



**Contraceptive and Reproductive Health
Technologies Research
and
Utilization Program**

July 1, 2008 - June 30, 2009

Annual Report

and

July 1, 2009 – April 28, 2010

Workplan

**Cooperative Agreement
GPO-A-00-05-00022-00**

Submitted to:
Office of Population and Reproductive Health
Research Technology and Utilization Division
United States Agency for International Development



ANNUAL REPORT
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Submitted to:
Office of Population, Research Technologies Unit
United States Agency for International Development

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ACRONYM LIST

A

ABC	-	Abstinence, Be Faithful - Condoms
ACASI	-	Audio Computer Assisted Self-interviewing
ADDO	-	Accredited Drug Delivery Outlets
AEs	-	Adverse Events
AMKENI	-	FHI subproject (from a Swahili word meaning coming together)
AMREF	-	African Medical and Research Foundation
APHA	-	American Public Health Association
APHIA	-	Population and Health Integrated Assistance Project
APROFAM	-	Asociación Pro-Bienestar de la Familia (Guatemala)
ARH	-	Adolescent Reproductive Health
ARHP	-	Association of Reproductive Health Professionals
ART	-	Antiretroviral Therapy
ARV	-	Antiretroviral
ASTM	-	American Society for Testing Materials

B

BASS	-	Behavioral and Social Sciences (FHI Group)
BCC	-	Behavior Change and Communication
BG	-	Buffer Gel
BIOS	-	Biostatistics (FHI group)
BMC	-	BioMed Central

C

CAs	-	Cooperating Agencies
CBD	-	Community Based Distribution
CCC	-	Comprehensive Care Centers
CCP	-	Central Contraceptive Procurement
CDC	-	Centers for Disease Control
CEMICAMP	-	Center for Mothers and Infants (Brazil)
CFHC	-	California Family Health Council
COC	-	Combined Oral Contraceptive
CONRAD	-	Contraceptive Research and Development Program
CRD	-	Clinical Research Department (FHI Group)
CRF	-	Case Report Form
CRTU	-	Contraceptive and Reproductive Health Technologies Research and Utilization Program
CS	-	Cellulose Sulfate
CSL	-	Commodities, Securities and Logistics

- CT - Chlamydia Trichomatis
- CTR - Contraceptive Technology and Family Planning Research
- CTU - Contraceptive Technology Update
- CV - Contingent Valuation

D

- DAIDS - Division of Acquired Immunodeficiency Syndrome
- DCFs - Data Collection Forms
- DFID - Department for International Development
- DMC - Data Monitoring Committee
- DMPA - Depot Medroxyprogesterone Acetate
- DOH - Department of Health
- DP - Dual Protection
- DRH - Division of Reproductive Health (Kenya MOH)
- DSMB - Data Safety Monitoring Board

E

- ECP - Emergency Contraceptive Pills
- EIS - Electronic Information System
- ERC - Ethics Review Committee (Ethiopia)
- ESA - East South Africa
- EVMS - Eastern Virginia Medical School

F

- FC - Female Condom
- FCO - Final Cost Objective
- FGD - Focus Group Discussion
- FHI - Family Health International
- FITS - Field, Information and Training Programs (FHI group formerly PRU)
- FP - Family Planning
- FPAK - Family Planning Association of Kenya
- FPAU - Family Planning Association of Uganda
- FTF - Face-to-Face

G

- GC - Gonorrhea
- GCP - Good Clinical Practices
- GLP - Good Laboratory Practice
- GMP - Good Manufacturing Practices
- GTZ - German Technical Cooperation

H

- HBC - Home Based Care
- HC - Hormonal Contraceptive
- HIPNET - Health Information and Publications Network
- HIV - Human Immunodeficiency Virus
- HMSC - Health Ministry Steering Committee (India)
- HSR - Health Services Research (FHI group)
- HSV - Herpes Simplex Virus

I

- IBP - Implementing Best Practices
- ICMR - Indian Council of Medical Research
- IDE - Investigational Device Exemption
- IEC - Information, Education and Communication
- IMCL - Immunological Markers of Chlamydial Infections
- IND - Investigational New Drug Exemption
- INTRAH - Program for International Training and Health
- IPPF - International Planned Parenthood Federation
- IRB - Institutional Review Board
- ISO - International Standards Organization
- IT - Information Technology (FHI Group)
- IUD - Intrauterine Device

J

- JHPIEGO - Johns Hopkins Program for International Education in Reproductive Health
- JHU - Johns Hopkins University
- JHU/CCP - Johns Hopkins University/Center for Communication Programs
- JSI - John Snow International
- JWG - Joint Working Group

K

- KATH - Komfo Anoky Teaching Hospital
- KZN - KwaZulu Natal

L

- LNG - Levonorgestrel
- LOI - Letter of Intent

M

- M&E - Monitoring and Evaluation
- MAQ - Maximizing Access and Quality
- MOH - Ministry of Health
- MOU - Memorandum of Understanding
- MRC - Medical Research Council (South Africa)
- MSH - Management Sciences for Health

N

- N-9 - Nonoxynol-9
- NAFDAC - National Agency for Food and Drug Control (Nigeria)
- NARI - National AIDS Research Institute
- NASCOP - National AIDS & STDs Control Program
- NDOH - National Department of Health (South Africa)
- NGO - Nongovernmental Organization
- NIAID - National Institute for Allergic and Infectious Diseases (NIH)
- NICHD - National Institute of Child Health & Human Development
- NIH - National Institutes of Health
- NIMR - Nigerian Institute of Medical Research
- NMIMR - Noguchi Memorial Institute for Medical Research (Ghana)

O

- OCs - Oral Contraceptives
- OD - Organizational Development
- OVC - Orphans and Vulnerable Children

P

- PAHO - Pan American Health Organization
- PATH - Program for Appropriate Technology for Health
- PEPFAR - President's Emergency Plan for AIDS Relief
- PHSC - Protection of Human Subjects Committee (FHI's IRB)
- PI - Principal Investigator
- PLA - Participatory Learning and Action
- PLWHA/PLHA - Person Living with HIV/AIDS
- PMA - Premarket Approval Application
- PMTCT - Prevention of Mother to Child Transmission
- PQC - Product Quality and Compliance (FHI group)
- PSA - Prostate-Specific Antigen/Project Support Association (S. Africa)
- PSI - Population Services International
- PSP-One - Private Sector Partnerships – One (PSP-One)
- PVO - Private Voluntary Organization

Q

- QA - Quality Assurance

R

- RA/QA - Regulatory Affairs and Quality Assurance (FHI group)
- RCT - Randomized Controlled Trial
- RETC - Research Ethics Training Curriculum
- RFA - Request for Application
- RFSU - Swedish Institute for Sexuality Education
- RH - Reproductive Health
- RHR - Department of Reproductive Health and Research
- RTI - Reproductive Tract Infection

S

- SA - South Africa
- SAGO - Society of African Gynecologists and Obstetricians (Senegal)
- SC - Save the Children
- SDM - Standard Days Method
- SOP - Standard Operating Procedures
- SOTA - State Of The Art
- SRM - Sexual and Reproductive Method
- STC - Society for Technical Communication
- STD - Sexually Transmitted Disease
- STI - Sexually Transmitted Infections

T

- TA - Technical Assistance
- TBD - To Be Determined
- TOC - Technical Oversight Committee
- TOT - Training of Trainers

U

- UNC - University of North Carolina
- UNFPA - United National Population Fund
- USAID - U.S. Agency for International Development
- USFDA - U.S. Food and Drug Administration

V

- VA - Virtual Access (Ghana)
- VCT - Voluntary Counseling and Testing

W

- WHO - World Health Organization

GLOSSARY

The following table provides key terms that are used in the individual subproject reports:

Collaborating Agency:	A USAID cooperating agency (CAs), a private or governmental group, or a nongovernmental organization (NGO) with which FHI is working in partnership. Such agencies provide additional technical or financial support to the subproject (e.g. providing related training or funding local costs). CAs that fund FHI directly for an effort are cited as the funding source, not as a “collaborating agency” on the subproject.
Final Cost Objective (FCO):	The accounting number assigned by FHI’s Contracts and Grants Office. It indicates a specific source of funding for a particular subproject. This is the key unit for all financial reports.
Subgrantee:	Institution(s) or organization(s) designated by FHI as responsible for executing some or all of the activities described in the subproject. A Subagreement generally exists between FHI and the named party. In past FHI reports, the term “implementing agency” was used in the same manner.
Subproject:	An activity within the Cooperative Agreement that has specific objectives and outputs. A subproject is generally related to only one FCO number. Multiple FCO numbers are necessary, however, if multiple funding sources are involved. Examples of subprojects are individual clinical trials, survey research studies, workshops or training efforts, major publications and regulatory or management support.
Total Approved Budget:	The most recently approved life-of-FCO or life-of-subproject budget. A subproject’s total budget may be supported by one or more FCOs, depending on the number of funding sources. Subprojects often span more than one fiscal year. Therefore, a subproject’s total approved budget figure is likely to be greater than the budget cited for any one year.

INTRODUCTION

The Contraceptive and Reproductive Health Technologies Research and Utilization (CRTU) Program is a five-year cooperative agreement between USAID and Family Health International (FHI). This agreement, awarded on April 29, 2005, builds on more than 35 years of FHI's experience and accomplishments in contraceptive technology and reproductive health research to advance and support USAID's family planning and reproductive health programs worldwide. The purpose of this cooperative agreement is to increase the range of available choices and the use of safe, effective, acceptable, and affordable contraceptive methods and reproductive health technologies, including microbicides, delivered through high-quality family planning and reproductive health services in developing countries.

This Annual Report provides a comprehensive picture of 163 subprojects that were fully or partially funded by the CRTU for the July 1, 2008–June 30, 2009 (Year 4) reporting period. Sixteen of these were new subprojects and began implementation during this period.

FHI's Institutional Capacity and Networks for Management of the CRTU Program

FHI is dedicated to improving lives, knowledge and understanding worldwide through a diversified program of research in family health. FHI has forged an alliance with US-based non-profit organizations active within the international arena, as well as with country-based and government entities, to facilitate achievement of our mission. This section provides some highlights of our achievements in these important areas of work.

Strategic Partnerships

Partnerships are an essential component of FHI's work under the CRTU. We have longstanding, well-established partnerships with many organizations and, while we continually seek to maintain and strengthen these, we also continue to try to foster new partnerships. At the initiation of the CRTU, FHI defined specific collaborations through Memorandum of Understanding (MOU) with eight organizations: CONRAD, EngenderHealth's ACQUIRE Project, JHU/CCP's INFO Project, Management Sciences for Health (MSH), Program for Appropriate Technology in Health (PATH), Population Council, Save the Children USA, and Adventist Development Relief Agency (ADRA).

Year One of the CRTU focused on establishing internal systems for managing, monitoring, and documenting MOU partner activities. FHI assigned an institutional point person for each MOU partner, and he or she was tasked with managing the various aspects of the MOU relationship, including documenting ongoing activities, soliciting MOU partner input into FHI's Priority Setting Process, and introducing new ideas or opportunities with the MOU partner.

In Year Two of the CRTU, FHI focused its efforts on developing and strengthening Implementation Plans with each MOU partner. These implementation plans outline specific activities FHI and the MOU partner will undertake each year under the MOU agreement. These implementation plans differ greatly, depending on the nature of the partnership, opportunities and mutual benefits, and research and research utilization goals. By mutual agreement a formal MOU agreement between FHI and ADRA was dissolved in December 2006. Notably, however, despite the lack of an MOU, FHI has continued to work with ADRA on several field-based activities.

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In Year Three of the CRTU, FHI upheld a commitment made at the start of the agreement to create partnerships with at least two innovative or nontraditional partners during the course of the project. In late 2007 and early 2008, we signed new MOUs with the Child Survival and Technical Support Plus Project (CSTS+), managed by Macro International and the Extending Service Delivery Project (ESD), led by Pathfinder International. Both partnerships are intended to strengthen the CRTU's capacity in and impact on service delivery. FHI also renewed older and formalized new partnerships with the International Best Practices Initiative and the Institute of Reproductive Health (IRH) at Georgetown, and is now engaged in on-going activities with both.

In Year Four, the CRTU had over 40 on-going subprojects that directly involved an MOU partner. New activities reflected collaboration at both the field and headquarters level. During Year Four an internal assessment of the partnership process was conducted in preparation for the CRTU Research Utilization Assessment. Lessons learned from this assessment included:

- Partnerships require time and effort;
- Every partnership is different;
- Careful assessment of the prospective partners' capacities and complementarities can help ensure that appropriate partnerships are formed;
- Efforts should be made to ensure that the terms of the partnership are fully understood and accepted by both parties before formalizing it;
- Ensure the existence of adequate financial and human resources to support the partnership from the start;
- More opportunities with bilateral partnerships should be considered; and
- Creativity, flexibility, goodwill, and shared vision can help overcome seemingly insurmountable obstacles.

In Year Five, deliberate efforts are being made to transition the partnerships beyond formal MOU agreements at the close of the CRTU. Activities with partners who have also recently closed out a cooperative agreement (EngenderHealth, INFO Project, CSTS+) will continue. FHI will manage relationships and embark on collaborative activities with these organizations via RESPOND, Knowledge for Health, and PROGRESS. We anticipate that staff will strive to apply lessons learned from the Year Four Assessment to the facilitation of these relationships going forward.

Country Programs

In an effort to affect change at the country level and improve the health status of individuals, FHI has focused resources and activities in several enhanced country programs under the CRTU. A number of criteria, including contraceptive prevalence, unmet need, USAID's country priorities, and FHI in-country presence served as a starting point for country selection. Ultimately, the focus, or enhanced, country program, was introduced in four Tier 1 countries (Kenya, Uganda, Madagascar and South Africa --in the latter for HIV/FP integration work only). Three Tier 2 countries were subsequently added (India, Nigeria and Tanzania). Tier 1 countries have a greater level of commitment to the CRTU from the MOH and the USAID mission, and expectations for program impact are greater.

Working side-by side with local implementing partners and decision-makers, the in-country staff of the enhanced country program provides dedicated advocacy, technical leadership, and capacity building within the local context, which FHI would not be able to achieve out of North Carolina alone. As detailed in the individual enhanced country program reports, each of the Tier 1 Countries has succeeded in securing additional field support-population and/or field support PEPFAR funds for CRTU activities.

During this reporting year, CRTU activities in Madagascar came to a somewhat abrupt end as a result of an overthrow of the seated government of Madagascar and the US government's subsequent decision to suspend all aid activities that work through or benefit the government of Madagascar. Even before FHI opened a small Madagascar office in February 2007, the CRTU program had become engaged in a number of research activities and during our time working in-country the program had seen many successes. These included research with partners that showed DPMA could be safely and effectively delivered by CBD agents, the initiation of scale-up of that practice to a national program; the Best Practices Package in Reproductive Health in Madagascar – particularly the systematic screening tool and pregnancy checklist; and the Mini-university where best practices were disseminated widely to the government program, other cooperating agencies and NGOs working in Madagascar. Additional initiatives working with IRH on Standard Days Method introduction and on postpartum family planning had to cease with the curtailment of U.S. government. The CRTU program transferred remaining funding to the PROGRESS Project, effective June 30, 2009; ultimately even PROGRESS had to cease their activities and the office was formally closed on September 30, 2009.

Discussion of CRTU Strategy Areas

The CRTU program, aims to achieve three intermediate results:

- Improved and new contraceptive and reproductive health technologies developed, evaluated and approved;
- Microbicides and microbicides/spermicides developed, evaluated and approved; and
- Use of contraceptives, microbicides and reproductive health technologies optimized and expanded.

To achieve these intermediate results, the CRTU program has been designed with six technical strategies that function to guide the selection and implementation of CRTU activities:

- Barrier Methods (Male and Female)
- HIV/AIDS and Contraceptive Services
- Hormonal Methods
- Long Acting and Permanent Methods
- Microbicides; and
- Youth

The technical strategies establish research and research utilization priorities, and set forth outcomes to be achieved by the end of the cooperative agreement. These priorities and outcomes are the basis for the CRTU monitoring and evaluation plan.

A seventh category of cross-cutting activities supports the 'research to practice' agenda, including a "focused" effort to achieve impact in a few selected countries where the CRTU concentrates resources. This category also includes activities that address global leadership, those that may address multiple strategy areas at once, and that address overarching needs of the CRTU such as monitoring and evaluation and regulatory oversight and quality assurance of our research.

Organization of This Report

Highlights of the CRTU Program, July 2008 – June 2009

This section provides a brief overview of the major areas of investment and selected accomplishments of the CRTU Agreement during the July 2008 to June 2009 reporting year. This section also graphically depicts geographic coverage, fiscal trends and strategic focus over the reporting year.

Subprojects' Annual Reports and Workplans

The main body of this report consists of subproject descriptions summarizing all of FHI/NC's program accomplishments (July 2008 – June 2009) under the CRTU Cooperative Agreement, as well as plans for the July 2009-April 2010 period for all new and on-going activities. This report is organized by strategy headings. Within the strategy areas, an effort has been made to group subproject reports in a logical order so those that address similar or sequential objectives appear together. Each subproject description provided in this report includes information on objectives, funding source(s) and total approved budget.

Financial Information

Financial information for all CRTU-funded activities is provided using FHI's internal accounting number, or FCO. Expenditures by FCO, for July 1, 2008 – June 30, 2009 are presented in the Financial Information section. There is also a Workplan budget, by FCO, for the reporting year July 1, 2009 – April 28, 2010.

Reference Information

Appendix A includes a list of the 40 articles and other writings published between July 2008 – June 2009 with full or partial support of either the CTR or CRTU Program.

Appendix B provides a listing of the subprojects by their region and country, along with the relevant FCO information. This is useful for anyone specifically interested in what work is being done under the CRTU in a particular country or region.

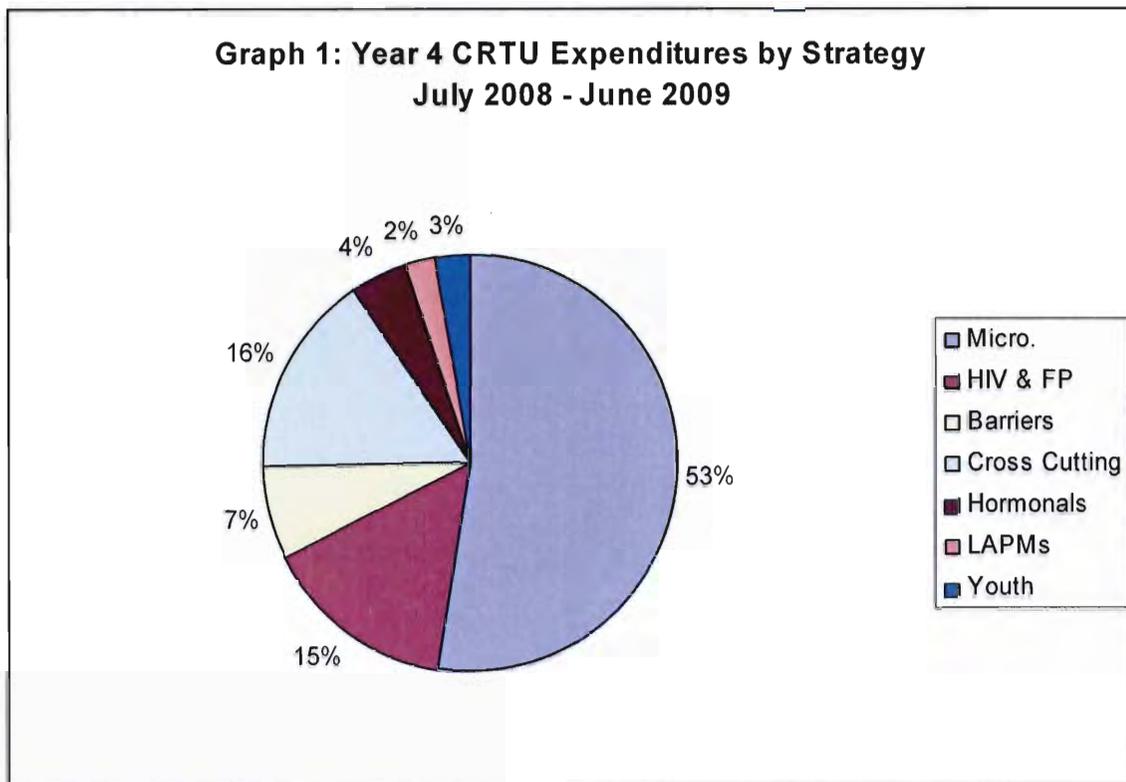
Appendix C contains the rosters of FHI's Product Quality and Compliance Technical Oversight Committee and that of FHI's Board. The work of both is essential to the successful implementation of our program.

