately 2½ years.

**FY' 97 Planned Activities:**

- The revised protocol containing the biocompatibility results will be completed and re-submitted to FHI's Protection of Human Subjects Committee (PHSC) for review and approval during its February 1997 meeting.
- Sites for the study will be identified, evaluated and selected. Subagreement negotiations and local IRB approvals will also be initiated.
- A decision will be reached as to who (FHI or a specific CRO) will do the monitoring.
- Subagreement negotiations with research sites and the local IRB approvals will be completed.
- Study supplies will be received from Mayer Laboratories, inventoried and shipped to research sites.
- CRFs will be completed and printed. The study procedures manual will be completed.
- An Investigators meeting will be held.
- The UK regulatory review and approval process is expected to be completed.
- Programming for the database will be completed and installed, and data entry will begin.
- If above are completed as scheduled, the study will be initiated, and participant recruitment will begin.

**Possible Problems, Barriers to Completion:**

- The receipt of biocompatibility testing results may be delayed. If so, this would cause a delay in protocol revisions and create problems in meeting the deadline for the February PHSC meeting. Without PHSC approval, the clinical trial cannot start.
- Insufficient number of adequate sites who could recruit the number of subjects needed may require shifting study to a larger country, such as the U.S.
- Delays in availability of product for the trials could result in postponing study initiation.

|                           |              |                            |          |
|---------------------------|--------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core   | <b>FCO Approved:</b>       | Feb 1996 |
| <b>FY '97 Budget:</b>     | \$ 303,591   | <b>Projected End Date:</b> | Oct 1999 |
| <b>Total Budget:</b>      | \$ 2,040,000 |                            |          |

|             |  |
|-------------|--|
| <b>USA:</b> | <b>Comparative Assessment of the Twin-Aperture Slip-On Condom and a Latex Condom: Breakage and Slippage (FCO 2233)</b> |
|-------------|--|

**Technical Monitor:** Gaston Farr

**Objective(s):** To determine if the clinical breakage and slippage rates of the twin-aperture slip-on polyurethane condom are similar to those of a latex condom marketed in the United States.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- 4.1 Effective interventions to reduce sexual transmission of HIV/STD identified, strengthened, implemented and evaluated in emphasis countries.

**Description:** As part of a new guidance issued by FDA in June 1995, data from a clinic-based breakage and slippage study are required before limited labeling will be granted for marketing synthetic condoms. This subproject will be a randomized, multicenter, cross-over study comparing breakage and slippage rates of the Twin-Aperture Slip-On polyurethane condom with a latex condom marketed in the United States. At least 240 contraceptive couples will be recruited and asked to use six of the polyurethane condoms and six of the latex condoms during two separate four-week study periods (the sequence of use will be determined by random assignment at the time of enrollment). Field work is expected to last six months from the date of study initiation.

**Implementing Agency(s):** To be determined

**FY' 97 Planned Activities:**

- The protocol will be completed and submitted to FHI's Protection of Human Subject's Committee in November for review and approval.
- Final approval from USAID to initiate the subproject is expected.
- Activities to identify two investigative sites will be initiated.
- Case report form development will be initiated and completed.
- Subagreement negotiations with the selected research sites will be completed.
- Case report forms will be printed, and subject study notebooks will be prepared.
- Study supplies are expected to be received from Mayer Laboratories, inventoried, tested by PQC (for quality control), and shipped to the two study sites.
- The study will be initiated, recruitment will begin, and on-site monitoring will be initiated.
- Programming for the ClinTrial database will be completed and tested, and data entry will begin.
- The programming for data analysis will be initiated.

**Possible Problems, Barriers to Completion:**

- Continued delays in the manufacture and shipment of condom may further delay the anticipated start date for the fieldwork portion of the study.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Jan 1997 |
| <b>FY '97 Budget:</b>     | \$287,880  | <b>Projected End Date:</b> | Jan 1998 |
| <b>Total Budget:</b>      | \$370,383  |                            |          |

**USA: Identification of New Methods of Nonsurgical Sterilization (FCO 2226)**

**Technical Monitor:** David Sokal

**Objective(s):** To review recent literature and identify new, promising approaches to nonsurgical sterilization methods for women and men.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** An extensive literature search is to be conducted on the potential for development of a nonsurgical sterilization method for women and men, reviewing both old and new compounds and methods. Promising ideas will be discussed within FHI and with external experts. If a suitable approach is identified, FHI will work with CONRAD on developing a product development strategy.

**Collaborating Agency(s):** CONRAD

**FY' 97 Planned Activities:**

- FHI will seek and outside funding source for a proof of concept study of erythromycin in an animal model.
- A decision will be made whether or not to proceed with the filing of a formal patent application for the use of erythromycin before the provisional application expires in April 1997.
- If the results of an animal study are promising, a more-detailed research plan will be drafted for review by USAID and possible private funding sources.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Dec 1995 |
| <b>FY '97 Budget:</b>     | \$ 31,176  | <b>Projected End Date:</b> | Sep 2000 |
| <b>Total Budget:</b>      | \$ 41,391  |                            |          |

**Mexico: Expanded Study of the Time to Infertility After Vasectomy (FCO 2217)**

**Technical Monitor:** Susan McMullen

**Objective(s):** To determine the time and number of ejaculations associated with infertility following vasectomy. Infertility is defined as three consecutive azoospermic semen samples taken at least seven days apart.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** This prospective, noncomparative study is being conducted in Mexico in collaboration with Access to Voluntary and Safe Contraception (AVSC) International and Instituto Mexicano de Seguro Social (IMSS). Approximately 225 volunteers who chose vasectomy were evaluated by semen analysis every other week to determine the time and number of ejaculations needed to achieve infertility (three consecutive azoospermic samples taken at least 7 days apart), as well as the time to the loss of sperm motility and loss of eosin staining ability. Subjects were followed up for a maximum of 24 weeks. In addition, a confirmation visit took place 8 weeks after infertility was determined. AVSC International funded all field costs.

**Implementing Agency(s):** IMSS (Mexico City, Mexico)  
**Collaborating Agency(s):** AVSC International

**FY' 97 Planned Activities:**

- Final queries will be completed, and the dataset will be frozen for analysis.
- Programming for analysis will be completed, and all analyses will be performed.
- The final report will be written and disseminated.
- Publication of the data from the study is planned by May 1997.

**Possible Problems, Barriers to Completion:**

- Reduced staff and conflicting priorities have delayed analysis programming and could further delay the completion of the final report.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Sep 1994 |
| <b>FY '97 Budget:</b>     | \$ 87,352  | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 288,218 |                            |          |

## Worldwide: Sterilization Paper Writing (FCO 2231)

**Technical Monitor:** Susan McMullen

**Objective(s):** To conduct secondary analyses on data from completed studies on male and female sterilization and to write papers for presentations and publications based on these analyses.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Following the completion of a clinical trial, staff continue to analyze data and/or prepare papers for presentation and publication in scientific journals to disseminate the results to providers and policymakers. This subproject supports staff time and travel costs related to these needs.

### FY' 97 Planned Activities:

- The final report for the Time to Infertility after Vasectomy Pilot Study will be completed.
- The final report for the Expanded Time to Infertility after Vasectomy Study will be completed.
- The first draft of two Filshie Clip papers on clinical cases involving expulsions and menstrual changes after sterilization will be written.
- Secondary analyses of both the pilot and the expanded Time to Infertility after Vasectomy studies will be completed.

### Possible Problems, Barriers to Completion:

- None foreseen

**Funding Source(s):** USAID/Core  
**FY '97 Budget:** \$ 21,701  
**Total Budget:** N/A-Annual

**FCO Approved:** Jan 1997  
**Projected End Date:** Aug 2000

**Senegal: Final Report: Pre-Introductory Clinical Trial of Norplant (FCO 2080)**

**Technical Monitor:** Randy Dunson

**Objective(s):** To complete a final report on the pre-introductory clinical trial of Norplant subdermal implants, introducing the method into Senegal.

Note: Objectives were initially defined under FCO 1880, which concluded at the end of FY'96. The final objective will continue to be addressed through the completion of a final report on the Senegal clinical trial funded under FCO 2080.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** FHI has been conducting studies of Norplant implants since 1984. During this time approximately 9000 subjects have been admitted to studies at 43 centers in 11 countries (El Salvador, Senegal, Nigeria, Ghana, Philippines, Pakistan, Sri Lanka, Bangladesh, Nepal, Singapore and Haiti). Based on positive responses to an initial pre-introductory study of 50 women, the study in Senegal was expanded to include over 300 women by 1991. All trial work has now been completed in Senegal.

**FY' 97 Planned Activities:**

- A study close-out visit will be conducted in October 1996.
- The final report will be drafted and submitted for review and approval.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Sep 1996 |
| <b>FY '97 Budget:</b>     | \$ 24,355  | <b>Projected End Date:</b> | Apr 1997 |
| <b>Total Budget:</b>      | \$ 24,355  |                            |          |

## Worldwide: Timing of Onset of Contraceptive Effectiveness in Norplant Implant Users (FCO 2213)

**Technical Monitor:** Randy Dunson

**Objective(s):** To determine the time point after Norplant insertion at which adequate contraceptive effect is achieved.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** This subproject investigated the changes in cervical mucus within the first hours to days after Norplant implant insertion. Changes in cervical mucus served as a surrogate marker for achieving contraceptive effect. This was determined by *in vitro* sperm penetration testing and cervical mucus scoring. A total of 42 women at two sites (Baltimore, Maryland; Santo Domingo, Dominican Republic) who were between days 8-13, inclusive, of their menstrual cycle and who requested Norplant implants were admitted to the study. Blood and mucus samples were taken over a period of 7 days to assess hormonal and mucus characteristics. Programmatically, the study findings are important to provide more rigorous scientific rationale behind the use and timing of back-up methods after Norplant implant insertion.

**Implementing Agency(s):** The Johns Hopkins Bayview Medical Center; Baltimore, MD  
PROFAMILIA; Santo Domingo, Dominican Republic

### FY' 97 Planned Activities:

- Data analysis will be completed.
- The final report will be prepared and disseminated.
- Several articles based on results will be submitted for publication.

### Possible Problems, Barriers to Completion:

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Nov 1993 |
| <b>FY '97 Budget:</b>     | \$ 13,359  | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 369,067 |                            |          |

**Brazil: Extending the Initial Injection Window in Cyclofem Users (FCO 22xx/TBD)**

**Technical Monitor:** Randy Dunson

**Objective(s):** To determine if contraceptive efficacy is supported if the first injection of Cyclofem is administered on days 6 and 7 of the menstrual cycle.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** This subproject will investigate cervical mucus changes in Cyclofem users when given the initial injection on days 6 or 7 of the menstrual cycle. Changes over time in cervical mucus will be used as a surrogate marker for contraception and will be determined by *in vitro* sperm penetration testing and cervical mucus scoring. Serum estradiol cypionate and progesterone concentrations and follow-up of ovarian follicle development by vaginal ultrasound scan will be secondary parameters used to determine whether suppressed ovarian activity may have occurred in individual subjects. A total of 15 women who are on days 6 and 7 of their menstrual cycle will be admitted to the study. Each subject will have cervical mucus collected, ultrasound scanning and blood drawn for serum hormone levels at 24 hours postinjection, and again on days 3, 7 and 14 postinjection. The total duration of the study including recruitment (approximately 7 months) and follow-up (14 days) is not anticipated to exceed 10 months. Programmatically, the study is important as the findings may result in extending the initial injection window for Cyclofem to 7 days, which should, in turn, result in more women starting the method.

**FY' 97 Planned Activities:**

- The study design will be finalized, and formal USAID approval will be sought.
- The protocol will be written.
- Data management and analysis plans will be developed.
- The protocol will be submitted to PHSC for approval
- The study will be initiated.

**Possible Problems, Barriers to Completion:**

- Delay in study initiation may occur while awaiting PHSC approval.

|                           |                  |                            |          |
|---------------------------|------------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core       | <b>FCO Approval:</b>       | Apr 1997 |
| <b>FY '97 Budget:</b>     | \$ 79,841        | <b>Projected End Date:</b> | May 1998 |
| <b>Total Budget:</b>      | To be determined |                            |          |

## Worldwide: TCU 380A Intrauterine Device (IUD) Clinical Research (FCO 2051)

**Technical Monitor:** Gaston Farr

**Objective(s):** To conduct secondary analysis on data from FHI's completed TCU 380A IUD studies and to write papers for presentation and publication based on these analyses.

Note: The original objective of this subproject was to establish the efficacy of the copper-bearing TCU 380A IUD when compared to the IUD most commonly used within a given country participating in the study. As studies were completed, the objective evolved to one of data analysis and dissemination as stated above.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Studies conducted in 23 developing countries between 1985 and 1991 provided data on safety, efficacy and acceptability of the TCU 380A IUD when compared with standard devices then provided in those countries. Since 1991, this subproject has supported report, monograph and manuscript writing, and presentation of these data at scientific meetings.

### FY'97 Planned Activities

- Four papers are to be completed utilizing data from FHI's TCU 380A database:
  - 1) Reinprayoon D, Hurst CG, Farr G, Amatya R. A 48-month comparative multicenter study of the TCU 380A and MLCu 250 IUDs in Bangkok, Thailand.
  - 2) Farr, G, Amatya R. Do nonphysicians have similar outcomes inserting Copper-T 380 IUDs as physicians?
  - 3) Analysis of Discontinuation Reasons Among Copper-T 380A IUD Users in 23 Countries.
  - 4) Analysis of Factors Affecting Discontinuation of IUD Use Due to Medical and/or Menstrual Problems.

### Possible Problems, Barriers to Completion:

- Resolving unanticipated issues with on-going research involving the same staff may take precedence over completing papers.

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|---------------------------|------------|----------------------------|-----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | <Aug 1995 |
| <b>FY '97 Budget:</b>     | \$ 36,888  | <b>Projected End Date:</b> | Sep 1997  |
| <b>Total Budget:</b>      | N/A-Annual |                            |           |

## Worldwide: General Systemics (FCO 2030)

**Technical Monitor:** Randy Dunson

**Objective(s):** 1) To support early developmental work on systemic-related projects; 2) to conduct secondary analyses on selected and completed systemic projects; 3) to write papers for presentations and publications based on these analyses; and 4) to occasionally support the completion of final reports for systemic studies.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** This subproject supports various activities related to FHI's research of systemic methods of contraception. The major activity involves secondary analyses. Following the completion of field research activities culminating in a subproject final report, data analysis continues and/or papers are prepared for presentation and publication in scientific journals to disseminate the results of FHI-supported research. This subproject supports staff time and travel costs related to these needs. The subproject also supports literature review and other very early development efforts for new systemic subprojects under consideration. Lastly, on a few occasions the completion of final reports for systemic studies is supported by this subproject.

### FY' 97 Planned Activities:

- A final report on the Time of Progestin-Only Oral Contraceptive (POC) Initiation Among Lactating Women study will be completed.
- Early development of cervical mucus project on Cyclofem will begin.
- Six papers are to be completed:
  - Nutley T and Dunson TR. Treatment of bleeding problems associated with progestin-only contraceptives: Survey results.
  - Dunson TR, Amatya RN, Ruminjo JK and Chi I-C. An assessment of pregnancies occurring among Norplant implant users: International experience.
  - Dunson TR and Ruminjo JK. Conducting clinical trials in developing countries.
  - Dunson TR and Amatya RN. A multi-country assessment of Norplant implant removals.
  - Dunson TR, Amatya RN, Dorflinger L and Rivera R. Pre-introductory clinical trials of the Norplant subdermal implant system: The international experience.
  - Gonzalez SC, Guidos MA, Hernández M, Salzar MA and Dunson TR. Clinical evaluation of Norplant implants in El Salvador.

### Possible Problems, Barriers to Completion:

- None foreseen.

|                           |            |                            |           |
|---------------------------|------------|----------------------------|-----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | <Aug 1995 |
| <b>FY '97 Budget:</b>     | \$ 36,605  | <b>Projected End Date:</b> | Aug 2000  |
| <b>Total Budget:</b>      | N/A-Annual |                            |           |

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|-------------|---|
| <b>USA:</b> | <b>Antiemetics to Prevent Nausea Associated with<br/>Emergency Contraceptive Pills (FCO 2230)</b> |
|-------------|---|

**Technical Monitor:** Elizabeth Raymond

**Objective(s):** To determine whether the antiemetic drug meclizine will prevent nausea associated with the Yuzpe regimen of emergency contraceptive pills

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** The purpose of this study is to determine whether the antiemetic drug meclizine will prevent nausea associated with the Yuzpe regimen of emergency contraception pills (ECPs). Three hundred forty-five participants using non-hormonal contraception at three clinical centers will be randomly assigned into three groups. One group will be treated with ECPs (two doses each containing 100 mcg ethinyl estradiol + 1 mg norgestrel, taken 12 hours apart). The second group will be treated with ECPs and meclizine (25 mg taken 1 hour before each ECP dose). The third group will be treated with ECPs and a placebo (taken on the same schedule as the meclizine). Each participant will complete questionnaires over 48 hours to record nausea, vomiting and other symptoms. The analysis will focus on comparing the incidence of nausea and other side effects among the three groups.

**Implementing Agency(s):** To be determined.

**FY' 97 Planned Activities:**

- The study will be implemented.
- Data cleaning and analysis will be completed.
- A manuscript will be written for publication.

**Possible Problems, Barriers to Completion:**

- Sites have not yet been selected. If it takes longer than expected to find sites and execute contracts, the study will be delayed.
- It is anticipated that participant recruitment will be completed within a few months. If it takes longer than expected, completion of the study will be delayed.
- Preliminary negotiations with the sites reveal that our initial budget estimates were too low. USAID may determine that the cost of doing the study exceeds its value. If so, other sources of funding will be sought.

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|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Jul 1996 |
| <b>FY '97 Budget:</b>     | \$ 85,744  | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 86,480  |                            |          |

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## BIOSTATISTICS

The Biostatistics Division serves primarily in a support capacity to the Research and Development Department and the Reproductive Health Programs Department. As such, it is involved in all stages of clinical and programmatic research. Staff of the Biostatistics Division collaborate with clinicians, epidemiologists and social scientists to define research objectives and to determine appropriate study designs and sample sizes. They also develop and carry out the data analysis plans for all clinical studies and provide statistical review and support on a consultative basis for programmatic studies.

### *Biostatistics Division's FY'97 Program*

In FY'97, the Biostatistics Division will continue to carry out these same activities. With a number of large studies concluding and the strong interest in secondary data analysis within the Clinical Trials Division, it is anticipated that data analysis and statistical review will be dominant activities. In addition, the Biostatistics Division will manage two on-going and one new subproject.

- Biostatistics Paper Writing (9102)
- Comparative Evaluation of Three Tactylon Condoms with a Latex Condom During Vaginal Intercourse: Breakage and Slippage (9103)
- Emergency Contraception Meeting (9104)\*

Individual workplans for these activities follow in the order presented above.

## Worldwide: Biostatistics Paper Writing (FCO 9102)

**Technical Monitor:** Rosalie Dominik

**Objective(s):** 1) To conduct research on statistical methods needed to answer reproductive health questions; 2) to review such methods; 3) to develop recommendations for analysis; and 4) to disseminate the findings to researchers at the country level as well as to other researchers working to improve reproductive health and family planning worldwide.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** During research protocol development and data analysis, several alternative approaches to study design, data collection or data analysis may be considered. The strengths and weaknesses of various approaches are not always apparent. The purpose of this subproject is to identify the advantages or disadvantages of competing approaches through the review of relevant literature or statistical research. Papers and handbooks that 1) explain the alternative research or analysis methods that might be considered, 2) recommend an approach, and 3) provide examples of applications will be developed.

### FY' 97 Planned Activities:

- Research and assess the applicability of the research tree regression method to identify family planning clinic clients at an increased risk of STDs.
- Revise a working paper on calculation of perfect use pregnancy rates.
- Finalize a paper on calculating event rates for barrier contraceptive effectiveness studies.
- Use data available from family planning clients in two FHI studies and the National Survey of Family Growth to conduct statistical research to determine the probability distribution that best fits coital frequency data and draft a paper describing the results.
- Revise a draft paper on recommendations for calculating discontinuation rates in barrier contraceptive studies.
- Finalize papers on:
  - interim analyses in contraceptive clinical trials.
  - approaches for accounting for correlation in condom breakage and slippage studies.
  - methods to detect and adjust for over dispersion in analysis of coital activity data.
  - the use of propensity scores for historical analyses.

### Possible Problems, Barriers to Completion:

- None foreseen.

**Funding Source(s):** USAID/Core  
**FY '97 Budget:** \$ 101,230  
**Total Budget:** N/A-Annual

**FCO Approved:** Oct 1995  
**Projected End Date:** Sep 2000

**USA: Comparative Evaluation of Three Tactylon Condoms with a Latex Condom During Vaginal Intercourse: Breakage and Slippage (FCO 9103)**

**Technical Monitor:** Rosalie Dominik

**Objective(s):** To provide protocol development support, data management and statistical analysis for a study designed to determine the clinical breakage and slippage rates of three types of Tactylon condoms similar to those of a currently marketed latex condom. Secondary study objectives include assessment of the following: product safety; other condom use factors such as the incidence of nonclinical breakage, partial slippage, and total failure; and each partner's acceptability ratings of the condoms (e.g., fit, sensitivity, ease of use, and product preference).

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Male latex condoms have long been available as nonhormonal alternatives for contraception and protection against STDs. Despite their usefulness, there are limitations to latex condoms, including an inability to withstand deterioration when exposed to oxidizing conditions, vulnerability to oil-based lubricants, and susceptibility to tearing. In addition, some users of latex condoms are allergic to components in the material. Hence the development of alternative male condoms for contraception and STD prevention has taken on increased importance. Tactyl Technologies, Inc. developed a synthetic material known as Tactylon. This material has proven to be hypo-allergenic in clinical studies of medical gloves and possesses other characteristics that make it potentially superior to latex for the production of condoms—namely, the ability to modify the elasticity of the material and resistance to decomposition by oxidizing forces such as ozone, UV light, and humidity.

In this multicenter trial involving approximately 440 couples and two U.S. sites, a standard cylindrical shaped Tactylon condom, a baggy shaped Tactylon condom and a low-modulus Tactylon condom are compared to a currently marketed standard shaped latex condom in an effort to determine whether the Tactylon condom types are equivalent to latex with respect to breakage and slippage. Additional information is collected in order to evaluate Tactylon condoms as safe, acceptable alternatives to latex.

**Collaborating Agency(s):** CONRAD, NIH

**FY' 97 Planned Activities:**

- Remaining data will be entered and queries will be generated.
- All outstanding CRFs and queries will be received by FHI.
- The full statistical analysis will be completed. This includes comparing each Tactylon condom type to the standard latex condom with respect to clinical breakage and complete slippage, as well as performing all secondary analyses.
- All study reports will be finalized and completed.
- Ideas for related publication will be explored.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Nov 1995 |
| <b>FY '97 Budget:</b>     | \$ 61,594  | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 196,594 |                            |          |

**USA: Emergency Contraception Meeting (FCO 9104)**

**Technical Monitor:** Julie Omohundro

**Objective(s):** To identify and address the implications of the availability of emergency contraception for future clinical trials of barrier contraceptives

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** The growing availability of emergency contraception has important implications for clinical trials of barrier contraceptives. The continued development of these methods will be facilitated if the clinical, statistical and regulatory professionals involved in reproductive health gain a common understanding of these issues. To explore the implications and to advance a common understanding, FHI will take the lead in two endeavors: 1) A two-day meeting will be organized and held among a broad group of clinical, statistical and regulatory professionals. On the first day, key issues will be identified and discussed. On the second day, a small group of experts will meet to integrate the information from the first day into a cohesive proposal for addressing key issues. 2) Proceedings will be printed and distributed which describe the presentations given at the consensus meeting and the discussion and conclusions reached at the experts meeting.

**FY' 97 Planned Activities:**

- The date and location of the meeting will be established; an agenda and a list of invitees will be developed.
- A background paper on the implications of the availability of emergency contraception for clinical trials of barrier contraceptives will be drafted and comments on the paper will be obtained from internal and external reviewers.
- Invitations will be sent, and all logistical arrangements for the meeting will be made.
- The meeting will be conducted during the third quarter of the fiscal year.
- The proceeding will be written up, printed and distributed.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Dec 1996 |
| <b>FY '97 Budget:</b>     | \$ 33,969  | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 33,969  |                            |          |

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## CONTRACEPTIVE USE AND EPIDEMIOLOGY

Many factors influence whether and how effectively contraceptive methods and information are used by clients. Aside from understanding biomedical issues of safety and efficacy, providers need to know how acceptor characteristics, differences in needs or preferences for specific methods, barriers to access, and perceived benefits and risks of methods influence individuals to adopt and continue to use family planning. In addition to pregnancy prevention, contraceptive methods have other potential health consequences for users, including changes in risk for sexually transmitted diseases (STDs) and other conditions. Research on the noncontraceptive benefits and risks of family planning can help programs address concerns about safety and identify methods that may or may not be suitable for users with certain characteristics, behaviors or needs.

### *Contraceptive Use and Epidemiology Division's FY'97 Program*

FHI's CUE Division conducts a broad research program that involves the study of currently available and new contraceptive technologies within diverse populations. At present, CUE efforts are focused in four strategic areas.

#### ■ **Acceptability and Use Behavior**

CUE's research agenda includes an emphasis on the acceptability of contraceptive methods that may also provide protection against STDs. In accordance with this priority, FHI is carrying out acceptability and use research on a range of barrier methods, including condoms, spermicidal film and the diaphragm. A major initiative is a series of related studies to examine safety and feasibility of multiple use of the female condom. Studies to assess the feasibility of dual contraceptive method use, such as N-9 lubricated condoms plus oral contraceptives (OCs), among individuals at elevated risk of STD are underway. The design of an investigation to determine the acceptability of the Uniject<sup>®10</sup> syringe as a delivery mechanism for DMPA is also on the agenda for FY'97.

#### ■ **Compliance**

Research by FHI and others has found that frequent errors are made in the correct and consistent use of temporary contraceptive methods. It is widely deduced that poor compliance is responsible for the bulk of the differential between perfect use and typical

<sup>10</sup> UniJect<sup>®</sup> is a registered trademark of Program for Appropriate Technology in Health for a Sterile, single-use, pre-filled mechanism used to deliver injectable contraceptives.

use pregnancy rates, but this has not been demonstrated. CUE is developing a subproject to measure the association between specific pill-taking errors and the risk of unintended pregnancy. Also, research is under way to describe combined oral contraceptive (COC) compliance among Bolivian pill users.

#### ■ **Benefits and Risks**

Using different modeling approaches, CUE is evaluating the effect of contraception on mortality and morbidity. In one approach, the most recent data on low-OCs are being incorporated into a deterministic probability model that compares the impact of OCs on cardiovascular mortality with the risk of pregnancy among noncontraceptors. Another approach, using a computer life-table model, incorporates both the short- and long-term effects of COCs in developing countries with different mortality and COC use-patterns from the U.S. Finally, the impact on reproductive health of shifting the contraceptive method mix towards barrier methods in an area of very high HIV prevalence is being evaluated using a model developed by AIDSCAP.

Associations between contraception and various long-term outcomes form a second research focus. Staff are investigating the association between vasectomy and prostate cancer and the role of detection bias in this relationship. FHI researchers are monitoring the Korean and New Zealand sites of the WHO Prostate Cancer study to evaluate the association in non-western populations and in a population where prostate cancer screening is not very prevalent. The relationship of barrier methods, parity, COC use, and smoking in relation to cervical cancer *in situ* is being investigated in secondary analyses, and a study of progesterone and human papilloma virus is currently under development. A pilot study of DEPO-PROVERA<sup>®11</sup> in teenage users is underway to assess the impact of this method on the development of bone in young users.

#### ■ **Contraception and STD/HIV**

The focus of research in this area is to measure the risk of STDs, including HIV infection, among users of specific family planning methods. In general, barrier methods reduce the risk of STDs; non-barrier methods provide no protection against STDs, and in some cases may increase the risk. Accurate data on these associations are needed by family planning policymakers, providers and clients.

After an initial four-month observation period was completed, two-year follow-up has commenced in a study of complications of IUD use among HIV-positive and HIV-negative women. A large prospective study is underway to measure the associations between use of COCs and DMPA and the extent of cervical ectopy and risk of cervical chlamydia in new users. Staff are beginning data analysis in an NIH-funded randomized controlled trial of N-9 spermicide use and the incidence of HIV, which will determine if N-9 protects women against HIV and so should be added to prevention programs. Finally, a community intervention trial is under development that will compare STD rates in comparable cohorts that receive or do not receive female condoms, thus demonstrating the population-level impact of the devices.

The CUE Division's continuing and new subprojects within each of these areas are listed below. Those denoted with an asterisk are new subprojects expected to get underway in FY'97. Individual workplans follow.

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<sup>11</sup> DEPO-PROVERA<sup>®</sup> is a registered trademark of Upjohn, Inc. for depo medroxyprogesterone acetate.

■ **Acceptability and Use Behaviors**

- Acceptability Paper Writing (6006)
- Jamaica: Dual Method Use and Factors Associated with STDs among Family Planning Clients (6027)
- Kenya: Dual Method Use and Factors Associated with STDs among Family Planning Clients (6313)
- Ghana: Contraceptive Service Provision in a Sexually Transmitted Diseases Clinic - an Opportunistic Service (6475)\*
- Feasibility of Female Condom Reuse (6029)
- Multiple Use Assessments of the Reality Female Condom (6384)\*
- Female Condom Demand Assessment (6314)
- Monograph on Latex Condom (6385)\*
- Latex Condom Performance in Human Use(6315)\*
- Philippines: Assessing the Acceptability, Service Delivery Requirements, and Use Effectiveness of the Diaphragm in a Developing Country (6026)
- Evaluation of the Uniject Syringe and Depo-Provera (6030)\*
- Impact of Menstrual Disturbances on Contraceptive Use (6381)\*
- Ghana: Vaginal Foaming Tablet User Dynamic Study (6476)\*
- Bolivia: Qualitative Study of the Acceptability of Reversible Contraceptive Methods, (6701)

■ **Compliance**

- Compliance Strategy (6382)
- Bolivia: OC Compliance Study among PROSALUD Clients (6473)

■ **Benefits and Risks**

- Benefits and Risks of OC Use (6216)
- Mexico: Copper IUD Use and Tubal Infertility (6205)\*
- Korea: Vasectomy and Prostate Cancer (6287)
- New Zealand: Vasectomy and Prostate Cancer Case-Control Study (6900)\*
- Teen DMPA Bone Pilot Study (6383)\*
- Kenya: Method Mix Modeling (6478)\*
- Jamaica: Symposium Long-Term Safety of Hormonal Methods (6479)\*

■ **Contraception and STD/HIV**

- Kenya: Risk of Short-term Complications with IUD Use and HIV (6204)
- Kenya: Female Condom Use and Risk of STD (6308/6477)\*
- Hormonal Contraceptive Use, Cervical Ectopy and Cervical Chlamydia (6311/6901)

■ **Other**

- USAID Technical Guidance Working Group (6312)
- Reproductive Health Paper Writing (6352)
- Study to Measure the Contraceptive Efficacy of Condoms and VCF Using a New Methodology (6217)

A description of each of these subprojects follows in the order listed above.