Highlights of the CRTU Program, July 2008 – June 2009

Expenditures by Strategy

Graph 1 highlights the areas for strategic investment of all CRTU funds, including core, designated core, field support-population funds, PEPFAR, commodities securities and logistics (CSL) and interagency agreements. The total amount of all CRTU expenditures was \$41,422,001 USD.

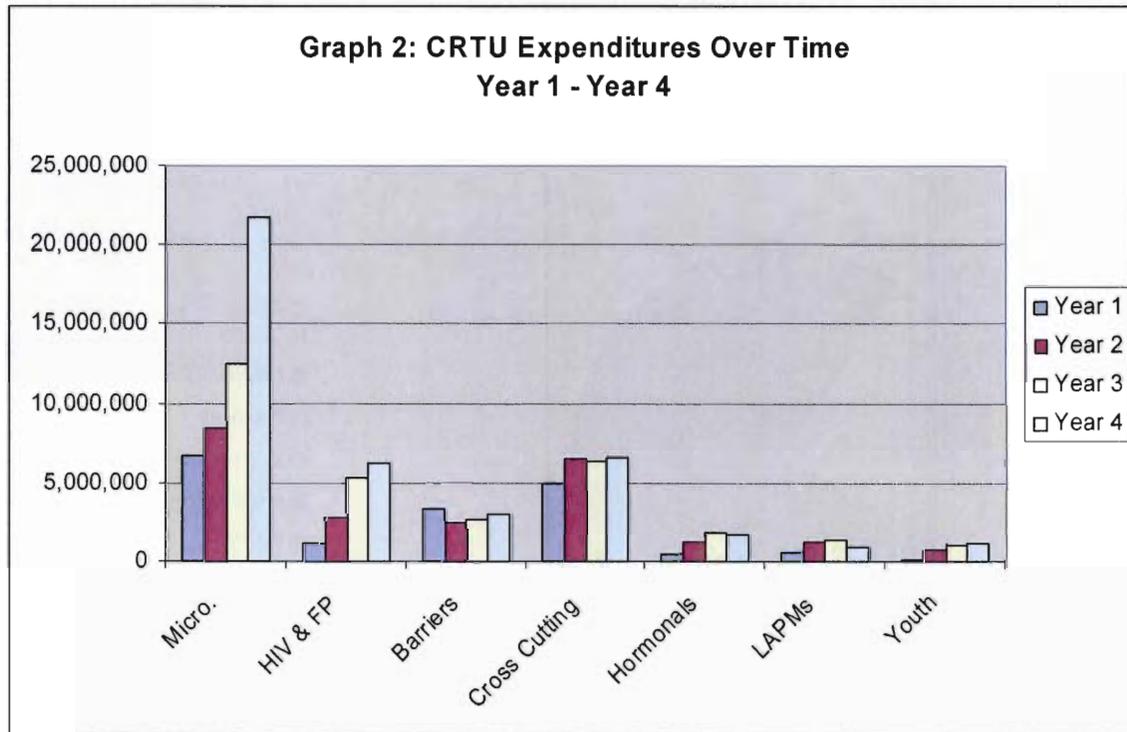
The graph shows that microbicides has received by far the highest level of investment among the CRTU strategy areas accounting for 53 percent of total expenses. This figure represents the trend seen in previous years, in which the microbicides share of overall CRTU expenditures rose from 35 percent in Year 2 to 40 percent in Year 3. Microbicide spending rose largely because of site identification efforts being ramped up and the large FemPrep (previously called Truvada) trial beginning in early 2009.



The next highest area of investment is the cross-cutting area. This area’s proportion of CRTU funds has decreased from 27 percent in Year Two, to 21 percent in Year Three, and finally to 16 percent in Year Four. Despite the decline in this area’s overall share of CRTU expenditures, the total amount spent in the cross-cutting area actually increased in Year Four. Cross-cutting is not strictly speaking a strategy area, but the research-to-practice subprojects that cut across all the various contraceptive methods—as well as the focus country programs- in addition to some CSL work. Because they facilitate and enhance all other CRTU activities, they help to ensure, both individually and collectively, that impact is realized.

Subprojects affiliated with the HIV/AIDS and Contraceptive Services strategy accounted for 15 percent of the total investment, a minor decrease from 16 percent in the previous reporting year. Despite this, Graph 2 below demonstrates how expenditures devoted to the HIV/AIDS and Contraceptive services have steadily increased since Year 1. In the past year, HIV and Contraceptives Services expenditures rose by 19%, even while the proportion that these expenses contributed to the overall CRTU expenses declined slightly. The prioritization of the strategy area has consistently grown since its introduction to FHI’s portfolio of work in 2002. An increased focus on Microbicides has played a part in the rising interest in HIV/AIDS and Contraceptive Services.

Barriers, is the fourth largest strategy area of investment at 7 percent of expenditures. This figure has steadily declined over the years, affected by the steadily increasing focus on alternative strategies and microbicides and HIV/AIDS and Contraceptive Services. The other areas of investment include Hormonals, Youth and LAPMs at 4 percent, 3 percent, and 2 percent, respectively.



Subprojects by Geographic Region

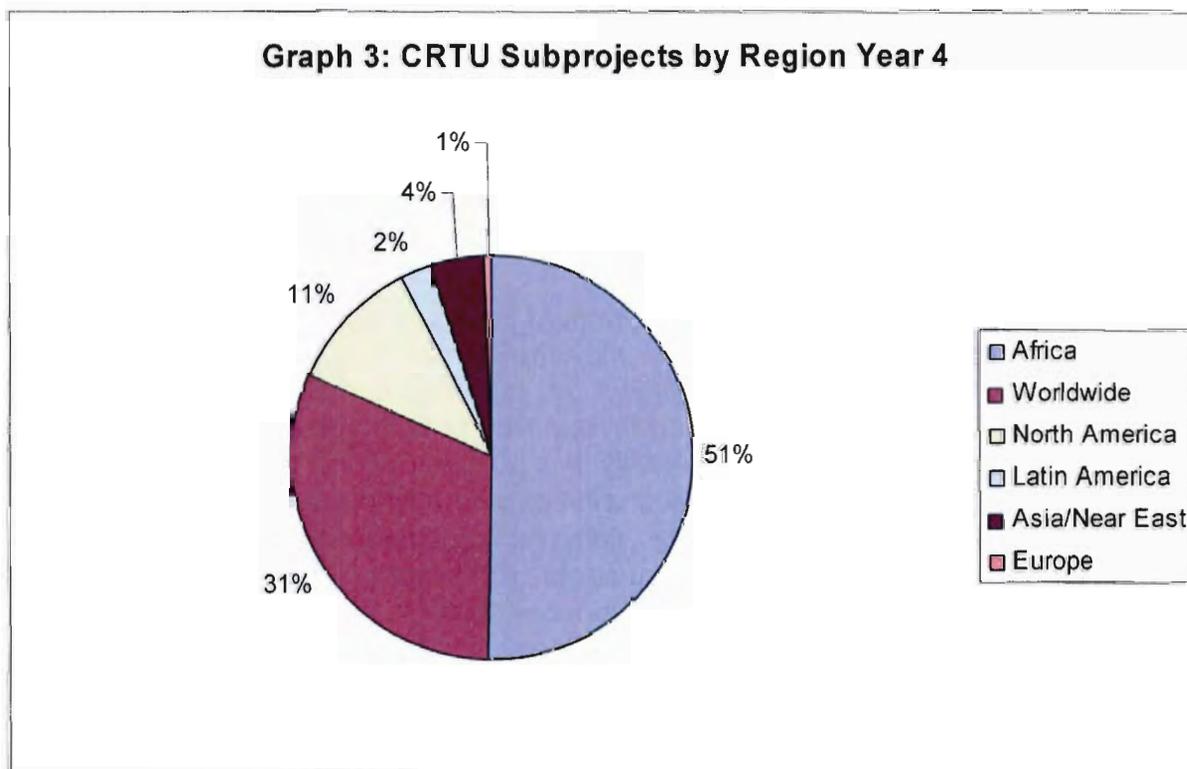
The geographic distribution of FHI’s Contraceptive and Reproductive Health Technologies and Research Utilization Program between July 1, 2008 and June 30, 2009 is reflected in Graph 3 below.

This graph illustrates that most CRTU-funded subprojects (51 percent) are implemented in Africa. With our focus country program work targeting areas with the greatest need, it is not surprising that such a large proportion of CRTU activities are located in this region. It also reflects the increase in PEPFAR and field support- population funds being provided to the CRTU by USAID’s country programs in Africa.

The next highest proportion of activities (31 percent) is said to have worldwide focus, rather than a region-specific one. Most, if not, all of these global activities likely have significance to Africa’s family planning and reproductive health programs as well. Included in the “worldwide” definition are research studies conducted across multiple countries as well as subprojects that have a global technical leadership objective.

The graph indicates a marginal and decreasing proportion (11 percent) of North American-based activities. Activities are instituted in the North American region for primarily two reasons: 1) most of the numerous subprojects involving statistics and data management support provided by FHI to CONRAD are included in the count of North American-based subprojects and 2) some of the efforts that involve research synthesis are conducted entirely by FHI's headquarters in North Carolina and hence fall into the North America region.

The proportion of subprojects in Asia/Near East and Latin America continues to remain low under the CRTU, reflecting, in part, the decreasing number of countries in these regions that receive USAID population-related funding. Of the two regions, Asia/Near East has seen an increase in funding due to increase work in India, now a Tier Two focus country. Lastly, FHI's subprojects in Europe is now limited to collaborations with WHO.



Key CRTU Results 2008-2009

The key results for the 2008-2009 reporting period are provided below, according to USAID's own intermediate results. Those pertaining to family planning are presented first; those pertaining to microbicides follow.

IR 1.0: Global leadership demonstrated in FP/RH policy, advocacy, and services

a) Experts support community-based access to injectable contraceptives

In an effort to inform future policies and programs, the World Health Organization (WHO), USAID, and Family Health International convened a Technical Consultation on Expanding Access to Injectable Contraception, held at WHO in Geneva in June 2009. At the consultation, 30 technical and program experts reviewed the evidence and experiences from programs designed to expand access to injectable contraceptives through service provision by community health workers.

The consultation concluded that there is sufficient evidence to support the introduction, continuation, and scale-up of community-based provision of progestin-only injectable contraception. A report of the consultation will contain more specific conclusions from the evidence review, as well as policy implications, programmatic guidance, and research priorities. It will be published and disseminated widely in late 2009. The CRTU and PROGRESS Projects worked together on this effort. (CRTU FCO 113108)

b) Stakeholder analysis and targeted mailings help make FP no longer a “best kept secret” in HIV prevention

Until very recently family planning was often referred to as the "best kept secret in HIV/AIDS prevention". FHI undertook a concerted effort to raise the profile of family planning by first conducting a systematic criteria-based stakeholder analysis, including PubMed and internet searches, and analyses of conference presentations, grants, and programs to identify the 400+ key stakeholders who have the most direct impact on HIV/AIDS research, policies, programs, or services. In the spring of 2009, all 400+ stakeholders received letters with key messages for FP/HIV and a link to or copy of the CD-Rom Toolkit "Increasing Access to Contraception for Clients with HIV". Additionally, 55 individuals prioritized as having a significant amount of global influence were sent tailored letters from FHI's President for Research offering highly personalized suggestions for ways that they could strengthen or promote FP/HIV linkages. This "Tipping Point Project" aims to influence the behavior of enough opinion leaders such that inclusion of family planning into PMTCT programs and broader HIV prevention programs becomes the norm rather than the exception. (FCO 113131)

c) Professionals convened to address the needs of young people most at risk of HIV
Representatives from USAID, the World Health Organization, the United Nations, and several youth-serving nongovernmental organizations presented at a June 2009 meeting of the Interagency Youth Working Group (IYWG). Nearly 100 professionals in the field of youth sexual and reproductive health gathered in Washington, DC, to discuss young people most at risk for HIV/AIDS. Panels of experts addressed the unique needs of adolescent sex workers, men who have sex with men, and injecting drug users. Highlights of the meeting included presentations about successful programs that work with these vulnerable populations, information-sharing about best practices, and a review of recent research on most-at-risk youth. The IYWG was formed in 2006, and provides global technical leadership to advance the reproductive health and HIV/AIDS outcomes of young people in developing countries.
(FCOs 183001, 113143)

d) Needs assessment results inform the development of a medical male circumcision (MCC) policy in Uganda

Male circumcision has been shown to offer some protection against HIV/AIDS. It may also offer a unique opportunity to engage men more broadly in reproductive health. A situation analysis, conducted with PEPFAR funding under the CRTU, showed a high level of acceptability for MMC among women and men in Uganda. Using guidelines proposed in the WHO document, "Male Circumcision Situation Analysis Toolkit", strategic information was gathered at the policy, program design, service delivery, community, and client levels regarding male circumcision. A final report was produced in November 2008. The national MMC task force, chaired by the Ministry of Health, accepted the findings of the national needs assessment in April 2009 and will use them in the development of a national MMC policy. (with PEPFAR funding, FCOs 156101, 156102)

e) New FP/HIV Integration Working Group Formed in Tanzania and funds leveraged for a RH/HIV assessment

In November 2008, a USAID-supported meeting in Dar es Salaam was held to launch a new Tanzania Ministry of Health technical working group for the integration of family planning and HIV services. The National AIDS Control Program (NACP) and the Reproductive and Child Health Services units of the MOH are co-chairs, while FHI is serving in the secretariat role for 2009-10.

The WHO Sexual Reproductive Health and HIV representative attended the launch and subsequently identified Tanzania as a country for the WHO project, Rapid Assessment of RH/HIV Linkages. In April 2009 an agreement was reached with WHO-Geneva to provide \$32,000 to FHI's Tanzania office to conduct a national Rapid Assessment of SRH/HIV Linkages. (FCOs 113131, 113113)

IR 2.0: Knowledge generated, organized, and communicated in response to program needs

a) Publications in *Sexually Transmitted Infections* summarize FP as a reliable and cost-effective way to reduce mother-to-child transmission of HIV

Scientists from Family Health International analyzed data from the 15 countries that receive funds from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). The results, reported in an October 2008 issue of the journal *Sexually Transmitted Infections*, demonstrate that even though contraceptive use is relatively uncommon in most PEPFAR countries, it prevents hundreds of thousands of HIV-positive births each year by preventing unintended pregnancies in infected women. The scientists also reported that using contraception to prevent an unintended pregnancy in an HIV-positive woman is significantly less expensive than giving an infant a single dose of nevirapine (a drug commonly given to prevent HIV in a child born to an infected woman). The savings that could be realized as a result of this approach in South Africa, for example, would be more than U.S. \$2.2 million. (FCO 113104)

b) A five-country study on FP-HIV integration reveals obstacles to be addressed

Findings from an FHI study of FP-HIV integration in five countries revealed significant challenges exist to offering integrated services, particularly related to provider training, misconceptions about FP use by HIV-positive women, and lack of tools to guide their work. Results of the study were presented to USAID's Integration Working Group in October 2008. (FCO 114124, 124106)

c) Job aid for re-injection for DMPA and NET-EN clients developed, tested, found effective

A new re-injection job aid for providers of DMPA and NET-EN FHI was developed and evaluated by FHI. The impetus for this work was a USAID-supported study, which found that DMPA and NET-EN clients in South Africa were often turned away if they were late for a scheduled re-injection—even if they fell within the approved grace period. An evaluation of the job aid showed that it made a significant difference with a 70% versus 97% re-injection rate in the control and intervention clinics, respectively. In July and August 2009, over 100 providers from four provinces were trained on the new tool. In September 2009, results were shared at a national policy review meeting in South Africa.

d) Job aid for increasing re-injection for DMPA and NET-EN adapted and scaled up

As the re-injection job aid was being evaluated in South Africa, IntraHealth expressed interest in using it in Senegal. In the spring of 2009, a field testing process was initiated in Dakar, Senegal in collaboration with IntraHealth. Twenty-one midwives were trained on the job aid and follow-up interviews were conducted. The feedback received was used to revise the job aid. The re-injection job aid was finalized in September 2009, reflecting the WHO's new recommendations regarding the grace period for DMPA (now a client can have a re-injection if she is up to 2 weeks early or 4 weeks past her scheduled re-injection date without ruling out pregnancy), and co-branded with IntraHealth. Two re-injection job aids are available (in English and French) for providers, one for DMPA and one for NET-EN. In addition, English versions are available specifically for community health workers. (FCO 114102)

e) New national training guidelines and checklists promote LAPMs in Uttar Pradesh

In 2008, the IUD checklist (along with the COC, DMPA, and Pregnancy checklists) developed and tested by FHI, was translated into Hindi and shared with India's State Innovations in Family Planning Services Project Agency (SIFPSA). SIFPSA will reprint and use these checklists in trainings in Uttar Pradesh (UP). In addition, the Hindustan Latex Family Planning Promotion Trust (HLFPPT) has agreed to take all four checklists forward to their Merry Gold/ Silver and Tarang Clinics (private franchisees). HLFPPT has also agreed to reprint and take forward the pregnancy checklist to the 120,000 ASHA's in the state. The checklist has also been disseminated to numerous other organizations involved with providing FP services in India. These include: Perna, Catholic Relief Services, Find Your Feet, Population Research Centre Lucknow University, Department of Social and Preventive Medicine King George Medical University and Family Planning Association India Lucknow Branch, and the UP Voluntary Health Association. (FCO 113132/113136.)

f) A new checklist for screening clients who want to use implants developed

A simple checklist has been developed with support from USAID to help health care providers screen women interested in using contraceptive implants. The checklist will be especially useful as implants continue to become more available around the world. The new checklist is based on recent updates to the World Health Organization's medical eligibility criteria for contraceptive use. It consists of 12 questions that health care providers should ask a woman to determine if implants are medically appropriate for her. (FCO 113114)

g) Postpartum FP protocol becomes part of Uganda's national Minimum Package for PMTCT Services

The National PMTCT Coordinator for the Uganda Ministry of Health (MOH) supported by the CRTU's Network of Champions project and in collaboration with a cadre of rural nurse midwives and the FHI Country Director, developed a postpartum family planning protocol to help prevent maternal-to-child transmission of HIV. The protocol was developed and tested between April and October 2008. The MOH and local technical working groups approved the protocol and it was included in a preliminary training of trainers conducted in the Gombe District in December 2008. Between February and May, FHI, MOH, and District Hospital staff monitored indicators linked to use of the protocol, and determined both that the protocol was acceptable to providers and that there was an increase in postpartum family planning provision in the maternal and postnatal care clinics. The protocol will now be included in Uganda's National Minimum Package for the Prevention of Maternal-to-Child Transmission services. (FCO 113113)

IR 3.0: Support provided to the field to implement effective and sustainable FP/RH programs

a) Standard Days Method shown to be socially and culturally acceptable in Kenyan district

A USAID-supported pilot project introduced the Standard Days Method (SDM) into Ijara district, in Kenya's North Eastern Province and confirmed that the method can attract new contraceptive users. A collaborative effort involving three USAID partners, the pilot study was done in an area where the community generally has not been receptive to modern methods of family planning. This weak support for family planning was evidenced by a 4% contraceptive prevalence in the province, according to preliminary DHS 2008 results. However, in the seven district facilities where health care providers were trained to provide SDM, 254 women accepted the method between January and June 2009. Importantly 92.6% of those adopting SDM had not used a family planning method previously. *(CRTU, FCO 113133; and IRH -core funds; Pathfinder had bilateral support through its role in Kenya's APHIA Project)*

b) South Africa DOE changes policy for school-based peer education

After conducting an assessment of peer educator programs across the country, the South Africa Department of Education (DOE) realized that national guidelines were needed to maintain consistency and standards. FHI, drawing upon its own new peer educator guidelines and in conjunction with USAID/South Africa, helped the DOE to draft the "Guidelines for the implementation of peer education, care and support programmes for learners in South African schools: A guide for programme managers". The DOE has endorsed and branded the guidelines. *(FCOs 183001, 113143)*

c) Training video to build country-based condom testing skills

With USAID funding, the CRTU Program produced a training video entitled "ISO 4074 Condom Testing Methods" in June 2009. FHI has disseminated copies to select country-based testing laboratories. Further dissemination will follow completion of an accompanying training manual, both of which seek to provide "on demand" technical assistance to country programs. *(FCO 118102)*

d) Donor procurement practices addressed through training

With USAID support, WHO Condom Supplier Pre-Qualification Workshops were conducted by FHI in Botswana and South Africa (February 2009) and in Vietnam and Indonesia (March 2009). These workshops, in which WHO also actively participated, serve to improve donor procurement practices and assist in the development of appropriate product specifications for field programs. *(FCO 118101)*

Microbicides tested and informed by new research methodologies

a) FEM-PrEP clinical trial initiates enrollment

The FEM-PrEP clinical trial has made significant gains in of the CRTU. The purpose of the study is to determine the effectiveness and safety of daily Truvada compared with a placebo for HIV prevention among HIV-uninfected women who are at higher risk of becoming HIV infected through sexual intercourse. The study has three components: 1) the clinical trial, 2) the socio-behavioral and ongoing community (SBC) preparedness activities and 3) the pilot intervention planning study for roll-out of Truvada, if found to be safe and effective, initiated in May 2009.

In July 2008 the first training was conducted and on June 11, 2009 the first participant was enrolled in the clinical trial at the Bondo, Kenya site. As of July 7, 2009, there were 227 participants screened and 21 enrolled. In addition, in June 2009 the Pretoria, South Africa site was trained and expected to enroll participants within two months.

b) Site Identification and Development Initiative brings results and is reconfigured

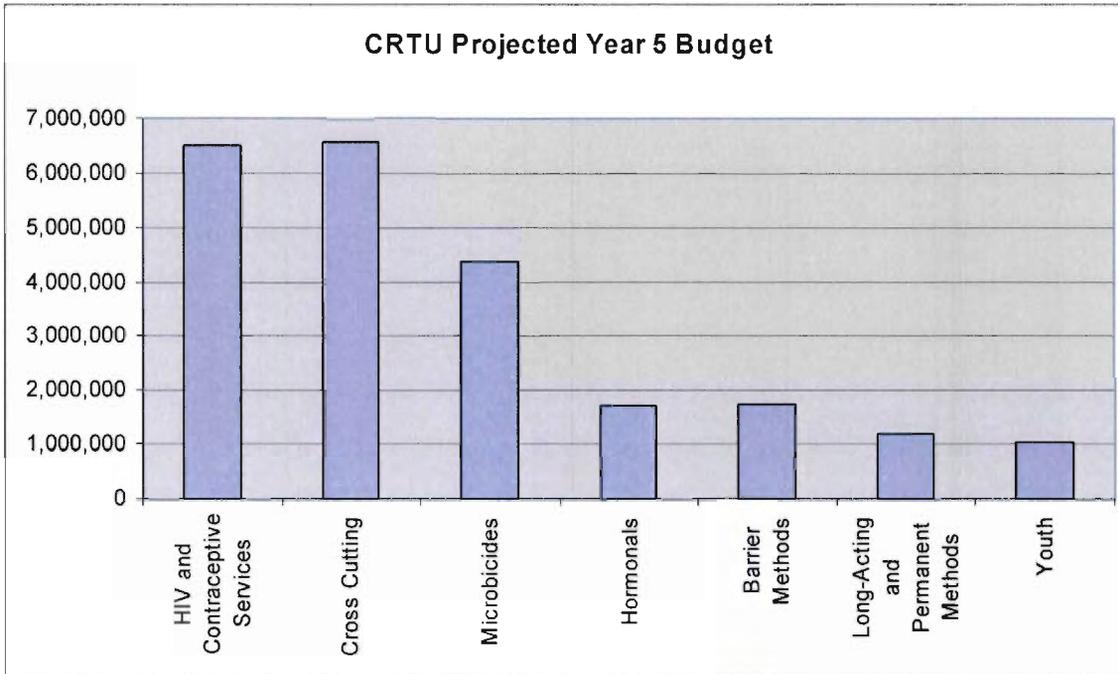
FHI began identifying sites for the Site Identification and Development Initiative in July 2006, the first year of the CRTU. Site assessments took place in 2006 and 2007. In 2008 and 2009, SIDI was in the development and research phase, testing the HIV incidence protocol and conducting behavioral research. These research exercises are answering important questions while at the same time strengthening research and laboratory capacities of the sites. The sites are given significant individual technical support. A challenge in Year Four was reducing expectations and expenditures as the growth of this large subproject could not be sustained. As of the June of 2009, the Vietnam site had a low HIV incidence and a sexual network analysis was ongoing. South Africa – Bloemfontein showed promising performance and is a possible FEM-PrEP site. The Ethiopia, Addis Ababa and Mozambique, Beira sites were ready to start incidence studies. Mozambique, Chokwe was awaiting final approvals. The Multiple Concurrent Partners (MCP) study in Zambia, Ndola continued and the MCP study in Lesotho was completed.

c) CAPRISA trial 004 continued and completed enrollment

The CAPRISA 004 Phase 2b trial to assess the safety & effectiveness of 1% Tenofovir gel for the prevention of HIV infection in SA women continued in Year 4 of the CRTU. This will be the first completed effectiveness trial of an ARV-based topical microbicide, with results expected 2 years before any similar trial. As of January 2009, 2,156 were screened and 1,085 were enrolled. Of these 185 were co-enrolled and thus 900 were eligible, 620 in Vulindlela and 280 Ethekewini. First and interim analyses were conducted in the fourth quarter of 2008 and the second quarter of 2009. The cohort accrual was completed in the first quarter of 2009. The study has seen a 90% retention rate after 12 months and a 94% rate of self reported adherence after last sex act. The study is a collaborative effort between CAPRISA, FHI, CONRAD, Gilead, and LIFElab. FHI is charged with award and project management, monitoring, communications, regulatory, and scientific and statistical support.

Proposed CRTU Activities by Strategy (July 2008 – June 2009)

Graph 4 provides an overview of the CRTU workplan for the 2009-2010 reporting cycle. This graph only includes a projected Microbicides budget until the end of August 2009. From September 2009 forward, the Preventive Technologies Agreement will begin supporting these activities with a total of \$23,157,128 USD. As a result the microbicides strategy will not dominate in the final year of the CRTU Program. Instead the HIV/AIDS and Contraceptive Services strategy and those activities that cut across all strategies, notably information dissemination and research utilization, will share the leading positions in terms of expenditures.



As FHI enters the final phase of the CRTU, the challenge will be to complete all activities that will not be transitioning to another Project and to ensure that the key lessons learned are shared and disseminated so that others can continue to build upon them. An End-of-Project meeting is planned for March 30, 2010 in Washington, DC.

In conclusion, FHI is proud of the accomplishments over the past four years of the CRTU Program and the advancement in research methodologies, provider practices and general knowledge of contraceptive technology and family planning services that this program has provided. The next section of this document includes the individual subproject reports, including accomplishments and workplans, for the 163 subprojects funded under the CRTU Cooperative Agreement, July 1, 2009 – April 28, 2010.

BARRIER METHODS

GOALS	OUTCOMES
<p>I. To bring to market new female barrier methods that are effective for dual protection and are affordable, acceptable, and conducive to widespread uptake and sustained use.</p>	<ul style="list-style-type: none"> A. Female condoms under development evaluated to identify the best candidate, in terms of user acceptability, to be carried forward for safety and effectiveness research. B. At least one lower cost female condom model assessed for safety and effectiveness in accordance with FDA requirements for evidence. C. A new, less expensive female condom submitted to the FDA for marketing approval, if warranted according to the safety and effectiveness findings. D. At least one promising new diaphragm evaluated for contraceptive effectiveness and/or prevention of sexually transmitted infections (STI). Evidence, if favorable, will be used for PMA submission. E. Innovative research methodologies that lower the cost and speed the pace of bringing new products to market developed and validated.
<p>II. To increase the use of existing barrier methods, and other risk reduction behaviors, by achieving greater acceptance on the part of users and service providers.</p>	<ul style="list-style-type: none"> A. Cost and effectiveness of alternative ABC delivery models targeting youth (including communication channels, messages, parental/adult involvement, community support, and collaborating partners) evaluated and applied in at least three countries. B. Training and supervision approaches and job aids that heighten family planning or HIV service providers' capacity to promote barrier methods (most immediately, male and female condoms) developed, tested and implemented in at least three countries. C. Evidence-based counseling approaches for male and female condom promotion incorporated into family planning service guidelines, including those used by HIV/AIDS programs in up to three countries. D. Research necessary to effect policy change and acceptance of female condom reuse among providers and local governments completed, with results incorporated into policies and service delivery guidelines, as appropriate. E. Feasibility, cost, and effectiveness of male condom distribution mechanisms assessed. F. Evidence regarding the effectiveness of female barrier methods disseminated to policy makers to influence procurement and programming decisions. G. Evidence-based strategies to increase use of barrier methods for contraception by couples with at least one HIV+ partner developed, evaluated and implemented. H. Approaches for overcoming male resistance to male condom use, informed in part by "exemplars" who succeed in using condoms more often than the norm, documented and replicated. I. Innovative research methodologies that produce more valid information about sexual behavior and barrier method use for programmatic decision making developed and validated.
<p>III. To make safe and effective RH products available in an efficient and less costly manner.</p>	<ul style="list-style-type: none"> A. An ISO standard for synthetic male condoms and female condoms established. B. In-country product testing capacity developed and or enhanced in up to ten sites in support of family planning and HIV/AIDS prevention programs; documented compliance with local government regulations.

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FHI/NC subprojects fully or partially funded by USAID's CRTU Agreement:

A. Female Barrier Methods

USA:	Pivotal Effectiveness Study of the PATH SILCS Diaphragm (FCO 2299/112101)
USA:	Next Steps for Clinical Research of New Female Condoms (FCO 112111/132114/132142)
USA:	Structural Integrity of the FC2 Female Condom (FCO 112117)
USA:	Formative Research to Determine the Feasibility of Recruitment for "True Efficacy" Trials (FCO 116104/116107/116112)
USA:	Female Condom Reuse: Assessing the Efficacy of Dish Detergent in Removing HIV and Chlamydia from the Surfaces of Inoculated FC2 Female Condoms (FCO 132115)
Kenya:	Improving FP Counseling of Clients (FCO 144102)
Jamaica:	A Randomized Trial Using Prostate-Specific Antigen (PSA) Among STI-Infected Patients (FCO 172008/172009/172011)

B. Male Barrier Methods:

Worldwide:	International Standards Development (FCO 118100)
Worldwide:	Immunological Markers of Chlamydial Infection (IMCI) (FCO 172006)
Kenya:	ABC Approach for Infection Prevention and Averting Unintended Pregnancies Among Youth in Institutions of Higher Learning (FCO 153110/153111)
Kenya:	Evaluating the "Young Men as Equal Partners" Project (FCO 114100/114122/114123)
Tanzania:	Improving Dual Protection Counseling for Youth (FCO 114120/114139/114140)
Zambia:	Evaluation of the Students Partnership Worldwide (SPW) Model of Peer Education (FCO 116113)
Zimbabwe:	Audio Computer-assisted Self-interviewing (ACASI) vs. Face-to-face (FTF) (FCO 132117/172004/172007)
Worldwide:	Document & Disseminate Condom Programming (FCO 113141)
Worldwide:	Production Surveillance of Condoms- Domestic and Off-Shore (FCO 148100)
Thailand:	Production Surveillance: Domestic and Off-shore Condoms (Bangkok) (FCO 148104)

Female Barrier Methods

USA: Pivotal Effectiveness Study of the PATH SILCS Diaphragm (FCO 2299/112101/132177)

Technical Monitor: GPittman

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Barriers I.E.: Innovative research methodologies that lower the cost and speed the pace of bringing new products to market developed and validated.
Barriers I.D.: At least one promising new diaphragm evaluated for contraceptive effectiveness and/or prevention of sexually transmitted infections (STI). Evidence, if favorable, will be used for PMA submission.

Objective(s): To provide data management, statistical analysis, regulatory audits, and monitoring of four of the six study sites for this pivotal study designed to assess the safety of the SILCS diaphragm and its effectiveness in preventing pregnancy.

Description: This CONRAD-led multi-center contraceptive effectiveness and safety study of the SILCS diaphragm enrolled 450 couples at risk for pregnancy with no contraindications to the use of a diaphragm at six study sites in the U.S. The study randomly assigned approximately 300 couples to use the SILCS diaphragm with BufferGel (BG) and approximately 150 couples to use the SILCS diaphragm with Gynol II (2% N-9 gel). At two sites, a substudy involving colposcopy and microflora is being conducted in about 80 women (40 at each site).

For certain evaluations of the SILCS diaphragm, the data from the NICHD contraceptive study will be used as historical controls. Participants in the NICHD study used either BG or N-9 (randomized 2:1) with the Ortho diaphragm. Thus in these comparisons, contraceptive gel use is comparable to that planned for the current study. To the extent possible, sites have been selected from among those which participated in the NICHD study, and inclusion/exclusion criteria and study visits follow those from the study as well.
NOTE: FCO 132177 was established in December 2008 to enable activities to continue under CRTU/Microbicides funding.

Collaborating Agency(s): CONRAD

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- For key prior accomplishments, please refer to the previous annual report(s).
- The next version of the protocol (v6.0, Amendment #3) was approved January 2008.
- Research Informatics provided RDT training for CONRAD and site study staff in January 2008.
- CRFs were approved in December 2007 and printed and shipped to the study sites.
- The final site initiation visit was conducted at EVMS in January 2008.
- The study manual was finalized and enrollment began in February 2008.
- The DM plan was approved in May 2008.
- Conference calls with the site staff were held in April, June, September, November and December 2008 to discuss enrollment and recruitment strategies, as well as any issues or concerns from the sites.

- RA/QA audits were conducted by FHI at each of the study sites in August/September 2008.
- The data management system was ready for production in September 2008.
- The analysis plan was approved in December 2008.
- FCO 132177 was established in December 2008 to enable activities to continue under the CRTU/Microbicides funding.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Interim site visits were conducted in six to eight week intervals.
- CONRAD/FHI team meetings were held monthly.
- Recruitment ended in February 2009 with 450 couples enrolled.
- FHI prepared an Interim Analysis for the IDMC in March 2009.
- The IDMC convened to discuss results from the Interim Analysis in March 2009 and recommended continuation of the study.
- Data entry and querying continued.
- Conference calls with site study staff were held in Jan., Feb., Mar., Apr., and June 2009 to discuss retention strategies, as well as any issues or concerns from the sites.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Table shells will be developed and finalized in preparation for the final statistical report.
- Interim site visits will be conducted in six to eight week intervals until participants complete follow-up.
- FHI will finalize baseline data and prepare a statistical report for CONRAD's presentation at the International Conference on Family Planning: Research and Best Practices, to be held in Kampala, Uganda, November 2009.
- Programming for the final statistical report will be initiated, verified, and completed.
- RA/QA will conduct final site audits at each of the study sites, after which, closeout monitoring visits will be conducted.
- CONRAD/FHI team meetings will be held monthly.
- Group meetings (via teleconference) to include site staff will be arranged by CONRAD.
- Data entry and querying will be completed and a final data freeze is anticipated to take place January-March 2010.
- The statistical report will be completed and sent to CONRAD late April 2010.
- Funding will continue under a new FCO to allow for completion of study activities (e.g. providing review of the final clinical report and manuscript as requested by CONRAD; and support of a 510K submission as requested by CONRAD and/or PATH).

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: Microbicides	FCO Approved: 2299 Jul 2005 112101 Jul 2005 132177 Dec 2008
Total Approved Budget:	2299 \$ 19,805 112101 \$ 1,313,190 132177 \$ 239,536 \$ 1,572,531	Projected End Date: Apr 2010

USA: Next Steps for Clinical Research of New Female Condoms (FCO 112111/132114/132142)

Technical Monitor: CJoanis

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Barriers I.A.: Female condoms under development evaluated to identify the best candidate, in terms of user acceptability, to be carried forward for safety and effectiveness research.

Objective(s): To facilitate: 1) the completion of a plan of action to take to the FDA to determine regulatory approval paths for the three new female condom (FC) types; 2) the selection of the best candidate(s) to move through the regulatory process; 3) quality assurance testing and assembly of clinical supplies for the CONRAD-sponsored study of two lengths of the Reddy FC; and 4) the provision of biostatistical input into the development of international standards for FC products.

Description: Providing female condoms for pregnancy and HIV prevention is a priority for USAID. Reality® (FC1), approved by the FDA in 1993, is sold globally, but sales are limited by its high price. A goal of USAID is to develop a low-cost FC equivalent to FC1. The three condoms studied in this subproject are: FC2, Reddy 6, and the PATH Woman's Condom. The subproject will cover four areas: 1) Strategy for and discussions with the FDA: Preliminary discussions will be held and possibly a meeting with the FDA to develop a strategy for clinical studies of FCs and regulatory paths for each FC type; 2) Assembly of clinical supplies and QA testing of the Reddy 90mm and 120mm devices (CONRAD sponsored): The PQC will test the condoms for water leakage, air burst, tensile strength, dimensions, and package integrity. After testing, the FCs and other clinical supplies will be assembled and shipped; 3) Research: This study will be conducted in South Africa. It will pinpoint slight variations in user preference and device performance of the three condom types. In this study, surveys and methods will be more market-specific compared to previous FC studies. Participation will include 180 women who will use five of each FC and complete an interviewer-assisted survey after using each type. After using all three FC types, the participants will enter Phase II of the study. In Phase II, participants will select the FC(s) of their choice (unlimited access) to use for about three months. Volume and preference for FCs will be recorded. In Phase III of the study, about 36 participants will be asked to take part in interviews to determine reasons for preference of a particular device; 4) Support at ISO: An FHI biostatistician will attend meetings of the ISO Female Condom Working Group to provide input in the development of international manufacturing standards for female condoms.

Subgrantee(s): Reproductive Health and HIV Research Unit (RHRU) at Witswatersrand University

Collaborating Agency(s): CONRAD

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Activities, Accomplishments, Problems through December 31, 2008

- The Reproductive Health and HIV Research Unit (RHRU) in Durban, South Africa was chosen as the study site.
- In May 2006, Protocol Version 1.0 was approved.
- During 2006, support continued for the development of ISO standards for FCs. An FHI biostatistician attended the ISO meeting in Delhi, India in October 2006.
- USAID requested a product change (from 120mm to 90mm -Reddy device). The protocol was resubmitted to the PHSC and local IRB (Version 2). It was approved by the PHSC in August 2006.

Minor changes were required by the Witwatersrand IRB, thus Version 3.0 was sent to the PHSC in November 2006.

- The subagreement was finalized in November 2006.
- Study products were quality control tested by FHI's PQC lab and shipped to the RHRU in January 2007.
- Site training and initiation was conducted in February 2007.
- Participant enrollment began in March 2007.
- Protocol Version 4.0, eliminating HIV testing and male informed consent, was approved by both IRBs in May 2007.
- Monitoring trips were conducted in July and October 2007. All forms were reviewed and errors corrected.
- A total of 180 women completed the study by February 2008.
- The data entry system was validated in February 2008.
- Quantitative data entry began in March 2008.
- In March 2008, the SA study coordinator came to FHI to work on the qualitative data and received additional training in NVivo software and data analysis.
- Table shells were approved in April 2008.
- A closeout visit was conducted in SA in April 2008. Data were reviewed for errors.
- Forms were shipped to FHI in May 2008.
- A total of 36 interviews conducted in Part 3 were translated/transcribed in May 2008.
- Query and cleaning of quantitative data were completed by June 2008.
- An initial data analysis was completed in November 2008 for Parts 1 and 2 of the study.
- Coding of 36 in-depth interviews (Part 3 of the study) continued through December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- A manuscript was drafted on Parts 1 and 2 of the study in June 2009.
- An abstract was submitted in June 2009 to the upcoming International Family Planning Conference in Kampala, Uganda.