## Worldwide: Acceptability Paper Writing (FCO 6006)

**Technical Monitor:** Carol Joanis

**Objective(s):** To write papers on completed acceptability and use behavior studies for presentation and publication.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Following the completion of individual studies, research staff conduct further in-depth analysis on specific topics and prepare papers for presentation and publication. This subproject supports staff time and travel costs related to these needs.

### FY' 97 Planned Activities:

- The paper entitled "Risk Factors for Condom Breakage at Three International Sites" by Spruyt, Steiner, Joanis and Glover will be finalized for publication by the *American Journal of Public Health*.
- The paper entitled "Sexually Transmitted Diseases Are Common in Women Attending Family Planning Clinics in Jamaica and Appropriate Tools Are Lacking" will be finalized for publication in the *Journal of Genital Urinary Medicine*.
- The paper entitled "Impact of Irregular Menses on Pregnancy Rates: A Reanalysis of the Female Condom Clinical Trial Data" will be submitted for publication.
- The paper entitled "Acceptability of Dual Method Use in a U.S. Family Planning Clinic" by Steiner et al. will be submitted for publication in *International Family Planning Perspectives*.
- A paper entitled "Potential for Reuse of the Female Condom" will be written by Joanis and Hurst and submitted to a technical journal.

### Possible Problems, Barriers to Completion:

- Delays in review of articles by editing boards could delay publication of articles.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Oct 1995 |
| <b>FY '97 Budget:</b>     | \$ 113,523 | <b>Projected End Date:</b> | Sep 2000 |
| <b>Total Budget:</b>      | N/A-Annual |                            |          |

## Jamaica: Dual-Method Use and Factors Associated with STDs Among Family Planning Clients (FCO 6027)

**Technical Monitor:** Alan Spruyt and Laurie Fox

**Objective(s):** 1) To evaluate prevalence and correlates of dual-method use among family planning clients; and 2) to assess methods of identifying family planning clients at increased risk of STD.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- 4.3 Enhanced capacity for organizations to design, implement & evaluate effective HIV/STD prevention and care programs

**Description:** This study was designed to measure STD prevalence, the value of perceived and behavioral risk indicators, and the prevalence and correlates of dual method use (use of two methods for the prevention of pregnancy and infection). The study was conducted among family planning clients at the Jamaican Family Planning Association (JFPA) Lenworth Jacobs Clinic and the Ministry of Health (MOH) Glen Vincent Clinic. Women were interviewed to assess past and present barrier method use, including reasons for use and nonuse with other contraceptives. STD risk assessments were made by the women themselves and by their providers. Each participant received a physical examination and specimens for STD were collected for laboratory analysis. Data were also collected on the cost of providing the STD services offered in the study. This research benefited from the combined efforts of the MOH, the MOH Epidemiology Unit, JFPA/International Planned Parenthood Federation (IPPF), University of North Carolina, AIDS Control and Prevention Project (AIDSCAP) and FHI.

**Implementing Agency(s):** Jamaican Ministry of Health (MOH), Epidemiology Unit  
**Collaborating Agency(s):** International Planned Parenthood Federation (IPPF), AIDSCAP

### FY' 97 Planned Activities:

- FHI will complete the analysis and prepare a draft final report in collaboration with MOH and JFPA.
- FHI, University of North Carolina/AIDSCAP and the Jamaican investigators will complete the final report and prepare separate manuscripts on modified algorithms for STD detection, prevalence and correlates of dual method use, and cost implications of adding STD services to family planning programs.

### Possible Problems, Barriers to Completion:

- Competing commitments of FHI, MOH and JFPA staff could result in delayed completion of the above.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Sep 1993 |
| <b>FY '97 Budget:</b>     | \$ 46,894  | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 302,902 |                            |          |

**Kenya: Dual-Method Use and Factors Associated with STDs among Family Planning Clients (FCO 6313)**

**Technical Monitor:** Alan Spruyt

**Objective(s):** 1) To estimate the prevalence of dual-method use among family planning clients; and 2) to evaluate the correlates of dual-method use among family planning clients.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- 4.3 Other PHNC results. Specify # and name.

**Description:** This study estimates the level of STD risk and awareness and evaluates the prevalence and correlates of dual method use (non-barrier and barrier family planning method for prevention of pregnancy and infection) among clients of the Family Planning Association of Kenya (FPAK). A sample of 300 women who are currently using a family planning method are being enrolled from each of three sites (two clinics and one community-based distribution (CBD) program) in the Kisumu and Nakuru districts. Each woman is to be interviewed to gather demographic and socio-economic characteristics, information on STD risk factors, current and past contraceptive use, factors that facilitate or inhibit dual method use, as well as method variation by partner type. Each woman assesses her own risk of current and future infection. Prior to the survey component of the study, eight focus group discussions were conducted with convenience samples of men and women from each of the three study sites.

**Implementing Agency(s):** Family Planning Association of Kenya (FPAK)

**FY' 97 Planned Activities:**

- Study recruitment and interviews are expected to be completed by December 1996.
- FHI will monitor final data collection, entry and cleaning.
- In collaboration with FPAK, FHI will complete preliminary analysis in preparation for dissemination of the study findings.
- During the third quarter of FY'97, FHI and FPAK will hold a meeting in Kenya to disseminate the study findings.
- FHI and FPAK will complete analysis of the focus group discussions and survey data and prepare the final report.
- A manuscript on prevalence and correlates of dual method use among FPAK clients will also be prepared.

**Possible Problems, Barriers to Completion:**

- An extended recruitment period and competing commitments of FHI and FPAK staff could result in delayed completion of the above.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | May 1995 |
| <b>FY '97 Budget:</b>     | \$ 56,088  | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 131,254 |                            |          |

## Ghana: Contraceptive Service Provision in a STD Clinic - An Opportunistic Service? (FCO 6475)

**Technical Monitor:** Markus Steiner

**Objective(s):** To assess contraceptive knowledge, practices and patterns of use among patients attending the Komfo Anokye Teaching Hospital STD Clinic.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- 4.1 Effective interventions to reduce sexual transmission of HIV/STD identified, strengthened, implemented, & evaluated in emphasis countries.

**Description:** Little is known about the contraceptive practices of clients attending STD clinics in Ghana. This study will explore the feasibility of integrating STD and family planning services. Interviews, using structured questionnaires, will be conducted with 300 consecutive clients attending the STD clinic who consent to taking part in the study. Demographic information and details of sexual history will be collected. Contraceptive history and details of use including compliance will be assessed. For those not using contraception, reasons will be ascertained. Women will be asked whether they would be willing to receive barrier methods if they were offered at the clinic. The clients will receive physical examinations, and appropriate diagnostic tests and evaluations will be performed. Specific STDs to be investigated are gonorrhea, chlamydia, syphilis and other genital ulcer diseases, and HIV (after appropriate counseling). Women will receive the clinic's standard treatments for any diagnosed STD free of charge. Moreover, clients desiring condoms will be supplied condoms free of charge. A workshop will be held to disseminate the results, and an article will be submitted to a relevant journal.

**Implementing Agency(s):** Komfo Anokye Teaching Hospital STD Clinic

### FY' 97 Planned Activities:

- The study will be initiated in November.
- A monitoring trip is planned for January.
- Data entry programs will be written.
- Technical assistance in data entry will be provided to the site.
- Data collection will be completed, and the data will be entered.
- A final report will be drafted by September 1997.

### Possible Problems, Barriers to Completion:

- Competing priorities at Komfo Anokye may result in delays in either study recruitment and/or data entry.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Aug 1996 |
| <b>FY '97 Budget:</b>     | \$ 26,840   | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 34,556   |                            |          |

**USA: Feasibility of Female Condom Reuse (FCO 6029)**

**Technical Monitor:** Carol Joanis

**Objective(s):** To determine the feasibility of female condom reuse by testing the device for structural integrity (seam strength, peak pressure and material strength) after a single use.

**Note:** The original objective for this subproject referred to a second study to determine the feasibility of multiple uses of the female condom. Those activities will now be conducted under a separate subproject, Multiple Use Assessments of the Reality Female Condom (FCO 6384).

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** A major drawback to widespread acceptance of the female condom is cost (currently about \$2.50 per device). This cost exceeds the amount most women are willing or able to pay for a single-use product. This is especially true for poor women and those in developing countries. Even at subsidized cost, it is doubtful that the device would be cost-competitive with latex condoms. Thus, device reuse appears to be a likely practice in order to reduce cost. Prior to this study, no data had been collected on reuse practices, and the device is not approved as a reusable method.

In a first stage, approximately 60 women in the Research Triangle Park area of North Carolina used the female condom in one act of intercourse. The used devices were collected and tested for tensile strength, material strength and air burst values. These test values were then compared to the test values of unused products from the same condom lot to determine if a change occurred in the structural integrity of the device. Similarly, microbial retention was measured after a minimal cleaning (warm water rinse) of the device. This first study assessed the feasibility of reusing the female condom after one use. A second study is being developed, under a separate FCO, to evaluate structural integrity, viral permeability and overall safety after five and ten uses.

**FY' 97 Planned Activities:**

- Data on approximately 100 female condoms used once by study participants will be analyzed and a report issued. Test condom values in water leakage, tensile strength and dimensions will be compared to values of unused condoms.
- A paper entitled "Potential for Reuse of the Female Condom" will be finalized and submitted to a technical journal for publication.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Sep 1993 |
| <b>FY '97 Budget:</b>     | \$ 34,384  | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 101,233 |                            |          |

**USA:**

**Multiple Use Assessments of the Reality Female  
Condom (FCO 6384)**

**Technical Monitor:** Carol Joanis

**Objective(s):** To determine whether the female condom maintains structural integrity, remains impermeable to virus, and is safe to use after five and ten uses. The study results will indicate whether there is a basis to change the product labeling for multiple use indication.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Reuse of the female condom is vital to the female condom's viability as an affordable alternative in disease control and pregnancy prevention. Research will be conducted to determine whether the female condom can be cleaned adequately to ensure safety of participants and whether the cleaning procedure itself is destructive. If safety is shown and the device remains within the manufacturer's specifications after multiple cleanings in the laboratory, a multiple use study will be undertaken. This study will explore the impact of five and ten uses on the female condoms structural performance by comparing values for tensile strength, water leakage and dimension measurements of unused (new) condoms with values obtained in like testing of devices that have been used multiple times. Furthermore, devices that have been used multiple times will be tested to determine if they remain impermeable to viral penetration and if selected microorganisms grow more readily after one, five and ten uses. In total, three condom lots will be tested, and about 1,500 couples will take part in this study.

**FY' 97 Planned Activities:**

- Study instruments and documentation will be written and finalized.
- Human Safety, Viral Permeability and Structural Integrity protocols will be finalized and sent to the Protection of Human Subjects Committee for approval.
- Study products and supplies will be ordered.
- A laboratory study to verify manufacturing data (specifications) will be completed.
- A laboratory study to determine the impact of glutaraldehyde disinfection on structural integrity (tensile strength) of the female condom will be completed.
- A protocol for a laboratory study to assess the impact of the proposed cleaning procedure on structural integrity of the female condom will be written, and the study will be initiated.
- If laboratory study results indicate that the cleaning procedure is adequate and the devices maintain strength, structural integrity and viral permeability studies will be initiated concurrently. This presumes negotiations with Nelson Laboratories (contractor for the viral permeability component of the study) have been completed.
- The viral permeability study recruitment will be completed. Used condoms will be sent to Nelson Labs for testing.
- Recruitment for the structural integrity component of the multiple use study will continue.
- Results of the viral permeability phase will determine whether the structural integrity study is stopped or continues. If devices pass the viral permeability testing, a microbial retention protocol will be developed.

**Possible Problems, Barriers to Completion:**

- It may be difficult to recruit participants which could prolong the research period.

**Funding Source(s):**

USAID/Core

**FCO Approved:**

Nov 1996

**FY '97 Budget:**

\$ 191,169

**Projected End Date:**

Mar 1999

**Total Budget:**

\$ 331,169

## Worldwide: Female Condom Demand Assessment (FCO 6314)

**Technical Monitor:** Dorace Trottier

**Objective(s):** The primary objective of this subproject is to assess the potential demand for the female condom among users and providers of the device within selected countries by tracking such aspects as re-supply, frequency of use and overall acceptability.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** While numerous studies have been conducted to determine the acceptability and efficacy of the female condom among selected populations, no real-world assessment of the potential demand for these devices has been done. In order for USAID to determine the feasibility of supplying these products internationally, one-time supplies of female condoms were purchased and shipped by FHI to interested countries and institutions. In total, 19 countries received a one-time supply. Some of the condoms are being used in research studies; others are distributed by selected family planning or health services clinics. Demand is being tracked through use of surveys completed by study investigators, users and providers.

### FY' 97 Planned Activities:

- An internal status meeting will be held at USAID/Washington in December 1996. At the meeting, additional activities under this subproject will be discussed.
- An Interim Report will be written by USAID/Washington and provided to FHI.
- FHI will prepare a summary report based on the countries that have provided final reports. The summary will contain sections on the socio-demographics of women who used the female condoms and on the various approaches and activities that were used to distribute them. The data will not be pooled. Data collected in research studies will be reported as study results by the research organizations conducting the studies. Data on community-based distribution programs will be collected from providers and users.

### Possible Problems, Barriers to Completion:

- If country programs have not been diligent in collecting and retaining their data, there may be little data to analyze.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Jun 1995 |
| <b>FY '97 Budget:</b>     | \$ 24,959  | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 403,103 |                            |          |

**USA: Monograph on Latex Condoms Technical (FCO 6385)**

**Technical Monitor:** Carol Joanis

**Objective(s):** To write a monograph that will center on latex condom technology and human use.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** An Experts Meeting on Latex Condoms was held at FHI in May 1996. One of the findings of this meeting was that some definite gaps exist in our knowledge of latex condom technology and the interaction of product performance and human use behavior. It was decided that a monograph on latex condoms should be written in order to clarify what is already known and to better guide future research efforts.

**FY' 97 Planned Activities:**

- Meetings will be held in order to finalize the monograph outline, decide on authors and set timelines.
- A literature search will be conducted to compile data for the monograph.
- Interviews will be conducted with industry experts to augment information gathered during the literature search.
- A draft of the monograph will be written.
- A monograph on latex condoms will be finalized and disseminated through FHI distribution channels.

**Possible Problems, Barriers to Completion:**

- Reliance on outside experts as authors may present difficulties in meeting all project deadlines.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Nov 1996 |
| <b>FY '97 Budget:</b>     | \$ 81,208  | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 81,208  |                            |          |

**USA: Latex Condom Performance in Human Use  
(FCO 6315)**

**Technical Monitor:** Carol Joanis

**Objective(s):** To conduct a series of studies on condom performance in human use. These studies will cover such areas as lubricants, condom designs, pre-stress and fatigue, plain vs. reservoir tip and condom thickness profiles, the development of a coital model, and comparison of stress/strain properties. The impact of these parameters on condom breakage and slippage will be assessed.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** An Experts Meeting on Latex Condoms was held at FHI in May 1996. Attendees included representatives from manufacturing firms, research companies, independent consultants and government agencies. Relevant past research was evaluated, and expert opinions concerning future research directions were rendered. Consensus emerged that a complex human use and laboratory testing project (proposed under the now closed subproject FCO 6052) would be redundant, costly and not answer questions remaining about latex condoms. Instead, it was proposed that seven discrete research studies be conducted. These studies are listed in the objectives above. It was decided that a monograph on latex condoms should be written as a first step in this process to clarify what was already known and to further structure the research. (See FCO 6385)

**FY' 97 Planned Activities:**

- The Summary Report of the Experts Meeting will be completed and disseminated.
- No studies will be started prior to the completion of the monograph and the Aladan latex condom breakage study (separately funded), as recommended by the participants of the Experts Meeting. The monograph and a study funded by Aladen on latex condom functionality in human use should provide guidance for studies planned under this subproject.
- A concept proposal will be prepared for the first study in this series. The first study will be on condom lubricants.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |                  |                            |          |
|---------------------------|------------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core       | <b>FCO Approved:</b>       | Dec 1995 |
| <b>FY '97 Budget:</b>     | \$ 84,039        | <b>Projected End Date:</b> | Aug 2000 |
| <b>Total Budget:</b>      | To be determined |                            |          |

**Philippines: Assessing the Acceptability, Service Delivery Requirements, and Use Effectiveness of the Diaphragm in a Developing Country (FCO 6026)**

**Technical Monitor:** Carol Joanis

**Objective(s):** To assess the acceptability and efficacy of the diaphragm as a contraceptive method in populations where there has been limited or no availability of this method.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** At a 1992 meeting organized by WHO's Special Programme of Research, Development and Research Training in Human Reproduction (HRP), strong support was expressed for promoting fertility regulation methods that: 1) are user-controlled; 2) provide protection against STDs, including HIV; 3) have minimal or no side effects; and 4) foster knowledge about one's body. One of the main recommendations made by women's health advocates was that more research be conducted on the introduction and reintroduction of barrier methods, with emphasis on user and provider perspectives on safety, efficacy and acceptability of barrier contraception. Following this meeting, an interagency working group on barrier methods identified the diaphragm as the available female-controlled method that most closely meets these criteria. This prospective study follows, for a minimum of 6 months, a group of women who have chosen to use the diaphragm as their primary form of contraception. The study is intended to identify the factors influencing initial and continued acceptability, determine the service delivery requirements, and document the contraceptive use effectiveness of the diaphragm in a developing country setting. In addition, the study gathers information on reasons for discontinuation, method switching and use practices.

**Implementing Agency(s):** Reproductive Health Philippines, Inc., Quezon City, Philippines  
**Collaborating Agency(s):** World Health Organization, The Population Council

**FY' 97 Planned Activities:**

- Data will continue to be collected on diaphragm users and users of other methods.
- Project monitoring and clinic site visitations will be made by FHI staff in October. Focus group data will be analyzed. A report will be issued by FHI staff and RHPI investigators on the results of the focus groups.
- A project monitors' meeting will be held in November at FHI. Plans and agendas for the upcoming Interagency Working Group will be finalized.
- The Interagency Working Group Meeting will be held at WHO offices in Geneva in February. Attendees will include project monitors from WHO, the Population Council and FHI; country investigators; and data entry and analysis people from WHO. Topics will include status reports, authorship of future publications, resolution of data problems, and project close-out plans.
- Project monitoring and field work close-out will occur during August 1997.
- Data will be sent to WHO for pooled analysis.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Oct 1993 |
| <b>FY '97 Budget:</b>     | \$ 113,523 | <b>Projected End Date:</b> | Jan 1998 |
| <b>Total Budget:</b>      | \$ 434,838 |                            |          |

**TBD: Evaluation of the Uniject Syringe and Depo-Provera® (FCO 6030)**

**Technical Monitor:** Caroline Hurst

**Objective(s):** To evaluate the clinical performance and acceptability of a single-use, pre-filled delivery system for Depo-Provera, being developed by PATH.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** The Uniject syringe is an easy-to-use, pre-filled, single-dose injection device that is designed to prevent re-use of syringes and needles. Because it combines the syringe, needle and medication in a single package, it is expected to be less expensive than a standard disposable syringe used with a single dose vial. While it is believed that these advantages make the Uniject system ideal for developing country family planning programs that have a large demand for Depo-Provera, field studies await agreements regarding future commercialization of the product. A collaborative effort among The Upjohn Company, USAID, Horizon Medical, PATH, Becton Dickinson and FHI is planned. FHI will be involved in a meeting to exchange technical information, will be responsible for an independent health provider acceptability evaluation, and will carry out appropriate studies of Depo-Provera in the Uniject device.

**Implementing Agency(s):** To Be Determined  
**Collaborating Agency(s):** Becton Dickinson, The Pharmacia & Upjohn Company, Horizon Medical and PATH

**FY' 97 Planned Activities:**

- On October 9, 1996, a meeting is scheduled for representatives from USAID, Becton Dickinson, PATH, and Pharmacia & Upjohn to complete the transfer of responsibility for this project from PATH to Becton Dickinson.
- It is anticipated that FHI will collaborate with Becton Dickinson in designing the evaluation format and preparing training and materials for introducing field testing of Uniject to develop country programs; develop a protocol for field introduction; and provided all development issues are resolved and commercialization agreements are reached, initiate the selection of tentative sites for introductory studies.

**Possible Problems, Barriers to Completion:**

- Successful negotiation of an agreement between Becton Dickinson and Pharmacia & Upjohn for the provision of Depo-Provera for filling the Uniject. This agreement is subject to reorganization issues.

|                           |                  |                            |          |
|---------------------------|------------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core       | <b>FCO Approved:</b>       | Oct 1995 |
| <b>FY '97 Budget:</b>     | \$ 35,859        | <b>Projected End Date:</b> | Dec 1997 |
| <b>Total Budget:</b>      | To be determined |                            |          |

**Worldwide/TBD: Impact of Menstrual Disturbances on Contraceptive Use (FCO 6381)**

**Technical Monitor:** Betsy Tolley

**Objective(s):** To determine how menstrual disturbances resulting from the use of hormonal methods and IUDs impact contraceptive use.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** A multi-country study is planned to determine how menstrual disturbances resulting from the use of hormonal methods and IUDs impact contraceptive use. Qualitative methods will be employed during the early stage of the study to understand culturally-bound attitudes towards bleeding; how these attitudes affect a woman's perceptions of herself and her intimate relationships; and how these, in turn, influence contraceptive use. Quantitative methods will then be employed to determine the impact of bleeding side-effects on contraceptive use, method switching and discontinuation. Traditional notions of health and disease, as well as factors affecting women's status, are believed to greatly influence women's attitudes towards bleeding and their ability to achieve family planning goals.

This subproject will serve to further assist policymakers in determining what contraceptive method mix would be appropriate for contraceptive users in their countries. At a service delivery level, it will provide valuable information for the improvement of counseling and the management of bleeding side-effects to encourage method continuation or facilitate contraceptive switching.

**Implementing Agency(s):** To be determined

**FY' 97 Planned Activities:**

- The sites for the study will be identified and visited during May-June 1997 in order to evaluate them and identify field investigators.
- The protocol will be developed in collaboration with the field investigators.
- Subagreements will be written and submitted for approval.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Oct 1996 |
| <b>FY '97 Budget:</b>     | \$ 23,242  | <b>Projected End Date:</b> | Jul 1998 |
| <b>Total Budget:</b>      | \$ 150,000 |                            |          |

**Ghana: Vaginal Foaming Tablet User Dynamic Study  
(FCO 6476)**

**Technical Monitor:** Markus Steiner

**Objective(s):** To assess the extent of misuse of Vaginal Foaming Tablets (VFTs), the role that VFTs play in the contraceptive method mix, and the distribution of VFTs through pharmacies and chemical shops in Ghana.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- 4.1 Other PHNC results. Specify # and name.

**Description:** According to the 1993 Ghana Demographic and Health Survey (DHS) Report, the largest distribution point of VFTs are pharmacies and chemical shops. Most VFTs are supplied by the Ghana Social Marketing Foundation (GSMF) through three wholesale distributors. The majority of VFTs appear to be distributed in Accra and Kumasi. A two-phased study, involving both pharmacy clerk interviews, and a client intercept study at pharmacies and chemical shops will be conducted in these two cities.

**Phase 1 - Pharmacy Clerk Interviews:** GSMF, in collaboration with Research International (RI), conducted a marketing study to determine the types of contraceptives stocked and sold by pharmacies and chemical shops in six regions in Ghana (Final Report, July 1995). For the marketing study, RI generated a comprehensive list of what they believed to be all pharmacies and chemical shops in Ghana (N=2,688). Of these, 470 are located in Accra and Kumasi, the target areas for FHI's study. A random sample of 100 of these 470 outlets will be drawn, and a short structured interview will be administered with the sales clerks to assess whether they currently and/or have ever stocked VFTs, what the demand for VFTs is, if they ever experience stock-outages, etc. The questionnaire will be jointly developed by FHI and RI staff.

**Phase 2 - Client Intercept Study:** The same random sample of 100 pharmacies and chemical shops will be used to draw a convenience sample of 12 outlets for the client intercept study. Criteria to consider when drawing this convenience sample include sufficiently large unit distribution to assure rapid data collection and socio-economic diversity of clients. At each pharmacy, 20 to 25 clients will be administered a short, structured questionnaire jointly developed by FHI and RI staff.

**Implementing Agency(s):** Research International, Accra

**FY' 97 Planned Activities:**

- The study will be initiated in October.
- A monitoring trip is planned for January.
- The data entry programs will be written.
- Technical assistance will be provided to RI with data entry.
- Data collection will be completed, and the data will be entered.
- A final report will be written by RI, in collaboration with FHI.

**Possible Problems, Barriers to Completion:**

- None foreseen.

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|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Jul 1996 |
| <b>FY '97 Budget:</b>     | \$ 24,630   | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 30,644   |                            |          |

**Bolivia: Qualitative Study of the Acceptability of Reversible Contraceptive Methods (FCO 6701)**

**Technical Monitor:** Dorace Trottier

**Objective(s):** 1) To determine why Bolivian women choose a certain contraceptive method; 2) to examine method-specific satisfaction among users; 3) to explore why women continue (or discontinue) use of a chosen method; 4) to analyze myths and taboos surrounding the use of methods; and 5) to examine the perceptions of family planning providers regarding various methods and how these perceptions influence their client's choice and use of those methods.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** The results from the 1994 Bolivia Demographic and Health Survey (DHS) have recently been published. FHI is conducting a series of focus groups to collect qualitative data to complement the DHS results. Information on reasons for choosing a method, typical use, discontinuation, and overall satisfaction are being collected. In addition, the study supports interviews with providers of family planning services. These interviews gather information on provider support for their client's choice of reversible methods, as well as their continued and correct use. These interviews will also help to identify the training needs of health providers, and thereby strengthen their support to family planning users.

**Implementing Agency(s):** Centro de Investigación, Educación y Servicios (CIES); Bolivia

**FY' 97 Planned Activities:**

- Focus group transcripts will be completed.
- Focus group data will be analyzed.
- A sample for the provider survey will be drawn.
- Provider surveys will be administered.
- Survey data will be analyzed.
- A final report will be written.

**Possible Problems, Barriers to Completion:**

- The completion of the study may be delayed due to problems in obtaining a sufficient number of providers for the provider survey component. Medical personnel, especially physicians, may not complete the surveys due to a lack of time. Also, there are some questions of a sensitive nature that may keep providers from completing the surveys in a timely fashion.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/OYB  | <b>FCO Approved:</b>       | Jun 1995 |
| <b>FY '97 Budget:</b>     | \$ 59,765  | <b>Projected End Date:</b> | Feb 1997 |
| <b>Total Budget:</b>      | \$ 162,871 |                            |          |

**Technical Monitor:** Paul Feldblum

**Objective(s):** To develop an epidemiologic study to measure the associations between OC pill-taking and pregnancy risk.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** The frequency of OC pill-taking errors has been amply documented, but no study has demonstrated the impact of such errors (if any) on OC effectiveness. FHI will design such a study in FY'97. This subproject will encompass all the preparatory work in designing such a study. Once approval of the study design is obtained and appropriate sites identified, this subproject will be concluded.

**Implementing Agency(s):** To be determined

**FY' 97 Planned Activities:**

- A preliminary proposal will be prepared and shared with USAID/W.
- Once approval is gained for further development, staff will write an expanded proposal that will be shared with Field Operations staff. A determination will be made regarding an appropriate site for the study.

**Possible Problems, Barriers to Completion:**

- Increasing use of emergency contraception could further complicate analysis and add to the need for a large sample size.
- The large sample size required may result in an expensive study.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Oct 1996 |
| <b>FY '97 Budget:</b>     | \$ 46,428  | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 46,428  |                            |          |

**Bolivia: Oral Contraceptive Compliance among PROSALUD Clients (FCO 6473)**

**Technical Monitor:** Donna McCarraher

**Objective(s):** 1) To measure knowledge and practices of current oral contraceptives (OC) users; 2) to explore reasons for OC discontinuation among ex-users; and 3) to examine partner support and/or resistance to OC use among OC users and ex-users.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Protección a la Salud (PROSALUD), a private non-profit network of 24 community-sponsored health clinics, grew out of a USAID-sponsored privatization effort initiated in 1983. The motivation for this effort was to provide primary care, including family planning services, to low income women whose medical needs were unmet given the financial constraints of the Bolivian Ministry of Health. PROSALUD now has clinics in Santa Cruz, La Paz, and El Alto. All currently provide only reversible methods of contraception. According to PROSALUD's 1993 Annual Report, 62% of all first-time PROSALUD contraceptors were given OCs; however, PROSALUD staff and CBD workers report high discontinuation rates among OC users.

This subproject is being conducted in selected clinics in the three cities and has various components. Eight focus groups were conducted with OC users and ex-users—four groups in Santa Cruz and two groups each in El Elto and La Paz. The focus groups lasted approximately 90 minutes. In addition, approximately 300 one-hour in-home interviews were conducted with both users and ex-users in all sites. Topics covered in both the focus groups and in-home interviews include method knowledge, method use, delivery system characteristics, and partner support and/or resistance to OC use.

**Implementing Agency(s):** Protección a la Salud (PROSALUD); Bolivia

**FY' 97 Planned Activities:**

- The data analysis strategy will be developed and implemented.
- The technical monitor will travel to Santa Cruz to help clean the data and to develop an outline for the final report.
- A final report will be prepared.
- An information dissemination plan will be developed and implemented. This will include presentation of the study results at a PROSALUD strategic planning meeting and a written executive summary for distribution to other Bolivia reproductive health providers.
- All field work will be completed and results disseminated by March 1997.
- Abstracts will be submitted for various conferences in order to present the study findings. In addition, preparation of a manuscript for publication will begin during this time frame.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |               |                            |          |
|---------------------------|---------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Bolivia | <b>FCO Approved:</b>       | Dec 1994 |
| <b>FY '97 Budget:</b>     | \$ 52,199     | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 107,423    |                            |          |

**Worldwide: Benefits and Risks of OC Use  
(FCO 6216)**

**Technical Monitor:** Pam Schwingl

**Objective(s):** To evaluate the impact of known benefits and risks of contraceptive methods on mortality and morbidity.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** The purpose of this subproject is to develop methods to clarify and update information on the impact of various contraceptive choices on the risk of mortality and morbidity. The subproject encompasses several substudies, all of which assess the impact of the benefits and risks of contraceptive methods on mortality and morbidity. The information generated by this activity will inform policymakers and family planning personnel about the use of various methods for particular subgroups of women or women in particular countries.

**FY' 97 Planned Activities:**

- A search of existing data on cervical carcinoma and cervical intraepithelial neoplasia will be conducted to elucidate the potential role of COCs as a cofactor in the progression of Human Papilloma Virus (HPV) to cervical cancer. Appropriate research questions and methods that apply findings from this new generation of research will be developed.
- The paper "Modeled estimates of myocardial infarction and venous thromboembolic disease in users of second and third generation oral contraceptives" will be revised and re-submitted to *Contraception*.
- The paper "Modeled estimates of cardiovascular mortality risks in the U.S. associated with low dose oral contraceptives" will be revised and re-submitted to *the American Journal of Obstetrics and Gynecology*.
- The paper "Modeled estimates of mortality in relation to oral contraceptive use in Jamaica and Costa Rica" will be submitted for publication to the *International Journal of Epidemiology*.
- A protocol for a study on hormonal contraception as a cofactor with HPV for cervical cancer will be drafted.