Findings and Outcomes:

- The purpose of this research study was to gather detailed information on comparative preference, acceptability and function for each of the female condom types. The primary endpoint was the determination of which of the three tested female condoms was preferred among study participants.
- The primary preference analysis showed a statistically significant difference in the preference probabilities among the three condom types, three pair-wise comparisons (PATH WC vs FC2; PATH WC vs. Reddy 6, and FC2 vs. Reddy 6) were performed using data from the subset of participants who preferred one of the types of FCs being compared. The participants clearly preferred the PATH WC and FC2 condoms over the Reddy 6 ($p < .0001$) and the PATH WC over the FC2 ($p = .0007$). Overall, out of 2423 condoms opened and 2376 condoms used all functionality problems such as breakage and invagination occurred in less than 2% of the devices. There were no significant differences among the FC types as regards to functional performance. Ordinal acceptability outcomes (range 1 thru 5, disliked very much to like very much, respectively) were compared across the three condom types. Of eight condom comparisons, five were statistically significant: feel/sensation ($p = .0140$); amount lubricant ($p < .0001$); appearance ($p = .0144$); ease of use ($p < .0001$); and, fit ($p = .0082$). The participants thought that the PATH WC was better than Reddy 6 in terms of feel, worse than both FC2 and Reddy 6 as regards lubrication volume, and better than FC2 and Reddy 6 in terms of appearance, ease of use and overall fit.
- Results showed that all women preferred one of the condom types and confirms the premise that if a range of options/choices are provided, couples may be more likely to select and use the method. These results could have important public health impact and provide women with additional options for contraception and STI prevention. The public sector price of FC1 is much higher than most developing country programs and individuals can support. By developing less expensive FC designs, comparing their acceptability and determining women's preferences for each type, donor agencies may be able to purchase more devices and expand distribution networks which would improve access

and availability of these devices. At present, FC2 and V-Amour are less expensive than the FC1. It is anticipated that the PATH WC will be comparably priced when marketed.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- A quantitative manuscript (Parts 1 and 2 of the study) will be submitted for publication in August 2009. The first qualitative manuscript (Part 3) will be drafted and submitted for publication by November 2009.
- Manuscripts for the study will be submitted to peer-reviewed journals.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: Microbicides	FCO Approved: 112111 Aug 2005 132114 Jun 2006 132142 Sep 2006
Total Approved Budget:	112111 \$ 65,764 132114 \$ 808,590 132142 \$ 155,595 \$ 1,029,949	Projected End Date: Dec 2009

USA: Structural Integrity of the FC2 Female Condom (FCO 112117)

Technical Monitor: CJoanis

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Barriers II.D.: Research necessary to effect policy change and acceptance of female condom reuse among providers and local governments completed, with results incorporated into policies and service delivery guidelines, as appropriate.

Objective(s): To determine the feasibility of reusing the new FC2 female condom. This subproject will compare the test values obtained at baseline and after each wash/bleach sequence (1X, 2X, etc.) with the manufacturer's specifications for water leakage, tensile strength, and air burst testing.

Description: A prototype female condom (FC2), made of synthetic latex and meeting the same structural specifications as the polyurethane female condom (FC1), has been developed by the Female Health Company. The major advantage of FC2 over its predecessor is cost, ~\$0.60 vs. \$0.74, respectively (public sector pricing). While FC2 will be less expensive than FC1, its projected public sector price is still 15 times the cost of a male latex condom. In relation to its indication for one-time use, donors may still be reluctant to supply the device.

Given the successes shown in cleaning FC1 and the fact that the FC2 device is still more expensive than a male latex condom, there is a need to study the reuse potential of this new FC. Since the FC2 material is a proprietary polymer, there is no published information, and no research has been conducted to assess the impact of detergents and disinfectants on the structural performance of the material. Such information

may be used to provide guidance on cleaning the FC and result in the provision of an FC product that can be cost-competitive with male condoms. Findings will be presented along with other recently completed FC research to members of the WHO panel on FC reuse. Depending on results, new guidance may have to be written concerning FC reuse when the FC2 becomes more widely available.

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- A draft protocol was completed in December 2005.
- The FC2 condoms (Lot #3007) were ordered from the Female Health Company (FHC) in March 2006.
- The protocol was approved in April 2006.
- Baseline and structural testing was completed on Lot #3007 at FHI's PQC lab in June 2006.
- The analysis and testing report was completed by PQC staff in June 2006.
- An analysis of the test report showed that the study was not conducted to protocol in all test cells. This resulted in the need to repeat airburst and tensile testing. Baseline data were analyzed and results were found to be consistent with manufacturer specifications.
- Condoms from the same Lot #3007 were ordered to repeat specific tests. Airburst and tensile tests were repeated in November 2006.
- Data analysis and a test report were completed in December 2006.
- The technical monitor reviewed the test report in February 2007. Results indicated an anomaly in the test data (i.e. baseline testing failed, but wash and bleach test cells passed).
- In March 2007, test procedures were reviewed and test results were evaluated. We believe that FHC Lot# 3007 was produced prior to validation of manufacturing equipment, resulting in the production of a non-uniform lot.
- In May 2007, PQC laboratory staff recommended repeating the study using a different lot of condoms.
- A decision was made in September 2007 to use surplus condoms (Lot #F3015) from the Comparative Study of 3 female condoms (FCO 132114).
- Condoms from the Comparative Study of 3 Female Condoms were made available in April 2008.
- In May 2008, the protocol was reviewed and minor modifications were made.
- Baseline, water leakage, tensile strength and airburst tests were conducted on Lot #F3015 condoms in May and June 2008.
- A laboratory report was issued in June 2008.
- No activities took place under this subproject during the period July-December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- No activities took place under this subproject during the period January–June 2009.
- Due to the lack of USAID interest, the subproject ended and the FCO was closed on June 30, 2009.

Findings and Outcomes:

- Reference: Internal report: Female Condom Test Report: Study to Assess Structural Integrity of the Nitrile Female Condom (FC2) after Multiple Washes with Either Sunlight® Dishwashing Detergent or Bleach. Lot # 3015 June 2008.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2005
Total Approved Budget:	\$ 43,864	Projected End Date:	Jun 2009

USA: Formative Research to Determine the Feasibility of Recruitment for "True Efficacy" Trials (FCO 116104/116107/116112)

Technical Monitor: ACorneli

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Barriers I.E.: Innovative research methodologies that lower the cost and speed the pace of bringing new products to market developed and validated.

Objective(s): 1) To identify characteristics of women who are most likely to participate in a one-month, placebo/no method-controlled contraceptive efficacy or effectiveness trial; and 2) to develop strategies to recruit women willing to join the study.

Description: Originally planned with two phases, formative research and a mock trial, this research subproject was scaled down such that it will now include formative research only in three sites: Madagascar, South Africa, and the U.S. Approximately 25 interviews will be conducted both in Madagascar and South Africa and up to 50 interviews in the U.S. with: community stakeholders, others in a position to provide information about the local culture, and 12 focus group discussions with potential participants. In this phase, we will: 1) identify characteristics of women who are most likely willing to participate in the trial (previous research has targeted women who actively desire pregnancy but who are willing to delay conception for one month and women who are willing to accept pregnancy but are not necessarily actively trying to conceive); and 2) develop culturally appropriate recruitment strategies directed at the women identified.

Collaborating Agency(s): University of North Carolina, Chapel Hill (UNC-CH)

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Activities, Accomplishments, Problems through December 31, 2008

- Approval for a scaled-down version of the original study was received from USAID on December 9, 2005. Study preparatory activities began in the same month.
- The protocol, data collection instruments, and consent forms were developed for the U.S. site, and approved by the PHSC in August 2006.
- All interviews with community stakeholders were conducted at the U.S. site, September-December 2006.
- The protocol, data collection instruments, and consent forms were modified for the Madagascar site from February-October 2006 and for the South African site May-October 2006. The documents were submitted for local ethics review in November 2006.
- The training curriculum was developed in January 2007.
- Local IRB approvals for the South Africa and Madagascar sites were obtained in January and PHSC approval was obtained in February 2007.
- Approval was obtained from the UNC IRB for the Madagascar site in March 2007.
- Training at both the Madagascar and South Africa sites was conducted for study staff in January and February/March 2007, respectively.
- Data analysis of stakeholder interviews from the U.S. site began in April 2007.

- Data collection at the Madagascar and South Africa sites began in May 2007 and June 2007, respectively.
- Focus group discussions began at the U.S. site in August 2007.
- As interviews with stakeholders were completed, interim analyses were conducted for all sites in order to inform the content of the subsequent focus group discussions.
- A data training workshop was held at the Madagascar site in May 2008.
- The South Africa and Madagascar sites submitted their final reports in June and August 2008, respectively.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Additional focus group discussions were conducted at the North Carolina site, based on a need identified through the analysis of the initial data.
- The majority of data analysis was completed by June 2009.

Findings and Outcomes:

- N/A

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Data analysis will be completed for all sites.
- The final report/manuscript will be written and disseminated by the end of December 2009.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 116104 Sep 2005 116107 Dec 2006 116112 Jan 2007
Total Approved Budget:	116104 \$ 252,628	Projected End Date: Jun 2009
	116107 \$ 94,260	
	116112 \$ 44,731	
	<u>\$ 391,619</u>	

USA: Female Condom Reuse: Assessing the Efficacy of Dish Detergent in Removing HIV and Chlamydia from the Surfaces of Inoculated FC2 Female Condoms (FCO 132115)

Technical Monitor: CJoanis

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Barriers II.D.: Research necessary to effect policy change and acceptance of female condom reuse among providers and local governments completed, with results incorporated into policies and service delivery guidelines, as appropriate.

Objective(s): To determine whether organisms which cause STIs, and which would be expected to be present on the interior surface of a condom following sexual intercourse with an STI infected male partner

can be inactivated after soaking the condom in detergent and bleach solutions for defined periods of time. In this study, the detergent is the experimental substance and the bleach is used as a control.

Description: This subproject was intended to add to the knowledge base on the advisability of female condom re-use. Previous research conducted by FHI and other agencies showed that the FC1 female condom maintained structural integrity after multiple (7) washes and disinfections with household detergents and bleach. Further, STI pathogens (HIV, GC, CT and HSV-2) were inactivated (killed) during a disinfection regimen consisting of a bleach soak for one minute. A safety study showed no damage to male or female genitalia after 5 disinfections and uses of FC1. FHI completed research to test the effectiveness of dish detergent to remove Gonorrhea, HIV, HSV-2 and Chlamydia from the surfaces of inoculated new and pre-washed FC1. A female condom (FC2), made of a synthetic polymer (synthetic latex) and meeting the same structural specifications as the polyurethane FC1 was developed by the Female Health Company. The new device was similar in appearance but was made from a different, proprietary material. FHI conducted a study to test the impact of bleach and detergent on the structural performance of the FC2 (FCO 112117) in the first two quarters of 2006. Results of these tests were inconclusive (i.e., the tested condoms did not pass manufacturer specifications of several of the structural tests at baseline, but passed these tests in the 1X-5X multiple bleach and detergent washings). These studies were repeated using a different lot of FC2 condoms. After testing these, we proposed to evaluate the effectiveness of bleach and detergent in removing microbes from the surfaces of the FC2 device. This latter study was needed because we did not know if the polymer material used in the FC2 was porous or became more porous with bleach and detergent use. Porosity of the material was important when testing microbes of small size (e.g. HIV). Ultimately work ended on this subproject with the decision that regardless of any testing results, it was doubtful WHO would recommend reuse of female condoms.

Collaborating Agency(s): ATS Laboratories

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Activities, Accomplishments, Problems through December 31, 2008

- This subproject was opened in June 2006.
- Conduct of this study was dependent on passing results of structural integrity tests conducted under FCO 112117.
- Tests of structural integrity (water leakage, airburst and tensile strength) were completed by technicians in FHI's PQC division in July 2006 on Lot #3007 (reference FCO 112117). An analysis of data and laboratory notes indicated cleaning and bleaching procedures were not conducted to protocol, resulting in inconsistent and confounding results in August 2006.
- Study product (Lot #3007) was reordered and tests were repeated in November 2006.
- An analysis of results was completed in December 2006.
- Results from the second testing of the same condom lot were inconclusive as well (i.e. baseline testing failed, but the bleached and washed female condoms passed five water leakage tests).
- As a result, this study (FCO 132115) was not undertaken in the last quarter of 2006.
- In discussions with the PQC division, Lot #3007 was produced prior to manufacturing validation which resulted in condoms that had inconsistent specification from condom to condom (i.e. condoms were not produced to GMP).
- A decision was made in June 2007 to repeat testing using a different lot of condoms.
- In September 2007, surplus condoms from the comparative acceptability study of 3 female condoms (FCO 132114) were tested (Lot #3015).
- The surplus condoms became available in April 2008.
- Using the same study protocol, we tested the new lot of condoms (FCO 112117). Structural testing (water leakage and airburst testing) of the female condoms began in May 2008 and was completed by end the of June 2008.
- A final report for Lot #3015 was issued in June 2008.
- A decision was made by FHI scientists in consultation with USAID in December 2008 not to proceed with this subproject based on the opinion that despite successful testing (i.e. the FC2 female condoms passed all testing parameters (air burst, water leakage) in both detergent and bleach test cells (for 3

uses of the device), it was doubtful that the WHO would suggest reuse as a means of reducing the cost of the product.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- There were no further activities planned for this subproject.
- The FCO was closed on January 31, 2009.

Findings and Outcomes:

- The FC2 female condom passed all testing parameters (air burst, water leakage) with both detergent and bleach, to 3 uses of the device.
- Despite these findings the decision was made by FHI staff not to continue this activity as it was judged unlikely that WHO would suggest reuse as a means of reducing the cost of the product.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:	Jun 2006
Total Approved Budget:	\$ 241,000	Projected End Date:	Jan 2009

Kenya: Improving FP Counseling of Clients (FCO 144102)

Technical Monitor: RHoman

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Barriers II.B.: Training and supervision approaches and job aids that heighten family planning or HIV service providers' capacity to promote barrier methods (most immediately, male and female condoms) developed, tested and implemented in at least three countries. Barriers II.C.: Evidence-based counseling approaches for male and female condom promotion incorporated into family planning service guidelines, including those used by HIV/AIDS programs in up to three countries.

Objective(s): 1) To improve the way in which family planning providers communicate contraceptive concepts and information to clients; 2) to assess the impact of improved counseling on client understanding of key concepts; and 3) to assess the sustainability of the intervention within the constraints of the service delivery system.

Description: In response to the priorities of key CRTU partners in Kenya, USAID/Kenya obligated funds for FHI to examine the ways in which family planning (FP) providers communicate information to clients. A key area of concern identified by the reproductive health (RH) stakeholders in-country relates to the quality of counseling received by clients and how that affects outcomes. Three factors that may affect the quality of client counseling are: the language used by providers to communicate family planning options, the materials used for counseling, and the quality of on-site supervision within the programs. The information generated from this subproject will strengthen FP services in Kenya. Examining the quality of care and the influence of language on people's attitudes and receptiveness to FP are key steps towards addressing factors surrounding FP decision-making and continuation. While previous balanced

counseling strategies have failed to show a statistically significant impact on the uptake of FP services or continuation rates, there were concerns with provider compliance with the intervention. Therefore, we plan to also strengthen on-site supervision in hopes of obtaining not just a quality improvement but also higher uptake or continuation rates.

If we can demonstrate improvements in the way FP providers communicate with potential clients and people's concepts of FP, these interventions have the potential to be expanded to other service delivery points within the Ministry of Health (MOH) system. In addition, through our focus country stakeholders network and collaboration with MOU partners, the intervention can be rolled out to additional service delivery points.

Collaborating Agency(s): Ministry of Health, Kenya; Population Council

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- The FCO was opened in February 2007 and the approval to implement was obtained in March 2007.
- The protocol was written and approved in February 2007.
- PHSC approval was obtained in March 2007.
- Local IRB approval was obtained in June 2007.
- Preliminary data were collected from three sites; Nakuru Provincial General Hospital, Naivasha District Hospital, and Uasin Gishu District Hospital in September – November 2007.
- Data was transcribed, entered and cleaned in October – November 2007.
- Preliminary data analysis commenced in December 2007.
- Results summaries were prepared and shared for team review.
- Additional funds totaling \$300,000 were approved by USAID/K for FY 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Data from the baseline were shared with the FP working group coordinated by MoH in February 2009.
- FHI obtained approval by Division of Reproductive Health to proceed with the training of service providers and the introduction of client cue cards. Part of this approval was contingent on increasing the number of intervention sites.

Findings and Outcomes:

- Based upon preliminary analyses, it appears that the language used by providers is acceptable to the clients but that clients do not feel empowered to raise questions with the providers. Therefore, we are working on shifting the focus of this study to explore strategies to improve client's ability to actively participate in the counseling session.
- Immediate outcomes of this subproject are anticipated to be:
 - 1) a step towards understanding and consolidating the language that best aids in communication with FP clients;
 - 2) revised balanced counseling job aids and training materials that take into account the findings regarding the language used to communicate with clients; and
 - 3) a model of supportive supervision that promotes the use of appropriate language and job aids with clients.
- Longer term outcomes are anticipated to be:
 - 1) whether the use of acceptable language will increase receptivity to the concept of FP and enhance discussion of this subject for more informed FP decision-making and continuation; and
 - 2) whether balanced counseling and supervision can lead to improved knowledge and is sustainable within the service constraints (available provider time, supplies, and on-site supervision capacity).

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Providers from twenty sites will be trained in the use of the counseling job aids and appropriate language with clients.
- Data collection to assess performance with new job aids will take place –August-September 2009.

- Results of final analysis will be disseminated in December 2009.

Funding Source(s):	USAID - US Agency for International Development/USAID: Field Support	FCO Approved:	Feb 2007
Total Approved Budget:	\$ 500,000	Projected End Date:	Apr 2010

Jamaica: A Randomized Trial Using Prostate-Specific Antigen (PSA) Among STI-Infected Patients (FCO 172008/172009/172011)

Technical Monitor: MSteiner

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Barriers II.I.: Innovative research methodologies that produce more valid information about sexual behavior and barrier method use for programmatic decision making developed and validated.

Objective(s): To work with CDC to assess compliance with current recommendations for abstinence among women being treated for an STI during the week following treatment. As part of this study, we will compare levels of unprotected intercourse following treatment via PSA evaluation between patients assigned to "abstinence only" messaging and patients assigned to hierarchical messaging of "abstinence backed up by condom provision."

Description: We will recruit approximately 500 women being treated syndromically for curable STI (gonorrhea or chlamydia) from the Comprehensive Health Centre, the largest STI clinic in Kingston, Jamaica. Half of the women will be randomized to the currently recommended guidance to document levels of compliance while the other half will receive both the currently recommended guidance and will also receive male (and possibly female) condoms and counseling on their use. Participants in both arms will be asked to return to the clinic the first Monday after enrollment to answer a series of questions about their sexual behavior since enrollment and to be administered a vaginal swab. Vaginal swabs will be tested for PSA levels to assess participation in unprotected sexual intercourse in both groups. We will use a rapid PSA test (ABAcad) for evaluation, as this test provides immediate results, requires no instrumentation, and can be performed easily and economically in resource-constrained settings. FHI's role of providing technical assistance to this CDC-led study is funded by the CDC through a CRTU Interagency Agreement.

Subgrantee(s): University of North Carolina - Chapel Hill

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- Funding was approved and provided by CDC through CRTU Interagency Agreements. In-house approval was obtained on July 1, 2007.
- An alternative study design and sample size calculations were developed and discussed during conference calls.
- US-based and Jamaica-based study teams were assembled.

- A site visit was conducted in August 2008. Operational aspects of study implementation and a draft budget were discussed.
- A draft protocol was submitted for team review in December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The draft protocol was reviewed.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- The protocol and DCFs will be finalized by July 2009 and submitted for IRB approvals.
- Study initiation is anticipated for September 2009.
- Note: The study is expected to continue past April 2010 under another award.

Funding Source(s):	USAID - US Agency for International Development/USAID: IAA	FCO Approved: 172008	Jul 2007
		172009	Jul 2007
		172011	Sep 2008
Total Approved Budget: 172008	\$ 38,659	Projected End Date:	Apr 2010
172009	\$ 11,341		
172011	\$ 150,000		
	\$ <u>200,000</u>		

Male Barrier Methods

Worldwide: International Standards Development (FCO 118100)

Technical Monitor: ECarter

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Barriers III.A.: An ISO standard for synthetic male condoms and female condoms established.

Objective(s): To actively participate in international standards organizations to establish new and/or revise existing performance standards for medical devices, pharmaceuticals, and other commodities procured and distributed by USAID.

Description: Product performance standards are required by regulatory agencies to ensure proper and consistent manufacturing and to protect consumers from harm. These internationally recognized consensus standards are used by USAID and other donor organizations when procuring products for developing country use. New standards typically take three to seven years to be developed. PQC will contribute its expertise and represent USAID's interests in the standards' community. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCO 8010).

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Activities, Accomplishments, Problems through December 31, 2008

- Eli Carter, Director of the PQC Division, has served as the Head of the US Delegation to ISO TC 157, and has been Chairman of the ASTM D11.57 Technical Advisory Group since 2001. Meetings are held annually and generally involve establishing and/or revising existing standards and revising laboratory test methods for evaluating the performance of male and female condoms, IUDs, and diaphragms.

Carter participated in the following meetings:

- 2005: ISO TC 157 Meeting, Berlin, Germany; and ASTM Meetings, Dallas, Texas
- 2006: ISO TC 157 Meeting; Delhi, India; and ASTM Meetings; Atlanta, GA
- 2007: ISO TC 157 Meeting; Rockville, MD; ISO TC 157 Meeting; Jeju Island, South Korea; and ASTM Meetings; Tampa, Florida
- 2008: ISO TC 157 Clinical Trials Working Group meeting; Rockville Maryland; ASTM Meeting; Denver, Colorado; ISO TC 157 Meeting; Montreux, Switzerland; and ASTM D11 Meetings; Miami, Florida.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- June 2009: Carter to Vancouver, BC to attend ASTM semiannual meeting.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Carter will participate in the following meetings:
- October 2009: ISO TC 157 Meeting; Shanghai, China
- December 2009: ASTM D11 Meetings, Dallas, Texas
- Ad Hoc meetings as deemed appropriate (ISO, ASTM, ANSI)

Funding Source(s):	USAID - US Agency for International Development/USAID: CSL-Core	FCO Approved:	Jul 2005
Total Approved Budget:	Annually Approved	Projected End Date:	Apr 2010

Worldwide: Immunological Markers of Chlamydial Infection (IMCI) (FCO 172006)

Technical Monitor: CMorrison

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Barriers II.I.: Innovative research methodologies that produce more valid information about sexual behavior and barrier method use for programmatic decision making developed and validated.

Objective(s): To examine immunological responses to Chlamydia trachomatis (CT) infection over time using existing serum and cervical swab specimens collected from women participating in the HC-HIV

study. More specifically, this subproject aims to measure serum immunological markers (Chlamydia major outer membrane protein (MOMP) IgG, MOMP-IgA, and chlamydia heat shock protein 60 (chsp60) antibodies) at baseline and at the time of Chlamydia infection(s) and to evaluate changes over time. Chlamydia genotypes from cervical swab specimens will also be evaluated.

Description: All serum immunological testing will be performed in the HC-HIV study research laboratories of the countries where the respective specimens were collected. Testing on about 3400 serum specimens will be performed in Uganda and testing on about 2300 serum specimens will be performed in Zimbabwe. Aliquots from cervical swab specimens will be sent to the Centers for Disease Control and Prevention (CDC) for Chlamydia genotyping; the original specimens will remain in-country. Genotyping will be performed on aliquots from up to 334 swab specimens from Uganda and up to 108 swab specimens from Zimbabwe.

Immune system responses to Chlamydia trachomatis (CT) infection are thought to contribute to adverse reproductive outcomes such as pelvic inflammatory disease (PID) and infertility. These same immune responses may also protect against harmful repeat CT infections. A better understanding of the immunological responses to one or more CT infections is needed to determine the best strategies to prevent the adverse outcomes of CT infection.

Collaborating Agency(s): Centers for Disease Control and Prevention (CDC)

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Activities, Accomplishments, Problems through December 31, 2008

- The IMCI protocol was approved by the UCSF IRB on January 10; by the Case IRB on January 22; by the CDC IRB on March 12 and by the Zimbabwe IRB on May 31, 2007.
- Please refer to the 2007-2008 Annual Report for all other activities that took place prior to July 2007.
- Training for the Zimbabwe laboratory staff took place in July 2007 by conference call.
- The CDC prepared pilot testing specimens and shipped them along with ELISA kits to Zimbabwe.
- Pilot testing took place in Zimbabwe in August 2007. The validation panel had thawed when it arrived at the lab. The CDC sent a new panel to repeat the pilot testing.
- The second round of pilot testing took place in Zimbabwe in October 2007. The results were acceptable and the site began actual testing of Group E specimens and entering test results into the project database.
- Testing in Zimbabwe began with a random sample of baseline specimens (no diagnosis of PID, no CT infection) until 50 participants were identified positive for CT MOMP-IgG at baseline. The first 10 positives and 10 negatives were sent to the CDC for verification.
- The CDC prepared pilot testing specimens and shipped them along with ELISA kits to Uganda.
- Zimbabwe completed IgG testing on all of Group E and most of Group A-D specimens. The Zimbabwe lab staff located all but 36 of the IMCI specimens.
- The Zimbabwe lab staff began sending the IMCI dataset to FHI on a monthly basis for data management activities.
- Uganda worked on pulling the Group A-D specimens.
- The Uganda lab discovered that all aliquots for some participant visits were discarded in error during freezer reorganization sometime in the past. This presents serious implications for the IMCI study as approximately 1300 samples cannot be located.
- Pilot testing took place in Uganda in May 2008.
- FHI ordered and shipped the lab supplies (shipping boxes, storage boxes, cryovials, pipettes and blue ice) to both labs.
- As of December 2008, about 2,000 (MOMP-IgG, MOMP-IgA and chsp60) specimens had been tested and the Uganda lab had sent FHI a list of those IMCI specimens which had been found.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Additional testing kits were sent to Uganda and Zimbabwe in June 2009.
- FHI staff continued to manage and clean data they received from the field sites.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Serologic testing (MOMP-IgG, MOMP-IgA and chsp60) will be completed in both Uganda and Zimbabwe.
- Specimens for IgG QA testing and chlamydia genotyping will be shipped to the CDC from Zimbabwe and Uganda labs.
- Chlamydia genotyping among women with ≥ 1 chlamydia infection(s) detected by DNA test will be done at the CDC.
- The Zimbabwe and Uganda IMCI databases will continue to be sent to FHI on a monthly basis for data management activities.
- Once all testing is complete, FHI will produce and send the cleaned datasets to CDC for analysis.

Funding Source(s):	USAID - US Agency for International Development/USAID: IAA	FCO Approved:	Jan 2007
Total Approved Budget:	\$ 127,271	Projected End Date:	Apr 2010

Kenya: ABC Approach for Infection Prevention and Averting Unintended Pregnancies Among Youth in Institutions of Higher Learning (FCO 153110/153111/153144/153145)

Technical Monitor: JLiku

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Barriers II.A.: Cost and effectiveness of alternative ABC delivery models targeting youth (including communication channels, messages, parental/adult involvement, community support, and collaborating partners) evaluated and applied in at least three countries

Objective(s): The specific objectives of this intervention are to: 1) promote messages among students in the universities on HIV risk reduction and elimination; 2) promote sexual and reproductive health (SRH) strategies and reduce unplanned/unintended pregnancies; 3) increase access to HIV counseling and testing for university students; and 4) collaborate with universities to implement the University HIV/AIDS policy.

Note: The objectives have changed due to the evolving nature of the project. It started as a test of the ABC approach and developed into an intervention.

Description: This ongoing subproject builds on the 2004 and 2005 study among University of Nairobi students (FCO 9493) under the CTR. In 2006 and 2007 activities focused on training peer educators (PEs) to promote ABC messages among their peers in order to prevent sexually transmitted infections including HIV and unplanned/unintended pregnancies. Lifeskills training was a key component of the intervention to enable students to make informed sexual reproductive health decisions. The intervention has expanded to two more campuses of the University of Nairobi (UON) and to the United States International University

(USIU). In the current project period, twenty five thousand students will be reached with ABC messages; 400 peer educators will be trained to promote ABC messages while 600 students will be counseled and tested. One hundred and fifty behavior change communication groups (BCCGs) will be formed to reach 1,800 students with ABC messages. Building on a radio program aired on a local radio station popular with young people in November 2007, a meeting will be held with media fraternity to engage them on promotion of ABC messages targeting the youth.

As a result of the activities of this subproject, ICL has been able to partner with APHIA II to promote ABC messages among youth in other institutions of higher learning in Rift Valley and Coast provinces.

Subgrantee(s): I Choose Life

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Activities, Accomplishments, Problems through December 31, 2008

- Approval to implement was approved by USAID on January 31, 2007.
- For accomplishments prior to 2008, please see the 2007-2008 CRTU annual report.
- A Memorandum of Understanding (MoU) was signed with USIU and 126 peer educators were recruited and trained in Sept-Oct 08.
- A strategy meeting was held with PE supervisors on BCCG formation and support at USIU and the UON.
- Project staff and peer educators participated in an orientation of UON first year students ("freshers") in Oct 08.
- A media advocacy workshop was conducted on April 12, 2008 and attended by 83 people, about 60 were from media houses.
- Over 1500 students were counseled and tested in Nov during a week VCT drive conducted on 6 campuses of UON and USIU.
- Thematic events continued to take place in the various campuses.
- Abstinence messages ICL shared at a USIU Fresher's Bash for the Fall Semester.
- Peer Educator Supervisor meetings held in UON and USIU.
- 15 members of a BCCG from Kikuyu campus recorded a BCCG session on HIV that was featured on a local TV station, Kenya Television Network (KTN), known as "Mending the Ribbon".
- An Emergency Contraceptives Exhibition was held in USIU to address misuse of ECs.
- A poster presentation was made in Dakar, Senegal in Dec 08.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Weeklong drives were held in March 9–21, and June 2-6 and 22 -26, 2009. In March two drives were held at UON and USIU counseled, tested and gave 1206 students (421 males and 785 females) their results, while in June 3 drives, at UON and USIU, reached 1161 students (512 males and 649 females). A VCT poster campaign took place at the UON.
- On 27 March, 138 PEs graduated from USIU and 133 PES completed refresher training in Jan. 37 students from UON and USIU completed training as PEs in May. PET commenced in May for 527 students and is ongoing. 43 more were recruited for PE training.
- More than 70 meetings were held at UON and USIU by 910 students to discuss abstinence, being faithful, condom use, HIV/AIDS stigmatization, contraception, VCT, relationships and other SRH issues. 8 new BCCGs formed in June and 20 BCCGs were active in Jan-June.
- 32 thematic events (4 USIU and 28 UON) were held; 12,886 students were reached with ABC and SRH messages.
- 9251, 8106 and 2705 students were reached with A, B and C messages respectively through thematic events & BCCGs; 3200 condoms were distributed.
- A supervision meeting was held in Jan to discuss BCCG sustainability, achievements and journaling in UON, 5 attended. 9 were held in UON in April, 62 attended. In May, 9 were held at USIU, 99 attended.
- A PAC meeting held in April at USIU was attended by 14 people.
- Bulk text messages were sent to 4,500 students at USIU.
- 3,000 copies of the Rape blitz card were produced in May.

- An M & E technical assessment conducted by FHI and a support meeting was held in April; data tools were developed.
- A project staff participated in a discussion on Youth SRH aired on a local media program, Straight Up, in June.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

Staff will:

- Recruit 500 UON and USIU students to undergo lifeskills PE training.
- Develop a refresher training manual and retrain previously trained PEs.
- Reach 25,000 students with ABC messages on University of Nairobi campuses and USIU.
- Further refine and expand Behavior Change Communication Groups (BCCGs) to equip more students with personal values, attitudes and life skills to prevent HIV infection and unintended pregnancy.
- Develop a BCCG tool kit to facilitate BCCG activities.
- Carry out 2 thematic events in each campus on VCT.
- Continue to disseminate the radio series developed in 2007 to reach an additional 50,000 with ABC prevention messages.
- Collaborate with the School of Journalism at the University of Nairobi and campus theatre groups and other student clubs and organizations to build their capacity to understand and incorporate ABC prevention messages into their ongoing work on various campuses.
- Conduct a project evaluation to evaluate the effectiveness and costs of the intervention.
- Synthesize and package lessons learned from the intervention.
- Disseminate findings and lessons learned from the evaluation in Nov/Dec 2009.
- Develop and implement a transition plan to promote sustainability and scale-up of the ABC intervention activities.
- Conduct a VCT mobilization and publicity event targeting 5, 000 students.
- Create a Youth SRH journalists' award category with KEMEP.
- Prepare research protocol, obtain ethical approval from relevant authorities, recruit and train RAs for data collection.
- Collect data in October to mid-November 2009.
- Analyze data from mid-Nov to January 2010.
- Hold one Project Advisory Committee (PAC) meeting to review progress and any emerging project issues.
- Conduct a project closure meeting/dissemination of evaluation findings and prepare final report in February 2010.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR;	FCO Approved: 153111	Jan 2007
	USAID - US Agency for International Development/USAID: IAA	153110	Jan 2007
		153144	Apr 2009
		153145	Apr 2009
Total Approved Budget: 153111	\$	379,230	Projected End Date: Feb 2010
153110	\$	260,770	
153144	\$	119,818	
153145	\$	480,183	
	\$	1,240,001	

Kenya: Evaluating the "Young Men as Equal Partners" Project (FCO 114100/114122/114123)

Technical Monitor: SThomsen

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Barriers II.H.: Approaches for overcoming male resistance to male condom use, informed in part by exemplars who succeed in using condoms more often than the norm, documented and replicated.

Objective(s): To measure change among young men 10-24 years of age after the implementation of the Young Men as Equal Partners subproject in the following indicators: 1) sexual and reproductive health knowledge and attitudes; 2) attitudes towards gender equity; and 3) sexual and reproductive health behaviors.

Description: Efforts to slow the rapid spread of HIV/AIDS in Eastern and Southern Africa often include heavy investments in educating youth on the dangers of HIV/AIDS through peer education, and school and health facility-based programs. However, despite frequent calls for more male involvement in such programs, little is known about how programs for young men should look and what works best. The Swedish Association for Sexuality Education (RFSU), in association with the Family Planning Associations of Kenya (FPAK) and Uganda (FPAU), implemented a program in 2007 entitled "Young Men as Equal Partners." The primary goal of the program is to sensitize, train and support young men ages 10-24 to act as role models in sexual and reproductive health and on gender issues within their community, and to advocate for male involvement in society at large. The subproject has three major modes of communication: young male peer educators, trained male schoolteachers, and trained service providers in sexual and reproductive health (SRH). FHI will evaluate the effectiveness of the RFSU-supported intervention.

The study was suppose to use a pre/post-test design. Household surveys of young men was to take place at baseline and two years after the initiation of the intervention, in order to determine the impact of the intervention. An extra district was surveyed in Uganda in order to provide a baseline measurement for the Health Communication Partnership's assessment of the "Be a Man" media intervention. The study included a process and cost evaluation. The results of this evaluation were to provide guidance for the program planners and policymakers in East Africa on the effectiveness of male sexuality education on improving the sexual attitudes and behaviors of youth.

Subgrantee(s): Impact Research and Development Organization (Kenya); Makerere Institute for Social Research (Uganda)

Collaborating Agency(s): Family Health Options of Kenya; Family Planning Association of Uganda (FPAU); Health Communication Partnership/Uganda (JHU); Swedish Institute for Sexuality Education (RFSU)

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Activities, Accomplishments, Problems through December 31, 2008

- The technical monitor conducted site visits in September and October 2005.
- The study protocol was approved by both PHSC and the Kenyan IRB in November 2005.

- Data collection instruments were pre-tested and 24 enumerators were trained in Kenya in December 2005.
- An analysis plan was developed and approved in February 2006.
- Baseline data were collected in Kenya and Uganda from January to March 2006.
- Baseline tables were developed and shared with collaborating organizations in May and June 2006.
- A presentation of baseline results was made to Family Health Options of Kenya (FHOK) in May 2006.
- A database with baseline data was provided to the Health Communication Partnership in Uganda in June 2006.
- Data were further analyzed between June and November 2006.
- A presentation of baseline results was made to FPAU in Kampala in July 2006 and to project leadership in Dar es Salaam in November 2006.
- A report: Baseline survey results for the "Young Men as Equal Partners" Project: 10-24 year-olds from Nyando, Bondo and Homa Bay districts in Nyanza Province, Kenya (M2007-02) was completed in February 2007.
- A baseline report of results in Uganda was completed in April 2007: "Baseline survey results for the "Young Men as Equal Partners" Project: 10-24 year-olds from Arua, Buschenyi, and Hoima District in Uganda" (M2007-15).
- Conversations with Family Health Options of Kenya in October 2008 to schedule and carry out follow-up data collection confirmed that the activities could not be accomplished in time to meet CRTU deadlines. As a result, the remainder of the project that was necessary to measure change was cancelled.

Findings and Outcomes:

Results from the Kenya baseline survey:

- Young men do not have sufficient knowledge about the value of "zero grazing" as an HIV prevention technique. This is reflected in the high rates of multiple partnerships, particularly among 15-19 year olds, and in the high proportion of married men who report unprotected sex with "other" partners.
- Knowledge of contraceptive methods among boys 13-24 is not high; only condoms are widely known.
- Attitudes towards inequitable gender norms, (e.g. women are responsible for contraception but they should not carry condoms) need to be addressed.
- The majority of 15-24 year olds are sexually active, and thus in need of SRH information and services.
- Almost all boys and young men listen to the radio at least once a week, making this medium an appropriate source of information for them.
- Few young men have had exposure to peer education.

Results from the Uganda baseline study:

- Few young men mentioned "being faithful" as an HIV prevention strategy and most do not know the time during the menstrual cycle when a woman is most likely to get pregnant.
- Many young men displayed inequitable attitudes toward gender norms in areas such as the role of women and violence within relationships.
- The percent reporting very risky behaviors was relatively low (especially compared to the results in Kenya) though there were some who had "other" partners and did not use condoms consistently.
- Few reported having an HIV test even among those who perceive themselves to be at medium to high risk of HIV infection.
- Of those who reported an STI symptom within the past six months, many did not seek treatment.
- Activities in churches or youth clubs, as well as over the radio, appear to be ways to reach large numbers of young men in Uganda.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 114100 114123 114122	Aug 2005 Oct 2006 Oct 2006
Total Approved Budget: 114100	\$ 404,835	Projected End Date:	Oct 2008
	114123 \$ 119,567		
	114122 \$ 119,791		
	<hr/> \$ 644,193		

Tanzania: Improving Dual Protection Counseling for Youth (FCO 114120/114139/114140)

Technical Monitor: THoke

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Barriers II.B.: Training and supervision approaches and job aids that heighten family planning or HIV service providers' capacity to promote barrier methods (most immediately, male and female condoms) developed, tested and implemented in at least three countries. Barriers II.C.: Evidence-based counseling approaches for male and female condom promotion incorporated into family planning service guidelines, including those used by HIV/AIDS programs in up to three countries.

Youth I.B.: Up to two integrated services models for youth evaluated, including one using the YouthNet counseling/testing manual.

Objective(s): 1) To design an evidence-based intervention focused on improved dual protection counseling messages and reinforced communication strategies targeting adolescents; 2) To assess the feasibility and effectiveness of training providers to deliver dual protection counseling in accordance with performance guidelines; 3) To assess adolescents' understanding and interpretation of dual protection counseling messages; and 4) To assess adolescents' retention of messages and behaviors related to dual protection.

Description: This subproject will consist of formative research conducted with youth seeking family planning or HIV/STI services. Applying qualitative methods, investigators will explore the reasoning skills young people apply in considering the dual risks of STI/HIV transmission and pregnancy. Through cognitive interviews, the formative research will examine youths' interpretation of selected dual protection counseling messages and the likelihood that alternative dual protection counseling approaches will successfully encourage risk-reducing behaviors. Through application of the technique known as PEER Research, the research team will recruit and train adolescents to conduct conversational interviews to explore factors influencing dual protection behaviors. Finally, the research team will conduct in-depth interviews with health care providers responsible for providing reproductive health services to young people to investigate their perspectives on the feasibility of dual protection promotion services. The study will result in insights to shape an intervention focused on improved dual protection counseling messages and reinforced communication strategies.

Subgrantee(s): Muhimbili University Health and Allied Sciences (MUHAS); Options Consultancy Services Ltd.

Collaborating Agency(s): Ministry of Health and Social Welfare

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Activities, Accomplishments, Problems through December 31, 2008

- The concept paper was developed and the Approval to Implement (ATI) letter and supporting documentation was sent to USAID in December 2006; changes were requested, and a revised letter was submitted in January 2007. The ATI was approved in June 2007.

- Tanzania was selected as the study site. The technical monitor traveled to Tanzania in October 2007 to advance study planning through discussions with FHI/Tanzania and field partners specializing in adolescent health services.
- The research team identified the Participatory Ethnographic Evaluation and Research (PEER) methodology as a useful qualitative technique for obtaining sensitive qualitative data.
- The protocol was prepared and submitted for ethical and technical approvals. PHSC approved the protocol in April 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Local ethical approval was obtained in February 2009.
- MUHAS named a new principal investigator (PI) who had more experience in navigating the obstacles inherent to conducting research in Tanzania.
- The subagreement with MUHAS was signed and initiated in March 2009.
- In April 2009 the technical monitor worked with a consultant specializing in cognitive interviews to refine interview guides and complete field worker training plans. The consultant then traveled to Tanzania to work with MUHAS in training interviewers.
- Instruments for cognitive interviews and in-depth interviews with providers were field tested and revised.
- The MUHAS investigator and FHI/Tanzania sought permission from public sector and non-governmental adolescent health services to conduct interviews with providers and adolescent clients.
- Field workers began conducting cognitive interviews in June 2009.