**Possible Problems, Barriers to Completion:**

- Much of the current work in HPV awaits findings of ongoing studies on the natural history and molecular biology of HPV. Until these studies are completed, a decision about which set of biological markers are most relevant/appropriate to consider in a study of hormonals and HPV may need to be postponed.

**Funding Source(s):** USAID/Core  
**FY '97 Budget:** \$ 43,418  
**Total Budget:** N/A-Annual

**FCO Approved:** <Aug 1995  
**Projected End Date:** Aug 2000

**Mexico: Copper IUD Use and Tubal Infertility (FCO 6205)**

**Technical Monitor:** David Hubacher

**Objective(s):** To determine whether IUD use among nulligravid women increases their risk of developing tubal infertility.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Previous research has shown an association between IUD use and tubal infertility among nulligravid women. Though the studies are widely cited, design flaws could have introduced biases that, in turn, resulted in spurious associations. A proposed case-control study will recruit nulligravid cases of tubal infertility and two control groups: nulligravid infertile women who have no tubal pathology and primigravid women in their first or second trimester of pregnancy. The research will compare the groups on previous IUD use, risk factors for exposure to sexually transmitted diseases, as well as previous exposure to chlamydia (serologic antibody test).

**Implementing Agency(s):** National Perinatology Institute, Mexico

**Collaborating Agency(s):** NICHD

**FY' 97 Planned Activities:**

- If funding is secured, the field work will be initiated in February 1997.

**Possible Problems, Barriers to Completion:**

- The study will not proceed until funds from NICHD become available.

|                           |                              |                                     |
|---------------------------|------------------------------|-------------------------------------|
| <b>Funding Source(s):</b> | USAID Core/OYB<br>from NICHD | <b>FCO Approved:</b>                |
| <b>FY '97 Budget:</b>     | \$ 120,136                   | <b>Projected End Date:</b> Sep 1998 |
| <b>Total Budget:</b>      | \$ 210,000                   |                                     |

## South Korea: Vasectomy and Prostate Cancer in Korea (FCO 6287)

**Technical Monitor:** Pam Schwingl

**Objective(s):** To ascertain if there is a relationship between vasectomy and prostate cancer in a non-Western population.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** 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 method that has been extensively studied. Recently, based on U.S. research, renewed concerns have been raised about a possible adverse effect on cancer of the prostate many years after the procedure. 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 China. The majority of epidemiological studies on the relationship between vasectomy and prostate cancer have been based in the U.S. with inconsistent findings and weak associations.

On the basis of currently available data from WHO, it is concluded that no changes in family planning policies with regard to vasectomy are warranted. However, 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. FHI is supporting one site in a WHO-coordinated 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.

**Implementing Agency(s):** Catholic Medical College, Seoul, Korea

**Collaborating Agency(s):** World Health Organization

**FY' 97 Planned Activities:**

- The Korean investigator will visit FHI in February 1997 to receive assistance with the analysis of the Korean data separate from the WHO study.
- Analysis will be completed.
- Results will be written-up.

**Possible Problems, Barriers to Completion:**

- None foreseen.

**Funding Source(s):** USAID/Core  
**FY '97 Budget:** \$ 15,746  
**Total Budget:** \$ 159,526

**FCO Approved:** Sep 1991  
**Projected End Date:** Sep 1998

## New Zealand: Case Control Study of Vasectomy and Prostate Cancer (FCO 6900)

**Technical Monitor:** Judith Fortney

**Objective(s):** To determine whether having had a vasectomy alters the risk of prostate cancer.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** This is a national case-control study being conducted in New Zealand. The study will compare 650 men who have been newly diagnosed with prostate cancer with 1300 men who are randomly selected from a national population base and who are not known to have prostate cancer. The study is part of a multi-center study coordinated by the Human Reproduction Programme of the World Health Organization. The protocol is consistent with the WHO protocol except that it is population-based rather than hospital-based. (See report for FCO 6287).

**Implementing Agency(s):** Dept of Preventive and Social Medicine, University of Otago, New Zealand

**Collaborating Agency(s):** World Health Organization, NICHD

**FY' 97 Planned Activities:**

- Questionnaires will be drafted.
- FHI's technical monitor will travel to New Zealand in February 1997 to assist with the questionnaire development, case selection criteria, and interviewer selections.
- Interviewers will be selected and trained.
- Case notification will begin.
- Data collection will be initiated, and approximately 6 months of the 3-year long process will be complete.

**Possible Problems, Barriers to Completion:**

- An extension to the completion date may be required. Due to a delay in the approval of the Interagency Agreement, the implementing agency is unable to start work until completion of other tasks accepted in the interim.

|                           |                               |                            |          |
|---------------------------|-------------------------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/OYB from<br>NICHD       | <b>FCO Approved:</b>       | Jul 1996 |
| <b>FY '97 Budget:</b>     | \$ 128,548                    | <b>Projected End Date:</b> | Jun 2000 |
| <b>Total Budget:</b>      | <b>FCO 6900</b><br>\$ 433,714 |                            |          |
|                           | <b>WHO</b><br>\$ 200,000      |                            |          |

**USA: Teen DMPA Bone Pilot Study (FCO 6383)**

**Technical Monitor:** Pam Schwingl

**Objective(s):** To gather preliminary data in support of an application to NIH on the relationship of DMPA and bone growth in young teenage women.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- 2.1 Approaches and technologies to enhance key reproductive health interventions identified, developed, evaluated and disseminated.

**Description:** DMPA is increasingly being used among teenage women. The partial suppression of estrogen by DMPA may affect bone metabolism during this time of rapid growth in limb length and increase in bone mineral density. While endogenous progesterone is thought to have a beneficial effect on bone growth, the effects of exogenous progestins are unclear. The planned pilot study will be conducted at a local site in North Carolina. Thirty new and current DMPA users 13-18 years of age, and the same number of girls using other methods of birth control (primarily COCs) will be included in this pilot in order to test recruitment, follow-up, informed consent procedures, biological sample collection and storage methods, and diary collection methods. Preliminary data on the rate of growth in bone length and bone density over a 6-month follow-up period will also be collected to generate more accurate estimates of rates of change for sample size calculations for the grant application. This pilot study will substantively address comments from the previous two rounds of NIH review. Data from this pilot study will be submitted in combination with similar data from Mt. Sinai Medical Center in support of an application to NIH.

**Implementing Agency(s):** TBD North Carolina  
**Collaborating Agency(s):** Mt. Sinai Medical Center, New York

**FY' 97 Planned Activities:**

- A site will be identified, and a protocol for the pilot study will be written and submitted to the Protection of Human Subjects Committee in November for their approval.
- Approximately 15 DMPA teen users and 15 non-users will be recruited into the study.
- Coordination plans between the North Carolina and Mt. Sinai sites will be developed.
- All participants will be recruited, and the first 30 will be followed for their 6 month visit.
- Preliminary results will be analyzed, and modifications to the study protocol will be made.
- Preparations for the NIH grant will begin.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Oct 1996 |
| <b>FY '97 Budget:</b>     | \$ 68,867  | <b>Projected End Date:</b> | Mar 1998 |
| <b>Total Budget:</b>      | \$ 80,900  |                            |          |

**Kenya: Method Mix Modeling (FCO 6478)**

**Technical Monitor:** Pam Schwingl

**Objective(s):** To determine the impact of various contraceptive mix strategies on reproductive health in Kenya.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** The fundamental question to be addressed by this modeling effort concerns the trade-offs involved in moving a family planning program from an exclusively fertility control orientation to one that encompasses broader reproductive health issues. If one is to approach the prevention and treatment of STDs at the level of the Family Planning /Service Delivery Point (FP/SDP), efforts to promote barrier methods must be increased. This subproject addresses the basic issue of changing the method mix to address STD concerns and the implications for this approach on programs and the people they serve; it also provides a low cost means of helping policymakers and programs to understand the trade-offs involved in such a transition. The number of new HIV infections, unintended pregnancies and maternal mortality among users of a variety of method mix scenarios will be estimated. Costs involved in shifting to scenarios associated with the lowest number of additional HIV and STD cases will also be calculated.

**Collaborating Agency(s):** Research Triangle Institute

**FY' 97 Planned Activities:**

- A full proposal will be finalized and submitted to USAID/W and USAID/Kenya.
- Specific modeling methods and procedures will be developed.
- FHI staff will meet with policymakers in Kenya to further outline the study problem and seek their input on data sources and assumptions. A dissemination strategy will be developed at this meeting.
- Modeling analysis will proceed, and a final report will be prepared. A dissemination meeting will be held in Kenya.

**Possible Problems, Barriers to Completion:**

- Appropriate data may be difficult to obtain.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Oct 1996 |
| <b>FY '97 Budget:</b>     | \$ 95,117   | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 95,117   |                            |          |

**Jamaica: Symposium on Long-term Safety of Hormonal Methods (FCO 6479)**

**Technical Monitor:** Pam Schwingl

**Objective(s):** 1) To present research results within Jamaica on the long-term safety of hormonal contraceptives, particularly in relation to cancer and cardiovascular disease; and 2) to disseminate data from both the FHI-Jamaica cervical cancer study and a risk/benefit modeling assessment using Jamaican data.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** USAID/Jamaica has asked FHI to organize a symposium to disseminate the findings from recent research on the long-term safety of hormonal contraceptives, with a particular emphasis on cancer and cardiovascular disease. Expert speakers will be invited to present the most recent data. In addition, data from the FHI-Jamaican study of hormonal contraceptives and cervical cancer *in situ* will be presented, as well as a risk-benefit analysis conducted at FHI placing these results in perspective with mortality from CVD and maternal causes. This symposium is tentatively planned to take place preceding the annual conference of the Medical Association of Jamaica in June 1997.

**FY' 97 Planned Activities:**

- Negotiations with the Medical Association of Jamaica will ensue to develop the appropriate format for this symposium. Once a format is decided upon, FHI staff will work with in-country conference staff to organize the conference.
- Final arrangements for the symposium will be made.
- The symposium will occur in June 1997.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Oct 1996 |
| <b>FY '97 Budget:</b>     | \$ 22,573   | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 22,573   |                            |          |

**Kenya: Risk of Short-term Complications with IUD Use and HIV (FCO 6204)**

**Technical Monitor:** Charles Morrison

**Objective(s):** To determine whether women infected with HIV (HIV+) are at greater risk of short-term complications related to IUD use than HIV-negative women.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- . Effective interventions to reduce sexual transmission of HIV/STD identified, strengthened, implemented and evaluated in emphasis countries.

**Description:** Women infected with HIV need safe, effective and long-lasting contraception. The current generation of IUDs fulfills these criteria and are also affordable. To date, it is unknown whether there is an increased risk of adverse effects in the early post-insertion period among HIV+ women. Despite the lack of data, the IPPF recently stated that an IUD should not be inserted in an HIV+ woman, and many providers in many developing countries are no longer inserting IUDs. In this study, IUD users (494 HIV- and 156 HIV+) recruited from two sites in Nairobi (Kenyatta National Hospital and Riruta City Commission Clinic) were initially followed for four months to assess their rates of short-term complications related to IUD use, notably pelvic inflammatory disease (PID). Also, in collaboration with researchers from the University of Washington, the infectiousness of HIV-infected IUD users was studied by measuring cervical shedding of HIV before and after insertion. A long-term (2-year) follow-up component is now planned to be added to this study.

**Implementing Agency(s):** University of Nairobi, Kenya; University of Washington, USA  
**Collaborating Agency(s):** American Foundation for AIDS Research (AMFAR)

**FY' 97 Planned Activities:**

- Final cleaning of the data set will be conducted, and component data sets will be constructed. "Short-term Complications" and "HIV-shedding" papers will be written, presented and submitted for publication.
- Between January and June 1997 an attempt will be made to follow all 650 study participants to assess complications associated with IUD use at approximately 2 years after insertion.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |                             |                            |          |
|---------------------------|-----------------------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core,<br>AMFAR (1654) | <b>FCOs Approved:</b>      | Sep 1993 |
| <b>FY '97 Budget:</b>     | \$ 127,395                  | <b>Projected End Date:</b> | Mar 1998 |
| <b>Total Budget:</b>      | <b>6204</b> \$ 586,895      |                            |          |
|                           | <b>1654</b> \$ 56,933       |                            |          |

## Kenya: Female Condom Use and Risk of STD (FCO 6308/6477)

**Technical Monitor:** Paul Feldblum

**Objective(s):** 1) To compare STD rates in cohorts provided with female condoms, compared with STD rates in cohorts not receiving female condoms; 2) to assess the acceptability of the female condom and the cost-effectiveness of provision in a routine service delivery program; and 3) to measure the effects of incorrect and non-use of male condoms among clinic attenders.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- 4.1 Effective interventions to reduce sexual transmission of HIV/STD identified, strengthened, implemented and evaluated in emphasis countries.

**Description:** As a female-controlled barrier product, the female condom offers the hope of better protection against STDs for women; however, the impact of its introduction and distribution among women at risk of infection has not been shown. A community intervention trial is planned with the comparison cohorts comprising factory workers, agricultural workers, and/or semi-urban residents. Intervention cohorts will receive female condoms and an information and motivation program on the devices. Comparison cohorts will receive information and motivation about male condoms. The incidence of cervical infection, trichomoniasis and other STDs will be measured during a year of follow-up. It is expected that there will be less unprotected coitus in the female condom cohorts and a corresponding reduction in STD incidence.

In a sub-study of male condoms at the same sites, cases will be men or women in a labor group who present to the clinic with evidence of STDs. Controls will be other workers in the labor group who do not have evidence of STDs. Cases and controls will be interviewed about recent sexual activity, level of condom use, perceived barriers to condom use, and asked to demonstrate condom application on a penis model. The analysis will compare levels of STDs among "incorrect" and non-users to determine the burden of STDs attributable to "incorrect" use. In addition, the analysis will identify barriers to correct use that could be removed through intervention.

**FY' 97 Planned Activities:**

- Considerable work will be done to develop the study design, sites and size. The study will be designed in concert with a Kenyan social scientists, AIDSCAP/Kenya staff and population staff in the FHI Nairobi office.
- The protocol will be finalized and submitted for PHSC approval.
- FHI will negotiate with the manufacturer for donation of the female condoms.
- The study is expected to be initiated in the second quarter of 1997.
- Observation will continue in the study cohorts.
- The male condom case-control sub-study will be conducted and completed.
- FHI staff (NC and Nairobi) will monitor the study sites.

**Possible Problems, Barriers to Completion:**

- This is a complicated study design. The study must locate adequate clinics for STD diagnosis to meet the recruitment goals.

|                           |             |                  |                            |          |
|---------------------------|-------------|------------------|----------------------------|----------|
| <b>Funding Source(s):</b> |             | USAID/Core/Field | <b>FCOs Approved:</b>      | Oct 1996 |
| <b>FY '97 Budget:</b>     | <b>6308</b> | \$ 152,449       | <b>Projected End Date:</b> | Jul 1999 |
|                           | <b>6477</b> | \$ 118,974       |                            |          |
| <b>Total Budget:</b>      | <b>6308</b> | \$ 250,000       |                            |          |
|                           | <b>6477</b> | \$ 250,000       |                            |          |

|             |  |
|-------------|--|
| <b>USA:</b> | <b>Hormonal Contraceptive Use, Cervical Ectopy and Cervical Infections (FCO 6311/6901)</b> |
|-------------|--|

**Technical Monitor:** Charles Morrison

**Objective(s):** To measure the impact of the initiation of oral contraceptive (OC) and Depo-Provera (DMPA) use on the presence and degree of cervical ectopy and on the incidence of cervical infections (chlamydia, gonorrhea).

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- 4.3 Other PHNC results. Specify # and name.

**Description:** A number of studies have documented an association between cervical ectopy and chlamydial and HIV infection. Likewise, OC use appears to be associated with cervical ectopy. However, no prospective studies have been conducted to carefully examine changes in cervical ectopy after initiation of hormonal contraceptives, including OCs and DMPA.. This study will examine the impact of the initiation of hormonal contraception (OC and DMPA) on the presence and degree of cervical ectopy at a U.S. site. The study will also measure the impact of hormonal contraceptive use and cervical ectopy on incident chlamydial and gonococcal infection.

**Implementing Agency(s):** Planned Parenthood of Maryland-Baltimore City Clinic, Johns Hopkins University

**Collaborating Agency(s):** National Institute of Child and Human Development (NICHD)

**FY' 97 Planned Activities:**

- Recruitment will be increased to 35-50 women per month by opening a second site in Towson, Maryland, further advertising, I ncreasing staff time on the study and other means.
- Follow-up rates will be increased to 70-80%.
- Entering of questionnaire data will continue and physical exam data entry will begin.
- Digitizing and measuring of cervical ectopy images will continue and reliability/validity checks by independent (expert) rater will begin.

**Possible Problems, Barriers to Completion:**

- The inability to recruit sufficient numbers of study participants (particularly DMPA users).
- Having lower than expected numbers of women with cervical infections.

|                           |             |                                |                            |          |
|---------------------------|-------------|--------------------------------|----------------------------|----------|
| <b>Funding Source(s):</b> |             | USAID/Core with OYB from NICHD | <b>FCOs Approved:</b>      | Nov 1994 |
| <b>FY '97 Budget:</b>     | <b>6311</b> | \$ 173,781                     | <b>Projected End Date:</b> | Sep 1999 |
|                           |             | \$ 114,678                     |                            |          |
|                           | <b>6901</b> |                                |                            |          |
| <b>Total Budget:</b>      | <b>6311</b> | \$ 462,078                     |                            |          |
|                           | <b>6901</b> | \$ 215,000                     |                            |          |

**USA: Technical Guidance Working Group (TGWG)  
(FCO 6312)**

**Technical Monitor:** Roberto Rivera

**Objective(s):** To develop updated, practical reference materials for health providers, addressing key family planning service delivery issues.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** As part of the Maximizing Access and Quality (MAQ) Initiative, FHI is working with USAID's Technical Guidance/Competence Working Group (TGWG) on the following issues: 1) sample guidelines for information in OC package inserts (completed in FY'95); 2) updating of community-based services (CBS) checklists for COC and injectable use; 3) STD screening in resource-poor settings; 4) Volume II of the TGWG Recommendations (chapters on Spermicides, Lactational Amenorrhea Method, POCs, and Emergency Contraception).

**FY' 97 Planned Activities:**

- FHI will collaborate in the review and completion of Volume II.
- The field test results on the checklists will be incorporated, and the final draft of such checklists will be produced.
- Volume II and the checklists will be disseminated via seminars and discussions (i.e., meetings, workshops, *Network*, etc.).

**Possible Problems, Barriers to Completion:**

- None foreseen.

**Funding Source(s):**  
**FY '97 Budget:**  
**Total Budget:**

USAID/Core  
\$ 39,831  
N/A-Annual

**FCO Approved:** May 1995  
**Projected End Date:** USAID Discretion

## Worldwide: Reproductive Health Paper Writing (FCO 6352)

**Technical Monitor:** Douglas Nichols

**Objective(s):** To conduct secondary analysis on data from completed studies and to write papers for presentations and publication based on these analyses.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Following the completion of field research activities culminating in a subproject final report, data analysis continues and/or papers are prepared for presentation and publication in scientific journals to disseminate results of FHI-supported research. This subproject supports staff time and travel costs related to these needs.

### FY' 97 Planned Activities:

#### In Press

- Bisgrove E, Popkin B. Does women's work improve their nutrition: Evidence from the urban Philippines. *Soc Sci & Med*.
- Bisgrove E. Use of DMPA and the risk of cervical carcinoma *in situ*. *Int J Epidemiology*.
- Feldblum PJ. Self-reported discomfort associated with use of different nonoxynol-9 spermicides. (letter) *Genitourin Med*.
- Hira SK, Feldblum PJ, Kamanga J, Mukelabai G, Weir SS, Thomas JC. Condom and nonoxynol-9 use and the incidence of HIV infection in serodiscordant couples in Zambia. *Int J STD AIDS*.
- Kennedy K, Visness C. Comparison of two United States surveys of infant feeding. *J Hum Lact*.
- Ramos R, Kennedy K, Visness C. The effectiveness of the Lactational Amenorrhea Method in Preventing Pregnancy in Manila, the Philippines. *B Med J*.
- Visness C, Kennedy K. Maternal Employment and Breastfeeding: Findings from the 1988 National Maternal and Infant Health Survey. *Am J Public Health*.

#### Submitted:

- Ephross SA, Schwingl PS, Nabulsi AA, Maguire A, White AD, Hutchinson RG, Burke G. Past oral contraceptive use and carotid artery atherosclerosis: The Atherosclerosis Risk in Communities (ARIC) Study. *Am J Epidemiol*.
- Kennedy K, Ramos R, Kazi A, Visness C, Khan T. Women's Understanding of LAM protection. *J Biosoc Sci*.
- Madrigal J, Schifter J, Feldblum PJ. Female condom acceptability among sex workers in Costa Rica. *AIDS Educ Prevent*.
- Morrison CS, Sunkutu MR, Musaba E, Glover L. Sexually transmitted disease among married Zambian women: The role of male and female behaviors in prevention and management. *Genitourin Med*.
- Musaba E, Morrison CS, Sunkutu MR, Spruyt A, Chamba AB. Long-term use and acceptability of the female condom among couples at high risk of HIV in Zambia. *Am J Public Health*.
- Oakley D, Potter L, Wong E, Visness C. Oral contraceptive pill use behaviors. *Obstet Gynecol*.

- Sekadde-Kigondu C, Nichols D, Nyagoro J, Jesencky K. Knowledge, attitude, practice and provision of family planning services among Kenyan doctors. *E Afr Med J*.
- Visness C, Kennedy K, Ramos R. The Duration and Character of Postpartum Bleeding in Breastfeeding Women. *Obstet Gynecol*.
- Visness C, Kennedy K, Gross B, Parenteau-Carreau S, Flynn A, Brown J. Fertility of fully breastfeeding women in the early postpartum. *Obstet Gynecol*.
- Weir SS, Fox L. Measurement of condom use among sex workers in the Dominican Republic. *Int J STD AIDS*.
- Weir SS, Roddy RE, Zekeng L, Ryan KA. Safer sex to prevent AIDS: Easy to say, hard to measure. *AIDS*.
- Weir SS, Roddy RE, Zekeng L, Ryan KA, Wong EL. Measuring condom use: asking 'do you or don't you' isn't enough. *AIDS Educ Prevent*.

**In Progress:**

- Dalberth P, Potter L, Cañamar R, Betz M. Characteristics of women switching to DMPA at Wake County Department of Health.
- Lafort Y, Morrison CS, Musaba E, Thomas J, Sunkutu MR. Reliability and validity of the reporting of sexual behavior: A study of couples at high risk for HIV infection in sub-Saharan Africa.
- Nichols D, Sekadde-Kigondu C, Mwathe E, Liku J. One-year acceptability study of three contraceptive methods.
- Nutley T, Potter L, Keller S. Discrepancies in guidelines for emergency contraceptive pills.
- Potter L, Dalberth B, Cañamar R, Betz M. Pioneers: The first cohort of DMPA acceptors at a county health department.
- Ramos R, Kennedy K, Visness C. Withdrawal Use by LAM acceptors in Manila and its effect on pregnancy rates.
- Roddy RE, Cordero M, Ryan KA. A clinical trial comparing nonoxynol-9 lubricated condoms with silicone lubricated condoms for prophylaxis.
- Roddy RE, Weir S, Zekeng L, Ryan KA. Prevalent and incident cervical gonorrhea and chlamydia infection as a risk factor for HIV infection.
- Roddy RE, Zekeng L, Ryan KA. Frequent nonoxynol-9 use and vaginal ecology.
- Roddy RE, Zekeng L, Ryan KA. Prevalence of sexually transmitted diseases among sex workers in Cameroon.
- Roddy RE, Zekeng L, Ryan KA. Nonoxynol-9 film use and the rate of cervical infection in Cameroon.
- Roddy RE, Zekeng L, Ryan KA. Nonoxynol-9 film use and the rate of HIV infection in Cameroon.
- Ryan KA, Roddy RE, Zekeng L, Weir SS. Characteristics associated with prevalent HIV infection in Cameroon.
- Schwingl PS, Wong E, Grey T. Prostate cancer screening practices among vasectomized and non-vasectomized men.
- Steiner M, Raymond E, Trussell J. The influence of fecundability on the pregnancy rate: a reanalysis of the Reality female condom clinical trial.
- Wilson D, Weir SS, Smith P, Schoenbach V. The use of capture-recapture methods to estimate the size of the female population at increased risk for STDs/HIV in Zimbabwe.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Aug 1995 |
| <b>FY '97 Budget:</b>     | \$142,703  | <b>Projected End Date:</b> | Aug 2000 |
| <b>Total Budget:</b>      | N/A-Annual |                            |          |

**USA: Study to Measure the Contraceptive Efficacy of  
Condoms and Vaginal Contraceptive Film Using a  
New Methodology (FCO 6217)**

**Technical Monitor:** Markus Steiner

**Objective(s):** To assess the utility and feasibility of a new methodology that will provide more precise estimates of the contraceptive efficacy of two barrier methods.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** No study has ever measured the true effectiveness of a contraceptive; this can only be done if the underlying fecundity of a study population is known. In this pilot study, 75 women who are intending to become pregnant will be enrolled during their menses. They will be randomized into three groups: 1) an unprotected group; 2) a male condom group; and 3) a VCF group. Each woman will be provided with a home ovulation detection kit and instructed on how to determine her next day of ovulation.

Participants in the unprotected group will be requested to abstain from vaginal intercourse until the next day of ovulation and engage in one act of vaginal intercourse on that day. They will then be asked to abstain for another five days. Two weeks after their day of ovulation and intercourse they will be asked to return to the clinic for a pregnancy test. The study's primary outcome of interest is the proportion of women becoming pregnant following one act of vaginal intercourse on the most fertile day. Each of the women in the two other groups (condoms and VCF) will be asked to have a single act of vaginal intercourse using their assigned barrier method on their next day of ovulation using the same study protocol as described above.

**Implementing Agency(s):** Department of Obstetrics and Gynecology, The Bowman Gray School of Medicine, Winston-Salem, NC; Brazos Valley Community Action Agency/Family Planning Clinic, Bryan, Texas

**FY' 97 Planned Activities:**

- Recruitment of participants will continue at Bowman Gray.
- One or two additional sites will be initiated.
- Data entry will begin.
- Routine monitoring will be conducted at all sites.

**Possible Problems, Barriers to Completion:**

- Recruitment has proceeded more slowly than anticipated and may continue to do so.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Jun 1995 |
| <b>FY '97 Budget:</b>     | \$ 86,604  | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 107,507 |                            |          |



■ **Preparation of Annotated Bibliographies**

Field Operations is responsible for ensuring that annotated bibliographies that describe FHI experience in selected countries are prepared. Bibliographies include all FHI reproductive health work-population, maternal health, and AIDS prevention.

■ **Identification of New Opportunities**

Field Operations staff seek new opportunities for FHI by emphasizing FHI capabilities in discussions with Mission personnel, leveraging USAID core funds in collaborative funding with other organizations, and obtaining bilateral Mission funds through add-ons to cooperative agreements or responses to Requests for Proposals that will complement USAID-funded core activities.

***Field Operations Division's FY'97 Program***

The Field Operations Division will continue to concentrate its work in the identified above five areas during FY'97. Those denoted with an asterisk are new subprojects, expected to get underway in FY'97. The activities, ongoing and new, which the division will implement during the coming year are listed below:

■ **Development of Regional and Country Strategies**

*New Activities:*

- Development of a country strategy for Bolivia and Mexico

■ **Liaison for Country Activities**

*Continuing Activities:*

- Coordination of Mission-funded programs in Ethiopia, Ghana, Kenya, Senegal, Egypt, Nepal, Bolivia, Mexico, Haiti and Jamaica
- Provision of regular quarterly feedback on FHI activities to these Missions

■ **Support to Regional and Country Offices**

*Continuing Activities:*

- Continuation of support to Kenya, Egypt, Nepal and Bolivia offices

■ **Preparation of Annotated Bibliographies**

*New Activities:*

- Preparation of bibliographies for Zimbabwe, Nepal, Sri Lanka, Brazil, Dominican Republic, Chile, Honduras and Jamaica

■ **Identification of New Opportunities**

*Continuing Activities:*

- Expansion of efforts in Ghana, Kenya, Senegal, Egypt, Bolivia and Mexico

*New Activities:*

- Exploration of opportunities for field support funding in Nicaragua, Guinea, Eritria and South Africa

Most Field Operations' activities as described above are support functions funded under general management accounts. Support to regional and country offices, however, is a discrete activity; as such, workplans for each of these follows:

- Egypt: Cairo Office (7095)
- Kenya: FHI Nairobi Office (7096)
- Nepal: Country Activities (7403)
- Bolivia: Field Office (7405)

**Egypt: Cairo Office (FCO 7095)**

**Technical Monitor:** Tara Nutley

**Objective(s):** To provide local coordination of FHI's reproductive health and Women's Studies research projects in Egypt

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** FHI's Cairo Office provides support for in-country activities of both the Contraceptive Technology and Family Planning Research Cooperative Agreement and the Women's Studies Project (WSP), as well as for USAID/Cairo's Population and Family Planning III Project (POP III), for which FHI is a subcontractor to Pathfinder. Costs for support of the Women's Studies Project are charged to that cooperative agreement.

**FY' 97 Planned Activities:**

- The Resident Regional Advisor will begin implementing the POP III study entitled "Special Study on Consumer's Perceptions of Quality."
- The Resident Research Advisor will continue to coordinate research and monitoring activities for WSP and population studies.
- The Resident Regional Advisor will represent FHI at professional and scientific meetings.

**Possible Problems, Barriers to Completion:**

- None foreseen.

**Funding Source(s):** USAID/Core  
**FY '97 Budget:** \$ 27,082  
**Total Budget:** N/A-Annual

**FCO Approved:** <Aug 1995  
**Projected End Date:** Aug 2000

**Kenya: Kenya: FHI Nairobi Office (FCO 7096)**

**Technical Monitor:** Tara Nutley

**Objective(s):** To provide local and regional coordination of FHI's reproductive health research projects in Kenya and in East and Southern Africa.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** FHI provides support for in-country and regional activities of the Contraceptive Technology and Family Planning Research Cooperative Agreement. This office, established in January 1992, is also responsible for exploring project opportunities and representing FHI in the region.