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Planned Activities for July 1, 2009 – April 28, 2010

- The subagreement with Options will be signed and initiated in July 2009.
- Options will lead the PEER Research field work beginning in August 2009.
- Provider interviews and cognitive interviews will be completed by August 2009.
- Data analysis will be completed using primarily qualitative techniques by October 2009.
- A dissemination meeting will be held with UJANA staff and their partners in November 2009.
- A final report and/or manuscript will be prepared by April 2010.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:114120	Nov 2006
		114140	Apr 2008
		114139	Apr 2008
Total Approved Budget:114120	\$ 250,142	Projected End Date:	Apr 2010
	114140 \$ 44,216		
	114139 \$ 37,928		
	<u>\$ 320,142</u>		

Zambia: Evaluation of the Students Partnership Worldwide (SPW) Model of Peer Education. (FCO 116113)

Technical Monitor: JDenison

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Barriers II.A.: Cost and effectiveness of alternative ABC delivery models targeting youth (including communication channels, messages, parental/adult

involvement, community support, and collaborating partners) evaluated and applied in at least three countries

Youth I.B.: Up to two integrated services models for youth evaluated, including one using the YouthNet counseling/testing manual.

Objective(s): To assess the behavioral impact and costs of the Students Partnership Worldwide (SPW) curriculum-based, school-based model for teaching students about pregnancy and HIV prevention in schools in Central Province of Zambia. Specific research objectives are: 1) to determine if key knowledge, attitude and behavioral outcomes related to pregnancy and HIV prevention are higher among students in SPW intervention schools compared to match comparison schools; 2) among the intervention participants, to determine if outcomes varied by exposure to the specific program elements; and 3) to characterize the cost of implementing the SPW intervention at both the current level of resources as well as at alternative models of scale-up.

Description: In order to evaluate the impact of the SPW program on knowledge, attitudes and behaviors, a non-randomized quasi-experimental design will be used to compare outcomes for students in 15 schools where SPW has been implemented for at least three years to those students in 15 schools where the SPW program has not been implemented. In addition to comparisons between students in SPW and non-SPW schools, we also examine how exposure to different program elements relates to the outcomes among students in the intervention schools.

In order to assess the costs of SPW activities in Zambia, we plan to conduct a cost analysis of the current level of resources attributed to the subproject and use that as a base case for identifying and analyzing the costs of scaling up to additional areas of Zambia and schools. FHI will develop an Excel-based spreadsheet workbook to examine the various costs of developing the initial SPW model in Zambia including training costs, curriculum development, per diems, transportation, housing, and other direct and indirect costs of the SPW model. After the initial costs are identified, FHI will work collaboratively with SPW staff to identify potential scale-up scenarios and model the costs of those scenarios for decision-makers including SPW staff and the Ministry of Education (MOE) in Zambia.

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Activities, Accomplishments, Problems through December 31, 2008

- Approval to implement the subproject was received in October 2007.
- The study protocol and research instruments received expedited approval from FHI's PHSC on November 11, 2007.
- The Ministry of Education (MOE) in Zambia approved the protocol on April 1, 2008.
- Initial review comments were received from ERES Converge, the in-country ethical review board, on April 15, 2008. Final approval was received on May 20, 2008.
- On May 29, 2008, PHSC approved the protocol revisions recommended by the in-country review board.
- From June 2-6, 2008, the study team trained 23 young people to be data collectors using PDAs followed by field testing of the instruments and data collection process.
- The first participant was enrolled on June 12, 2008. By the end of June around 1,123 participants from roughly half the 30 schools had been interviewed.
- Behavioral data collection took place from June 12-July 23, 2008.
- 2,476 students were screened, 2,464 were enrolled and 2,455 completed the survey.
- The final data analysis plan was approved by FHI's biostatistics department in August 2008.
- Sharon Tsui cleaned the behavioral data and prepared the data tables, including an analysis of the main outcomes by study groups controlling for age and gender, using GEE.
- Julie Denison went to NC the week of Nov 17, 2008 to work with Tsui of BBR and Mark Weaver of BIOS on the analysis.
- Denison and Tsui presented a brown bag presentation on the use of PDAs for data collection in November 2008 at FHI/HQ.

- John Bratt visited Zambia in November 2008 and worked with SPW on developing cost scale-up scenarios.
- The FHI SPW team submitted a 6-month ethical progress review report to the IRB in Zambia (ERES Converge) in November 2008.
- Mark Weaver verified the behavioral data analysis in December 2008 and January 2009.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The final report (M2009-12) and research brief were finalized.
- A dissemination meeting was held in Zambia with 19 participants from the Ministry of Education and other key stakeholders on Tuesday June 23, 2009 (250 research briefs were distributed). FHI received informal feedback at the meeting regarding the lack of difference in behavioral outcomes between the intervention and comparison groups. The issue of causality and associations and the use of the data as an advocacy tool for SPW for the future was also discussed.
- SPW began dissemination of study findings at the 30 participating schools. In order to receive the remaining funds from FHI/Zambia, these schools were required to submit a report detailing these visits. FHI NC has not yet received a copy of that report.
- An abstract of the results was accepted for oral presentation at the APHA November 2009 meeting.
- The study ended June 30, 2009.

Findings and Outcomes:

- Overall, 2,133 respondents from 26 schools were included in the analysis (13 intervention and 13 comparison schools).
- Sexually active students in SHEP schools were more likely to have had only one lifetime sex partner (49% vs. 42%, $p < .05$) and to have abstained from sex in the past year (63% vs. 56%, $p = 0.03$) than sexually active students from comparison schools.
- SHEP students, compared to comparison school students, have significantly higher levels of HIV and reproductive health knowledge, and scores related to positive attitudes towards people living with HIV: HIV transmission and prevention (higher levels SHEP=59%; Non-SHEP=49%);
- Abstinence as a pregnancy prevention method (SHEP=49% vs. Non-SHEP=42%); condom use for pregnancy prevention (SHEP=57% vs. Non-SHEP=51%); reproductive physiology (mean score out of 3; SHEP=1.91 vs. Non-SHEP=1.61; $p < .01$); and PLWHA attitudes (mean score out of 4: SHEP=3.28 vs. Non-SHEP=2.88; $p < .001$).
- The two pillars that VPEs spent the most time on – the ASRH classes and the extracurricular activities – were also statistically associated with a higher level of knowledge and better attitude scores among SHEP students who reported exposure to those program elements. No association was found between exposure to SHEP pillars and reported sexual behavior in the past year.
- The annual cost of implementing SHEP is US\$8,222 (GBP£4,966) per school and US\$20.61 (GBP£12.45) per young person reached.
- See the final report (M2009-12) for further details.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2007
Total Approved Budget:	\$ 279,963	Projected End Date:	Jun 2009

Zimbabwe: Audio Computer-assisted Self-interviewing (ACASI) vs. Face-to-face (FTF) (FCO 132117/172004/172007)

Technical Monitor: MSteiner

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Barriers II.I.: Innovative research methodologies that produce more valid information about sexual behavior and barrier method use for programmatic decision making developed and validated.

Objective(s): To compare the validity of reports on sexual behaviors obtained using two interview modes (ACASI and FTF) with prostate-specific antigen (PSA) as a biomarker for unprotected intercourse. Specifically, we will compare the proportion of women in the two groups (ACASI and FTF) who are PSA positive but report they have not engaged in unprotected intercourse (i.e. intercourse without a condom) in the past 48 hours.

Women exiting the MIRA diaphragm trial will be invited to return for this ancillary study. Providing they give informed consent, they will be randomized to either the ACASI or FTF group and asked questions with their assigned data collection method. Following the interview, study staff will collect a vaginal swab that will be tested for PSA.

A sample size of 1,294 women would provide about 80% power to detect a 30% reduction in discordance (reporting no sex in previous 48 hours but PSA positive), assuming the discordance in the FTF group is 20% (two-sided test; alpha 0.05).

Description: The collection of valid information about coital activity and product adherence is crucial for the interpretation of randomized controlled trials as well as the evaluation of programs. Especially urgent is a better understanding of the consistency of condom use during trials as several FHI trials are currently encountering low HIV incidence. Only recently have two FHI studies in Madagascar and Kenya, using prostate specific antigen (PSA) as a biomarker for unprotected intercourse, provided objective measures of the extent of misreporting (Gallo, in press and Gallo, in press).

PSA can be detected in the vagina immediately after unprotected intercourse and clears the vagina in 24-48 hours (Macaluso 99). Thus, the presence of PSA in the vagina indicates that a woman has been exposed to a partner's ejaculate at least once in the past 48 hours and can be used to uncover misreporting. For example, in a clinical trial in Madagascar, 21% of commercial sex workers reported they did not have intercourse in the past 48 hours but tested positive for PSA. This 21% represents the lower limit of misreporting because, depending on the timing of intercourse during this 48 hour window, a specimen may already be PSA negative due to PSA clearance from the vagina.

With this high level of documented misreporting in a clinical trial, PSA offers a unique opportunity to objectively evaluate different data collection techniques with the goal of providing empirical evidence to the approach that will minimize misreporting. A MIRA diaphragm randomized controlled trial conducted by Dr. Padian with Gates funding uses ACASI to collect information on sexual activity during the trial. About 2,000 female participants exited this trial at the Zimbabwe site between June-September 2006.

Subgrantee(s): University of California- San Francisco

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Activities, Accomplishments, Problems through December 31, 2008

- An ancillary protocol was finalized and reviewed by PHSC and the UCSF IRB in August 2006.

- The data collection forms were finalized in September 2006.
- A protocol was approved by the local IRB in November 2006.
- The study was initiated the week of December 11, 2006.
- Data collection was completed in June 2007.
- Data entry was completed in November 2007.
- PSA testing was completed at UNC laboratories in January 2008.
- A draft manuscript was written in March 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- A manuscript was submitted in February 2009 to the American Journal of Epidemiology and accepted in June 2009. (FHI Pub 2009-050).
- Team members presented study results to key stakeholders in-country.

Findings and Outcomes:

- Overall, 196 participants (21.5%) tested positive for PSA, providing biological evidence of recent semen exposure. Twenty-three (11.7%) of the women who tested positive for PSA reported no sex in the previous two days, with no difference between interview modes (12.5% ACASI vs. 10.9% FTFI, p-value, 0.72). 36.2 percent of women who tested positive for PSA reported condom-protected vaginal sex only, also with no difference by interview mode (33.7% ACASI vs. 39.1% FTFI, p-value, 0.26). Thus, the overall level of discordance between self-reports of recent sex and condom use and an objective biomarker of semen exposure was 47.9%.

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Planned Activities for July 1, 2009 – April 28, 2010

- The subproject will end and the FCO will be closed by September 30, 2009.

Funding Source(s):

	USAID - US Agency for International Development/USAID: IAA;	FCO Approved:172004	Jul 2006
	USAID - US Agency for International Development/USAID: Microbicides	132117	Sep 2006
		172007	Oct 2006
Total Approved Budget:	172004	\$ 163,170	Projected End Date: Sep 2009
	132117	\$ 64,170	
	172007	\$ 88,097	
		<u>\$ 315,437</u>	

Worldwide: Document and Disseminate Condom Programming (FCO 113141)

Technical Monitor: SHarlan

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Barriers II.F.: Evidence regarding the effectiveness of female barrier methods disseminated to policy makers to influence procurement and programming decisions.

Objective(s): FHI aimed to carry out a series of tasks to identify strengths and weaknesses of condom programming initiatives. Research utilization specialists set out to document success stories and develop case studies and lessons learned to serve as advocacy and resource mobilization tools. In contributing to this global inter-agency effort, FHI intended to fill one of the remaining gaps in the Barrier Method outcomes: Feasibility, cost, and effectiveness of male condom distribution mechanisms assessed.

Description: This exercise was intended to serve two purposes: 1) to capitalize on existing evidence about successful interventions and to facilitate its application in other venues; and 2) to identify pervasive programmatic challenges to be prioritized for operations research. FHI aimed to provide technical leadership for a well-targeted, evidence-based advocacy component aimed at mobilizing champions, and meaningfully engaging leaders and donors at all levels, including those in multi- and bilateral, governmental and civil society organizations.

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Activities, Accomplishments, Problems through December 31, 2008

- Staff participated in the Advocacy Working Group of the Interagency Task Team (IATT) for CCP. Activities included:
 - Helping plan a satellite session on CCP at the Mexico City AIDS Conference (Aug 2008); and
 - Attending the Dec 2008 meeting of the Civil Society Advocacy Working Group (one of the five working groups of the overall Interagency Task Team on CCP), in which staff participated in discussions of the overall goals and objectives of the Civil Society Advocacy Working Group, made contacts with others in the CCP field, and discussed potential collaborations and FHI contributions to the working group.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

CCP materials:

- Staff contributed to, reviewed, and suggested edits for 3 documents for the CCP working group: An advocacy letter about female-initiated barrier methods; a detailed guidance document for CCP; and a document outlining the purpose and goals of the inter-agency task team (IATT) on CCP.
- Staff developed a dissemination plan for these materials. Once UNFPA prints them, FHI will disseminate to policymakers and others. We will also have copies available at conferences and other events.
- FHI gave feedback on the CCP document "Changing Behaviour, Saving Lives," written by UNFPA.

CCP Briefs:

- From Jan-Mar 2009, staff worked on 3 CCP briefs, which were requested by UNFPA, who had agreed to provide guidance to the staff writer working on the briefs. However, the writer did not receive this guidance during the process.
- A draft of the briefs were sent to UNFPA in Mar 2009 and feedback was requested. In late May, UNFPA suggested that FHI stop working on the briefs. When asked for feedback so that FHI could revise the briefs, UNFPA declined to do so. In June, UNFPA told FHI that they had been simultaneously producing materials on CCP. FHI was participating in these activities as part of the larger CCP working group, for which UNFPA is the secretariat. To continue working on this activity would have undermined the working group. Thus, FHI ceased production, while continuing to contribute to the production of the other materials for the working group (mentioned in the first bullet under "CCP materials").

Other activities:

- Staff translated (into Fr.), edited, and posted existing FC briefs to the web.
- Staff updated existing FC information on fhi.org based on the FDA approval of new FC2 female condom.
- Staff participated in calls with the CCP Advocacy Group, including planning sessions to promote CCP at the First Ladies Summit in LA in April 2009.

Findings and Outcomes:

- FHI contributed to the development of materials that will be disseminated to policy makers and donors during FY10. These documents address the issue of feasibility of male and female condom distribution, and advocate for comprehensive condom programming (CCP).
- Staff ensured that female condom materials on fhi.org were updated with new information about the FC2, as well as other current research.
- Staff established connections with the larger inter-agency working group on CCP.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Jul 2008
Total Approved Budget:	\$ 36,817	Projected End Date:	Jun 2009

Worldwide: Production Surveillance of Condoms- Domestic and Off-Shore (FCO 148100)

Technical Monitor: SHamel

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Barriers III.B.: In-country product testing capacity developed and or enhanced in up to ten sites in support of family planning and HIV/AIDS prevention programs; documented compliance with local government regulations.

Objective(s): To ensure pre-distribution quality of condoms procured domestically and offshore by USAID, at FHI's NC laboratory.

Description: This program began in 1990 to provide close scrutiny of condom production and to ensure that condoms, procured domestically and distributed to developing countries by USAID, meet all performance standards. In 2005, the program was extended to include condoms procured from offshore factories. One hundred percent of production lots are evaluated for acceptance prior to distribution, and factories are periodically inspected for adherence to GMPs and USAID contract requirements. This subproject tracks payments for contracted sampling services including reimbursements to the manufacturers for samples taken for quality testing. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCOs 8015 Condom Production Surveillance and 8018 Production Surveillance Sampling).

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Activities, Accomplishments, Problems through December 31, 2008

- October 2005: New contract meetings were held with Qingdao, China and UNIDUS, Korea.
 - September 2006: The PQC/NC Laboratory was re-accredited for two years (through September 2008) by AALA.
- October 2006:
- GMP/Contract compliance audits were conducted at USAID offshore condom suppliers Qingdao and UNIDUS.
 - The USAID Contraceptive Warehouse in Busan, South Korea was inspected.

- A GMP/Contract compliance audit was conducted at USAID US supplier Alatech Healthcare.
- A GMP/Contract compliance audit was conducted at Qingdao.
- Confidential reports for these audits and inspection were filed.

October 2007:

- GMP/Contract compliance audits were conducted at USAID offshore condom suppliers Qingdao and UNIDUS.
- The USAID Contraceptive Warehouse in Busan, South Korea was inspected.
- A GMP/Contract compliance audit was conducted at USAID US supplier Alatech Healthcare, Alabama.
- A GMP/Contract compliance audit was conducted at Qingdao.
- Confidential reports for these audits and inspection were filed. In August 2008 a GMP/Contract compliance audit was conducted at USAID offshore supplier UNIDUS.
- January 2008: A GMP/Contract Compliance audit was conducted at USAID offshore condom supplier Qingdao Double Butterfly, in Qingdao, China; a confidential report was filed.
- March 2008: PQC Bangkok Laboratory was re-accredited for two years (through March 2010) by the Thai FDA. September 2008: The PQC/NC Laboratory was re-accredited for two years (until September 2010) by AALA.
- October 2008: Luis Lleras and Allen All attended the 2008 ASQ Audit Conference in Augusta, Georgia.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- In June 2009 a qualification audit was conducted at USAID offshore suppliers Qingdao, UNIDUS, Karex and Female Health Company.
- Between Jan 1 - June 30, 2009 the following was accomplished: 381 condom lots and 4 lots of UNIDUS lubricant were evaluated for compliance with contract specifications; 1 FC2 stability study was conducted; and 5 intralab proficiency studies were conducted.

Findings and Outcomes:

- Twenty-one supplier surveillance audits have been conducted since the beginning of the subproject.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- In July/August 2009 PQC will participate in Enersol's interlaboratory proficiency study.
- 100% of condom batches procured by USAID will be evaluated for compliance with contract specifications prior to shipment
- Each condom supplier (Alatech, Karex, Qingdao, Unidus and Female Health Company) will be audited for compliance with GMPs semiannually and visited when necessary to ensure compliance with contract requirements.
- Condom stocks stored in domestic and international warehouses will be monitored for acceptability.
- Shelf-life studies (accelerated and real-time) will be conducted when necessary to verify product stability.
- Field complaints will be investigated, monitored and analyzed. Recommendations will be submitted to USAID when warranted.
- Product failure investigations will be conducted to determine cause and effect. Corrective actions will be recommended/initiated as necessary.
- Supplier report cards will be established and maintained for all suppliers
- Other site visits, audits, and meetings will be held with USAID condom suppliers as scheduled or as needed to insure contract and GMP compliance.

Funding Source(s):	USAID - US Agency for International Development/USAID: Field Support	FCO Approved:	Jul 2005
Total Approved Budget:	Annually Approved	Projected End Date:	Apr 2010

Thailand: Production Surveillance: Domestic and Off-shore Condoms (Bangkok) (FCO 148104)

Technical Monitor: ECarter

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To ensure pre-distribution quality of condoms procured domestically and offshore by USAID, at FHI's Bangkok laboratory.

Description: This subproject was created in 2007 to reflect work being carried out by FHI's Bangkok laboratory. The purpose is to provide close scrutiny of condom production and to ensure that condoms, procured offshore and distributed to developing countries by USAID, meet all performance standards. One hundred percent of production lots are evaluated for acceptance prior to distribution, and factories are periodically inspected for adherence to GMPs and USAID contract requirements.

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Activities, Accomplishments, Problems through December 31, 2008

- Following ISO 17025 accreditation of the PQC Bangkok Laboratory in 2006, a portion of testing performed on offshore procured condoms was transferred from the NC lab. Between February 2007 and June 2008, the laboratory tested 285 lots. In addition to USAID, other organizations have contracted the facility for testing of condoms.
- Between July 2008 and December 31, 2008, 296 condom lots were tested for USAID's offshore suppliers (UNIDUS and Qingdao) prior to distribution.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- 226 condom batches were tested for USAID's offshore suppliers (UNIDUS and Qingdao) prior to distribution.
- PQC management visits were made to monitor operations and to train staff.

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Planned Activities for July 1, 2009 – April 28, 2010

- 100% of condom batches procurement by USAID will be evaluated for compliance with USAID specifications prior to shipment. Approximately 40% of the batches will be tested in the Bangkok Laboratory. Supplier and warehouse audits, and complaint investigations will be coordinated through the Bangkok laboratory when necessary.
- In July/August 2009 the Bangkok laboratory will participate in Enersol's Interlaboratory Proficiency Study.