**FY' 97 Planned Activities:**

- FHI will continue to support ongoing projects and seek new program opportunities consistent with FHI's corporate mission.
- An annotated bibliography of all completed, ongoing and planned activities related to family planning/STD intervention in Kenya will be developed.
- The final report of the Pan African Federation of Maternal and Child Health (PAFMACH) Conference will be prepared and distributed.
- Contacts made in South Africa will be followed up.
- FHI will begin project development activities in Zimbabwe.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |           |
|---------------------------|------------|----------------------------|-----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | <Aug 1995 |
| <b>FY '97 Budget:</b>     | \$ 161,876 | <b>Projected End Date:</b> | Aug 2000  |
| <b>Total Budget:</b>      | N/A-Annual |                            |           |

## Nepal: Nepal Country Activities (FCO 7403)

**Technical Monitor:** Matthew Tiedemann

**Objective(s):** 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.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** FHI has been providing technical support to the Government of Nepal (GON) in family planning and the population sector for over a decade. At the request of the GON and with support of the USAID Mission, FHI has provided, since 1993, a Technical Advisor to assist the Family Health Division of the Ministry of Health and the Population Division of the Ministry of Population and Environment (MOPE). FHI has been assisting the GON in assessment of program performance, utilization of data for policy and program development, and investigation of implementation issues and problems. The subproject also provides research and training opportunities to local population and health professionals. The program continues to focus on increasing access to contraception and monitoring and analyzing data on the performance of the family planning program.

Note: This subproject was previously funded under FCOs 7498 and 7098, since closed. Activities under the current cooperative agreement have been funded under FCO 7403.

**FY' 97 Planned Activities:**

- In early 1997, the technical advisor will lead a delegation of three senior MOPE staff on a study tour to Indonesia.
- Dissemination materials will be prepared based on the 1996 Nepal Health Survey.
- The advisor will analyze data from the 1996 Nepal Health Survey to update policymakers and program managers at the national and local levels. This analysis will be used in the development of GON's five-year Development Plan. In addition, the analysis will provide up-to-date information for local CTUs, trainings for researchers and local experts, and material for dissemination for USAID, local NGOs and international NGOs (INGO).
- A discussion forum on reproductive health and reproductive rights will be organized for members of Parliament in the Spring of 1997.
- FHI will assist the MOH conduct additional safe motherhood workshops, similar to that held in Kathmandu in September, at the local level.
- Technical support to the Government of Nepal, Mission, and various NGOs and INGOs will continue to be provided as necessary.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Oct 1995 |
| <b>FY '97 Budget:</b>     | \$348,189   | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | N/A-Annual  |                            |          |

**Bolivia: Bolivia Field Office (FCO 7405)**

**Technical Monitor:** William Conn

**Objective(s):** To provide local coordination of FHI's reproductive health research projects in Bolivia.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Through its field office in La Paz, FHI's Resident Advisor provides coordination of all its reproductive health activities in Bolivia.

**FY' 97 Planned Activities:**

- The Resident Advisor will participate in the International Medical Parliamentary Organization (IMPO) meeting in Santa Cruz in October 1996.
- Small Grants projects, including research projects and scholarships, will be implemented.
- Dissemination of the results from the "DMPA Introduction" study will occur countrywide.
- The Field Office will continue to coordinate the distribution of CTU modules and *Network en Español* in Bolivia.
- The Field Office will continue its support of the Reproductive Health Research Subcommittee and of the publication of "Research Updates."
- The Resident Advisor will publish further research abstracts in "Opciones."
- The FHI/Bolivia country strategy will be finalized and disseminated.
- The Resident Advisor will visit FHI/NC in April or May 1997.
- Project field visits will be conducted.
- The Field Office will continue to coordinate research projects and to plan future projects with CARE/Bolivia and other agencies.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Oct 1995 |
| <b>FY '97 Budget:</b>     | \$75,000    | <b>Projected End Date:</b> | Sep 1998 |
| <b>Total Budget:</b>      | N/A-Annual  |                            |          |



activities to update providers, managers, and policymakers will continue to be a major activity under the HCTP Unit in FY'97. New modules on Adolescent Reproductive Health and on sterilization are being developed. In FY'97, HCTP will work with country and regional programs to integrate the modules into training and in-service education programs.

#### ■ **Maximizing Access and Quality (MAQ)**

FHI continues its commitment to improving client access to high quality family planning services. FHI has taken a leadership role in the USAID MAQ initiative to improve service practices and to ensure access to and delivery of quality contraceptive services. The organization and implementation of educational activities, including regional and in-country seminars to support the improvement of service practices, is an important part of PRU's MAQ initiative. Through such activities, service providers and policymakers are updated on current scientific information regarding service provision and contraceptive methods.

In FY'97, PRU will begin working in collaboration with AVSC International in Paraguay to update national service delivery policies and guidelines. This multi-year activity will also help the Ministry of Health establish a routine system for updating and revising family planning guidelines and ensuring that providers comply with policy changes. In other educational activities, FHI will continue working with private sector providers in Haiti and Jamaica to help widen the range of quality services provided.

#### ■ **Policy**

PRU works to ensure that reproductive health research findings are made available to policymakers through conferences, workshops and publications. It also supports direct technical assistance to ministries of health and governments in policy development in research and family planning service delivery. Currently, one staff member is assigned to Nepal as a research advisor to the Ministry of Health and the Ministry of Population and Environment.

#### ***Policy and Research Utilization Division's FY'97 Program***

Priorities for the PRU Division for FY'97 under the Cooperative Agreement emphasize the utilization of the latest information from research to strengthen population programs and improve the quality of contraceptive services. This work will include written dissemination through publications and educational materials, maintenance of the FHI library and information services, and training and technical assistance to developing world collaborators. In FY'97, PRU will work closely with other cooperating agencies including the Population Council, JHPIEGO, AVSC, The Focus Project and with international agencies such as WHO and IPPF.

The ongoing and new subprojects that PRU will implement in FY'97 are listed below. Those denoted with an asterisk are new subprojects, expected to get underway in FY'97.

#### ■ **Information Dissemination**

- English *Network* (3202)
- *Network en español* (3228)
- *Network en français* (3250)
- Publications Catalog (3221)
- Information Dissemination (3205)
- Library and Information Services (3260)
- Ghana: Ministry of Health/Health Research Unit Library Technical Assistance (3565)
- Jamaica: National Family Planning Board Library Technical Assistance (3405)\*

■ **Health Communication and Training**

- Contraceptive Technology Update Modules Series (3210)
- Expert Slide Sets: CTUs (3211)

■ **Maximizing Access and Quality (MAQ)**

- Haiti: Contraceptive Technology Continuing Medical Education (3269/3265/3728)
- Contraceptive Technology Update Seminars: Development (3208)
- Paraguay: Contraceptive Technology Update Regional Workshops (3400)
- Paraguay: National Family Planning Guidelines Revision Project (3406)\*
- Jamaica: Family Planning Seminars for Private Physicians (3404/3722)
- Jamaica: Training Workshop in Contraceptive Technology & Counseling for Jamaican Nursing Tutors (3401)
- Paraguay: FLASOG Congress (3266)
- Senegal: Young Adults Contraceptive Technology Update Workshop (3402)\*

Individual descriptions of each of these subprojects follow in the order presented above.

## Worldwide: English Network (FCO 3202)

**Technical Monitor:** William Finger

**Objective(s):** To disseminate important research results and provide timely information on contraceptive technologies and reproductive health issues to family planning providers, health policymakers, women's organizations, developing country media and other relevant groups.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Through this quarterly bulletin, FHI distributes the latest scientific and programmatic information on reproductive issues in a timely manner to readers around the world. The articles synthesize a broad range of information to enhance the understanding and improve the knowledge base of policymakers, providers, health officials and others. Up-to-date information on contraceptive technology and family planning research serves to improve the quality of family planning services offered by providers. The attractive, easy-to-understand format, involving overseas experts as contributors, also facilitates policy reform and program planning. *English Network* is translated in French and Spanish four times a year (see FCOs 3228 and 3250), yielding a combined subscription list of some 60,000. Many more copies are distributed for special needs, and translation projects in other languages are also undertaken. Other publications, including newspapers, frequently reprint articles from *Network*, and the full text of all articles are available in the three languages through FHI's homepage.

### FY' 97 Planned Activities:

- Four issues of *English Network*, 24 to 32 pages each, will be published and distributed. Issues will cover family planning and AIDS, young adults, and sterilization; the final FY'97 issue may cover contraception after pregnancy, or contraceptive acceptance/continuation. About 29,000 copies will be printed of each English issue, of which more than 25,000 will go to regular subscribers.
- Issues for FY'98 will be planned. Ways to reduce costs further will be explored, focusing on more efficient distribution and mailing procedures.

### Possible Problems, Barriers to Completion:

- None foreseen.

|                           |            |                            |           |
|---------------------------|------------|----------------------------|-----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | <Aug 1995 |
| <b>FY '97 Budget:</b>     | \$ 300,469 | <b>Projected End Date:</b> | Aug 2000  |
| <b>Total Budget:</b>      | N/A-Annual |                            |           |

## Worldwide: Network en español (FCO 3228)

**Technical Monitor:** Marina McCune

**Objective(s):** To disseminate important research results and provide timely information on contraceptive technologies and reproductive health issues to family planning providers, Ministries, USAID Missions, health policymakers, women's organizations, media and other relevant groups in Latin America and the Caribbean.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Through this quarterly bulletin, FHI distributes the latest scientific and programmatic information on reproductive issues in a timely manner to Latin American and the Caribbean readers. The articles synthesize a broad range of information to enhance the understanding and improve the knowledge base of policymakers, providers, health officials and others. Up-to-date information on contraceptive technology and family planning research serves to improve the quality of family planning services offered by providers. The attractive, easy-to-understand format, involving overseas experts as contributors, also facilitates policy reform and program planning. Approximately 23,000 copies of each issue are sent to regular subscribers, and to meet special requests from other agencies. A press release accompanies each issue sent to journalists. This results in newspapers and other publications frequently reprinting articles, giving greater dissemination of topics covered in *Network en español* ..

### FY' 97 Planned Activities:

- The issue on fertility awareness (Vol. 17, No. 1) will be published and 29,000 distributed.
- An issue on family planning and AIDS will be published.
- Four issues of *Network en español*, 24 to 32 pages each, will be translated, published and distributed. These issues will cover such topics as fertility awareness, family planning and AIDS, sterilization, and young adults.
- Press releases on each issue will be sent to journalists in Latin America, the Caribbean and elsewhere.
- All issues will be made available through FHI's homepage at <http://www.fhi.org>.

### Possible Problems, Barriers to Completion:

- None foreseen.

|                           |            |                            |           |
|---------------------------|------------|----------------------------|-----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | <Aug 1995 |
| <b>FY '97 Budget:</b>     | \$ 198,588 | <b>Projected End Date:</b> | Aug 2000  |
| <b>Total Budget:</b>      | N/A-Annual |                            |           |

## Worldwide: Network en français (FCO 3250)

**Technical Monitor:** Mary Bean

**Objective(s):** To disseminate important research results and provide timely information on contraceptive technologies and reproductive health issues to Francophone family planning providers, ministries, USAID Missions, health policymakers, women's organizations and media, primarily in Africa and Haiti.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Through this quarterly bulletin, FHI distributes the latest scientific and programmatic information on reproductive issues in a timely manner to Francophone readers around the world. The articles synthesize a broad range of information to enhance the understanding and improve the knowledge base of policymakers, providers, health officials and others. Up-to-date information on contraceptive technology and family planning research serves to improve the quality of family planning services offered by providers. The attractive, easy-to-understand format, involving overseas experts as contributors, also facilitates policy reform and program planning. Approximately 13,500 copies of each issue are sent to regular subscribers and to meet special requests from USAID Missions, Ministries of Health and health agencies. A French press release accompanies each issue sent to Francophone journalists, resulting in newspapers and other publications frequently reprinting articles, giving greater dissemination of topics covered in *Network en français*. The full texts of all articles are available through FHI's homepage.

### FY' 97 Planned Activities:

- Publish and distribute Vol. 17, No 1 on fertility awareness.
- Translate, publish and distribute Vol. 17, No. 2 on family planning and AIDS.
- Translate, edit, produce and distribute four issues of *Network en français*, 24 to 32 pages each. These issues will cover topics such as fertility awareness, family planning and AIDS, young adults and sterilization.
- More than 11,500 copies of each issue will be sent to regular subscribers; 2000 additional copies will be distributed later upon request.
- A French press release on each issue will be sent to journalists in Africa.
- Work to increase circulation of the bulletin and to evaluate distribution lists and systems will continue.
- All issues will be made available through FHI's homepage, <http://www.fhi.org>.

### Possible Problems, Barriers to Completion:

- None foreseen.

|                           |            |                            |           |
|---------------------------|------------|----------------------------|-----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | <Aug 1995 |
| <b>FY '97 Budget:</b>     | \$ 135,662 | <b>Projected End Date:</b> | Aug 2000  |
| <b>Total Budget:</b>      | N/A-Annual |                            |           |

## Worldwide: Publications Catalog (FCO 3221)

**Technical Monitor:** Nash Herndon

**Objective(s):** To compile information for a catalog of current FHI scientific publications in order to facilitate dissemination of research findings on reproductive health.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. This subproject serves a support function. The Publications Catalog assists researchers, providers and policymakers in accomplishing their objectives. It thereby contributes, albeit indirectly, to all the PHNC results.

**Description:** This catalog provides a listing of current FHI scientific publications, including journals, articles and monographs, and makes this listing available to a selected group of family planning and reproductive health specialists. It includes an order form for obtaining free copies of most articles listed.

### FY' 97 Planned Activities:

- Staff will compile information for the 1996 catalog on a PROCITE database, edit the listings, arrange the listing in a catalog, and print and distribute the publication.
- The catalog will include an order form allowing readers to obtain reprints of scientific studies. Staff will disseminate reprints as requested.

### Possible Problems, Barriers to Completion:

- None foreseen.

|                           |            |                            |           |
|---------------------------|------------|----------------------------|-----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | <Aug 1995 |
| <b>FY '97 Budget:</b>     | \$ 6,247   | <b>Projected End Date:</b> | Aug 2000  |
| <b>Total Budget:</b>      | N/A-Annual |                            |           |

## Worldwide: Information Dissemination (FCO 3205)

**Technical Monitor:** Elizabeth Robinson

**Objective(s):** To increase access to and availability of high-quality family planning services and to improve acceptance of family planning among couples worldwide by increasing the knowledge of reproductive health issues among family planning research and service delivery personnel, policymakers and media, and NGOs that provide reproductive health services.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Under this subproject, FHI provides recent research findings to health-care professionals; responds to controversies and disseminates information to providers, USAID Missions, and media; encourages developing country news media to cover reproductive health issues; and supports development of information dissemination capacity among reproductive health agencies in priority countries.

### FY' 97 Planned Activities:

- Two brochures and 2 posters on contraceptive technology research will be published.
- Staff will respond to approximately 10,000 requests for information on FHI research.
- Information Programs staff will provide 2-3 targeted responses to contraceptive technology controversies, and organize two media efforts related to FDA meetings on new technologies.
- At least 50 FHI articles will be disseminated via commercial electronic media other than FHI's home page.
- Staff will write and distribute six news releases (in three languages) to international health journalists.
- Databases and information collections for use in responding to controversies, queries and requests for assistance related to contraceptive technology and reproductive health will be maintained.
- Systems to reach women's health advocates, NGOs and program managers with FHI research findings will be strengthened and dissemination of FHI findings through United Nations communication channels will be improved.
- Staff will develop listserv and infobot capacity to disseminate FHI publications to developing country institutions having e-mail but not full internet access.
- Staff will publish a scientific journal article on communicating reproductive health information: New approaches post-Cairo and post-Beijing.
- FHI will work to improve the quantity and quality of FHI manuscripts submitted to scientific journals.
- The migration of all information databases to new computer platforms and applications will be completed.

### Possible Problems, Barriers to Completion:

- None foreseen.

|                           |            |                            |           |
|---------------------------|------------|----------------------------|-----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | <Aug 1995 |
| <b>FY '97 Budget:</b>     | \$ 168,176 | <b>Projected End Date:</b> | Aug 2000  |
| <b>Total Budget:</b>      | N/A-Annual |                            |           |

**USA: Library and Information Services (FCO 3260)**

**Technical Monitor:** William Barrows

**Objective(s):** To provide library information services to FHI staff, consultants, visitors and projects, and to assist in the dissemination of information on contraceptive research.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- This subproject serves essentially a support function. The library and information service assists researchers, policymakers and health providers identify and locate the latest literature on family planning and reproductive health. It thereby contributes, albeit indirectly, to all the PHNC's results.

**Description:** This subproject supports the FHI Library which provides information services to all FHI staff, investigators and others. The library collection contains approximately 6000 monographs and 700 journals and newsletter titles emphasizing contraception, family planning, sexually transmitted diseases, AIDS prevention, demography, statistics and research methodology. It is one of the largest special libraries covering contraceptive and family planning research. Since 1989, the FHI library has been part of Information Programs in the Policy, Research & Utilization (PRU) Division providing an integrated system of information management that combines acquisition, organization and dissemination.

**FY' 97 Planned Activities:**

- All circulation records will be converted from a manual system to an automated system.
- Document databases will be converted to Windows software and made accessible for all staff.
- Development of standardized subject heading lists and authority files for the online catalog will begin. The online catalog will also be converted to network compatible software.
- Electronic and CD databases will be reorganized and access will be simplified. Electronic information resources will be consolidated.
- Improved subject searching access will be provided.
- Internet guides and references will be provided to staff.
- Improved means for resource-sharing with other population libraries will be developed.

**Possible Problems, Barriers to Completion:**

- Unanticipated staff vacancies could slow the automation process and the conversion to network compatible software.

|                           |            |                            |           |
|---------------------------|------------|----------------------------|-----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | <Aug 1995 |
| <b>FY '97 Budget:</b>     | \$ 259,553 | <b>Projected End Date:</b> | Aug 2000  |
| <b>Total Budget:</b>      | N/A-Annual |                            |           |

**Ghana: Ministry of Health/Health Research Unit Library  
Technical Assistance (FCO 3565)**

**Technical Monitor:** William Barrows

**Objective(s):** To further improve the effectiveness and efficiency of the Ministry of Health, Health Research Unit (MOH/HRU) Library in the areas of information, communication and information dissemination.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** This subproject provides technical assistance to the library of the Health Research Unit to improve the organization, operation and dissemination of information activities of the MOH/HRU library.

**FY' 97 Planned Activities:**

- If funds for equipment and software are approved, the FHI Information Services Manager will return to Accra to install the software and train staff in its use. Local Internet service providers will be identified and communication links assessed for availability and tested to access individuals and information resources in the U.S. and other institutions in the region.
- Training materials and information on documentation resources will be gathered and sent to the MOH/HRU library. Catalog record formats will be developed and conversion of catalog information will be underway. New journal titles and books will be selected and ordered.

**Possible Problems, Barriers to Completion:**

- Funds may not be allocated. Insufficient library staff may slow the automation process. Unavailability of PCs may limit access to library information.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Jul 1995 |
| <b>FY '97 Budget:</b>     | \$ 18,954   | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 29,491   |                            |          |

**Jamaica: National Family Planning Board Library Technical Assistance (FCO 3405)**

**Technical Monitor:** William Barrows

**Objective(s):** To improve the collections and services of the library of the National Family Planning Board of Jamaica.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** This subproject will support technical assistance to the National Family Planning Board to develop the resources and services of the National Family Planning Board (NFPB) Library. The FHI Information Services Manager will travel to Jamaica to assess the resources of the NFPB Library, provide lists of materials and draft a plan for improving their library and information services.

**FY' 97 Planned Activities:**

- The Information Services manager of FHI will travel to Jamaica early in 1997 to assess the resources of the NFPB Library and provide lists of recommended journals and books for the library. The assessment will cover equipment, manpower and software requirements, training needs, other resources in the local area and a plan for implementing the development of the library to support the activities of the NFPB.
- Follow-up activities will be carried out to ensure that the library development proceeds smoothly and efficiently.

**Possible Problems, Barriers to Completion:**

- Insufficient funding may slow the library development.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Nov 1996 |
| <b>FY '97 Budget:</b>     | \$ 6,954    | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 6,954    |                            |          |

## Worldwide: Contraceptive Technology Update Modules Series (FCO 3210)

**Technical Monitor:** Lucy Harber

**Objective(s):** To provide trainers and presenters of family planning information with easy-to-use, current, and scientifically accurate overviews of various contraceptive methods.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** The Contraceptive Technology Update (CTU) modules series is a set of training modules that provides a 45-60 minute slide presentation about a single method or single issue in family planning. The modules are used as a tool for influencing policymakers, and changing the knowledge and updating the practices of family planning service providers. The CTU modules project is a collaborative effort between FHI and other cooperating agencies and includes the development of consensus on key issues. Subjects for new modules to be completed this year include Adolescent Reproductive Health and Sterilization. The technical content addresses issues such as method advantages and disadvantages, indications and contraindications, client care issues, care provider requirements, counseling and quality of care issues. Each module includes a suggested narrative, 35-mm color slides, audience handout materials, a list of key reference materials, and reprints of book chapters and journal articles for additional background information.

**Collaborating Agency(s):** In FY'97, The FOCUS Project, AVSC International

### FY' 97 Planned Activities:

- Distribution of all previously completed modules will continue.
- French and Spanish translations of the OC and Barrier Methods modules will be completed and approximately 500 of each of the modules will be printed.
- The LAM module will be reprinted in French and Spanish, approximately 150 copies each.
- Translation of the Oral Contraceptives module slides into Russian will be completed.
- The translations the OC and Barrier Methods modules slides in Portuguese will be completed. 50 sets of each will be produced.
- Production and initial distribution of the English version of the Adolescent Reproductive Health module will be completed and approximately 750 will be printed. Translation into French and Spanish will be initiated.
- Production and initial distribution of the English version of the Male and Female Sterilization module will be completed and approximately 750 will be printed. Translation into French and Spanish will be initiated.
- Additional funding for development costs will be pursued from other organizations. Module sales will be actively pursued.
- The Adaptation Guide will be completed and circulated to module recipients.
- Pre-/post-tests will be designed for existing modules and included in the Adaptation Guide.

**Possible Problems, Barriers to Completion:**

- The extended review process and difficulty of reaching consensus on key scientific aspects of slides and texts may delay production. The development process may be further complicated by the collaboration with outside organizations.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | May 1992 |
| <b>FY '97 Budget:</b>     | \$ 451,437 | <b>Projected End Date:</b> | Sep 1998 |
| <b>Total Budget:</b>      | N/A-Annual |                            |          |

## Worldwide: Expert Slide Sets (FCO 3211)

**Technical Monitor:** Lucy Harber

**Objective(s):** To produce and distribute in collaboration with other cooperating agencies, 35mm color slide sets on contraceptive technology topics for use by leading international family planning experts when giving presentations.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** This subproject funds the development and production of a series of 35mm color slide sets covering various topics related to contraceptive technology. Unlike the CTU modules series, these sets are designed for presenters who are experts in the subject area. The information in the slides is targeted specifically for technically competent clinical audiences. There are no speaker notes, suggested narrative or supplemental materials. The topics included in the currently available slide sets are DMPA, IUDs, Combined Oral Contraceptives, Maximizing Access & Quality (MAQ), Emergency Contraception, Barrier Methods, Pregnancy Related Care, Benefits of Family Planning, and Sterilization (male and female). The slides are grouped in volumes according to contraceptive method, with the first volume containing four slide sets on the topics of DMPA, IUDs, Combined Oral Contraceptives, and MAQ.

**Collaborating Agency(s):** Pathfinder International, Population Communication Services, INTRAH, JHPIEGO, and PATH

**FY' 97 Planned Activities:**

- Revisions to slides currently included in English version of Volume I will be completed.
- Quality of Care expert slides will be finalized.
- 35mm slides on various contraceptive technology topics will continue to be created for USAID and other CTU presenters on an as-needed basis.
- Final production of the translation of Volume I slide sets into French and Spanish will be completed.

**Possible Problems, Barriers to Completion:**

- The staff assigned to work on this project are also key in the development of the CTU modules. Additional demands on their time or production delays on the modules project will have an effect on this project's output.

**Funding Source(s):** USAID/Core  
**FY '97 Budget:** \$ 51,374  
**Total Budget:** N/A-Annual

**FCO Approved:** Aug 1993  
**Projected End Date:** Aug 2000

**Haiti: Contraceptive Technology Continuing Medical Education Program (CME) Program (FCO 3269/3265 and previously 3728)**

**Technical Monitor:** Kevin Young

**Objective(s):** 1) To strengthen the institutional capacity of the Asociacion Médicale Haitienne (AMH) and Institut Haitien de Santé Communautaire (INHSAC) to design, manage, and implement a national CME program by improving administrative, technical and managerial capabilities; 2) to implement a three-day workshop for approximately 15 key Haitian physicians to improve their presentation skills on reproductive health topics; 3) to implement a contraceptive technology update workshop for the same select cadre of approximately 15 Haitian physicians; 4) to implement a series of CTU seminars in Port-au-Prince, Cap Haitien and Cayes on select family planning and reproductive health topics which will target 50% of the AMH membership (three seminars proposed for each site per year); and 5) to evaluate the effectiveness of the CME program and determine any change in knowledge and/or practices as a result of the program.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** An important intervention for addressing gaps in service providers' knowledge of contraceptive technology is through regular CTU educational opportunities. FHI is developing a continuing medical education program for AMH members to culminate with a series of 2 to 3 CTU seminars in each of the following sites: Port-au-Prince, Cap Haitien, and Cayes. In order to build on Haiti's local capacity, FHI will work in close collaboration with the AMH and INHSAC. This multi-year program will assist to improve the quality of family planning and other reproductive health services offered by members of the AMH. Association members can enhance their contributions to Haiti's family planning program if they have access to the most up-to-date, accurate information on contraceptive technology and service delivery issues. This pilot program could be used as a foundation from which other CME programs can be modeled to address other pertinent health issues.

Phase I of this program encompassed Objectives #1-2 and was funded in FY'96 by Core funds (FCO 3265) and Haiti Buy-in funds (FCO 3728). Phase II, November 1996-April 1997, intends to accomplish Objective #3 and will be funded for an interim period under FCO 3269 until such time that Field Support funds are made available. It is anticipated that Phase III will accomplish Objectives #4-5 with allocated Field Support funds (FCO TBD).

**Implementing Agency(s):** Institut Haitien de Santé Communautaire (INHSAC)  
**Collaborating Agency(s):** Haitian Medical Association

**FY' 97 Planned Activities:**

- The technical presentation skills-building workshop will be conducted Oct. 21-23, 1996.
- A needs assessment survey will be developed and administered for the CTU seminar series.
- The AMH Scientific Education Committee will meet to determine a schedule of events for the seminar series, set priorities for CTU topics based on survey results and make recommendations for speakers and resource materials.
- A CTU workshop will be conducted for 10-15 potential CTU seminar speakers.
- At least one of the CTU seminars for the AMH membership will be conducted.

**Possible Problems, Barriers to Completion:**

- The complexity of funding sources may affect the pace and scope of the program.

|                           |             |                   |                            |           |
|---------------------------|-------------|-------------------|----------------------------|-----------|
| <b>Funding Source(s):</b> |             | USAID/Core/ Field | <b>FCO 3728 Approved:</b>  | Mar 1996  |
| <b>FY '97 Budget:</b>     | <b>3265</b> | \$ 18,537         | <b>FCO 3265 Approved:</b>  | Mar 1996  |
|                           | <b>3269</b> | \$ 72,758         | <b>FCO 3269 Approved:</b>  | Nov 1996  |
| <b>Total Budget:</b>      | <b>3265</b> | \$ 41,369         | <b>Projected End Date:</b> | Sep 1997* |
|                           | <b>3728</b> | \$ 17,719         |                            |           |
|                           | <b>3269</b> | \$ <u>72,758</u>  |                            |           |
|                           |             | \$ 131,846        |                            |           |

\* The projected end date and total budget reflect current funding. It is anticipated that Field Support funding will be made available to continue the subproject training to June 1998.

## Worldwide: Contraceptive Technology Update Seminars for Maximizing Access and Quality (FCO 3208)

**Technical Monitor:** Lynn Adrian

**Objective(s):** To organize educational events in developing countries and sponsor individual participation at international meetings that emphasize current contraceptive technology research, correct misconceptions about family planning methods, and encourage improved service delivery practices and an increase in quality of care.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Dissemination of recent research findings in the fields of reproductive health, contraceptive technology and service delivery is the primary focus of this category of activities. FHI employs a variety of appropriate information dissemination and educational activities to share up-to-date information about contraceptive research and service delivery practices to family planning providers, program managers and policymakers.

### FY' 97 Planned Activities:

- Development will continue on the proposed FHI/Johns Hopkins Program for International Education in Reproductive Health (JHPIEGO) regional training activity for nurse educators in Kenya. (A separate FCO will eventually be established for this activity.)
- A staff member will attend the American Public Health Association conference in New York in November 1996.
- An FHI staff member will be supported to speak on adolescent reproductive health at The First International Conference on Health and Culture in Adolescence in Jerusalem, Israel from November 24-27, 1996.
- Technical assistance and materials will be provided at the SAGO conference, scheduled to be held in Abidjan, Cote d'Ivoire on December 9-13, 1996.
- FHI plans to participate at the XV meeting of the Latin American Association on Research on Human Reproduction (ALIRH) in Cusco, Peru on April 27-30, 1997; a staff member and several regional medical experts will serve as speakers. (A separate subproject will be established for this activity, with funds currently allocated to 3208, as plans develop.)

### Possible Problems, Barriers to Completion:

- None foreseen.

|                           |            |                            |           |
|---------------------------|------------|----------------------------|-----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | <Aug 1995 |
| <b>FY '97 Budget:</b>     | \$ 245,137 | <b>Projected End Date:</b> | Aug 2000  |
| <b>Total Budget:</b>      | N/A-Annual |                            |           |

**Paraguay: Contraceptive Technology Update Regional Workshops (FCO 3400)**

**Technical Monitor:** William Conn

**Objective(s):** 1) To update the technical knowledge of approximately 100 health professionals on contraceptive technology; 2) to examine origins of cultural and medical barriers for family planning in Paraguay and how these affect access to quality contraceptive service; and 3) to analyze how cultural and medical barriers can be reduced by reviewing updated family planning service protocols.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** FHI worked with the Paraguayan Ministry of Health and AVSC International to conduct four two-day workshops in regional centers throughout Paraguay between September 9 - 20, 1996. The purpose of the workshops was to update physicians, nurses and other healthcare providers on contraceptive technology including Oral Contraceptives, Injectables, Intrauterine Devices (IUDs), Lactational Amenorrhea Method (LAM), Sterilization, Barrier Methods and Quality of Care/Counseling. Participants analyzed medical barriers to contraception in small working groups and examined ways medical barriers can be reduced.

**Collaborating Agency(s):** AVSC International, Ministry of Health

**FY' 97 Planned Activities:**

- While this activity concluded at the end of FY'96, there remained outstanding expenses to be paid. Once all bills are submitted and paid, the subproject will be closed. A follow-on subproject, see FCO 3406, will address the participants interest in developing family planning service delivery guidelines.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Oct 1995 |
| <b>FY '97 Budget:</b>     | \$ 3,979    | <b>Projected End Date:</b> | Dec 1996 |
| <b>Total Budget:</b>      | \$ 62,864   |                            |          |

**Paraguay: National Family Planning Guidelines Revision Project (FCO 3406)**

**Technical Monitor:** Teresa Longenecker

**Objective(s):** To assist the Paraguay Ministry of Health in the development of national guidelines for contraceptive service provision.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** This subproject will continue initiatives began in 1996 when (under FCO 3400) FHI conducted four regional Contraceptive Technology Update workshops in collaboration with AVSC International and Ministry of Health to update health-care providers on contraceptive technology. The subproject will develop family planning service delivery guidelines for Paraguay, a recommendation made by workshop participants and a need expressed by USAID/Asunción.

**Implementing Agency(s):** AVSC International  
**Collaborating Agency(s):** Paraguay Ministry of Health

**FY' 97 Planned Activities:**

- Coordinate with the Ministry of Health, AVSC International and USAID/Asunción to design and implement activities leading to the development of national family planning service delivery guidelines. This plan will be further defined following the first meeting of all involved parties.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Dec 1996 |
| <b>FY '97 Budget:</b>     | \$ 99,999   | <b>Projected End Date:</b> | Nov 1997 |
| <b>Total Budget:</b>      | \$ 100,000  |                            |          |

**Jamaica: Family Planning Seminars for Private Sector Physicians (FCO 3404 and previously 3722)**

**Technical Monitor:** Teresa Longenecker

**Objective(s):** 1) To provide current, accurate information to private sector physicians on contraceptive methods and family planning services; and 2) to encourage the participation of private sector physicians as providers of family planning services by presenting current contraceptive information through educational seminars.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** FHI, working in collaboration with the Medical Association of Jamaica (MAJ), will provide financial and technical assistance for a series of seminars, in three locations, designed to increase the provision of family planning services by private sector physicians. A total of eight seminar series will be conducted from April 1995 to September 1997 for approximately 200 physicians and healthcare providers per seminar series: Kingston, 120; Montego Bay, 50 and Mandeville, 30.

In FY'95 and FY'96, five seminar series were conducted under FCO 3722. In FY'97, the remaining three seminar series will be conducted under FCO 3404. In the series, family planning experts from Jamaica and the U.S. present current information on contraception and reproductive health. Presentations focus on issues of maximizing access and quality of care for a range of contraceptive methods and topics: Combined OCs; Progestin-only Contraception; IUDs; Natural Family Planning; Voluntary Surgical Contraception; Barrier Methods; Counseling and Couples with Special Needs. The project also serves to enhance the institutional capability of the MAJ to implement continuing education seminars on family planning topics for healthcare providers in Jamaica.

**Implementing Agency(s):** The Medical Association of Jamaica (MAJ)

**FY' 97 Planned Activities:**

- FHI will develop a new subagreement to conduct three seminar series and renew the consultancy agreement with the project's technical advisor.
- One contraceptive technology update seminar will be conducted, most likely in February 1997, on a topic selected by the MAJ Continuing Education Advisory Committee.
- FHI will work closely with the MAJ to plan two subsequent seminar series to be conducted April 1997-September 1997.

**Possible Problems, Barriers to Completion:**

- Scheduling and implementation of the 1997 seminar series is contingent upon determination by the MAJ of its 1997 meeting schedule.

|                           |                               |                            |          |
|---------------------------|-------------------------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field                   | <b>FCO 3722 Approved:</b>  | Feb 1995 |
| <b>FY '97 Budget:</b>     | \$ 108,815                    | <b>FCO 3404 Approved:</b>  | Oct 1996 |
| <b>Total Budget:</b>      | <b>3722</b> \$ 242,846        | <b>Projected End Date:</b> | Sep 1997 |
|                           | <b>3404</b> \$ <u>114,418</u> |                            |          |
|                           | \$ 357,264                    |                            |          |

**Jamaica: Training Workshop in Contraceptive Technology and Counseling for Jamaican Nursing Tutors (FCO 3401)**

**Technical Monitor:** Teresa Longenecker

**Objective(s):** 1) To enhance nursing tutors' capabilities to provide accurate information on contraception through improved understanding of: Oral Contraceptives; Injectables; Intrauterine Devices (IUDs); Barrier Methods; Postpartum Methods including LAM; STD treatment and prevention including HIV prevention; and 2) to enhance nursing tutors' capabilities to provide more comprehensive information on counseling to their students through improved understanding of principal issues involved in counseling family planning clients.

Note: The title and objectives of this activity were revised. Originally targeted at physician assistants and their supervisors, USAID/Jamaica requested that nursing tutors be the target audience.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** FHI will work with the Jamaica Ministry of Health to conduct a 4.5 day workshop in Kingston, Jamaica to train approximately 25 nursing tutors on contraceptive methods and counseling practices. Nursing tutors are responsible for updating nursing students on contraceptive technology, STD/HIV prevention and counseling techniques. The workshop responds to identified training needs for nurses in order to sustain Jamaica's contraceptive prevalence trend (62% in 1993), per recommendations in the recently completed McFarlane Consultants/FHI evaluation, "The Quality of Care of Jamaican Public Sector and NGO Family Planning Services: Perspectives of Providers and Clients" (McFarlane, et al, 1996).

**Collaborating Agency(s):** Jamaica Ministry of Health

**FY' 97 Planned Activities:**

- FHI will implement, in collaboration with the Jamaica Ministry of Health, the 4.5 day workshop in Kingston, Jamaica October 28-November 1, 1996. Speakers will include local and international experts from FHI. Three FHI staff will attend the workshop (two presenters and one coordinator).

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Dec 1995 |
| <b>FY '97 Budget:</b>     | \$ 41,854   | <b>Projected End Date:</b> | Nov 1996 |
| <b>Total Budget:</b>      | \$ 50,989   |                            |          |

**Paraguay: XV Latin American Congress of Gynecology and Obstetrics (FLASOG) (FCO 3266)**

**Technical Monitor:** Teresa Longenecker

**Objective(s):** 1) To disseminate current information on adolescent reproductive health to Latin American specialists in obstetrics and gynecology by sponsoring a symposium in conjunction with the FLASOG Congress, October 6-11, 1996, in Asunción, Paraguay; and 2) to inform family planning practitioners and policymakers involved in continuing medical education activities about FHI training resources available in Spanish on contraceptive technology topics.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Technical support will be provided to the FLASOG '96 Congress, a regional meeting which takes place in Latin America every three years. Two activities will be carried out: (1) an Adolescent Reproductive Health Symposium; and (2) an introductory session on FHI's Contraceptive Technology Update modules available in Spanish.

FLASOG Congress participants will include leading experts in reproductive health, family planning and maternal and child health. Approximately 1,000 participants are expected to attend this scientific meeting which addresses topics in gynecology, oncology, reproductive medicine and family planning.

**Collaborating Agency(s):** XV Latin American Congress of Gynecology and Obstetrics (FLASOG) Organizing Committee

**FY' 97 Planned Activities:**

- In October, FHI will sponsor a symposium on Adolescent Reproductive Health in conjunction with FLASOG for 60-70 persons. This will include funding travel costs for five reproductive health experts (four international experts and one FHI senior staff member) and technical oversight of presentation content.
- FHI will conduct a session to introduce Latin American reproductive health experts to FHI's training module series on contraceptive technology topics. The following modules, all in Spanish, will be demonstrated by three international experts experienced in continuing medical education activities: (1) Oral Contraceptives; (2) Postpartum Contraception; and (3) the Expert Slide Set, designed for highly technical audiences.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Apr 1996 |
| <b>FY '97 Budget:</b>     | \$ 21,115  | <b>Projected End Date:</b> | Dec 1996 |
| <b>Total Budget:</b>      | \$ 28,679  |                            |          |

**Senegal: Young Adult Contraceptive Technology Update  
(CTU) Workshop (FCO 3402)**

**Technical Monitor:** Lynn Adrian

**Objective(s):** 1) To give service providers the opportunity to discuss their questions and beliefs about reproductive health services, including contraception for young adults; 2) to update them about the special reproductive health needs of young men and women and how best to tailor their services to this unique and underserved client group; and 3) to review appropriate counseling techniques for interacting with this specific group of clients.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Building on the joint study conducted by FHI and the Comité d'Etude sur les Femmes, la Famille et l'Environnement en Afrique (CEFFEVA) entitled "Measuring Access to Family Planning Education and Services for Young Adults in Dakar, Senegal", a three day workshop will be conducted for approximately 30 service providers who represent clinics involved in the study. As recommended in the final report, there is a need to sensitize service providers to the unique needs of their young adult clients to ensure they receive access to quality family planning and reproductive health services. The workshop will incorporate the experience of other Francophone countries' efforts to address young adult reproductive health needs.

**Collaborating Agency(s):** Programme National de Planning Familiale (PNPF)

**FY' 97 Planned Activities:**

- A subagreement will be developed with a local logistical assistance organization.
- Participants and resource persons will be identified and confirmed.
- The workshop is tentatively scheduled for February 1997.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Jul 1996 |
| <b>FY '97 Budget:</b>     | \$ 62,258   | <b>Projected End Date:</b> | Apr 1997 |
| <b>Total Budget:</b>      | \$ 63,603   |                            |          |



## ■ **Improving Resource Allocation and Financial Sustainability**

While demand for family planning services in developing countries has increased rapidly in recent years, funding from governments and donors has stagnated or even declined. SDR helps family planning programs bridge this funding gap by carrying out research to improve the use of existing resources through studies to determine the cost of method-service delivery combinations and also to increase the financial resources generated locally through diversification of services and increased cost recovery.

### ***Service Delivery Research Division's FY'97 Program***

The SDR division will continue to emphasize these three priority areas in research carried out under the Cooperative Agreement during FY'97. SDR's key objective of increasing access to contraception will be pursued in several ways: by evaluating the impact of DMPA and Norplant implant introduction in Jordan; by analyzing the impact of improving service practices in Ghana; by assessing the impact of restrictive eligibility criteria in Kenya by developing methodologies to improve measurements of efficiency and cost and to link these with quality; by determining service delivery factors affecting method choice and continuation rates in Bolivia; by conducting research to design family life education programs in Senegal; and by carrying out economic analyses to increase program efficiency or cost recovery in Mexico and Ecuador.

The studies, ongoing and new, which the Service Delivery Research Division will implement in FY'97 are listed below: those denoted with an asterisk are new subprojects.

## ■ **Maximizing Access and Quality**

- Improving Services for Menstruating Clients, Kenya (9344)
- Method Choice (9346)\*
- PROSALUD Quality of Care Assessment, Bolivia (9402)
- The Impact of Service Delivery Guidelines, Ghana (9417)
- Improvement and Expansion of Family Planning Services, Ethiopia (9440)
- Factors Affecting Continuation Rates of Hormonal Methods, Bolivia (9451)
- Maximizing Access to Reproductive Health Care in Sucre, Bolivia (9720)
- Identifying Ways to Improve Family Life Education (FLE) Programs, Senegal (9453)\*
- Secondary Analysis of Public Sector and NGO QOC Study, Jamaica (9455)\*
- Efficient Provision of Contraceptive Methods in Follow-up Visits (93xxTBD)\*

## ■ **Evaluation of Combinations of Methods and Delivery Systems**

- A Study to Determine the Acceptability of Long-acting Progestin Methods, Jordan (9345)
- IUD Provision by IMSS Midwives, Mexico (9446)
- Assessment of Impact of Family Planning Options Project, Guinea (9450)
- A Study to Determine the Quality of Norplant Provision in Dakar, Senegal (9452)
- Users' Perspective on Method and Services, Jamaica (9454/7407)\*
- Costs of Extending Family Planning Services to Indigenous Populations, Ecuador (9457)\*

## ■ **Improving Resource Allocation and Financial Sustainability**

- Comparison of Methodologies for Measuring Staff Time Used to Provide Reproductive Health Services, Ecuador (9343)
- Costs of Family Planning Services Provided by ADS, El Salvador (9400)
- Method Specific Costs of Family Planning, Mexico (9424)
- Price Elasticity of Demand for Reproductive Health Care, Ecuador (9448)
- FEMAP Contraceptive Method and Service Provision, Mexico (9449)

- Family Planning Finance Strategy, Africa (9731)
- Development of Sustainability Projects, El Salvador (9456)\*
- Cost and Quality of Care (93xxTBD)\*

■ Other

- Service Delivery Research Paper Writing (9304)

Individual descriptions of each of these subprojects follow in the order presented above.

**Kenya: Improving Services for Menstruating Clients  
(FCO 9344)**

**Technical Monitor:** John Stanback

**Objective(s):** 1) To demonstrate that non-menstruating women can safely and effectively initiate contraceptive use; 2) to test the effectiveness of checklists for ruling out pregnancy; and 3) to determine the acceptability of pregnancy checklists to providers.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** FHI studies carried out in Cameroon, Ghana, Jamaica and Kenya have shown that women who are not menstruating face significant barriers to receiving family planning services. This study will use dipstick pregnancy tests and questionnaire evaluation in five Kenyan family planning clinics to assess the effectiveness of checklists to rule out pregnancy in non-menstruating women. In two other clinics, researchers will assess provider prescription in the absence of dipstick pregnancy tests, as well as assess the feasibility of providing clients with OCs that they may carry home while awaiting the onset of menses. The estimated sample size for the study is 1,500 first time clients.

**Implementing Agency(s):** Dept. of Ob/Gyn, University of Nairobi

**FY' 97 Planned Activities:**

- A subagreement will be written and approved.
- Data collection instruments will be finalized.
- The study will begin in early 1997 in seven clinics in three regions of Kenya. Monitoring duties will be shared by FHI staff and the Principal Investigator.
- Data collection will be ongoing. Periodic monitoring visits will be made to assure data quality.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | May 1996 |
| <b>FY '97 Budget:</b>     | \$ 74,759  | <b>Projected End Date:</b> | Dec 1997 |
| <b>Total Budget:</b>      | \$ 100,000 |                            |          |

## Worldwide: Method Choice (FCO 9346)

**Technical Monitor:** Lynda Cole

**Objective(s):** To further help family planning managers identify the service delivery factors influencing whether a woman receives the method she wants.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Previous research in Indonesia has demonstrated that continuation rates are higher when family planning clients receive their preferred method. However, this study has not been replicated in other countries. It may be that continuation rates could be improved by ensuring clients receive the methods they want. This subproject focuses on method choice and is the first half of a larger effort that will measure continuation rates and further investigate linkages between continuation rates and method choice.

The subproject will be conducted in three countries: one each in Asia, Latin America, and Africa. The results will be used to document the magnitude of the problem and will serve to identify sites where client follow-up systems are adequate for measuring continuation rates related to method choice.

### FY' 97 Planned Activities:

- The protocol will be developed.
- Potential sites for initiating the research effort will be selected.

### Possible Problems, Barriers to Completion:

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | Dec 1996 |
| <b>FY '97 Budget:</b>     | \$ 98,735  | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 98,735  |                            |          |

**Bolivia: PROSALUD Quality of Care Assessment (FCO 9402)**

**Technical Monitor:** Patsy Bailey

**Objective(s):** 1) To conduct a quality of care assessment at selected Protección a la Salud (PROSALUD) clinics; and 2) to develop measurement tools to enable PROSALUD to monitor and improve the quality of care provided to their clients.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** PROSALUD is a private non-profit network of community-sponsored health clinics. It was initiated in Santa Cruz, Bolivia in 1985 with support from USAID under a cooperative agreement with Management Sciences for Health (MSH). This subproject responds to PROSALUD's desire to conduct a quality of care assessment of its services, from the users' perspective. Ultimately, PROSALUD hopes to design a monitoring tool for longer term surveillance. A client satisfaction survey (in the form of exit interviews) has been designed and is being administered in a high- and low-client volume clinic in La Paz, El Alto, and Santa Cruz (a total of six clinics). Approximately 1,600 interviews will be conducted. Clinic staff will meet on a regular basis to outline areas of improvement in service quality based on the findings of the exit interviews.

**Implementing Agency(s):** Protección a la Salud (PROSALUD)

**FY' 97 Planned Activities:**

- Data collection will be concluded in La Paz by the end of October.
- A data analysis plan and an outline for the final report will be developed and implemented. FHI staff will travel to Bolivia to participate in this process.
- Study findings will be presented at a PROSALUD national meeting. At that time, further strategies for dissemination of results will be discussed.

**Possible Problems, Barriers to Completion:**

- Data analysis may take longer than anticipated due to the relative inexperience of the PROSALUD staff in conducting data analysis.
- While no analysis has been completed as of yet, there are significantly fewer FP/RH health clients interviewed in Santa Cruz than anticipated. This may be explained, in part, by the active role the community-based distributors play in the delivery of contraceptives. However, the clinic-based tool developed for this project may present only a partial picture of PROSALUD's delivery of family planning commodities.

**Funding Source(s):** USAID/Field  
**FY '97 Budget:** \$ 23,530  
**Total Budget:** \$ 61,353

**FCO Approved:** Jan 1995  
**Projected End Date:** Sep 1997

## Ghana: The Impact of Family Planning Service Delivery Guidelines (FCO 9417)

**Technical Monitor:** John Stanback

**Objective(s):** To measure the impact on provider practices of new family planning service delivery guidelines developed in Ghana.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** This study uses a pre-test/post-test design to assess the impact of a joint MOH, Program for International Training and Health (INTRAH), FHI intervention. Study sites throughout Ghana are surveyed before and after dissemination of new guidelines to evaluate adherence to new standards and other changes in clinic practices that might improve access to quality family planning services. Three different data collection methods—situational analysis, record review, and mystery clients—are used in order to better estimate the true impact of the intervention on provider practices.

**Implementing Agency(s):** QBR, Ltd. and Ghana Statistical Service

### FY' 97 Planned Activities:

- The Ghana Statistical Service will conduct a nationwide Situation Analysis of family planning service delivery points.
- Data from the Simulated Client study will arrive at FHI and be scanned prior to analysis.
- A subagreement will be finalized with the Ghana Statistical Service to undertake a record review and follow-up situation analysis at a sub-sample of Situation Analysis sites.

### Possible Problems, Barriers to Completion:

- Unforeseen delays in the 1996 Situation Analysis are this study's most likely threat to completion.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Aug 1995 |
| <b>FY '97 Budget:</b>     | \$ 6,070    | <b>Projected End Date:</b> | Dec 1997 |
| <b>Total Budget:</b>      | \$ 80,000   |                            |          |

**Ethiopia: Improvement and Expansion of Family Planning Services (FCO 9440)**

**Technical Monitor:** Douglas Nichols

**Objective(s):** 1) To assess the demand for contraception in Ethiopia; and 2) to set up a monitoring and evaluation system for a new 5-year USAID-supported private sector family planning project

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** FHI is providing technical assistance in monitoring and evaluation to this national program to increase the capacity of nongovernmental organizations (NGOs) and private, for-profit organizations to deliver family planning. Specifically, FHI has created a standardized and comprehensive monitoring and evaluation system and is assisting in its integration into project activities, enabling the project to obtain timely and programmatically useful information on its service delivery objectives.

**Implementing Agency(s):** Ethiopia NGO Family Planning Consortium  
**Collaborating Agency(s):** Pathfinder International, AVSC International

**FY' 97 Planned Activities:**

- Microcomputers and data management/analysis software will be purchased and sent to project staff in Addis Ababa.
- A training workshop for data collection staff working at the service delivery point level will be conducted in December 1996.
- Field data collection activities (Monthly Monitoring; Client Exit Survey) will be initiated.
- Data collection activities will continue. One or more Catchment Area Surveys will be designed to provide information on special populations.

**Possible Problems, Barriers to Completion:**

- Field support funding may not be available through the conclusion of the project in 1999.
- Transfer of the monitoring and evaluation system to the NGO Consortium may be delayed due to lack of availability of in-country technical expertise and facilities.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Sep 1995 |
| <b>FY '97 Budget:</b>     | \$ 143,393  | <b>Projected End Date:</b> | Dec 1999 |
| <b>Total Budget:</b>      | \$ 750,000  |                            |          |

**Bolivia: Factors Affecting Continuation Rates of Hormonal Methods (FCO 9451)**

**Technical Monitor:** David Hubacher

**Objective(s):** To determine the extent to which service delivery factors affect continuation rates of Depo-Provera and oral contraceptives.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Many factors affect continuation rates of hormonal methods. Most of what we know has been documented in comparative clinical trials, is very limited in scope, and centers on side effects—especially changes in menstrual patterns. The decision to continue using a method, however, involves a constellation of factors, of which side effects is only one. Other factors might include the extent to which the user was aware of the possible side effects she might experience, whether the adopted method was her first choice, and the extent of information and discussion concerning other contraceptive options. These initial counseling factors along with tolerance of side effects, subsequent clinical care (for the management of side effects), access to a resupply source, and personal characteristics and motivation, may also affect continuation rates.

CARE/Bolivia has asked FHI to assist in a comparative study which will help CARE understand the program-specific variables affecting continuation rates of OCs and Depo-Provera, thereby allowing them to improve the way family planning services are provided, and increase satisfaction with these important methods. Depo-Provera has not been approved for general use by the Bolivian Secretary of Health; it may only be used in family planning research efforts to document the acceptability and help the government determine whether it should be approved for general use.

**Implementing Agency(s):** Bolivian Secretary of Health  
**Collaborating Agency(s):** CARE/Bolivia

**FY' 97 Planned Activities:**

- The protocol will be finalized, the instruments will be pre-tested, and data collection will be initiated by March 1997.
- The progress of the data collection will be monitored.
- The data analysis plans will be developed by September 1997.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Aug 1996 |
| <b>FY '97 Budget:</b>     | \$ 33,884   | <b>Projected End Date:</b> | Sep 1998 |
| <b>Total Budget:</b>      | \$ 69,500   |                            |          |

**Bolivia: Maximizing Access to Reproductive Health Care in Sucre, Bolivia (FCO 9720)**

**Technical Monitor:** Alan Spruyt

**Objective(s):** 1) To identify barriers to the utilization of reproductive health services; 2) to assess quality of care as provided by public and private health-care facilities; 3) to assess the level of unmet need for reproductive health services in Sucre; 4) to identify the reproductive needs of the migrant population living in the rural areas of Sucre; 5) to compare the results of this study with those of a similar study conducted in El Alto, to illustrate the various reproductive health needs and services present in these two distinct areas; and 6) to make recommendations regarding Pro Mujer's reproductive health training programs.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** This study will assess the reproductive health needs and services available in Sucre, Bolivia. The study will be conducted in both urban and rural areas of Sucre, particularly among migrant populations and areas where Pro Mujer—an NGO that provides small business loans and training in finances, maternal and child health, and reproductive health—currently conducts its programs. Methods of data collection include a situation analysis of a sample of public and private reproductive health services available in the Sucre area and focus groups (with both men and women).

**Implementing Agency(s):** Pro Mujer

**FY' 97 Planned Activities:**

- Pro Mujer, with assistance from FHI, will conduct the situation analysis; enter, clean and analyze the data; and conduct several focus group discussions in Sucre and surrounding rural areas by March 1997.
- Pro Mujer and FHI will complete data analysis, prepare a final report and a manuscript, and disseminate the findings.

**Possible Problems, Barriers to Completion:**

- The project end date is later than originally reported due to postponed initiation of field work. Competing commitments of FHI and Pro Mujer staff could result in other delays.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | OYB        | <b>FCO Approved:</b>       | Oct 1995 |
| <b>FY '97 Budget:</b>     | \$ 91,386  | <b>Projected End Date:</b> | Aug 1997 |
| <b>Total Budget:</b>      | \$ 123,334 |                            |          |

## Senegal: Identifying Ways to Improve Family Life Education (FLE) Programs (FCO 9453)

**Technical Monitor:** Karen Katz

**Objective(s):** To identify strengths and weaknesses of family life education programs in Dakar.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Previous research conducted in Dakar has shown that Family Life Education (FLE) courses can have a positive impact on contraceptive knowledge and use among young adults. This study will compare various FLE programs in Dakar in order to identify their relative strengths and weaknesses. A survey will be conducted of FLE participants in different programs to measure their reproductive health knowledge, attitudes and behavior. Focus group discussions will also be conducted to assess the students' perceptions and to elicit their opinions on the positive and negative aspects of these programs.

### FY' 97 Planned Activities:

- A prestudy visit will be made in December 1996 to identify FLE programs, potential study sites, study coordinator and implementing agency.
- A study protocol will be developed.
- Data collection will begin.

### Possible Problems, Barriers to Completion:

- None foreseen.

**Funding Source(s):** USAID/Field  
**FY '97 Budget:** \$50,239  
**Total Budget:** \$78,260

**FCO Approved:** Dec 1996  
**Projected End Date:** Apr 1998

**Jamaica: Secondary Analysis of Public Sector and NGO QOC Study (FCO 9455)**

**Technical Monitor:** Karen Hardee

**Objective(s):** To provide the Ministry of Health (MOH) and the National Family Planning Board (NFPB) with additional information on the quality of care in public sector and NGO family planning health facilities through secondary analysis of the data collected during the 1995 study of "The Quality of Public Sector and NGO Family Planning Services in Jamaica: Perspectives of Providers and Clients."

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** FHI assisted with the implementation of a 1995 study that focused on training and quality of care in public sector and NGO family planning facilities. This study included surveys of workers and supervisors and a simulated client component. FHI will conduct additional analysis of the data to help the MOH and the NFPB improve the training providers receive and improve the quality of care for clients in health facilities.

**FY' 97 Planned Activities:**

- FHI staff will work with the NFPB and the Ministry of Health (MOH) to conduct secondary analysis on topics identified: detail on the IUD for use by the Personal Choice Social Marketing program, pockets of need for training of private physicians and training needs in the public sector (e.g. staff who have attended didactic but not practical training and those who still need specific training courses).
- FHI staff will carry out the secondary analysis.
- A report will be provided to the NFPB, the MOH and to USAID/Kingston.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Dec 1996 |
| <b>FY '97 Budget:</b>     | \$10,546    | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$10,546    |                            |          |

**Worldwide/TBD: Efficient Provision of Contraceptive Methods in Follow-up Visits (FCO 93xx/TBD)**

**Technical Monitor:** To be determined

**Objective(s):** To collect information to be used to develop efficient systems for client resupply of contraceptive methods.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Safe and effective provision of contraception in follow-up visits depends upon the technical characteristics of the method as well as the desires and characteristics of the client. "Efficient" provision adds another dimension—provider and client resources, including time, used during the visit process. Efficiency can be enhanced if clients are served according to the particular characteristic of their visit type and chosen method. This study will obtain information on services performed during follow-up visits, the interpretation by providers on how this information would be applied using a case study approach, and a literature review on how the information should be used. Information on client waiting times, provider time and on provider attitudes at representative clinics in two countries will be obtained. This information will be used to design a second study which will test "efficient provision systems."

**Implementing Agency(s):** To Be Determined

**FY' 97 Planned Activities:**

- Sites where the study can be conducted will be determined.
- Study protocol will be developed.

**Possible Problems, Barriers to Completion:**

- None foreseen.

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|---------------------------|------------|----------------------------|-----|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | TBD |
| <b>FY '97 Budget:</b>     | \$ 41,041  | <b>Projected End Date:</b> | TBD |
| <b>Total Budget:</b>      | TBD        |                            |     |

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| <b>Jordan: A Study to Determine the Acceptability of Long-acting Progestin Methods (FCO 9345 and previously 9729)</b> |
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**Technical Monitor:** Betsy Tolley

**Objective(s):** 1) To evaluate users' satisfaction with Norplant and Depo-Provera, including side effects, counseling, and other aspects of method use; 2) to assess the quality of counseling at the three sites; and 3) to determine clients' reasons for discontinuing method use.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** This study is part of a larger project to introduce two long-acting progestin methods, Norplant and Depo-Provera, in Jordan. The country has made progress in increasing the use of contraceptives and lowering fertility rates. Even so, while contraceptive use grew from 23% of married women in 1976 to 40% of married women in 1990, over 20% of births in the five years preceding the last DHS survey were "not wanted when they occurred". The most commonly used modern methods available to Jordanian women have been IUDs and oral contraceptives. This study elicits information from new acceptors of Norplant and Depo-Provera about their reasons for choosing their respective method, what they like and dislike about it, their experience of side effects, and their overall satisfaction with either of the progestin methods. Information is also collected through focus group discussions on reasons for discontinuing either of the methods within the first six months of use. To this end some staff of a local organization have been trained in conducting focus groups and analysis of qualitative data, and technical assistance is being provided on conducting and analyzing survey data. OYB funds covered costs of the study in FY'96 under FCO 9729.

**Implementing Agency(s):** Center for Consultation, Technical Services, and Studies (CCTSS)  
**Collaborating Agency(s):** AVSC International

**FY' 97 Planned Activities:**

- The second round of data collection will be completed in February 1997.
- Focus group discussions will be conducted with discontinuers of Norplant and Depo-Provera.
- Analysis of focus group survey data will begin by March 1997.
- A final report will be written and distributed to USAID officials and appropriate national policymakers.
- A dissemination meeting is planned in late April 1997 to present findings from the research and discuss issues related to the provision of Norplant and Depo-Provera in Jordan.

**Possible Problems, Barriers to Completion:**

- None foreseen.

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|---------------------------|------------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/OYB/Core   | <b>FCO 9729 Approved:</b>  | Feb 1996 |
| <b>FY '97 Budget:</b>     | \$ 27,403        | <b>FCO 9345 Approved:</b>  | Aug 1996 |
| <b>9729</b>               | \$ 13,910        | <b>Projected End Date:</b> | Aug 1997 |
| <b>9345</b>               | \$ <u>27,402</u> |                            |          |
| <b>Total Budget:</b>      | \$ 41,312        |                            |          |

## Mexico: IUD Provision by IMSS Midwives (FCO 9446)

**Technical Monitor:** David Hubacher

**Objective(s):** To evaluate midwife IUD services and compare them to nurse/physician IUD services provided at clinics.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** The Mexican Social Security Institute (IMSS) works closely with midwives to expand reproductive health services in rural areas of Mexico. Over the past decade, midwives have been trained to provide family planning methods, including IUDs. This program is an important service delivery strategy of IMSS, yet little is known about the quality of services and how they compare with what is offered by nurses and physicians at clinic facilities. In order to evaluate this program, midwife and clinic clients will be interviewed about the services they received, including the preinsertion counseling, the insertion procedure, and subsequent follow-up care. IMSS wants to make sure that midwives are providing the same level of care that is provided at clinics by professional staff. The results of this study will help IMSS identify strengths and weaknesses in the IUD services provided by rural midwives; ultimately, the results of this study can be used to improve the program.

**Implementing Agency(s):** Mexican Social Security Institute (IMSS)

**Collaborating Agency(s):** Pathfinder/Mexico

### FY' 97 Planned Activities:

- Data collection will be initiated; it is expected to be completed by June 1997.
- A draft final report will be prepared.

### Possible Problems, Barriers to Completion:

- The research staff at IMSS is managing numerous projects simultaneously; some delays in the implementation of different aspects of this study are possible.

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|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Feb 1996 |
| <b>FY '97 Budget:</b>     | \$ 35,935   | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 43,517   |                            |          |

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| <b>Guinea:</b> | <b>Assessment of Impact of the Family Planning Options Project (FAMPOP) (FCO 9450)</b> |
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**Technical Monitor:** Karen Katz

**Objective(s):** To measure the impact of Family Planning Options Project (FAMPOP) activities in increasing demand for and access to contraceptive services for family planning and prevention of STDs/AIDS.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** FAMPOP was initiated in 1991 with an objective to increase demand for and access to contraceptive services for family planning and the prevention of STDs/AIDS. FAMPOP works through a variety of approaches. These include a social marketing campaign which sells condoms in urban centers, the integration of family planning services into existing public health centers in smaller cities and towns, a national information, education and communication (IEC) campaign, and a community-based distribution program. At the request of USAID/Guinea, FHI developed a study to evaluate the impact of these efforts. Initial development work was funded under FCO 7407.