Funding Source(s):	USAID - US Agency for International Development/USAID: Field Support	FCO Approved:	Jun 2007
Total Approved Budget:	Annually Approved	Projected End Date:	Apr 2010

HORMONAL CONTRACEPTION

GOALS	OUTCOMES
<p>I. To bring to market new hormonal and non-hormonal reversible contraceptives.</p> <p><i>(NB: USAID considers this to be a lower priority goal.)</i></p>	<ul style="list-style-type: none"> A. A more efficient design than the traditional long-term follow-up study for studying the efficacy of methods developed, evaluated and shared with other research organizations, funding agencies, and other interested parties. B. In collaboration with partners, a new, reversible, short term female contraceptive submitted to the FDA, other regulatory bodies, or other interested parties as appropriate. C. In collaboration with partners, a new reversible short term male contraceptive submitted to the FDA, other regulatory bodies, or other interested parties as appropriate.
<p>II. To improve uptake, continuation rates and use patterns of existing hormonal contraceptives.</p>	<ul style="list-style-type: none"> A. Self-injection of injectables such as subcutaneous DMPA introduced in at least one country. <i>(NB: USAID says this is not likely to be feasible before 2007.)</i> B. Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated. C. Strategies to enhance uptake of hormonal methods developed and evaluated. D. Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated. E. Policies and service delivery guidelines will be changed in at least one country to reflect new research findings.
<p>III. To expand the use of newer hormone delivery systems such as rings and patches in developing countries.</p> <p><i>(NB: USAID considers this to be a low priority goal until/unless the cost of such methods becomes substantially less.)</i></p>	<ul style="list-style-type: none"> A. The impact of newer delivery systems on continuation, compliance, and pregnancy rates in developing countries assessed. B. If feasible and cost competitive, newer delivery systems introduced in at least one country.
<p>IV. To establish the relative benefits of the currently available short-term hormonal methods.</p> <p><i>(NB: USAID considers this to be a lower priority goal.)</i></p>	<ul style="list-style-type: none"> A. A job aid to assist programs, providers and clients in assessing and balancing competing risks of using different hormonal and non-hormonal methods tested in at least one country. B. Results of these evaluations disseminated via professional literature, outreach, technical assistance, client materials, or other means to service delivery partners, normative bodies, USAID, clients, and other interested parties for incorporation into practice and procurement decisions.
<p>V. To answer important questions about positive and negative non-contraceptive effects of currently available hormonal methods.</p>	<ul style="list-style-type: none"> A. Critical questions regarding the long term safety and benefit of hormonal contraceptives identified, and at least one high priority question addressed through research. B. Results of these evaluations disseminated via professional literature, outreach, technical assistance, client materials, or other means to service delivery partners, normative bodies, USAID, clients, and other interested parties for incorporation into practice and procurement decisions.

FHI/NC subprojects fully or partially funded by USAID's CRTU Agreement:

Guatemala:	Continuous vs. Cyclic Use of COC Pills (FCO 112118/112130/112142/112144)
Jamaica:	Feasibility of Randomized Trial to Evaluate the Effect of DMPA on STI (FCO 112119/112132/112133/112134)
South Africa:	Improving Continuation Rates for Injectable Contraceptives (FCO 114102/114126)
Africa Regional:	Promoting DMPA Provision by Community Health Providers (FCO 113108)
Uganda:	Improving Service Delivery of CBD of DMPA (FCO 114111/114129)
Madagascar:	Taking Community-based Distribution of DMPA to Scale: Process, Cost, and Outcome Evaluation (FCO 114134)
Madagascar:	Taking CBD of DMPA to Scale (FCO 143109)
Nigeria:	Expand Global Evidence Base CBD-DMPA Introduction to Nigeria (FCO 113142/113152)
Madagascar:	Assessment of Late DMPA Client Management (FCO 114113/114137)
Tanzania:	Expanding Access to Hormonal Contraceptives through Drug Shops in Tanzania (FCO 113135/113155)
Uganda:	Drug Shops and Private Clinics as Sales Outlets for Injectable Contraception (FCO 114131/114149)
Africa Regional:	Do Pregnancy Tests Increase FP Uptake? (FCO 112137/114128)
Nigeria:	Evidence-based Child Spacing Intervention Development for Northern Nigeria (FCO 143104/146001)
Worldwide:	Pregnancy Provider Checklist & Reference Guide 2005 Update & Implementation (FCO 113107)
Worldwide:	A DHS Analysis of the Effects of Increased Injectable Use on Contraceptive Behavior Worldwide (FCO 114133)
Madagascar:	Immunization Services as an Entry Point to Family Planning (FCO 114141/114148)
Madagascar:	Taking Best Practices Package to Scale (FCO 143107)
Madagascar:	Scale Up Norms and Procedures (FCO 143108)
Uganda:	Advocacy for CBD of DMPA in Uganda (FCO 143115)
USA:	CONRAD: Development of LNG-butanoate (FCO TBD)
Kenya:	Development and Evaluation of a Campaign to Increase Continuation of Hormonal Methods (FCO 113149/116105/116110)

Africa Regional: Increasing Family Planning Uptake among Postpartum Women:
Testing Supply and Demand Solution
(FCO112137/114128/890030)

Kenya: Kenya CBD of DMPA Promotion (FCO 143119)

USA: Population level impact of injectable contraception (FCO 114152)

Guatemala: Continuous vs. Cyclic Use of COC Pills (FCO 112118/112130/112142/112144/890046)

Technical Monitor: KNanda

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal I.I.D.: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated.

Objective(s): To evaluate continuation rates, adherence, and acceptability of combined oral contraceptives (COCs) used by the 21/7 cyclic regimen compared with continuous use.

Description: Over 1 million unintended pregnancies annually are related to OC use, misuse or discontinuation. COC discontinuation rates are very high in developing countries, ranging from 16% in Zimbabwe to 52% and 73% in the Dominican Republic and Turkmenistan, respectively. The monthly regimen of 21 active pills followed by 7 inactive pills was created to mimic spontaneous menstrual cycles. However, the 7-day hormone-free interval is associated with withdrawal symptoms including bleeding, pain, breast tenderness, bloating/swelling and headaches. Alternate regimens of oral contraceptive pills, in which the duration of the active pill phase is longer than 21 days and/or the placebo phase is shorter than 7 days, may provide advantages over currently available standard 28-day regimens by reducing symptoms associated with the hormone-free interval, decreasing bleeding (and potentially anemia), enhancing acceptability, and thus improving continuation rates. There are no published data on the use or acceptability of extended use COC regimens in women in developing countries. This will be a prospective, randomized, controlled clinical trial, to be conducted in a family planning clinic in a developing country. Approximately 350 healthy 16-30 year-old, non-pregnant, and non-lactating women with regular menstrual cycles will be randomized to monophasic COCs (ethinyl estradiol 30 mcg and levonorgestrel 150 mcg) using either the conventional 21/7 regimen or continuous use. Participants in the continuous COC group will use active pills without interruption unless bleeding or prolonged spotting signals need for a hormone-free interval. We will evaluate pill continuation through 12 months, assess adherence, acceptability (both quantitatively and qualitatively), bleeding, and side effects. Additional outcomes are pill instruction comprehension, 12-month pregnancy probabilities, and hemoglobin levels.

Subgrantee(s): PROFAMILIA, Dominican Republic; PROFAMILIA, Nicaragua

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- FHI obtained preliminary approval to work on this study in the 2006 Workplan.
- Please refer to Annual Report (2007-2008) for accomplishments that took place prior to January 2008.
- The Guatemala site staff resigned in Dec. 2007 due to staff disputes over salary and hence the site was closed early in Feb. 2008.
- FHI staff conducted a site evaluation visit at PROFAMILIA in the Dominican Republic (DR) in Mar. 2008.
- PHSC approved the revised study protocol and consent forms on May 9, 2008. The Spanish versions of the protocol and informed consents were approved by the IRB of PROFAMILIA in the DR in May 2008.
- FHI staff conducted a site evaluation visit to PROFAMILIA in Nicaragua in May 2008 and in June they conducted study initiation training at PROFAMILIA in the DR.
- A sub-agreement was finalized for the DR site in July 2008.

- A site initiation visit took place at the Nicaragua site in Sept. 2008.
- The PROFAMILIA, DR site started screening and enrolling participants on Oct. 23, 2008.
- The sub-agreement was drafted and the budget was finalized for the PROFAMILIA, Nicaragua site (FCO 112144). Study initiation was delayed because the pills had not been released from customs as of Dec. 2008. The site drafted a study implementation plan for the Nicaragua Ministry of Health in order to release the pills from customs.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The first periodic site monitoring visit took place at the DR site in January 2009.
- In February 2009, the in-depth interviews began at the DR site. Through June 2009, a total of 23 in-depth interviews had taken place.
- Due to ongoing administrative and logistical issues at the Nicaragua site, we decided to cease study preparations at this site and to withdraw Nicaragua as a site. Unresolved issues include failed attempts by the site staff to obtain necessary approvals from the MOH; inadequate communication with FHI; inadequate ability to provide regulatory documents; and failure to pass the FHI financial audit. FCO 112144 was closed in March 2009.
- In March 2009, PHSC and the DR PROFAMILIA IRB approved the amended protocol version 2.4.
- The DR site exceeded enrollment targets and agreed to enroll all study participants. A total of 241 women have been enrolled through May 2009.

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Planned Activities for July 1, 2009 – April 28, 2010

- Note that FHI has proposed transitioning some of this activity to PROGRESS. If approved with the PROGRESS Year 2 Workplan, the projected end date will be extended.
- The study team will continue to monitor data on a continual basis through DMNET.
- Two interim monitoring visits will take place in the upcoming year.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 112118 Sep 2005 112130 Jan 2007 112142 May 2008 112144 Sep 2008 890046 Jul 2009
Total Approved Budget:	112118 \$ 486,642	Projected End Date: Apr 2010
	112130 \$ 90,050	
	112142 \$ 126,313	
	112144 \$ 86,764	
	890046 \$ 225,134	
	\$ 1,014,903	

Jamaica: Feasibility of Randomized Trial to Evaluate the Effect of DMPA on STI (FCO 112119/112132/112133/112134)

Technical Monitor: DHubacher

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Hormonal V.A.: Critical questions regarding the long term safety and benefit of hormonal contraceptives identified, and at least one high priority question addressed through research.

Objective(s): To determine whether or not a proposed randomized trial to evaluate the effect of DMPA on STIs is feasible.

Description: Data from observational studies published 2004-2006 have suggested that use of progestin-only contraceptive methods may increase the risk of acquisition of sexually transmitted infections (STIs), including chlamydia (CT), gonorrhea (GC), and HIV. However, this conclusion is suspect because of possible failure to control adequately for selection bias and confounding. For example, a higher rate of risky behaviors among progestin-only method users than among non-users could result in an apparent but false association between method use and infection. Considering the public health importance of both progestin-only methods and STIs, clarification of this issue is urgently needed. In addition, the role of herpes simplex virus (HSV) infection in mediating an increased HIV risk associated with depot medroxyprogesterone acetate (DMPA), as suggested in one recent study, needs further evaluation. The best way to provide this clarification would be through a randomized trial. This subproject assessed the feasibility of a randomized trial to investigate the effects of DMPA on the incidence of GC and CT.

Subgrantee(s): Epidemiology Research & Training Unit; University of Witwaterstrand; Westridge Medical Ctr

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Activities, Accomplishments, Problems through December 31, 2008

- Three potential sites were identified including two in South Africa and one in Jamaica.
- Budgets were negotiated with the South Africa and Jamaica sites.
- One additional potential site in Madagascar was investigated but dropped because a reasonable budget could not be negotiated.
- Informed consent forms and survey instruments were drafted and reviewed by the site investigators.
- Approval to implement was provided by USAID in June 2006.
- All three sites signed and returned the subagreements and received their first payment.
- The protocol was revised and approved by all IRBs in October 2006.
- The questionnaire was pre-tested and finalized.
- Data collection began at all three sites in January 2007.
- Completed forms were sent to FHI, and data entry was completed in July 2007.
- A data analysis plan was approved, SAS analysis programs were written, and a mock analysis was completed.
- A paper titled "Hormonal contraception and the risks of STI acquisition: results of a feasibility study to plan a future randomized trial" was published in *Contraception* 2008 May. 77 (5): 366-70 (FHI Pub 2008-52).
- A secondary analysis was conducted and the article (letter) examining condom use and STI was submitted for publication.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The second paper was rejected by the journal and no further work was done to revise it.
- The subproject ended and the FCO was closed on January 31 2009.

Findings and Outcomes:

- Abstract: Hubacher D, Raymond EG, Beksinska M, Delany-Moretlwe S, Smit J, Hylton-Kong T, Moench TR.
- Hormonal contraception and the risks of STI acquisition: results of a feasibility study to plan a future randomized trial. *Contraception* 2008 May. 77 (5): 366-70.

- **Background:** Because of limitations in observational studies, a randomized controlled trial (RCT) would help clarify whether hormonal contraception increases the risks of acquiring a sexually transmitted infection (STI). However, the feasibility of such a trial is uncertain.
- **Study Design:** We conducted a study to assess the feasibility of conducting an RCT that would compare the acquisition risk for Chlamydia trachomatis and Neisseria gonorrhoeae in women randomized to an intrauterine device (IUD) or depot medroxyprogesterone acetate (DMPA). In our cross-sectional survey conducted at three clinics, we gave information on a potential RCT to clients, asked them questions to assess comprehensibility and finally asked respondents whether they would consider enrolling in such a trial. In addition, the 190 participants provided urine or endocervical swab specimens so we could estimate the prevalence of STIs.
- **Results:** Overall, 70% of participants stated that they would take part in a future trial and accept randomization to either the IUD or DMPA. Participant understanding of the trial requirements was high. Twenty-nine percent of the participants were infected with either N. gonorrhoeae or C. trachomatis.
- **Conclusion:** With a high prevalence of STI in this population and the apparent willingness of appropriate candidates to participate, an RCT to measure risks of incident STI infection from hormonal contraception appears feasible.
- **Research to Practice Statement:** Based on this study in the selected clinics, the feasibility of randomizing participants to either an IUD or DMPA is no longer a major concern. This evidence will help researchers interested in this topic to propose a trial to measure STI acquisition and how incidence might differ by type of contraceptive method.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 112119 112132 112133 112134	Sep 2005 Oct 2006 Oct 2006 Oct 2006
Total Approved Budget:	112119 \$ 155,605	Projected End Date:	Jan 2009
	112132 \$ 8,545		
	112133 \$ 21,144		
	112134 \$ 3,490		
	\$ 188,784		

South Africa: Improving Continuation Rates for Injectable Contraceptives-South Africa (FCO 114102/114126)

Technical Monitor: KRademacher

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal I.I.D.: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated.

Objective(s): To improve continuation rates for injectable contraceptives by developing and testing an intervention tool for family planning providers in South Africa that will: 1) reduce the proportion of DMPA/NET-EN clients who discontinue (i.e. do not come back at all); 2) reduce the proportion of DMPA/NET-EN clients who are late for their re-injections; and 3) increase the proportion of late DMPA/NET-EN clients who leave the clinic with a re-injection or another temporary contraceptive method until their next scheduled re-injection.

Note: USAID approved the Research Utilization global activity entitled, "Enhancing Continuation of DMPA" which was added to this existing FCO for \$45,000 in January 2009. The objective of this RU subproject is to consolidate evidence to date on DMPA continuation efforts/ DMPA management and promote relevant programmatic messages among service delivery CAs and FHI offices in the field.

Description: Injectable contraceptives such as DMPA and NET-EN account for a large proportion of the method mix for women in low resource settings; however, continuation rates are low. In addition to women who choose to discontinue, a proportion of women who are considered "discontinuers", are in fact, women who are actually late for their re-injections. Following up on a previous FHI study in South Africa (FCO 9515), this study will be a prospective cohort study of hormonal injectable users. This study will develop and evaluate a new tool for providers that encourages client continuation and helps ensure re-injections for late clients who would like to continue using injectables. The intervention will be composed of: 1) enhanced counseling by providers for initial injectable clients; and 2) provider training on how to manage late continuing injectable clients.

Once the new intervention tool has been developed, a prospective injectable client cohort study will be conducted with 1,400 new and restarting injectables clients at 12 purposefully selected family planning clinics (divided into six matched pairs) in rural areas near the town of Umtata in the Eastern Cape in order to test the effectiveness of the provider tool intervention. Six clinics will receive training on the intervention tool and six will be control clinics. The primary study outcome for testing the effectiveness of the intervention is continuation rates after one re-injection cycle for new and re-starting injectable clients at intervention clinics versus control clinics.

Subgrantee(s): Women's Health Research Unit - University of Cape Town (WHRU); Women's Health Research Unit of the University of Cape Town (UCT)

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- In October 2005, the Women's Health Research Unit at the University of Cape Town (UCT) was identified as the subgrantee.
- The TM met with UCT collaborators to discuss the study design and protocol development.
- The protocol was completed and approved by PHSC in June 2006.
- Approval to implement was obtained in July 2006.
- The subagreement with UCT was approved in August 2006 (FCO 114126).
- The TM visited Cape Town and Umtata, South Africa in September 2006 to work with UCT. The trip included meetings with family planning providers, supervisors, and health officials in the Eastern Cape in order to present findings from the first study (FCO 9515). The trip also included visits to potential clinic study sites and discussions with UCT staff on the study protocol, study instruments, and tool development.
- The intervention tool and study instruments were completed and approved internally at FHI and pre-tested in the field.
- Interviewer training was conducted in March 2007.
- Provider training on the intervention tool was conducted in May 2007.
- Initiation of data collection was delayed until July due to a national health worker strike.
- A subagreement amendment was prepared to extend the end date by three months to June 30, 2008 because of the strike and slower than expected recruitment due to out of stock injectables. In addition, the budget was revised to \$208,948 to accommodate the added months and also the salaries to retain the trained data collectors during the strike.
- Data collection was completed by March 2008.
- Data entry and cleaning were completed by December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Data analysis was completed in May 2009.
- A presentation was prepared for a local dissemination meeting in Umtata, South Africa held on June 8, 2009. The local PI presented the study results to provincial stakeholders and provided feedback to all 12 study clinics who participated in the study.
- A consultant agreement with the local PI (Chelsea Morroni) was prepared so she could complete dissemination activities (presenting at a national dissemination meeting and training the control clinics on use of the new intervention tool).

Findings and Outcomes:

- Injectable study clients were often late for their re-injections (no difference in lateness between cohort clients at intervention and control clinics). However, among cross-sectional and cohort clients arriving with the 2 week grace period 94% and 78% were re-injected in the intervention and control clinics respectively (NOTE: This is of clients who arrive late but within the grace period). In addition, among clients arriving 2-12 weeks late 80% and 34% were re-injected in the intervention versus control clinics respectively.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- A national dissemination meeting for the study will be held in consultation with the National DOH.
- The study control sites (who did not receive the intervention) will be trained on the revised DMPA and NET-EN re-injection job aids.
- The TM will prepare and submit a manuscript to a peer-reviewed journal highlighting the study results.
- Global RU activities on “Enhancing continuation of DMPA” will include 1) completing revisions and printing the DMPA and NET-EN re-injection job aids based on providers’ feedback in Senegal where a global version is being field-tested, 2) finalizing versions for community based health workers, 3) developing and implementing a global dissemination plan which will include dissemination of the job aids in South Africa, Senegal, Kenya, Uganda, Nigeria and elsewhere.
- Global dissemination meetings and/or trainings for the global job aids will be planned where appropriate and feasible (e.g. an abstract has been submitted to the International Conference on Family Planning that will take place in Kampala, Uganda in November, 2009).

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:114102 Sep 2005 114126 Jul 2006
Total Approved Budget:114102	\$ 308,275	Projected End Date: Apr 2010
114126	\$ 236,520	
	\$ 544,795	

Africa Regional: Promoting DMPA Provision by Community Health Providers (FCO 113108)

Technical Monitor: KKrueger

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal II.B.: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated
Hormonal II.C.: Strategies to enhance uptake of hormonal methods developed and evaluated.
Hormonal II.E.: Policies and service delivery guidelines will be changed in at least one country to reflect new research findings.

Objective(s): 1) To improve the quality of family planning services offered at selected community health programs in Uganda and one other East African country (Kenya) by providing technical assistance for the expansion of contraceptive options to include injectable contraception; 2) to generate interest in scale-up and replication of DMPA provision by community health workers among policy-makers and community health programs throughout the African continent and other regions; 3) to initiate discussions with Ministries of Health in Uganda and Kenya, which may result in amendment of the National RH Guidelines so that eligibility to provide injections is based upon appropriate training and demonstrated skill; 4) to update FHI's DMPA Checklist in line with the WHO Medical Eligibility Criteria and disseminate it; and 5) to produce and print 500 toolkits or "how-to" guides to enable programs to expand their choice of contraceptive methods to include injectables.