FHI will work with StatView, a Guinean research firm. A household survey, focus group discussion, and in-depth interviews will be used to assess the impact of these activities on demand and access. The results will be used to identify the strengths and weaknesses of the program and to plan for future activities.

**Implementing Agency(s):** StatView

**FY' 97 Planned Activities:**

- A subagreement with StatView (under FCO 9450) will be executed.
- Interviewers and data entry agents will be trained .
- Data collection instruments will be pretested, finalized and translated into two local languages.
- Data entry programs will be revised and finalized.
- Data collection will begin in November 1996.
- Data collection will be completed.
- Data will be analyzed and a final report written.

**Possible Problems, Barriers to Completion:**

- None foreseen.

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|---------------------------|-------------|----------------------------|-----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | June 1996 |
| <b>FY '97 Budget:</b>     | \$ 121,154  | <b>Projected End Date:</b> | Sep 1997  |
| <b>Total Budget:</b>      | \$ 150,000  |                            |           |

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| <b>Senegal: A Study to Determine the Quality of Norplant Provision in Dakar (FCO 9452)</b> |
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**Technical Monitor:** Betsy Tolley

**Objective(s):** 1) To evaluate the satisfaction of clients who have used Norplant for more than one year, including clients' experiences with side effects and their management and any requests for removal; 2) to determine the reasons for discontinuation of Norplant before five years of use and document women's experiences in obtaining removal; 3) to identify any provider-based barriers to removal before five years of use; and 4) to locate and document the situations of women whose records indicate five years or more of Norplant use without removal.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.

**Description:** Because Norplant is such an effective, long-lasting and easy to use hormonal contraceptive method, it has been seen as an important addition to the contraceptive mix of numerous countries. However, its dependence on well-trained providers for insertion and removal means that Norplant programs must counsel potential users thoroughly on Norplant advantages, disadvantages and side effects, and must guarantee women access to removal of their implants at any time, for the method to expand contraceptive choice. Concern about timely access to removal and fear of coercion has drawn international criticism of programs in countries like Bangladesh and Haiti (BBC Horizon 1995), where acceptance of the method is widespread and studies have shown a high level of client satisfaction. Therefore, access to early removal is one issue of primary concern in this study.

A second issue to be examined is how women are monitored to ensure removal of their implants at five years of use. Although there are no known health hazards associated with retention of the empty capsules, Norplant's effectiveness decreases after five years until it is no longer effective. If a woman continues to desire protection against pregnancy, she must have the capsules removed and new ones implanted, or change to another contraceptive method. There is some concern that number of women who took part in the clinical trial of Norplant in Senegal, and who have used the method for at least five years, may be lost to follow-up. This study will attempt to locate women for whom there are no records of removal to determine status of Norplant use.

**Implementing Agency(s):** Comite d'Etude sur les Femmes, La Famille et l'Environnement en Afrique (CEFFEVA)

**FY' 97 Planned Activities:**

- A report will be finalized to present study findings to USAID/Senegal and the MOH. Recommendations will be made to address any issues that are found regarding early access to removal of Norplant; follow-up and removal of Norplant at five years; or other aspects of service delivery found to affect women's satisfaction with the method.

**Possible Problems, Barriers to Completion:**

- None foreseen.

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|---------------------------|-----------------|----------------------------|----------|
| <b>Funding Source(s):</b> | OYB/Field       | <b>FCO Approved:</b>       | Sep 1996 |
| <b>FY '97 Budget:</b>     | \$ 6,352        | <b>Projected End Date:</b> | Dec 1996 |
| 9730                      | \$ 40,679       |                            |          |
| 9452                      | \$ <u>6,351</u> |                            |          |
| <b>Total Budget:</b>      | \$ 47,030       |                            |          |

## Jamaica: Users' Perspective on Methods and Services (FCO 9454)

**Technical Monitor:** Karen Hardee

**Objective(s):** To ascertain the views of various target populations on 1) their access to contraceptive and reproductive health care and the quality of services they have received; and 2) the experience users have had with contraceptive acceptance and discontinuation.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.

**Description:** FHI has assisted with the implementation of two studies of family planning providers in Jamaica. The first study assessed the service delivery practices of private physicians (1993) and the second focused on training and quality of care in public sector and NGO family planning facilities (1995). The public sector and NGO study also included a simulated client component. Both studies found that providers do not base their care on the most up-to-date international evidence regarding contraceptives. Furthermore, counseling needs to be improved. The public sector and NGO study found a discrepancy between the views of providers and simulated clients on quality of services in health facilities. FHI has been requested to complement these two studies with a study of contraceptive users.

The study will collect information on decision-making regarding use and discontinuation of methods, method switching and experience with the methods, including side effects. The study will also collect information on experience with the service delivery system (e.g. counseling received, continuity of care, treatment of side effects). Counseling will be a particular emphasis of this study. Clients will be asked what they remember being told about methods of contraception, whether they think they have sufficient information about the methods they have used, whether lack of information influenced past clients to discontinue methods, and whether clients think the way they were treated during counseling influenced their experience with various methods. Focus group discussions with clients and potential clients will be conducted, as will exit interviews with current clients. The study will be carried out in one urban, one peri-urban and one rural area of Jamaica. The locations for the study will be decided jointly with the National Family Planning Board (NFPB) and the MOH. The study population will include clients and potential clients of both public and private sector family planning services.

### FY' 97 Planned Activities:

- FHI staff will travel to Jamaica to discuss the study with the NFPB and the MOH.
- FHI will design the protocol for the study and locate a research organization in Jamaica to implement the study.
- A subagreement will be signed with a research organization.
- Fieldwork for the study will be initiated.

### Possible Problems, Barriers to Completion:

- None anticipated.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Oct 1996 |
| <b>FY '97 Budget:</b>     | \$ 61,275   | <b>Projected End Date:</b> | Mar 1998 |
| <b>Total Budget:</b>      | \$ 120,000  |                            |          |

## Ecuador: Costs of Extending Family Planning Services to Indigenous Populations (FCO 9457)

**Technical Monitor:** John Bratt

**Objective(s):** 1) To measure costs of deploying mobile teams from two Centros Medicos de Orientación y Planificación Familiar (CEMOPLAF) clinics to provide family planning services in selected indigenous communities; and 2) to measure cost-effectiveness of clinic resources, comparing the costs and output of the current model vs. the model including mobile service provision to indigenous groups.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Access to family planning services is often difficult for indigenous populations in marginal rural areas. Costs of transport and time may be too high to justify traveling to clinics in distant towns. Meanwhile, many clinic-based FP providers have excess service capacity. One option for reducing excess capacity would be to close clinics on certain days of the week, and deploy mobile teams of clinic staff to underserved areas. This project will compare the cost-effectiveness of the current static clinics with a new system which sends mobile teams to market towns on two days per week. Results will show whether mobile teams can be used to increase access at low additional cost to the program.

**Implementing Agency(s):** Centros Medicos de Orientación y Planificación Familiar (CEMOPLAF)

**Collaborating Agency(s):** INOPAL III

### FY' 97 Planned Activities:

- The scope of work and subagreement will be written.
- Data collection will begin in March 1997.
- Data collection will be completed in September 1997.

### Possible Problems, Barriers to Completion:

- None foreseen.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Feb 1997 |
| <b>FY '97 Budget:</b>     | \$ 40,049   | <b>Projected End Date:</b> | Mar 1998 |
| <b>Total Budget:</b>      | \$ 48,766   |                            |          |

**Ecuador: Comparison of Methodologies for Measuring Staff Time Used to Provide Reproductive Health Services (FCO 9343)**

**Technical Monitor:** John Bratt

**Objective(s):** To compare the results obtained from an observational time-motion study with results from three alternative methodologies for measuring staff time, including Patient Flow Analysis, self-administered timesheets, and structured interviews with key staff.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Methodologies for measuring staff time range from costly and intrusive techniques such as observational time-motion studies, to much less intrusive approaches like structured recall interviews with key staff. Observational time-motion studies are thought to produce the most accurate and complete data, but this assumption has not been tested. Information on the relative precision and cost of the principal approaches for measuring staff time would be useful for future cost studies, and also to guide decisions about adding a cost component to the situation analysis methodology.

**Implementing Agency(s):** Centros Medicos de Orientación y Planificación Familiar (CEMOPLAF)

**Collaborating Agency(s):** INOPAL III/Population Council

**FY' 97 Planned Activities:**

- Data will be analyzed and a paper will be written and submitted for publication.

**Possible Problems, Barriers to Completion:**

- None foreseen.

**Funding Source(s):** USAID/Core  
**FY '97 Budget:** \$ 13,015  
**Total Budget:** \$ 30,122

**FCO Approved:** May 1995  
**Projected End Date:** Mar 1997

## El Salvador: Calculating Direct Costs of Family Planning Services (FCO 9400)

**Technical Monitor:** John Bratt

**Objective(s):** To calculate direct costs per service provided through Asociación Demográfica Salvadoreña (ADS) clinics and the ADS rural outreach program.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** USAID/El Salvador is in the process of changing the mechanism used to provide financial support to ADS. Beginning in 1997, the Mission will replace the current system of program grants with an agreement to reimburse ADS for specific service provided. In order to negotiate these reimbursement amounts, ADS needs to know current costs of producing services. FHI will provide technical assistance in the use of methodologies to identify costs of all resources used to produce services, and to allocate these costs to visits.

**Implementing Agency(s):** Asociación Demográfica Salvadoreña(ADS)

### FY' 97 Planned Activities:

- A visit to ADS will be made in mid-October to finalize the estimates of cost per visit in clinics and cost per unit sold in the rural programs.
- The final report will be written.

### Possible Problems, Barriers to Completion:

- None foreseen.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Aug 1995 |
| <b>FY'97 Budget:</b>      | \$ 20,445   | <b>Projected End Date:</b> | Dec 1996 |
| <b>Total Budget:</b>      | \$ 56,931   |                            |          |

**Mexico: Method Specific Costs of Family Planning  
(FCO 9424)**

**Technical Monitor:** David Hubacher

**Objective(s):** To determine the method-specific cost per couple-year-of-protection of family planning services within the Ministry of Health programs.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** This study estimates the method-specific costs of providing family planning services through different delivery models within the Ministry of Health. Observational studies are used to record the amount of time providers spend with clients and the type of services provided. Combined with data on salaries and benefits of employees, infrastructure and material costs, and services statistics, the total costs of different types of visits will be estimated. Particular emphasis will be on the IUD, since this is the most common form of reversible contraception in Mexico. The study includes clinic-based and rural outreach services.

The study will help the Ministry of Health evaluate existing services and determine the contraceptive methods and ways of delivering services that are most economical. The results will enable administrators to make better decisions regarding future direction of the national family planning program and ultimately improve the allocation of scarce resources.

**Implementing Agency(s):** Ministry of Health  
**Collaborating Agency(s):** Pathfinder/Mexico

**FY' 97 Planned Activities:**

- Data analysis will be completed.
- English and Spanish final reports will be finalized.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Sep 1994 |
| <b>FY '97 Budget:</b>     | \$ 38,991   | <b>Projected End Date:</b> | Mar 1997 |
| <b>Total Budget:</b>      | \$ 100,923  |                            |          |

**Ecuador: Price Elasticity of Demand for Reproductive Health Care (FCO 9448)**

**Technical Monitor:** John Bratt

**Objective(s):** 1) To use a true experimental design to estimate the elasticity of demand for different contraceptive methods and related visits provided by Centros Medicos de Orientación y Planificación Familiar (CEMOPLAF); and 2) to evaluate whether a client interview can provide similar information to a pricing experiment, but at lower cost.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Clients in a sample of CEMOPLAF clinics will be interviewed on their willingness to pay current and higher prices for various contraceptive methods. Prices will then be increased, and changes in use of contraceptive methods will be measured. The level of agreement between the two methodologies will be assessed.

**Implementing Agency(s):** Centros Medicos de Orientación y Planificación Familiar (CEMOPLAF)

**Collaborating Agency(s):** INOPAL III/Population Council, The Futures Group

**FY' 97 Planned Activities:**

- Prices will be increased on November 1996. Prices will increase by 20% in the control group, by 40% in one of the experimental groups, and by 60% in the other experimental group.
- A second round of client surveys will be conducted in January/February 1997 to measure changes in client profile after the price increase.
- A third round of client surveys will be conducted in April/May 1997 to determine longer-term reaction to the price increase.
- Data will be analyzed and a report written by the end of FY '97.

**Possible Problems, Barriers to Completion:**

- None foreseen.

**Funding Source(s):** USAID/Field  
**FY '97 Budget:** \$ 42,438  
**Total Budget:** \$ 50,736

**FCO Approved:** Apr 1996  
**Projected End Date:** Sep 1997

**Mexico: FEMAP Contraceptive Method and Service Provision  
(FCO 9449)**

**Technical Monitor:** Matthew Holtman

**Objective(s):** To provide information that will help Federación Mexicana de Asociaciones Privadas de Salud y Desarrollo Comunitario (FEMAP) improve the efficiency of out patient services at three hospitals in different Mexican states.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** FEMAP has found that some of their clinics are having trouble dealing with an increased client load. Inefficiencies in the way clients are processed may be making it difficult for family planning clients to get the services they need in a timely manner. Data will be collected with a patient-flow study and through observation of service providers to improve the efficiency of clinic operations, and to ensure that the quality of family planning service is not adversely affected by long waiting times or service provision bottlenecks.

**Implementing Agency(s):** Federación Mexicana de Asociaciones Privadas de Salud y Desarrollo Comunitario (FEMAP)

**FY' 97 Planned Activities:**

- In October 1996, two FHI staff will travel to three cities in Mexico to set up data collection for the patient flow and provider observations. Observers will be trained and the logistics of the data collection will be arranged in each chosen clinic.
- FHI staff will organize the data collection strategy at each clinic and help train the observers.
- Data collection will be initiated.
- CDC Patient Flow Analysis software will be installed on computers at the FEMAP offices.
- Data entry programs will be written.
- Data entry will be performed by FEMAP staff who, with FHI assistance, will also analyze the data and write up the results.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |             |                            |          |
|---------------------------|-------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/Field | <b>FCO Approved:</b>       | Apr 1996 |
| <b>FY '97 Budget:</b>     | \$ 63,963   | <b>Projected End Date:</b> | Jun 1997 |
| <b>Total Budget:</b>      | \$ 78,195   |                            |          |

## Africa Region: Family Planning Finance Strategy (FCO 9731)

**Technical Monitor:** Barbara Janowitz

**Objective(s):** To provide information on costs and funding of family planning activities in the Africa Region; to identify possible ways that costs could be reduced or funding increased; and to determine areas in which additional research is needed.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** This subproject supports the preparation of a strategic framework and policy briefs in the area of costs and finance of family planning activities in the Africa Region. An expert review panel will meet and review various outlines and document drafts. Funding covers a literature review, preparation of documents, holding of meetings and translation and printing of documents. No travel to Africa will be covered in this subproject.

### FY' 97 Planned Activities:

- A meeting of persons with expertise in Economics and/or programmatic research in sub-Saharan Africa will be held at FHI to review the plan for the document; and their suggestions and concerns will be taken into consideration.
- The final documents will be drafted, reviewed, revised and disseminated.

### Possible Problems, Barriers to Completion:

- None foreseen.

|                           |           |                            |          |
|---------------------------|-----------|----------------------------|----------|
| <b>Funding Source(s):</b> | OYB       | <b>FCO Approved:</b>       | Jun 1996 |
| <b>FY '97 Budget:</b>     | \$ 97,976 | <b>Projected End Date:</b> | Sep 1997 |
| <b>Total Budget:</b>      | \$ 97,976 |                            |          |

## Worldwide/TBD: Costs and Quality of Care (FCO 93xx/TBD)

**Technical Monitor:** Barbara Janowitz

**Objective(s):** 1) To explore interactions between costs and quality of care; 2) to use this information to develop methodologies to study these interactions; and 3) to implement one study to test those methodologies.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Research has been carried out on the components of quality of care and on the cost of family planning services. However, the interactions between costs and quality of care have not been investigated. These interactions may be complex. For example, upgrading clinical facilities or training staff to improve their skills may raise costs but may also attract new clients and reduce the per unit costs of visits. Improved service delivery may increase the willingness of clients to bear the costs of service. The focus of this project is to develop methodologies to study the interactions between costs and quality, and to develop subprojects to test these methodologies.

**Implementing Agency(s):**

**Collaborating Agency(s):**

**FY' 97 Planned Activities:**

- A draft protocol will be written which will explore, on both the demand and on the supply side, interactions between costs and quality of care. Sites for conducting study(ies) will be explored.
- A study will be implemented in one study site.

**Possible Problems, Barriers to Completion:**

- Failure to hire a new staff member who can take primary responsibility for carrying out research in this new area.

**Funding Source(s):**

USAID/Core

**FCO Approved:**

**FY '97 Budget:**

\$ 107,946

**Projected End Date:**

**Total Budget:**

TBD

**Worldwide: Service Delivery Research Paper Writing  
(FCO 9304)**

**Technical Monitor:** Barbara Janowitz

**Objective(s):** To conduct secondary analysis on data from completed Service Delivery Research (SDR) studies, and to write papers for presentation and publication based on these analyses.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Following the completion of field research activities culminating in a subproject final report, staff will continue to analyze data and/or prepare papers for presentation and publication in scientific journals to disseminate results of FHI-supported research. This subproject supports staff time and travel costs related to these needs.

**FY' 97 Planned Activities:**

- Hubacher D. M Suazo, S Terrell, M Pinel. "Examining the Increasing Prevalence of Traditional Contraceptive Methods in Honduras." *International Family Planning Perspectives*.
- Janowitz B. M Holtman, D Hubacher, K Jamil. "Options for Increasing Contraceptive Use in Bangladesh; The Role of Costs."
- Hardee K. S Balogh and M Villinski. "Three Countries' Experience with the Introduction of Norplant."
- Hardee K. C McFarlane, R McCloskey. "Perspectives of Client and Providers on Quality of Care: Evidence from Jamaica."
- Katz K. C Nare. "Access to Family Planning Education and Services for Young Adults in Dakar, Senegal."
- Katz K. F Doumbia, M Kane, C West. "Increasing Access to Family Planning in Rural Mali."
- Stanback J. A Thompson, K Hardee, R McCloskey, B Janowitz. "Menstruation Requirements: A Barrier to Oral Contraception Access."
- Stanback J. "Provider Attitudes to Restrictive Service Practices in Ghana"
- Stanback J. "Local Manufacture of Contraceptives"
- Stanback J. "Why is IUD use slowing in Kenya?"

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |           |
|---------------------------|------------|----------------------------|-----------|
| <b>Funding Source(s):</b> | USAID/Core | <b>FCO Approved:</b>       | <Aug 1995 |
| <b>FY '97 Budget:</b>     | \$ 126,017 | <b>Projected End Date:</b> | Aug 2000  |
| <b>Total Budget:</b>      | N/A-Annual |                            |           |



## Worldwide: Contraceptive Field Stock Evaluations (FCO 8011)

**Technical Monitor:** Eli Carter

**Objective(s):** 1) To assess the quality of stored contraceptive stock in selected developing countries; and 2) to evaluate, upon request, contraceptive inventories of questionable quality, and recommend to USAID their proper disposition.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Contraceptive users and potential users must be assured that the products they receive are of good quality. Frequent use failure may discourage their acceptance. This subproject helps to ensure that the integrity of USAID-provided contraceptives is adequately maintained during in-country storage.

**FY' 97 Planned Activities:**

- Technical assistance will be provided to field programs where needed to address/resolve commodity quality problems.
- Country specific contraceptive stock surveys will be conducted to evaluate product quality and user acceptability. Countries will be selected on the basis of commodity mix, product age and stock accessibility.
- Remaining Prospective Aging Study samples from the Mexico study sites will be retrieved. Samples may be used in future use breakage studies.

**Possible Problems, Barriers to Completion:**

- Completion of activities may be affected by workload from other sub-projects, staff limitations, or changes in priorities.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/CLM  | <b>FCO Approved:</b>       | Aug 1990 |
| <b>FY '97 Budget:</b>     | \$ 46,019  | <b>Projected End Date:</b> | Aug 2000 |
| <b>Total Budget:</b>      | N/A-Annual |                            |          |

## Worldwide: Production Surveillance - Condoms (FCO 8015)

**Technical Monitor:** Eli Carter

**Objective(s):** To ensure pre-distribution quality of condoms procured by USAID for developing country programs.

### Contributes to PHNC's Results:

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** This program began in 1990 to provide closer scrutiny of condom production and to ensure that condoms distributed to developing countries by USAID meet all 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.

### FY' 97 Planned Activities:

- Monthly product surveillance, including statistical analyses of laboratory test data, will continue.
- Bi-monthly GMP/contract compliance audits will continue. Incidents of non-compliance will be addressed/resolved.
- The Technical Oversight Committee (TOC) will convene in January at FHI Headquarters, and in July 1997, in Rosslyn, VA.

### Possible Problems, Barriers to Completion:

- If open communication between USAID, FHI and the contractors is maintained, no problems are anticipated. However, completion of activities may be affected by workload from other subprojects, staff limitations, or changes in priorities.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/CLM  | <b>FCO Approved:</b>       | Aug 1990 |
| <b>FY '97 Budget:</b>     | \$ 244,366 | <b>Projected End Date:</b> | Aug 2000 |
| <b>Total Budget:</b>      | N/A-Annual |                            |          |

**USA: PATH - Condom Research Activities (FCO 8016)**

**Technical Monitor:** Eli Carter

**Objective(s):** To provide funding to Program for Appropriate Technology in Health (PATH) to conduct specific research assignments and to sponsor participation in technical conferences and meetings as deemed appropriate by the USAID/Contraceptive Logistics Management (CLM) Division and FHI.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

Note: FHI's contribution in this case is only indirect. PATH's involvement is, however, designed to assure further quality of condom supplies.

**Description:** PATH has significant experience and expertise in condom evaluation and is a valuable resource when condom technical issues arise which require investigation and recommendations to the CLM and FHI controlled programs (i.e., condom production surveillance). This funding 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 CLM based on the recommendations of FHI.

**Implementing Agency(s):** Program for Appropriate Technology in Health (PATH)

**FY' 97 Planned Activities:**

- PATH representatives will attend four ASTM meetings (New Orleans, 12/96, W. Conshohoken 3/97; St. Louis 6/97; W. Conshohoken 9/97), one International Standards Organization (ISO) meeting (Harare, Zimbabwe 4/97)
- PATH will provide technical assistance and attend other meetings at the request of FHI and/or USAID.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/CLM  | <b>FCO Approved:</b>       | Aug 1995 |
| <b>FY '97 Budget:</b>     | \$ 51,711  | <b>Projected End Date:</b> | Aug 2000 |
| <b>Total Budget:</b>      | N/A-Annual |                            |          |

|   |
|---|
| <b>USA: Production Surveillance - Other Contraceptives<br/>(FCO 8017)</b> |
|---|

**Technical Monitor:** Eli Carter

**Objective(s):** To ensure 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 expected shelf-life.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

USAID distributes a wide range of contraceptives other than condoms, including IUDs, OCs, implants and injectables. 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 have been developed to allow expansion of the program to include additional contractors and increase the number of lots evaluated.

**FY' 97 Planned Activities:**

- A strategic plan for the continued operation of the chemical testing laboratory will be submitted to USAID in October. If approved, a new set of performance objectives for the in-house quality evaluation of contraceptive drugs procured for USAID distribution will be implemented.
- The chemical laboratory will be evaluated by the American Association for Laboratory Accreditation.
- The strategic plan for the chemical laboratory will be implemented to meet the agreed upon objectives.
- Production surveillance audits of the pharmaceutical manufacturers will continue on a pre-determined schedule or as needed to insure compliance with USFDA Good Manufacturing Practices (GMPs) and USAID contract requirements.

**Possible Problems, Barriers to Completion:**

- In many instances, pharmaceutical and device manufacturers may not be willing to divulge proprietary information and/or may limit technical scrutiny of production and testing processes.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/CLM  | <b>FCO Approved:</b>       | Aug 1995 |
| <b>FY '97 Budget:</b>     | \$ 241,749 | <b>Projected End Date:</b> | Aug 2000 |
| <b>Total Budget:</b>      | N/A-Annual |                            |          |

**USA:**

**Condom Package Integrity Study (FCO 8028)**

**Technical Monitor:** Eli Carter

**Objective(s):** To evaluate and compare the protective effect(s) of foil and cellophane packaging used for latex condoms in a long-term accelerated heat aging process.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Description:** Two latex condom formulations, each type packaged in both foil and cellophane materials, are to be oven-aged for a period of three years, periodically sampled and evaluated for changes in test performance. These data will help us determine the better packaging material to recommend for future CLM procurement. This study should resolve the question of which material provides the best protection for latex condoms at elevated temperatures.

**Implementing Agency(s):** PATH

**FY' 97 Planned Activities:**

- PATH will complete and submit a final report on this project in December 1996.

**Possible Problems, Barriers to Completion:**

- None foreseen.

**Funding Source(s):** USAID/CLM  
**FY '97 Budget:** \$ 31,295  
**Total Budget:** \$ 138,965

**FCO Approved:** Jun 1992  
**Projected End Date:** Feb 1996

**USA: Laboratory Monitoring - Condoms (FCO 8029)**

**Technical Monitor:** Eli Carter

**Objective(s):** To evaluate FHI's laboratory testing competence through annual interlaboratory trials.

**Contributes to PHNC's Results:**

- 1.1 Developing, evaluating new and/or improved technologies and approaches.
- 1.2 Improved policy environment & increased global resources for FP programs.
- 1.3 Enhanced capacity of organizations to design, implement & evaluate sustainable FP programs.
- 1.4 Demand for, access to and quality of FP and RH information & services increased.
- Other PHNC results. Specify # and name.

**Note:** This subproject is one of maintaining quality assurance. It provides assurance that the FHI condom testing Laboratory remains qualified to evaluate condoms for compliance with USAID and other international product standards. It's contribution to the PHNC results is therefore indirect.

**Description:** Data from condom lots tested at different facilities may be inconsistent because condom testing equipment and procedures may vary. To resolve this issue, FHI has established a subagreement with PATH to perform comparative laboratory testing at five testing locations: FHI, Akron Rubber, Smithers, Aladan, and PATH. Samples from a single condom production lot are tested at each location and test results are compared for consistency. This subproject was initiated in June 1993 with testing at 6-month intervals.

**Implementing Agency(s):** PATH

**FY' 97 Planned Activities:**

- The seventh inter-laboratory trial will be conducted in November 1996. A report will be issued within two months of the completion of the trial.

**Possible Problems, Barriers to Completion:**

- None foreseen.

|                           |            |                            |          |
|---------------------------|------------|----------------------------|----------|
| <b>Funding Source(s):</b> | USAID/CLM  | <b>FCO Approved:</b>       | Sep 1993 |
| <b>FY '97 Budget:</b>     | \$ 42,155  | <b>Projected End Date:</b> | Aug 2000 |
| <b>Total Budget:</b>      | N/A-Annual |                            |          |

**CONTRACEPTIVE TECHNOLOGY AND FAMILY  
PLANNING RESEARCH PROGRAM**

**CCP-3079-A-00-5022-00**

- **FY 1997 Summary Budget by Division**
- **FY 1997 Budget Information by Region/Country**

**FAMILY HEALTH INTERNATIONAL**

**A. Fiscal Year 1997 Summary Budget Cooperative Agreement #CCP-3079-A-00-5022-00**

FHI - FY97 Workplan

Prevention Usage Budget

145

|                                      | Clinical Trials  | Product Quality and Compliance (1) | Regulatory Affairs | Biostatistics  | Contraceptive Use & Epidemiology | Service Delivery Research | Policy & Research Utilization | Field Operations | Executive Offices | Core Population Coop Agmt | Field Support Population Coop Agmt | Buy-Ins Population Coop Agmt | Total Population Coop Agmt |
|--------------------------------------|------------------|------------------------------------|--------------------|----------------|----------------------------------|---------------------------|-------------------------------|------------------|-------------------|---------------------------|------------------------------------|------------------------------|----------------------------|
| Salaries                             | 848,958          | 292,397                            | 168,530            | 220,929        | 845,861                          | 462,169                   | 1,018,513                     | 435,011          | 348,525           | 4,039,784                 | 474,267                            | 124,842                      | 4,638,893                  |
| Fringes                              | 217,472          | 78,947                             | 45,503             | 59,651         | 228,382                          | 124,786                   | 274,459                       | 117,453          | 94,102            | 1,078,995                 | 128,052                            | 33,707                       | 1,240,754                  |
| Contract Employees                   | 0                | 62,500                             | 0                  | 0              | 0                                | 61,301                    | 0                             | 0                | 500               | 77,539                    | 32,300                             | 14,462                       | 124,301                    |
| Contract Emp Fringe                  | 0                | 5,563                              | 0                  | 0              | 0                                | 5,456                     | 0                             | 0                | 45                | 6,902                     | 2,875                              | 1,287                        | 11,084                     |
| Statutory Employees                  | 0                | 0                                  | 0                  | 0              | 17,890                           | 0                         | 0                             | 0                | 0                 | 12,300                    | 0                                  | 5,590                        | 17,890                     |
| Statutory Emp Fringe                 | 0                | 0                                  | 0                  | 0              | 1,369                            | 0                         | 0                             | 0                | 0                 | 941                       | 0                                  | 428                          | 1,369                      |
| Consultants                          | 8,000            | 3,500                              | 2,000              | 2,000          | 35,125                           | 26,200                    | 43,460                        | 0                | 6,000             | 78,100                    | 37,985                             | 10,200                       | 128,285                    |
| Professional Fees                    | 0                | 65                                 | 0                  | 0              | 39,500                           | 0                         | 2,275                         | 200              | 0                 | 23,540                    | 13,500                             | 5,000                        | 42,040                     |
| Contracted Labor                     | 0                | 0                                  | 0                  | 0              | 1,200                            | 0                         | 5,000                         | 20,335           | 0                 | 15,005                    | 11,530                             | 0                            | 28,535                     |
| Domestic Travel                      | 92,853           | 38,002                             | 13,200             | 26,500         | 26,602                           | 17,670                    | 19,700                        | 14,200           | 23,000            | 268,255                   | 2,202                              | 1,270                        | 269,727                    |
| Foreign Travel                       | 64,250           | 21,345                             | 3,000              | 0              | 122,392                          | 210,845                   | 197,898                       | 69,900           | 12,000            | 407,478                   | 255,742                            | 28,408                       | 691,828                    |
| Subscriptions                        | 0                | 0                                  | 3,300              | 0              | 0                                | 0                         | 21,970                        | 0                | 0                 | 25,270                    | 0                                  | 0                            | 25,270                     |
| Publications                         | 1,100            | 0                                  | 2,000              | 700            | 0                                | 0                         | 3,500                         | 700              | 500               | 6,000                     | 500                                | 0                            | 8,500                      |
| Postage (network only)               | 0                | 0                                  | 0                  | 0              | 0                                | 0                         | 84,000                        | 0                | 0                 | 84,000                    | 0                                  | 0                            | 84,000                     |
| Office Supplies                      | 3,700            | 7,342                              | 2,600              | 100            | 1,950                            | 3,450                     | 4,650                         | 1,168            | 1,000             | 21,842                    | 4,018                              | 100                          | 25,960                     |
| Medical Supplies                     | 4,500            | 51,252                             | 0                  | 0              | 71,200                           | 0                         | 0                             | 0                | 0                 | 92,952                    | 25,000                             | 9,000                        | 128,952                    |
| Printing                             | 19,390           | 0                                  | 1,500              | 200            | 16,200                           | 33,897                    | 195,298                       | 4,500            | 1,500             | 234,065                   | 18,871                             | 19,547                       | 272,483                    |
| Reprints                             | 10,000           | 0                                  | 0                  | 0              | 3,650                            | 0                         | 500                           | 2,500            | 800               | 14,450                    | 3,000                              | 0                            | 17,450                     |
| Office Equipment                     | 5,000            | 925                                | 0                  | 0              | 2,300                            | 5,000                     | 0                             | 0                | 0                 | 13,125                    | 0                                  | 100                          | 13,225                     |
| Medical Equipment                    | 0                | 2,400                              | 0                  | 0              | 21,800                           | 0                         | 0                             | 0                | 0                 | 24,200                    | 0                                  | 0                            | 24,200                     |
| Freight                              | 6,230            | 8,150                              | 700                | 744            | 10,950                           | 3,250                     | 102,088                       | 5,600            | 350               | 123,422                   | 13,290                             | 1,350                        | 138,062                    |
| Registration Fees                    | 1,000            | 1,360                              | 4,200              | 5,000          | 3,550                            | 6,000                     | 1,250                         | 2,200            | 1,250             | 19,810                    | 6,000                              | 0                            | 25,810                     |
| Other Purch Svcs                     | 41,400           | 31,000                             | 100                | 8,000          | 70,000                           | 1,000                     | 79,860                        | 3,500            | 0                 | 217,760                   | 17,100                             | 0                            | 234,860                    |
| Workshops & Seminars                 | 0                | 0                                  | 0                  | 0              | 0                                | 0                         | 24,740                        | 0                | 0                 | 10,500                    | 14,240                             | 0                            | 24,740                     |
| Other Expenses                       | 22,350           | 7,856                              | 0                  | 3,495          | 15,610                           | 23,900                    | 5,800                         | 7,500            | 0                 | 44,701                    | 36,810                             | 5,000                        | 86,511                     |
| Temporaries                          | 5,000            | 800                                | 2,500              | 0              | 1,500                            | 0                         | 0                             | 0                | 0                 | 9,800                     | 0                                  | 0                            | 9,800                      |
| Bank Charges                         | 0                | 0                                  | 0                  | 0              | 0                                | 50                        | 0                             | 760              | 0                 | 10                        | 800                                | 0                            | 810                        |
| Field Office Costs                   | 0                | 0                                  | 0                  | 0              | 0                                | 0                         | 0                             | 384,512          | 0                 | 179,777                   | 204,735                            | 0                            | 384,512                    |
| Subcontracts with G&A                | 168,524          | 0                                  | 0                  | 0              | 270,494                          | 261,800                   | 33,197                        | 43,418           | 0                 | 399,605                   | 282,673                            | 103,155                      | 765,433                    |
| Software                             | 1,000            | 0                                  | 0                  | 0              | 500                              | 0                         | 5,150                         | 0                | 500               | 7,150                     | 0                                  | 0                            | 7,150                      |
| Equipment Mnt & Repairs              | 0                | 30,500                             | 0                  | 0              | 0                                | 0                         | 0                             | 0                | 0                 | 30,500                    | 0                                  | 0                            | 30,500                     |
| Computer Equipment                   | 0                | 0                                  | 0                  | 0              | 1,000                            | 0                         | 0                             | 0                | 0                 | 1,000                     | 0                                  | 0                            | 1,000                      |
| Subcontracts w/o G&A                 | 256,461          | 120,542                            | 0                  | 0              | 343,255                          | 63,469                    | 6,700                         | 0                | 0                 | 547,834                   | 102,755                            | 140,038                      | 790,427                    |
| <b>Subtotal</b>                      | <b>1,755,187</b> | <b>762,448</b>                     | <b>249,133</b>     | <b>327,319</b> | <b>2,152,280</b>                 | <b>1,310,243</b>          | <b>2,128,004</b>              | <b>1,113,457</b> | <b>490,072</b>    | <b>8,116,412</b>          | <b>1,668,245</b>                   | <b>503,484</b>               | <b>10,288,141</b>          |
| Gen & Admin                          | 448,118          | 182,424                            | 74,740             | 98,196         | 535,178                          | 372,532                   | 636,391                       | 324,594          | 147,021           | 2,245,488                 | 464,695                            | 109,005                      | 2,819,188                  |
| Transfer From (To)                   | 0                | 0                                  | 0                  | 0              | 0                                | 0                         | 6,300                         | (51,682)         | 0                 | (47,932)                  | 2,550                              | 0                            | (45,382)                   |
| <b>Totals Before Service Centers</b> | <b>2,203,305</b> | <b>944,870</b>                     | <b>323,873</b>     | <b>425,514</b> | <b>2,687,458</b>                 | <b>1,682,775</b>          | <b>2,770,695</b>              | <b>1,386,369</b> | <b>637,093</b>    | <b>10,313,968</b>         | <b>2,135,490</b>                   | <b>612,489</b>               | <b>13,061,947</b>          |
| Service Centers                      | 25,000           | 2,500                              | 0                  | 0              | 10,000                           | 0                         | 2,500                         | 0                | 0                 | 40,000                    | 0                                  | 0                            | 40,000                     |
| <b>Totals</b>                        | <b>2,228,305</b> | <b>947,370</b>                     | <b>323,873</b>     | <b>425,514</b> | <b>2,697,458</b>                 | <b>1,682,775</b>          | <b>2,773,195</b>              | <b>1,386,369</b> | <b>637,093</b>    | <b>10,353,972</b>         | <b>2,135,492</b>                   | <b>612,488</b>               | <b>13,101,947</b>          |

(1) Includes projects funded by Special CLM monies

## B. FY 1997 Budget Information by Region/Country

| <u>FCO #</u>  | <u>REGION/<br/>COUNTRY</u> | <u>SUBPROJECT TITLE</u>                          | <u>CORE</u> | <u>FIELD<br/>SUPPORT</u> | <u>ADD-ON/<br/>OYB</u> | <u>TOTAL<br/>FISCAL YEAR<br/>BUDGET</u> |
|---------------|----------------------------|--|-------------|--------------------------|------------------------|---|
| <b>AFRICA</b> |                            |  |             |                          |                        |   |
| 3250          | Multi National             | French Network                                   | 135,662     |                          |                        | 135,662                                 |
| 7002          | Multi National             | Africa Devel. & Management                       | 55,120      |                          |                        | 55,120                                  |
| 7097          | Multi National             | Africa: Regional Program Development             | 75,094      |                          |                        | 75,094                                  |
| 9731          | Multi National             | Family Planning Finance Strategy                 |             |                          | 97,976                 | 97,976                                  |
| 9440          | Ethiopia                   | Improvement and Expansion of FP Services         |             | 143,393                  |                        | 143,393                                 |
| 3565          | Ghana                      | MOH/HRU Library Technical Assistance             |             | 18,954                   |                        | 18,954                                  |
| 6475          | Ghana                      | Contraceptive Service Provision in an STD Clinic |             | 26,840                   |                        | 26,840                                  |
| 6476          | Ghana                      | Vaginal Tablets User Dynamics                    |             | 24,630                   |                        | 24,630                                  |
| 7400          | Ghana                      | Field Support Admin/Mgt                          |             | 17,157                   |                        | 17,157                                  |
| 9417          | Ghana                      | Impact of Service Delivery Guidelines            |             | 6,070                    |                        | 6,070                                   |
| 9450          | Guinea                     | FAMPOP Impact                                    |             | 121,154                  |                        | 121,154                                 |

| <u>FCO #</u>        | <u>REGION/<br/>COUNTRY</u> | <u>SUBPROJECT TITLE</u>               | <u>CORE</u>    | <u>FIELD<br/>SUPPORT</u> | <u>ADD-ON/<br/>OYB</u> | <u>TOTAL<br/>FISCAL YEAR<br/>BUDGET</u> |
|---------------------|----------------------------|---------------------------------------|----------------|--------------------------|------------------------|---|
| 6204                | Kenya                      | Short-Term IUD Risk and HIV           | 127,395        |                          |                        | 127,395                                 |
| 6308                | Kenya                      | Female Condom Use and Risk of STD     | 152,449        |                          |                        | 152,449                                 |
| 6313                | Kenya                      | Dual-Method Use/STDs Among FP Clients | 56,088         |                          |                        | 56,088                                  |
| 6477                | Kenya                      | Female Condoms & STDs                 |                | 118,974                  |                        | 118,974                                 |
| 6478                | Kenya                      | Method Mix Modeling                   |                | 95,117                   |                        | 95,117                                  |
| 7094                | Kenya                      | FHI Nairobi Office (General)          | 51,682         |                          |                        | 51,682                                  |
| 7096                | Kenya                      | Office Support (Population Only)      | 161,876        |                          |                        | 161,876                                 |
| 7404                | Kenya                      | APHIA Project Management              |                | 62,108                   |                        | 62,108                                  |
| 9344                | Kenya                      | Menstrual Requirements                | 74,759         |                          |                        | 74,759                                  |
| 9445                | Mali                       | Mali: SDR/FS Project Development      |                | 6,404                    |                        | 6,404                                   |
| 2080                | Senegal                    | Norplant Final Report                 | 24,355         |                          |                        | 24,355                                  |
| 3402                | Senegal                    | Young Adult CTU                       |                | 62,258                   |                        | 62,258                                  |
| 7402                | Senegal                    | Senegal Support                       |                | 29,975                   |                        | 29,975                                  |
| 9452                | Senegal                    | Quality of Norplant Provision         |                | 6,352                    |                        | 6,352                                   |
| 9453                | Senegal                    | Improving FLE Programs                |                | 50,239                   |                        | 50,239                                  |
| <b>TOTAL AFRICA</b> |                            |                                       | <b>914,480</b> | <b>789,625</b>           | <b>97,976</b>          | <b>1,802,081</b>                        |

| FCO #                       | REGION/<br>COUNTRY | SUBPROJECT TITLE                           | CORE           | FIELD<br>SUPPORT | ADD-ON/<br>QYB | TOTAL<br>FISCAL YEAR<br>BUDGET |
|-----------------------------|--------------------|--|----------------|------------------|----------------|--------------------------------|
| <b>ASIA/NEAR EAST</b>       |                    |  |                |                  |                |                                |
| 7001                        | Multi National     | Asia/NE Devel. & Management                | 56,255         |                  |                | 56,255                         |
| 7095                        | Egypt              | FHI/Cairo Office                           | 27,082         |                  |                | 27,082                         |
| 9345                        | Jordan             | Acceptability of Progestin Methods         | 27,403         |                  |                | 27,403                         |
| 7403                        | Nepal              | Nepal Country Activities                   |                | 348,189          |                | 348,189                        |
| 6026                        | Philippines        | Diaphragm Acceptability Developing Country | 113,931        |                  |                | 113,931                        |
| 6287                        | S. Korea           | Vasectomy & Prostate Cancer in Korea       | <u>15,746</u>  |                  |                | <u>15,746</u>                  |
| <b>TOTAL ASIA/NEAR EAST</b> |                    |  | <b>240,417</b> | <b>348,189</b>   | <b>0</b>       | <b>588,606</b>                 |

| <u>FCO #</u>                   | <u>REGION/<br/>COUNTRY</u> | <u>SUBPROJECT TITLE</u>                           | <u>CORE</u> | <u>FIELD<br/>SUPPORT</u> | <u>ADD-ON/<br/>QYB</u> | <u>TOTAL<br/>FISCAL YEAR<br/>BUDGET</u> |
|--------------------------------|----------------------------|---|-------------|--------------------------|------------------------|---|
| <b>LATIN AMERICA/CARIBBEAN</b> |                            |   |             |                          |                        |   |
| 3228                           | Multi National             | Spanish Network                                   | 198,588     |                          |                        | 198,588                                 |
| 7003                           | Multi National             | Latin America Devel. & Management                 | 31,512      |                          |                        | 31,512                                  |
| 6473                           | Bolivia                    | OC Compliance Study PROSALUD Clients              |             | 52,199                   |                        | 52,199                                  |
| 6701                           | Bolivia                    | Qualitative Study of Acceptability Rev Contracept |             |                          | 59,765                 | 59,765                                  |
| 7405                           | Bolivia                    | Bolivian Office                                   |             | 127,386                  |                        | 127,386                                 |
| 7408                           | Bolivia                    | Field Operations Field Support Admin/Management   |             | 26,056                   |                        | 26,056                                  |
| 9402                           | Bolivia                    | PROSALUD Quality of Care Assessment               |             | 23,530                   |                        | 23,530                                  |
| 9451                           | Bolivia                    | Factors Affecting Cont Rates of Homonal Methods   |             | 33,884                   |                        | 33,884                                  |
| 9720                           | Bolivia                    | Max Access to RH Care in Cochabamba, Bolivia      |             |                          | 91,386                 | 91,386                                  |
| 9343                           | Ecuador                    | Comp of Methodologies for Meas RH Staff Time      | 13,015      |                          |                        | 13,015                                  |
| 9448                           | Ecuador                    | Price Elasticity of Demand                        |             | 42,348                   |                        | 42,348                                  |
| 94XX                           | Ecuador                    | Extending Family Planning to Rural Areas          |             | 40,049                   |                        | 40,049                                  |
| 9400                           | El Salvador                | Costs of Family Planning Services/ADS             |             | 20,445                   |                        | 20,445                                  |
| 94XX                           | El Salvador                | Sustainability Project Development                |             | 45,350                   |                        | 45,350                                  |
| 3265                           | Haiti                      | Continuing Education Program (Phase I)            | 18,537      |                          |                        | 18,537                                  |
| 3269                           | Haiti                      | CTU CME Program (Phase II)                        | 72,758      |                          |                        | 72,758                                  |

| <u>FCO #</u>                         | <u>REGION/<br/>COUNTRY</u> | <u>SUBPROJECT TITLE</u>                              | <u>CORE</u>    | <u>FIELD<br/>SUPPORT</u> | <u>ADD-ON/<br/>OYB</u> | <u>TOTAL<br/>FISCAL YEAR<br/>BUDGET</u> |
|--------------------------------------|----------------------------|--|----------------|--------------------------|------------------------|---|
| 3401                                 | Jamaica                    | Wkshp on CT and Counseling for Nursing Tutors        |                | 41,854                   |                        | 41,854                                  |
| 3404                                 | Jamaica                    | FP Continuing Education Seminar                      |                | 108,815                  |                        | 108,815                                 |
| 3405                                 | Jamaica                    | National Family Planning Board Library TA            |                | 6,954                    |                        | 6,954                                   |
| 6027                                 | Jamaica                    | Dual-Method Use/STDs Among FP Clients                | 46,894         |                          |                        | 46,894                                  |
| 6479                                 | Jamaica                    | Symposium on Long-term Safety of Hormonal Methods    |                | 22,573                   |                        | 22,573                                  |
| 7406                                 | Jamaica                    | Jamaica Activities Coordination                      |                | 10,843                   |                        | 10,843                                  |
| 9454                                 | Jamaica                    | Users' Perspective on Method and Services            |                | 83,342                   |                        | 83,342                                  |
| 9455                                 | Jamaica                    | Secondary Analysis Quality of Care                   |                | 10,546                   |                        | 10,546                                  |
| 2217                                 | Mexico                     | Time to Infertility after Vasectomy: Expanded Study  | 87,352         |                          |                        | 87,352                                  |
| 6205                                 | Mexico                     | Copper IUD and Tubal Infertility                     |                |                          | 120,136                | 120,136                                 |
| 7401                                 | Mexico                     | Field Operations Field Support Admin/Management      |                | 12,354                   |                        | 12,354                                  |
| 9401                                 | Mexico                     | SDR Project Development                              |                | 46,280                   |                        | 46,280                                  |
| 9424                                 | Mexico                     | Method Specific Costs of Family Planning             |                | 38,991                   |                        | 38,991                                  |
| 9446                                 | Mexico                     | IUD Provision by IMSS Midwives                       |                | 35,935                   |                        | 35,935                                  |
| 9449                                 | Mexico                     | FEMAP Service Efficiency                             |                | 63,963                   |                        | 63,963                                  |
| 3266                                 | Paraguay                   | FLASOG   | 21,155         |                          |                        | 21,155                                  |
| 3400                                 | Paraguay                   | Regional Workshops on Contraceptive Technology       |                | 3,979                    |                        | 3,979                                   |
| 3406                                 | Paraguay                   | National Family Planning Guidelines Revision Project |                | 100,000                  |                        | 100,000                                 |
| <b>TOTAL LATIN AMERICA/CARIBBEAN</b> |                            |  | <b>489,811</b> | <b>997,676</b>           | <b>271,287</b>         | <b>1,758,774</b>                        |

| FCO #                             | REGION/<br>COUNTRY | SUBPROJECT TITLE                                    | CORE             | FIELD<br>SUPPORT | ADD-ON/<br>OYB | TOTAL<br>FISCAL YEAR<br>BUDGET |
|-----------------------------------|--------------------|---|------------------|------------------|----------------|--------------------------------|
| <b>NORTH AMERICA/CANADA</b>       |                    |   |                  |                  |                |                                |
| 2059                              | USA                | Lea's Shield PMA Support                            | 22,349           |                  |                | 22,349                         |
| 2213                              | USA                | Timing Onset Contraceptive Norplant Users (US & DR) | 24,018           |                  |                | 24,018                         |
| 2224                              | USA                | Plastic Condom Development and Management           | 43,861           |                  |                | 43,861                         |
| 2226                              | USA                | Ident of New Methods of Nonsurgical Sterilization   | 31,176           |                  |                | 31,176                         |
| 2227                              | USA                | Anti-HPV Vaginal Microbicide                        | 56,960           |                  |                | 56,960                         |
| 2229                              | USA                | Effectiveness of Slip-on vs. Latex Condom           | 303,591          |                  |                | 303,591                        |
| 2230                              | USA                | Antiemetic to Prevent Nausea from EC                | 85,744           |                  |                | 85,744                         |
| 3212                              | USA                | FHI Fellow - USAID/W                                | 60,858           |                  |                | 60,858                         |
| 3268                              | USA                | USAID IEC Fellow                                    | 105,762          |                  |                | 105,762                        |
| 6029                              | USA                | Feasibility of Female Condom Reuse                  | 34,384           |                  |                | 34,384                         |
| 6217                              | USA                | Efficacy of Condoms & VCF w/ new methodology        | 86,604           |                  |                | 86,604                         |
| 6311/6901                         | USA                | Hormonal CU, Cervical Ectopy and Chlamydia          | 173,781          |                  | 114,678        | 288,459                        |
| 6315                              | USA                | Latex Condoms Performance in Human Use              | 84,039           |                  |                | 84,039                         |
| 6383                              | USA                | Teen DMPA/Bone Pilot Study                          | 68,867           |                  |                | 68,867                         |
| 6384                              | USA                | Multiple Use Assessments of the Reality Female Con  | 191,169          |                  |                | 191,169                        |
| 6385                              | USA                | Monograph on Latex Condoms                          | 81,208           |                  |                | 81,208                         |
| 8016                              | USA                | PATH: Condom Research Activities                    | 51,711           |                  |                | 51,711                         |
| 8017                              | USA                | Contraceptive Production/Surveillance               | 290,391          |                  |                | 290,391                        |
| 8028                              | USA                | Condom Package Integrity Study                      | 0                |                  |                | 0                              |
| 8029                              | USA                | Condom Laboratory Monitoring                        | 42,155           |                  |                | 42,155                         |
| 9060                              | USA                | General Toxicology Support                          | 5,521            |                  |                | 5,521                          |
| 9101                              | USA                | CONRAD/General Statistical Support                  | 27,313           |                  |                | 27,313                         |
| 9103                              | USA                | Comp Eval of 3 Tactylon Condoms w/ Latex            | 61,594           |                  |                | 61,594                         |
| 9104                              | USA                | Emergency Contraception Meeting                     | 34,181           |                  |                | 34,181                         |
| <b>TOTAL NORTH AMERICA/CANADA</b> |                    |   | <b>1,967,237</b> | <b>0</b>         | <b>114,678</b> | <b>2,081,915</b>               |

| <u>FCO #</u>     | <u>REGION/<br/>COUNTRY</u> | <u>SUBPROJECT TITLE</u>                        | <u>CORE</u> | <u>FIELD<br/>SUPPORT</u> | <u>ADD-ON/<br/>QYB</u> | <u>TOTAL<br/>FISCAL YEAR<br/>BUDGET</u> |
|------------------|----------------------------|--|-------------|--------------------------|------------------------|---|
| <b>WORLDWIDE</b> |                            |  |             |                          |                        |   |
| 2000             | Worldwide                  | Clinical Trials Development/Management         | 425,181     |                          |                        | 425,181                                 |
| 2001             | Worldwide                  | Data Management                                | 52,347      |                          |                        | 52,347                                  |
| 2030             | Worldwide                  | Systemics - General                            | 36,605      |                          |                        | 36,605                                  |
| 2051             | Worldwide                  | IUD - TCU 380A                                 | 36,888      |                          |                        | 36,888                                  |
| 2070             | Worldwide                  | Vaginal Methods/General Development            | 31,805      |                          |                        | 31,805                                  |
| 2211             | Worldwide                  | Clinical Evaluation of VCF and Conceptrol      | 375,252     |                          |                        | 375,252                                 |
| 2218             | Worldwide                  | Femcap w/Spermicide vs. Diaphragm              | 123,739     |                          |                        | 123,739                                 |
| 2220             | Worldwide                  | WHO Vaginal Microbicide Development            | 29,225      |                          |                        | 29,225                                  |
| 2231             | Worldwide                  | Sterilization Research                         | 21,701      |                          |                        | 21,701                                  |
| 2232             | Worldwide                  | Lea's Shield Development                       | 23,432      |                          |                        | 23,432                                  |
| 2233             | Worldwide                  | Breakage & Slippage Plastic Condom             | 287,880     |                          |                        | 287,880                                 |
| 22XX             | Worldwide                  | Cervical Mucous & Injectables                  | 79,841      |                          |                        | 79,841                                  |
| 3011             | Worldwide                  | Health Communication and Training: Development | 64,506      |                          |                        | 64,506                                  |
| 3021             | Worldwide                  | Maximizing Access and Quality: Development     | 103,986     |                          |                        | 103,986                                 |
| 3200             | Worldwide                  | PRU Development & Management                   | 163,678     |                          |                        | 163,678                                 |
| 3202             | Worldwide                  | English Network                                | 300,469     |                          |                        | 300,469                                 |
| 3205             | Worldwide                  | Information Dissemination                      | 168,176     |                          |                        | 168,176                                 |
| 3208             | Worldwide                  | CTU Meetings: Development                      | 245,137     |                          |                        | 245,137                                 |
| 3210             | Worldwide                  | Contraceptive Technology Update Module Series  | 451,437     |                          |                        | 451,437                                 |
| 3211             | Worldwide                  | Expert Slide Sets: CTUs                        | 51,374      |                          |                        | 51,374                                  |
| 3221             | Worldwide                  | Publications Catalog                           | 6,247       |                          |                        | 6,247                                   |
| 3260             | Worldwide                  | Library and Information Services               | 259,553     |                          |                        | 259,553                                 |
| 6000             | Worldwide                  | CUE Development and Management                 | 221,476     |                          |                        | 221,476                                 |
| 6006             | Worldwide                  | Acceptability Paper Writing                    | 113,523     |                          |                        | 113,523                                 |
| 6030             | Worldwide                  | Evaluation of Uniject Syringe and Depo-Provera | 35,859      |                          |                        | 35,859                                  |
| 6216             | Worldwide                  | Benefits and Risks of Contraceptive Methods    | 43,418      |                          |                        | 43,418                                  |
| 6312             | Worldwide                  | Technical Guidance Working Group               | 39,831      |                          |                        | 39,831                                  |
| 6314             | Worldwide                  | Female Condom Demand Assessment                | 24,959      |                          |                        | 24,959                                  |
| 6352             | Worldwide                  | RH Paper Writing for Completed Projects        | 142,703     |                          |                        | 142,703                                 |
| 6381             | Worldwide/TBD              | Impact of Menstrual Disturbances on Method Use | 23,242      |                          |                        | 23,242                                  |

| FCO #                          | REGION/<br>COUNTRY | SUBPROJECT TITLE                                 | CORE                 | FIELD<br>SUPPORT    | ADD-ON/<br>OYB    | TOTAL<br>FISCAL YEAR<br>BUDGET |
|--------------------------------|--------------------|--|----------------------|---------------------|-------------------|--------------------------------|
| 6382                           | Worldwide/TBD      | Compliance Strategy Development                  | 46,428               |                     |                   | 46,428                         |
| 7000                           | Worldwide          | Field Operations Development and Management      | 293,679              |                     |                   | 293,679                        |
| 8010                           | Worldwide          | Condom Quality Testing/Administration            | 204,001              |                     |                   | 204,001                        |
| 8011                           | Worldwide          | Condom Field Stock Evaluations                   | 46,019               |                     |                   | 46,019                         |
| 8015                           | Worldwide          | Condom Production Surveillance                   | 310,594              |                     |                   | 310,594                        |
| 9001                           | Worldwide          | Regulatory Affairs                               | 68,630               |                     |                   | 68,630                         |
| 9002                           | Worldwide          | Regulatory Support                               | 87,559               |                     |                   | 87,559                         |
| 9003                           | Worldwide          | General Quality Assurance                        | 83,967               |                     |                   | 83,967                         |
| 9006                           | Worldwide          | R & D Interdivisional SOPS                       | 45,994               |                     |                   | 45,994                         |
| 9007                           | Worldwide          | Clinical Support Management                      | 32,201               |                     |                   | 32,201                         |
| 9100                           | Worldwide          | Population Biostat Activity                      | 201,196              |                     |                   | 201,196                        |
| 9102                           | Worldwide          | Biostatistics Paper Writing                      | 101,230              |                     |                   | 101,230                        |
| 9300                           | Worldwide          | Service Delivery Research Devel. & Management    | 177,243              |                     |                   | 177,243                        |
| 9304                           | Worldwide          | Service Delivery Research Paper Writing          | 126,017              |                     |                   | 126,017                        |
| 9318                           | Worldwide          | Maximizing Access and Quality (MAQ) Development  | 8,980                |                     |                   | 8,980                          |
| 9346                           | Worldwide          | Method Choice                                    | 98,735               |                     |                   | 98,735                         |
| 93XX                           | Worldwide/TBD      | Efficient Provision                              | 41,041               |                     |                   | 41,041                         |
| 93XX                           | Worldwide/TBD      | Cost Quality of Care                             | 107,946              |                     |                   | 107,946                        |
| 9990                           | Worldwide          | Medical Review                                   | 93,145               |                     |                   | 93,145                         |
| 9991                           | Worldwide          | Interregional Contraceptive Research/Development | 343,303              |                     |                   | 343,303                        |
| 9995                           | Worldwide          | Interregional Population Coop. Agr. Mgt.         | 200,645              |                     |                   | 200,645                        |
| 6900                           | New Zealand        | Vasectomy Study                                  |                      |                     | 128,548           | 128,548                        |
| <b>TOTAL WORLDWIDE</b>         |                    |  | <b>6,702,023</b>     | <b>0</b>            | <b>128,548</b>    | <b>6,830,571</b>               |
| <b>GRAND TOTAL ALL REGIONS</b> |                    |  | <b>\$ 10,313,968</b> | <b>\$ 2,135,490</b> | <b>\$ 612,489</b> | <b>\$ 13,061,947</b>           |



# APPENDIX A

## RESULTS FRAMEWORK

# Results Framework

Agency Goal...

Stabilizing world population and protecting human health

Agency Strategic Objectives...

Sustainable reduction in unintended pregnancies

Sustainable reduction in maternal mortality

Sustainable reduction in infant and child mortality

Sustainable reduction in STI/HIV transmission among key populations

PHNC Strategic Objectives...

Increased use by women & men of voluntary practices that contribute to reduced fertility

Increased use of safe pregnancy, women's nutrition, family planning, & other key R.H. interventions

Increased use of key child health and nutrition interventions

Increased use of proven interventions to reduce HIV/STD transmission

PHNC Intermediate Results...

1.1 New & improved technologies & approaches for contraceptive methods and F.P. identified, developed, tested, evaluated, and disseminated  
R

1.1 Approaches and technologies to enhance key R.H. interventions identified, developed, evaluated and disseminated  
R

1.1 New and improved cost-effective interventions developed and disseminated  
R

1.1 Effective interventions to reduce sexual transmission of HIV/STD identified, strengthened, implemented, & evaluated in R emphasis countries  
R

Core Functions:

R = Research & evaluation  
GL = Global leadership

TS = Technical support

1.2 Improved policy environment and increased global resources for family planning programs  
GL

1.2 Improved policies and increased public and private sector resources and capacity to deliver key reproductive health services  
GL

1.2 Improved policies & increased global, national and local resources for appropriate child health interventions  
GL

1.2 Improved methods & tools for reducing perinatal & parenteral HIV transmission available for program use in emphasis countries  
R

1.3 Enhanced capacity for public, private, NGO & community-based organizations to design, implement, & evaluate sustainable F.P. programs  
TS

1.3 Access to essential obstetric services increased in selected priority countries  
TS

1.3 Enhanced knowledge of key child health and nutrition behaviors & practices in selected countries  
TS

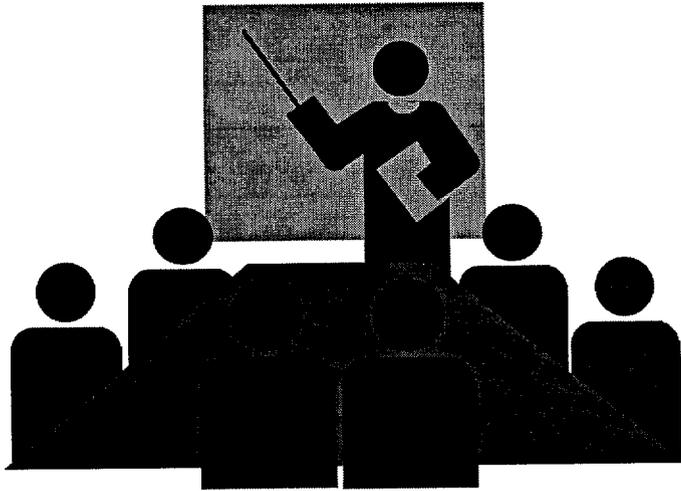
1.3 Enhanced capacity for public, private, NGO and community-based organizations to design, implement & evaluate effective HIV/STD prevention & care programs  
TS

1.4 Demand for, access to, and quality of family planning and other selected reproductive health information and services increased  
TS

1.4 Quality of essential obstetric services increased in selected countries  
TS

1.4 Improved quality and availability of key child health/nutrition services  
TS

1.4 Knowledge, availability and quality of HIV/STD services increased in emphasis countries  
TS



## APPENDIX B

### ADVISORY COMMITTEES

October 1, 1996  
through  
September 30, 1997

**Family Health International**  
**Technical Advisory Committee**  
**for**  
**Contraceptive Technology and Family Planning Research**  
**1996 - 1997 Roster**

- |      |   |      |  |
|------|---|------|--|
| 1996 | <p><b>Obstetrics-Gynecology/Reproductive Biology</b><br/>           Deborah J. Anderson, PhD<br/>           Associate Professor<br/>           Obstetrics, Gynecology &amp; Reproductive Biology<br/>           Harvard Medical School<br/>           Director, Fearing Research Laboratory<br/>           250 Longwood Avenue-SGMB 204<br/>           Boston, Massachusetts 02115<br/>           617/432-0841; 617/432-2190<br/>           FAX: 617/432-0359</p> | 1997 | <p><b>Social Science</b><br/>           Amy O. Tsui, PhD<br/>           Project Director, The Evaluation Project<br/>           Carolina Population Center<br/>           University of North Carolina<br/>           CB #8120, University Square<br/>           Chapel Hill, North Carolina 27516<br/>           919/966-1737; FAX 919/966-2361</p>   |
| 1996 | <p><b>Endocrinology/Reproductive Biology</b><br/>           Gregorio Pérez-Palacios, MD<br/>           Director General de Salud Reproductiva<br/>           Secretaría de Salud<br/>           Insurgentes Sur 1397, 6to Piso<br/>           Insurgentes Mixcoac<br/>           03920 México, DF, México<br/>           52-5-598-5816; FAX: 598-6528</p>   | 1998 | <p><b>Obstetrics-Gynecology</b><br/>           Soledad Díaz, MD<br/>           Consultorio de Planificación Familiar<br/>           Instituto Chileno de Medicina Reproductiva<br/>           José Ramón Guiterrez 295<br/>           Depto. 3, Correo 22, Casilla 96<br/>           Santiago, Chile<br/>           56-2-632-1988; 56-2-222-5887; FAX: 56-2-633-6204</p>                                     |
| 1997 | <p><b>Obstetrics-Gynecology/Preventive Medicine</b><br/>           David A. Grimes, MD (Chair)<br/>           Professor and Vice Chair<br/>           Department of Obstetrics, Gynecology<br/>           &amp; Reproductive Sciences<br/>           University of California, San Francisco<br/>           1001 Potrero Avenue<br/>           San Francisco, California 94110<br/>           415/206-8358; FAX: 415/206-3112</p>                                 | 1998 | <p><b>Obstetrics-Gynecology</b><br/>           Mahmoud F. Fathalla, MD<br/>           Senior Advisor<br/>           Biomedical &amp; Reproductive Health<br/>           Research &amp; Training<br/>           The Rockefeller Foundation<br/>           Post Office Box 30<br/>           Assiut, Egypt<br/>           20-88-334820; FAX: 20-88-337333</p>  |
| 1997 | <p><b>Reproductive Biology</b><br/>           Michael J. K. Harper, PhD, ScD<br/>           Senior Scientist<br/>           CONRAD Program<br/>           1611 North Kent Street, Suite 806<br/>           Arlington, Virginia 22209<br/>           703/276-4022; FAX: 703/524-4770</p>   | 1998 | <p>New York City Address:<br/>           Senior Advisor<br/>           The Rockefeller Foundation<br/>           420 Fifth Avenue<br/>           New York, New York 10018-2702<br/>           212-869-8500; FAX: 212/764-3468; 398-1858</p>  |
| 1997 | <p><b>Consumer Advocate</b><br/>           Judy Norsigian<br/>           Co-director<br/>           The Boston Women's Health Book Collective<br/>           240A Elm Street<br/>           Somerville, Massachusetts 02144<br/>           617/625-0271; FAX: 617/625-0294</p>  | 1998 | <p><b>Medical Anthropology</b><br/>           Cynthia Myntti, PhD, MPH<br/>           Hubert Humphrey Institute<br/>           130 Humphrey Center<br/>           301 19th Avenue South<br/>           Minneapolis, Minnesota 55455<br/>           612/625-0576; FAX: 612/625-6351</p>   |
| 1997 | <p><b>Epidemiology</b><br/>           Judith P. Rooks, CNM, MS, MPH<br/>           Associate, Pacific Institute for Women's Health<br/>           2706 SW English Court<br/>           Portland, Oregon 97201<br/>           503/243-2253; FAX: 503/248-4671</p>  | 1998 | <p><b>Economics</b><br/>           James Trussell, PhD<br/>           Office of Population Research<br/>           The Woodrow Wilson School<br/>           of Public &amp; International Affairs<br/>           Department of Economics<br/>           Princeton University<br/>           21 Prospect Avenue<br/>           Princeton, New Jersey 08544<br/>           609/258-4946; FAX: 609/258-1418</p> |
| 1997 | <p><b>Social Science</b><br/>           Rochelle N. Shain, PhD<br/>           Professor, Department of Obstetrics/Gynecology<br/>           The University of Texas<br/>           Health Science Center<br/>           7703 Floyd Curl Drive<br/>           San Antonio, Texas 78284<br/>           210/567-5051; FAX: 210/567-4963</p>  |      |  |

**Family Health International  
Protection of Human Subjects Committee  
1997 Roster**

**Clergy**  
1999 Dennis M. Campbell, PhD, BD (*Chair*)  
Dean, The Divinity School  
Duke University  
Durham, NC 27708-0968  
919/660-3434 (B)

**Internal Medicine**  
1998 Elizabeth S. Mann, MD (*Vice Chair*)  
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)  
E-mail: esmann@med.unc.edu

**Consumer/Social Science**  
1997 Aida Beshara, PhD  
738 Braniff Drive  
Cary, NC 27513  
919/319-1011 (R)

**Medical Sociology**  
1998 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  
919/966-6055 (B); 942-5289 (R)

**Public Health**  
1999 Betty H. Dennis, PharmD  
Clinical Specialist in Ambulatory Care  
Department of Pharmacy  
University of North Carolina Hospitals  
Manning Drive  
Chapel Hill, NC 27514  
919/966-4140, Ext. 2240 (B)  
E-mail: bdennis.PHA3@mail.unch.unc.edu

**Consumer/Public Health**  
1997 Margaret F. McCann, PhD  
Epidemiologic Consultant  
Maternal and Child Health Issues  
105 Wisteria Drive  
Chapel Hill, NC 27514  
919/489-0423

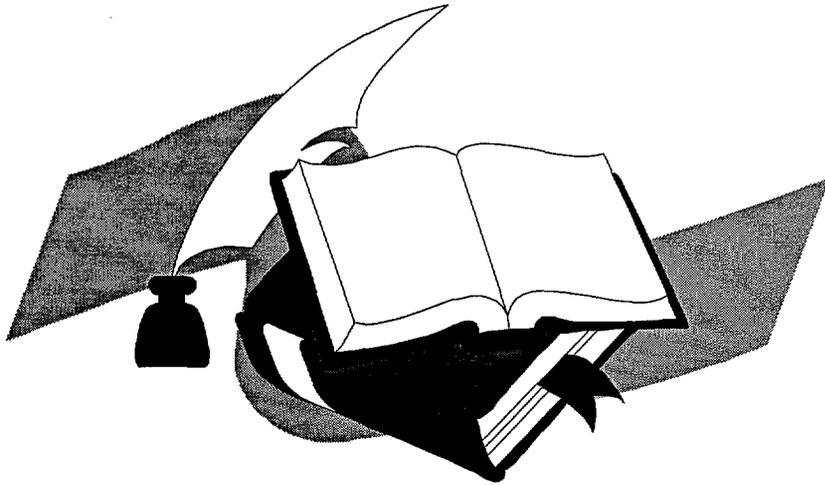
**Legal**  
1997 Steven M. Shaber, JD  
Jordan, Price, Wall, Gray & Jones  
PO Box 2021  
Raleigh, NC 27602  
919/828-2501 (B)  
831-4467 (voice mail)

**Internal Medicine/Applied Ethics**  
1999 Jeremy Sugarman, MD, MPH, MA  
Assistant Professor of Medicine  
Duke University School of Medicine  
Co-Director, Program in Medical Ethics  
Division of General Internal Medicine  
Box 3040  
Duke University Medical Center  
Durham, NC 27710  
919/681-4651 (B)

**FHI Staff**  
1997 Evelyn J. Studer, RN, BSN (Ex-officio\*)  
Institutional Representative  
Protection of Human Subjects Committee  
Family Health International  
Durham, NC 27713  
919/405-1445 (B)  
E-mail: estuder@fhi.org

\*Nonvoting member

January 1, 1997



## APPENDIX C

### FHI PAPER PROPOSALS

The list which follows includes all current paper proposals submitted to and approved by the relevant Division Directors at FHI. It does not distinguish by funding source. It, therefore, includes some papers which will be written with funding other than that provided by the Contraceptive Technology and Family Planning Research Cooperative Agreement. The list is included in this Workplan as it further illustrates FHI's on-going and prospective efforts to synthesize and disseminate current information on both contraceptive technology and broader reproductive health issues.

# OUTSTANDING FHI PAPER PROPOSALS

## **IN PROGRESS**

Adair LS; Guilkey DA; Bisgrove EZ.

Effect of childbearing on Filipino women's labor force participation and earnings.  
J Hum Resour.

Behets F; Ward E; Fox L; Reed R; Spruyt A; Bennett L; Johnson L; Hoffman I; Figueroa JP.

Management of sexually transmitted diseases (STDs) in women attending Jamaican family planning clinics using syndromic approaches.

Blaney CL; Solis JA; Rivera R.

Postpartum and post-abortion contraceptive care in Latin America: interviews with health providers, policymakers and women's advocates in Ecuador, Honduras and Mexico.

Bratt JH; Foreit JR; de Vargas T.

A comparison of three strategies for improving the sustainability of an Ecuadorian NGO.

Bratt J; Foreit J; Janowitz B; Pinto E; West C.

A comparison of four methods for measuring staff time.  
Health Policy Plan.

Chen PL; Wong E; Dominik R; Steiner M.

A transition model to adjust intervention effect for nonrandom loss to follow-up.  
Stat Med.

Chi I; Petta C.

Tubal sterilization for postpartum contraception-pros and cons.

Dalberth P.

Implementing cascading update functionality in Oracle 7.

Dominik R.

Efficacy and safety of the Filshie Clip and Wolf Clip applied via laparoscopy or minilaparotomy.

Dominik R; Raymond E; Glover L; Mauck C.

Calculating life-table rates for accidental pregnancy and reasons for product discontinuation in vaginal contraceptive trials.

Dunson R; Amatya R; Rivera R.

An analysis of reasons of early discontinuations of Norplant use: FHI's International experience.  
Contraception.

Dunson R; Amatya R; Ruminjo J; McPheeters M; Chi IC.

An assessment of pregnancies occurring among Norplant implant users: international experience.

Dunson R; Blumenthal P; Alvarez F; Brache V; Cochon L; Dalberth B; Glover L; Katz D.

Timing of onset of contraceptive effectiveness in Norplant implant users as determined by changes in cervical mucus: project overview.

Dunson R; Ruminjo J.

Conducting clinical trials in developing countries.

Ephross S; Schwingl P; Nabulsi A; McGuire A; White A; Hutchinson R; Burke G.  
Post OC use and carotid artery wall thickness in black and white women: the ARIC study.  
Am J Epidemiol.

Flick A; Barone M; Amatya R; McMullen S.  
Results of a pilot study of the time to infertility after vasectomy.

Flick A; McPheeters M; Amatya R.  
Are baseline sperm count and baseline motility associated with the time required to reach sterility after vasectomy?

Fox L; Bailey P; Johnson H; Odom DJ.  
Sex and adolescents in Belle Glade: an evaluation of an AIDS prevention project.  
Am J Public Health.

Glover LH; Chen PL; Dominik R.  
Use of a propensity score in an historical control analysis of clinical trials.  
Am J Epidemiol.

Glover LH; Mauck C; Dominik R.  
Comparison of the effectiveness of Lea's Shield with historical data.  
Contraception.

Hall JE; Bonhomme M; Fortney J; McCann M; Bisgrove E; Dominik R.  
Use of DMPA and the risk of cervical carcinoma in situ.  
Int J Epidemiol.

Hanenberg R; Rojanapithayakorn W.  
Commercial sex in Thailand and its effects on the HIV epidemic.

Hardee K; Villinski MT; Ulin P.  
Male involvement in family planning: building a partnership for responsible parenthood.

Hogle J; Hassig SE.  
Combining anthropology and epidemiology in international AIDS interventions.

Hubacher D; Fortney J; Savitz D.  
The role of frequent clinical contact in preventing upper genital tract infections among IUD users.  
J Clin Epidemiol.

Janowitz B; Bratt J.  
Methods for costing family planning programs and services.  
Chapter IUSSP Volume on Methods for Evaluation of Family Planning Program Impact.

Janowitz B; Holtman M; Hubacher D; Jamil K.  
Options for increasing contraceptive use in Bangladesh: the role of costs.

Katz K; Nare C.  
Contraceptive knowledge and use among young adults in Dakar, Senegal.

Katz K; Waszak C; Hieu D; Vinh D; Tong N.  
Determinants and consequences of abortion among hospitalized women in Vietnam.

162

Katz K; West C; Doumbia F; Kane M.  
Increasing access to family planning services in rural Mali.

Kennedy K; Visness C.  
Frequency of coitus during breastfeeding.  
Birth.

Kennedy KI; Visness C; Ramos R; Kazi A; Khan T.  
Women's understanding of LAM protection.

Morrison C; Sinei S; Kigonda C.  
Short-term complications following IUD insertion among HIV+ and HIV- women.  
Lancet.

Nutley T; Dunson R.  
Treatment of bleeding problems associated with progestin-only contraceptives: results from a questionnaire.

Nutley T; Potter L.  
Discrepancies in guidelines for use of emergency contraception pills.

Oakley D; Potter L; Wong E; Visness C.  
Oral contraceptive use-behaviors.  
Obstet Gynecol.

Petta C.  
Method choice in postpartum contraception - recent findings and programmatic considerations.

Pfannenschmidt S; McKay A.  
Gender resources for population, health and nutrition projects.

Reinprayoon D; Hurst C; Farr G; Amatya R.  
A four-year comparative clinical evaluation of the TCu380A and MLCu 250 IUDs in Bangkok, Thailand.  
Contraception.

Rivera R; Amatya R.  
An analysis of client's characteristics that may affect early discontinuations of IUD 380A use: international experience.  
Contraception.

Rivera R; Amatya R.  
Relationship of menstrual cycle characteristics and early discontinuation due to bleeding/pain among TCu380A IUD users: international experience.  
Contraception.

Rivera R; Hardee K.  
International and national public health issues and implications for drug development in and for women.  
Book Chapter.

Roddy RE; Zekeng L; Ryan KA; Tamoufe U; Weir SS; Wong E.  
A randomized controlled trial of the effect of nonoxynol-9 use on male-to-female transmission of HIV-1.  
N Eng J Med.

Ryan KA; Zekeng L; Roddy RE; Wong E.  
An RCT to measure the effect of nonoxynol-9 film use on cervical gonorrhea and chlamydial infection.  
JAMA.

- Schwingsl P; Laborde DJ; Fortney JA; King TDN.  
Impact of potential OC use in a region with high breast and cervical cancer mortality.
- Searing H; Robinson E.  
Improving women's lives through family planning research: process monitoring for accountability.
- Smith JB; Fortney JA; Wong E; Amatya R; Coleman NA; de Graft-Johnson J.  
Estimates of the maternal mortality ratio in two districts of Brong Ahafo Region of Ghana.  
Stud Fam Plann.
- Smith PH; Smith JB.  
The measurement trap: conceptualizing and measuring woman battering with implications for cross-cultural research.  
Womens Psychol Q
- Sokal D.  
The use of monoclonal antibodies for passive immunologic contraception (letter).  
Sci Am.
- Sokal D; Chi I; Zipper J; Guzman-Serani R.  
Long-term intrauterine and ectopic pregnancy rates among women sterilized with transcervical quinacrine.
- Sokal D; Flick A.  
Non-surgical female sterilization: its potential impact on the quality of life.
- Sokal D; Wiwat R; Kunasol P; Hanenberg R.  
Decline of HIV prevalence among Thai military recruits (letter).
- Stanback J; Maribe S.  
Family planning's medical paradigm: myths and realities.
- Steiner M; Glover L; Bou-Saada I; Piedrahita C.  
Randomized study to assess barrier method use among OC users.  
Am J Public Health.
- Steiner M; Hertz-Picciotto I; Raymond E; Trussell J; Wheelless A.  
The influence of fecundability on the pregnancy rate: a reanalysis of the Reality female condom clinical trial.  
Fam Plann Perspect or Obstet Gynecol.
- Thapa S.  
Timing of family formation in ethnic mosaic Nepal: a district-level analysis.  
J Marriage Fam.
- Thompson A; Janowitz B; Stewart J; Guilkey D; Herrin A; Tsui A.  
Is there a simple and replicable methodology for estimating country expenditures on family planning?  
Int Fam Plann Perspect.
- Visness C; Potter L; Oakley D; Wong E; Chen P.  
GEE methods in over-dispersed prospective coital data.

164

Weir S; Roddy R; Zekeng L; Ryan K.

The association between prevalent HIV infection and cross-sectional measures of exposure and susceptibility.

J Infect Dis.

Weir S; Roddy R; Zekeng L; Ryan K; Wong E; Dominik R.

Gonorrheal and chlamydial infections as risk factors for HIV acquisition.

Am J Epidemiol.

Wilson D; Weir S; Smith P; Schoenbach V.

The use of capture-recapture methods to estimate the size of the female population at increased risk for STDs/HIV in Zimbabwe.

Wong E; Glover L; Chen PL; Dominik R; Steiner M.

Longitudinal discrete data analysis of use of contraceptive barrier methods.

Controlle Clin Trials.

Zhang J; Lofy L; Fortney J.

The effects of birth spacing on maternal mortality.

## **SUBMITTED**

Cates W Jr.; Chesney MA; Cohen MS.

Primary HIV infection: a key prevention window.

Am J Public Health.

Dominik R; Trussell J; Walsh T.

Failure rates among perfect users and during perfect use: a distinction that matters.

Farr G; Katz V; Spivey S; Amatya R; Warren M; Oliver R.

Safety, functionality and acceptability of a prototype polyurethane condom.

Adv Contracept.

Fortney JA; Feldblum PJ; Raymond EG.

Advantages of the modern IUD in family planning programs.

Int Fam Plann Perspect.

Hardee K; Balogh S; Villinski MT.

Worldwide experience with Norplant introduction.

Pop Policy Plan.

Jackson J; Eggleston E; Lee A; Hardee K.

Sexual activity and family planning: knowledge, attitudes and behavior among young adolescents in Jamaica.

Soc Econom Stud.

Kennedy K; Short RV; Tully M.

Premature introduction of progestin-only contraceptive methods during lactation.

BMJ.

Lafort Y; Morrison C; Musaba E; Thomas J; Sunkutu R.  
Reliability and validity of the reporting of sexual behavior: a study of married couples in sub-Saharan Africa.

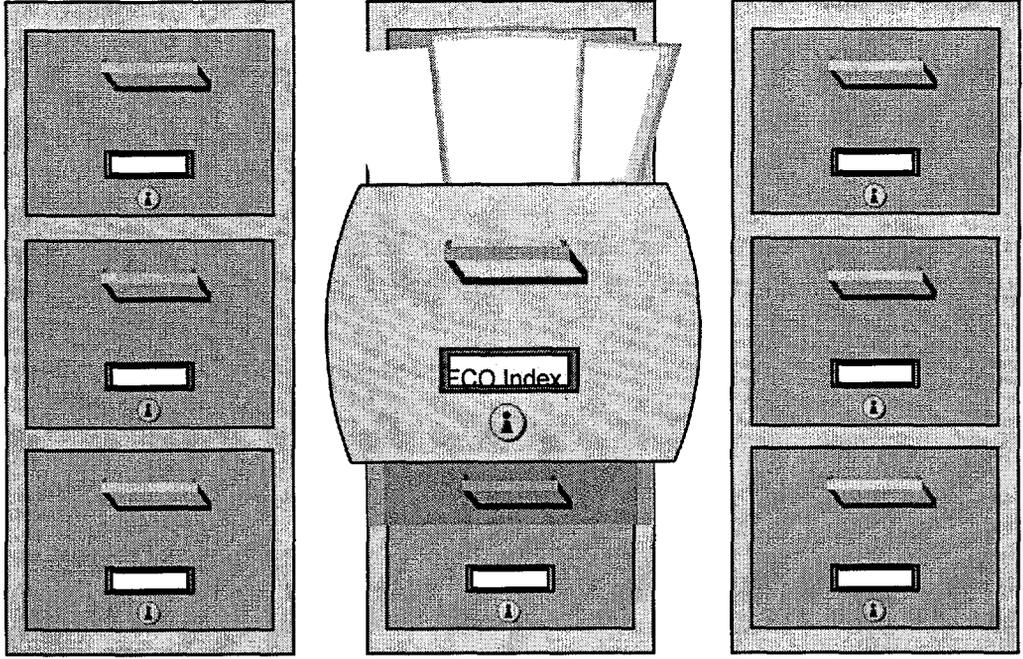
Musaba E; Morrison C; Sunkuta M; Spruyt A; Moeng S; Chomba T.  
Long-term use and acceptability of the female condom among couples at high risk of HIV infection.  
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**FCO INDEX**

167

The following FCO Index is grouped chronologically by division.

### 2000s - CLINICAL TRIALS

|          |   |    |
|----------|---|----|
| 2030     | General Systemics.....  | 34 |
| 2051     | TCu 380A Intrauterine Device (IUD) Clinical Research.....   | 33 |
| 2059     | Lea's Shield PMA Panel Support.....   | 16 |
| 2070     | Vaginal Methods - General Development.....  | 18 |
| 2080     | Final Report: Pre-Introductory Clinical Trial of Norplant/Senegal.....  | 30 |
| 2211     | A Comparative Clinical Evaluation of VCF and Conceptrol.....  | 19 |
| 2213     | Timing of Onset of Contraceptive Effectiveness in Norplant Implant Users.....   | 31 |
| 2217     | Expanded Study of the Time to Infertility After Vasectomy.....  | 28 |
| 2218     | Safety and Efficacy Study of Femcap Used with Spermicide vs the Ortho All-Flex<br>Diaphragm Used with Spermicide..... | 20 |
| 2220     | Collaboration With WHO on Vaginal Microbicide Development.....  | 22 |
| 2224     | Plastic Male Condom Development and Management.....   | 24 |
| 2226     | Identification of New Methods of Nonsurgical Sterilization.....   | 27 |
| 2227     | Developing a Vaginal Microbicide to Prevent HPV Infection.....  | 23 |
| 2229     | Comparative Contraceptive Effectiveness Assessment of the Twin-Aperture Slip-On<br>Condom and Latex Condoms.....      | 25 |
| 2230     | Antiemetics to Prevent Nausea Associated with Emergency Contraceptive Pills.....                                      | 35 |
| 2231     | Sterilization Paper Writing.....  | 29 |
| 2232     | Lea's Shield Development.....   | 17 |
| 2233     | Comparative Assessment of the Twin-Aperture Slip-On Condom and a Latex Condom:<br>Breakage and Slippage.....          | 26 |
| 22xx/TBD | Extending the Initial Injection Window in Cyclofem Users.....   | 32 |

### 3000s - POLICY AND RESEARCH UTILIZATION

|           |  |     |
|-----------|--|-----|
| 3202      | English Network.....   | 86  |
| 3205      | Information Dissemination.....   | 90  |
| 3208      | Contraceptive Technology Update Seminars for Maximizing Access and Quality.....                  | 99  |
| 3210      | Contraceptive Technology Update Modules Series.....  | 94  |
| 3211      | Expert Slide Sets.....   | 96  |
| 3221      | Publications Catalog.....  | 89  |
| 3228      | Network en español.....  | 87  |
| 3250      | Network en francais.....   | 88  |
| 3260      | Library and Information Services.....  | 91  |
| 3266      | XV Latin American Congress of Gynecology and Obstetrics (FLASOG).....                            | 104 |
| 3269/3265 | Contraceptive Technology Continuing Medical Education Program (CME) Program.....                 | 97  |
| 3400      | Contraceptive Technology Update Regional Workshops.....  | 100 |
| 3401      | Training Workshop in Contraceptive Technology and Counseling for Jamaican<br>Nursing Tutors..... | 103 |
| 3402      | Young Adult Contraceptive Technology Update (CTU) Workshop.....                                  | 105 |
| 3404/3722 | Family Planning Seminars for Private Sector Physicians.....                                      | 102 |
| 3405      | National Family Planning Board Library Technical Assistance/Jamaica.....                         | 93  |
| 3406      | National Family Planning Guidelines Revision Project.....  | 101 |
| 3565      | MOH/Health Research Unit Library Technical Assistance/Ghana.....                                 | 92  |

168

## 6000s - CONTRACEPTIVE USE AND EPIDEMIOLOGY

|           |  |    |
|-----------|--|----|
| 6006      | Acceptability Paper Writing .....  | 44 |
| 6026      | Assessing the Acceptability, Service Delivery Requirements, and Use Effectiveness of the Diaphragm in a Developing Country ..... | 53 |
| 6027      | Dual-Method Use and Factors Associated with STDs among Family Planning Clients.....  | 45 |
| 6029      | Feasibility of Female Condom Reuse .....   | 48 |
| 6030      | Evaluation of the Uniject Syringe and Depo-Provera® .....  | 54 |
| 6204      | Risk of Short-term Complications with IUD Use and HIV.....   | 67 |
| 6205      | Copper IUD Use and Tubal Infertility.....  | 61 |
| 6216      | Benefits and Risks of OC Use.....  | 60 |
| 6217      | Study to Measure the Contraceptive Efficacy of Condoms and Vaginal Contraceptive Film Using a New Methodology.....               | 73 |
| 6287      | Vasectomy and Prostate Cancer in Korea .....   | 62 |
| 6308/6477 | Female Condom Use and Risk of STD/Kenya.....   | 68 |
| 6311/6901 | Hormonal Contraceptive Use, Cervical Ectopy and Cervical Infections.....   | 69 |
| 6312      | Technical Guidance Working Group (TGWG).....   | 70 |
| 6313      | Dual-Method Use and Factors Associated with STDs among Family Planning Clients.....  | 46 |
| 6314      | Female Condom Demand Assessment .....  | 50 |
| 6315      | Latex Condoms Performance in Human Use.....  | 52 |
| 6352      | Reproductive Health Paper Writing .....  | 71 |
| 6381      | Impact of Menstrual Disturbance on Contraceptive Use.....  | 55 |
| 6382      | Compliance Strategy .....  | 58 |
| 6383      | Teen DMPA Bone Pilot Study .....   | 64 |
| 6384      | Multiple Use Assessments of the Reality Female Condom .....  | 49 |
| 6385      | Monograph on Latex Condoms.....  | 51 |
| 6473      | Oral Contraceptive Compliance among PROSALUD Clients .....   | 59 |
| 6475      | Contraceptive Service Provision in a STD Clinic - An Opportunistic Service?.....   | 47 |
| 6476      | Vaginal Foaming Tablet User Dynamic Study.....   | 56 |
| 6478      | Method Mix Modeling .....  | 65 |
| 6479      | Symposium on Long-term Safety of Hormonal Methods .....  | 66 |
| 6701      | Qualitative Study of the Acceptability of Reversible Contraceptive Methods.....  | 57 |
| 6900      | Case Control Study of Vasectomy and Prostate Cancer .....  | 63 |

## 7000s - FIELD OPERATIONS

|      |                                |    |
|------|--------------------------------|----|
| 7095 | Cairo Office .....             | 78 |
| 7096 | Kenya: FHI Nairobi Office..... | 79 |
| 7403 | Nepal Country Activities ..... | 80 |
| 7405 | Bolivia Field Office.....      | 81 |

## 8000s - PRODUCT QUALITY AND COMPLIANCE

|      |  |     |
|------|--|-----|
| 8011 | Contraceptive Field Stock Evaluations.....           | 136 |
| 8015 | Production Surveillance - Condoms.....               | 137 |
| 8016 | PATH - Condom Research Activities .....              | 138 |
| 8017 | Production Surveillance - Other Contraceptives ..... | 139 |
| 8028 | Condom Package Integrity Study.....                  | 140 |
| 8029 | Laboratory Monitoring - Condoms.....                 | 141 |

**9100s - BIostatistics**

|      |   |    |
|------|---|----|
| 9102 | Biostatistics Paper Writing .....   | 38 |
| 9103 | Comparative Evaluation of Three Tactylon Condoms with a Latex Condom During Vaginal Intercourse: Breakage and Slippage..... | 39 |
| 9104 | Emergency Contraception Meeting.....  | 40 |

**9300s/9700s - SERVICE DELIVERY RESEARCH**

|          |  |     |
|----------|--|-----|
| 9304     | Service Delivery Research Paper Writing.....   | 133 |
| 9343     | Comparison of Methodologies for Measuring Staff Time Used to Provide Reproductive Health Services..... | 126 |
| 9344     | Improving Services for Menstruating Clients .....  | 110 |
| 9345     | A Study to Determine the Acceptability of Long-acting Progestin Methods.....                           | 120 |
| 9346     | Method Choice.....   | 111 |
| 93xx/TBD | Costs and Quality of Care.....   | 132 |
| 93xx/TBD | Efficient Provision of Contraceptive Methods in Follow-up Visits .....                                 | 119 |
| 9400     | Calculating Direct Costs of Family Planning Services .....   | 127 |
| 9402     | PROSALUD Quality of Care Assessment.....   | 112 |
| 9417     | The Impact of Family Planning Service Delivery Guidelines .....  | 113 |
| 9424     | Method Specific Costs of Family.....   | 128 |
| 9440     | Improvement & Expansion of Family Planning Services/Ethiopia.....                                      | 114 |
| 9446     | IUD Provision by IMSS Midwives.....  | 121 |
| 9448     | Price Elasticity of Demand for Reproductive Health Care .....  | 129 |
| 9449     | FEMAP Contraceptive Method and Service Provision.....  | 130 |
| 9450     | Assessment of Impact of the Family Planning Options Project .....                                      | 122 |
| 9451     | Factors Affecting Continuation Rates of Hormonal Methods.....  | 115 |
| 9452     | A Study to Determine the Quality of Norplant Provision in Dakar.....                                   | 123 |
| 9453     | Identifying Ways to Improve Family Life Education (FLE) Programs.....                                  | 117 |
| 9454     | Users' Perspective on Methods and Services .....   | 124 |
| 9455     | Secondary Analysis of Public Sector and NGO QOC Study.....   | 118 |
| 9457     | Costs of Extending Family Planning Services to Indigenous Populations .....                            | 125 |
| 9720     | Maximizing Access to Reproductive Health Care in Sucre, Bolivia .....                                  | 116 |
| 9731     | Family Planning Finance Strategy .....   | 131 |