Description: The results of a cohort study conducted by FHI in collaboration with Save the Children/USA (SC) (FCO 9327) demonstrate the safety, feasibility, and acceptability of CBD in a rural Ugandan district. The study results reinforce the wealth of successful experiences from other regions such as Asia and South America, and provide a strong basis to affirm that well trained community health workers can provide injectable contraception safely in the African context.

Improvements in access to and knowledge of contraceptive options, can have a tremendous impact on the RH outcomes of women. In addition since DMPA is a strongly preferred method in the proposed country sites (accounts for over 40 percent of the method mix) and since community health programs remain an important mechanism for contraceptive distribution in the rural areas, the introduction of injectables to this distribution system has the potential to increase demand for DMPA, and substantially increase contraceptive prevalence.

This subproject will involve a multi-tiered approach. First, FHI will strengthen our efforts in Uganda to build consensus, expand provision of DMPA by community health workers, and amend national FP guidelines. Second, a toolkit will be designed to enable community health programs to expand their choice of contraceptive methods to include injectables. Third, FHI will develop and implement a comprehensive action plan in collaboration with a selected partner in East Africa to implement DMPA service provision in their community health programs. Finally, FHI will disseminate and showcase the toolkit as a means to generate interest and further promote inclusion of DMPA among methods provided by community health workers throughout the African continent and other regions.

Note: As of mid 2009 see also FCO 143119 (Kenya), FCOs 143115 and 143110 (Uganda). Also, see FCO 113118 for printing and dissemination.

Collaborating Agency(s): Christian Children's Fund (CCF); Conservation Through Public Health (CTPH); Jhpiego; Minnesota International Health Volunteers (MIHV); Save the Children; World Health Organization (WHO)

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- Approval to implement was granted April 06.
- Please refer to 07-08 annual report for accomplishments prior to July 08.

Uganda:

- Held a study tour with 22 delegates, Feb 08.
- Re-printed and added the DMPA checklists to the national FP curriculum (5,000), April 08.
- Signed MOUs with two local NGOs and supported their stakeholder meetings and trainings (143110).
- Reprinted 150 cartoon manuals for SC's training, May 08.
- Collaborated with local media to publish CBD of DMPA articles (May/July 08).
- Assisted DRH to encourage uptake in 73 districts (Sep 08).

- Convened exchanges between SC and MOH CBD program managers from Bugiri and Busia (July 08) and held quarterly meetings, a refresher training, and collected data (July and Oct 08).
- Held National core team meetings (Aug and Dec 08).

Kenya:

- Finalized and signed an MOU with JHPIEGO (Sep 08).
- Held a meeting with Tharaka district officials (Oct 08), and met agents and supervisors in the Turima site (Nov 08). The meeting in Turima revealed a paucity of active agents and a new location was identified in early 2009.

Globally:

- Delegates from Rwanda and Nigeria presented evidence to local FP and RH TWGs (Feb 08). Introduction activities are now underway in both countries. In Rwanda, FHI provided support to an MOH assessment; a local consultant was hired and a protocol drafted (see 890025). In Nigeria, FHI developed a budget and MOU with partners in Nigeria (113142).
- Discussions were held with ChildFund International (formerly CCF) to pilot in Zambia, March 08. A pilot project is now underway (890017).
- FHI served as resource at USAID SOTA for HPN officers in S. Africa, April 08. FHI presented at the GHC conference in DC (May 08), the MAQ Mini-U (Aug 08), the FlexFund Partners Meeting (Sept 08), the MEASURE conference in Tanzania (Dec 08), and the SAGO Meeting in Mali (Dec 08).
- FHI developed: new case studies, Introducing the CBD of Injectable Contraception in Uganda and Expanding the CBD of Injectable Contraception in Africa (Aug 08; cost share 113118); the DMPA module of the FPRP (FCO 113128); and a variance letter through the end of the CRTU.
- Advocacy tool needs were identified with USAID, WHO, and IBP.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

Uganda:

- Signed MoU with Bwindi Comm. Hospital for replication to additional seven parishes (113108/143115). Drafted report, Scaling-up CBD of Injectable Contraceptives in Uganda: Lessons Learned from Private and Public Sector Implementation.

Kenya:

- Conducted a rapid assessment of, Kanyuru and Rukenya, the original location was deemed a non-starter due to insufficient agents (Feb 09); this added to delays but new locations were selected.
- Received a field support award (\$65K) in April 09 (143119). Prepared a training curriculum; however, the draft required significant revision adding to delays in training, scheduled for July/Aug 09.
- FCO 143119 opened May 2009 for Kenya activities.

Globally:

- Planned for a technical consultation on expanding access to injectables which convened at WHO, June 09 with 30 experts (113108/890010).
- Community-based providers offer quality injectable contraceptive services in rural Guatemala brief was finalized and produced by WHO.
- Hosted V. Graham in NC to debrief on CBD of DMPA activities, Feb 09.
- Met to identify new advocacy materials to be developed for website for Mission HPN officers.
- Presented at CSTS+'s regional FP workshop in Ghana and ECSA in Swaziland (Q1, 09) (890009).
- Updated English providers manuals and implementation handbook.
- Produced new research briefs from recent Uganda and Madagascar studies in May 09.
- Supported rapid assessment in Rwanda, but with limited technical involvement to the MOH led activity.
- In-country IRB approval was obtained and data collection began (113108/890025).
- Fast-tracked CBA of Depo for K4Hs online toolkit with FHI serving as the technical lead (113108/16542).
- Submitted panel abstracts to the Gates Institute International FP Conference in Kampala.
- Developed survey to gauge stakeholder interest in Ghana for the USAID HPNO and DMPA module for training CHWs (113108/113128).
- Signed an agreement between FHI and CCF to prepare for the pilot project/study in Zambia (890017).

Findings and Outcomes:

- Please refer to the 07-08 annual report for findings prior to July 08.
- Opportunities to promote CBD of DMPA were pursued with Malawi, Tanzania, Madagascar, Kenya, Rwanda, Nigeria, Senegal, Mali, Benin, Burkina Faso, Ivory Coast, DRC, and Zambia.
- As of Dec 08 in Uganda, CBD programs run by the MOH, MIHV, and CTPH are replicating.
- A report of the Kenyan educational tour (Mar 07) to Uganda was written (M2007-19).
- At the Mission's request, "Mapping of CBD programs in Uganda" was written (M2007-51).
- Over 5000 DMPA checklists and 3000 advocacy kits were distributed.
- Funds were leveraged from the Uganda MOH for an extra training through SC.
- The Uganda Mission allocated field support (\$200,000) to ramp up advocacy efforts (FCO 143115).
- A study tour with 22 delegates from Nigeria, Rwanda, Tanzania, and local NGOs was held (Feb 08). After the tour, Rwanda initiated a national assessment of CBD programs; Tanzania prioritized repositioning FP before advocating for CBD of DMPA; and Nigeria began a pilot project with FHI's support.
- A CBD of DMPA article was published in Uganda's Monitor Newspaper with FHI help (May 08).
- FHI produced new case studies, Introducing the Community Based Distribution of Injectable Contraception in Uganda and Expanding the Community-Based Distribution of Injectable Contraception in Africa (Aug 08; cost share 113118).
- New research briefs Community-based Access to DMPA: Madagascar and Drug Shops and the Provision of DMPA: Uganda were produced in May 09.
- Using Local Data to Move 30 Years of Evidence into Practical Solutions: The Case of CBD of Injectable Contraceptives in Africa was presented at the MEASURE evaluation symposium in Tanzania Jan 09.
- The USAID/FHI/ WHO technical consultation on expanding access to injectables was convened at the WHO in Geneva, June 15-17 with 30 technical and program experts. The consultation concluded that there is sufficient evidence to support the introduction, continuation, and scale-up of community-based provision of progestin-only injectable contraception (113108; cost share with PRGS).

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- A request for a budget increase to cover additional activities was approved in February 2009.
- For Uganda see FCO 143110 and 143115.
- For Kenya see 143119.

Globally staff will:

- 1) At USAID request, participate in the planning committee for a 1 day Technical Update for CAs in Sept 09
- 2) Finalize the HPN webpage content to be housed on the USAID website
- 3) Continue to present evidence at global and national conferences, such as FIGO, ECSA, and the Kampala conference (cost-shared with PROGRESS)
- 4) Continue to strategize with USAID, WHO, and IBP to develop new promotional materials.
- 5) Provide follow-up support to field implementation in Kenya, Uganda & Nigeria.
- 6) Continue to collect and strategically assess information on countries interested in introducing the practice. Follow up with countries that have expressed interest in CBD of DMPA (Benin, Burkina Faso, Ivory Coast, DRC, Senegal, Togo, Rwanda, Mali) (PROGRESS cost share).
- 7) Pre-test and produce a limited number of the DMPA modules of the FP Resource Package.
- 8) Support coordination of in-country activities and with key partners such as USAID, IBP, WHO (cost shared with PROGRESS)
- 9) Develop an end-of-project document for all FHI CRTU research and research utilization efforts.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2005
Total Approved Budget:	\$ 956,537	Projected End Date:	Apr 2010

Uganda: Improving Service Delivery of CBD of DMPA in Uganda (FCO 114111/114129)

Technical Monitor: JStanback

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal II.D.: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated.

Objective(s): To assess scale-up of a program for service delivery of DMPA in a community-based distribution program.

Description: An FHI study conducted in collaboration with Save the Children demonstrated the safety, feasibility and acceptability of community-based distribution (CBD) of depot medroxyprogesterone acetate (DMPA) in a rural Ugandan district. Results showed that CBD provision of DMPA appears to be as safe as provision by nurses. DMPA clients of CBD agents are equally satisfied compared to their clinic-going counterparts and may even prefer CBD provision to clinic-based provision. Given that DMPA is a strongly preferred method in Uganda and that CBD programs serve a broad sector of the population, the introduction of injectables to this distribution system has the potential to increase demand for DMPA and substantially increase contraceptive prevalence particularly in rural areas.

The objective of this research subproject was to assess the planned scale-up of this program for CBD of DMPA in Uganda. The research included four components; 1) to document all the systems put in place for safety, logistics, re-supply, supervision, etc.; 2) to examine the costs of the program to determine whether adding injectable contraceptives to a CBD program can make it more cost-effective; 3) to re-visit the original CBD clients who received DMPA in 2004 to assess their current contraceptive practices as well as how they coped with district-wide stock-outs of DMPA in 2006; and 4) to assess the potential of private nurses in rural areas to act as community-based distributors of DMPA.

Subgrantee(s): Save the Children

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Activities, Accomplishments, Problems through December 31, 2008

- Joy Noel Baumgartner met with Save the Children/USA in Uganda in June 2006 to discuss design and protocol development. A meeting with USAID/Uganda was also held to solicit their feedback on the study design.
- John Stanback became the new Technical Monitor for the study in September 2006.
- Stanback traveled to Kampala, Uganda in November 2006 to discuss the study protocol and the plans for study initiation.
- Stanback drafted a protocol and study instruments for the study in March/April 2007.
- Stanback traveled to Uganda in May 2007 to make final arrangements for research.
- At the Mission's request, Stanback made visits to rural drug shops and private clinics in Uganda to assess their potential as DMPA providers.
- The study was exempted from IRB review at both FHI and Uganda in June 2007.
- The subagreement was approved and sent to Save the Children in June 2007.
- Stanback and Otterness traveled to Uganda in July 2007 to train data collectors and data entry staff.

- Study staff in three rural districts conducted three separate surveys from August through December 2007.
- Olivia Nakayiza entered and sent to FHI data from the three surveys.
- Conrad Otterness completed data cleaning in May 2008.
- Otterness and John Stanback began data analysis in June 2008
- Otterness and Stanback conducted data analysis periodically through Spring 2009, focusing on three separate reports.
- Stanback completed a report for Save the Children on "Injectable Provision in Drug Shops" in August 2008, which was also turned into an "FHI Research Brief."

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Stanback and Otterness drafted manuscripts for publication for the drug shop and scale-up sub-studies, and provided Cheri Poss technical assistance for her Master's paper on the long-term follow-up sub-study. Stanback, Otterness and Poss will finalize and submit all three papers for publication in the near future using FCO 114106.
- The FCO was closed in June 2009.

Findings and Outcomes:

- The initial assessment by Stanback revealed that small private clinics, usually operated by unlicensed nurses, were a major provider of health care, including family planning services, in the three rural districts served by Save the Children. A subsequent CRTU study (FCO 114131) is building on this study by training drug shop operators in safe injection and family planning skills and evaluating the outcomes.
- Scale-up of CBD of DMPA was successful. Most client outcomes in scale-up districts were similar to those in the pilot district and in clinics. However, client knowledge of side effects remained a problem.
- Findings showed that injectable contraceptives are sold and injected in most rural drug shops, an illegal practice, yet one with the potential to increase contraceptive access.
- Findings from the long-term follow-up study were included in the evidence review for the WHO consultation on community-based provision of DMPA in June 2009.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:114111 114129	Feb 2006 Jun 2007
Total Approved Budget:114111 \$ 114129	166,454 N/A	Projected End Date:	Jun 2009

Madagascar: Taking Community-based Distribution of DMPA to Scale: Process, Cost, and Outcome Evaluation (FCO 114134)

Technical Monitor: ABrunie

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal II.B.: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated
Hormonal II.C.: Strategies to enhance uptake of hormonal methods developed and evaluated.

Objective(s): 1) To evaluate the performance of CBD agents offering DMPA services in pilot and scale-up sites; 2) to assess the functioning of the systems for training, supervision, and logistics for CBD of DMPA; 3) to identify the over-arching factors influencing the success of scale-up; and 4) to estimate the incremental costs of adding DMPA provision to the range of services offered in the CBD program. An objective on assessing the influence of a recent change in contraceptive pricing policies on client demand for CBD of DMPA was abandoned due to the low interest expressed by stakeholders in Madagascar. The other objectives were reordered and reworded for clarity but remain the same. Note: Following recent political development and the change of leadership in Madagascar, USAID suspended non-humanitarian aid. The funds supporting the study have been transferred to PROGRESS and the study was cancelled.

Description: Community-based provision (CBD) of DMPA holds great potential for increasing access to highly effective contraception. FHI and partners studied the feasibility and acceptability of adding DMPA to the contraceptive methods offered by CBD workers in 13 communities in Madagascar. Based on positive findings, the Ministry of Health and Family Planning (MOH FP) was planning scale-up. It was envisioned that CBD of DMPA could be introduced in up to four times as many sites with greater reliance on the existing public sector health infrastructure.

This study of DMPA scale-up was to examine the research utilization process, providing an opportunity to study factors facilitating and impeding success. The evaluation team was to rely on a combination of methods to meet the evaluation objective. Field workers were going to conduct key informant interviews with MOHFP managers at the national, regional and district levels to document the intended and actual process by which responsibility for CBD of DMPA was decentralized. The integrity of essential support mechanisms was also to be examined, and the barriers and facilitators of success to be explored. Interviews were also to be conducted with NGO managers and CBD supervisors at the facility level to gain their perspectives on program configuration. The evaluation team was to estimate the incremental costs of implementing the intervention. To monitor service delivery quality and continuity, the evaluation team was going to conduct interviews with CBD workers and review service delivery records. Finally, review of service statistics, along with client interviews, was also supposed to serve to meet the final objective of assessing the effect of price changes on uptake of DMPA from CBD workers. Following political events in Madagascar, research activities were suspended and the study was transferred under PROGRESS. A new FCO will be opened as appropriate.

Collaborating Agency(s): Ministry of Health and Family Planning, Madagascar

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- The approval to implement letter was submitted to USAID and approved in January 2008.
- The research team provided technical guidance to FHI/Madagascar on monitoring tools to be used for the scale-up of CBD of DMPA. These same tools will serve as one mechanism to assess service quality in the scale-up study.
- FHI/Madagascar hired, trained, and deployed a field worker to support supervisors in collecting performance data and service statistics that will be used for the rapid interim assessment of the scale-up process.
- The research team reviewed the literature on scale-up to guide development of the conceptual framework for the scale-up study in July and August 2008.
- A reconnaissance trip was made to Madagascar at the end of August/beginning of September 2008 to learn about the CBD of DMPA intervention and to assess stakeholders' information needs. The project was introduced to a panel of 19 local and state-level stakeholders.
- Preliminary contact was made with a local research organization to manage data collection in September 2008.
- The research team worked with a CRTU health economist to consider options for measuring costs in the study in October 2008.
- The protocol and data collection instruments were drafted in December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The protocol was approved in March 2009.
- Data collection instruments and informed consent forms were drafted in March 2009.
- The materials required for exempt review by PHSC were prepared in March 2009.
- The FCO was closed in June 2009 because USAID suspended non-humanitarian aid in Madagascar due to recent political development and the change of leadership. The funds supporting the study have been transferred to PROGRESS.

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Planned Activities for July 1, 2009 – April 28, 2010

- PROGRESS FCOs will be opened as appropriate.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2007
Total Approved Budget:	\$ 203,389	Projected End Date:	Jun 2009

Madagascar: Taking CBD of DMPA to Scale in Madagascar (FCO 143109)

Technical Monitor: MMalkin/TZan

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal II.B.: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated
Hormonal II.C.: Strategies to enhance uptake of hormonal methods developed and evaluated.

Objective(s): To assist the MOHFP/Madagascar and its partners to institutionalize the CBD of DMPA into their CBD programs.

Description: Activities to scale up CBD provision of DMPA will take place in the two districts in Madagascar served by phase one of this project, Moramanga and Anosy, and will expand into six new geographic locations - Alaotra Mangoro, Analamanga, Vakinankaratra, Amoron'i Mania, Atsimo Andrefana, and Ihorombe. It is currently envisioned that a total of 360 CBD agents will be trained in the provision of DMPA by the end of 2008. (The original sites that were part of phase one of this project will continue to be supported in terms of monitoring and supervision).

Collaborating Agency(s): Action Santé Organisation Secours (ASOS); Adventist Development Relief Association (ADRA); CARE; MCDI; Ministry of Health and Family Planning, Madagascar; Santénet

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Activities, Accomplishments, Problems through December 31, 2008

- Approval to implement was received from USAID in Nov 07.
- In Nov and Dec 07, study results and findings from the pilot phase were shared with MOH central and regional staff, as well as with the key partners. Suggestions for scale-up plan were also collected.

- Based on pilot study results and implementation lessons learned, all training manuals were revised. Revisions included enhancing the interaction between trainers, CBD agents and supervisors during the trainings. The heightened participation of CBD agents resulted in higher post-test scores and an observed increase in CBD agents' efficiency in providing DMPA.
- The pre-test document used to select qualified CBD workers for training was revised to make it more comprehensible for CBD agents.
- Negotiations with partners were held to identify new sites, define roles and responsibilities and develop partnerships.
- New implementing partners were identified for scale-up in 3 regions: Atsinanana Mercy Ministries, Analamanga with PENSER, and Vatovavy Fito Vinany with Saf FJKM.
- In June 08, FHI collaborated with the MOH to host a study tour on the CBD of DMPA for a Malawian delegation. The delegation consisted of key stakeholders from the MOH, USAID, MSH, Futures Group, DELIVER and CHAM. The main objectives of the trip were to: 1) gain first-hand experience implementing CBD of DMPA; and 2) develop recommendations for the next steps for the MOH in Malawi.
- Monitoring (via telephone discussions with regional health representatives, health center representatives, and NGOs) of CBD agents was conducted to determine the progress of CBD workers' activities for the 11 regions (21 districts) where the program was implemented.
- FHI staff met with the MOHFP in December 08 to discuss goals for scale-up, locations, and a revision for a second edition of the training manuals for trainers, providers, and supervisors.
- FHI conducted trainings for 448 persons (including 331 CBD agents, 57 trainers, and 60 supervisors) in 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- FHI conducted training for 138 persons (including 75 CBD agents, 49 supervisors, and 12 trainers) from January – April 2009.
- In March 2009, Andry Rajoelina, mayor of Antananarivo, took power from President Marc Ravalomanana and put a new government into place. In response, the U.S.—via the State Department and USAID—announced that all non-humanitarian assistance would cease. CRTU activities were suspended, although FHI continued to conduct some training on CBD of DMPA in the field through April, at which point these activities completely ceased. Discussions with USAID/W and Mission led FHI to transfer remaining funds from CRTU to PROGRESS effective July 1 2009. The CRTU FCO (143100) was closed as of June 30, 2009.

Findings and Outcomes:

- Malawi adopted CBD of DMPA informed by their June 2008 study tour to Madagascar.

Funding Source(s):	USAID - US Agency for International Development/USAID: Field Support	FCO Approved:	Jan 2008
Total Approved Budget:	\$ 539,144	Projected End Date:	Jun 2009

Nigeria: Nigeria: Expand Global Evidence Base CBD-DMPA Introduction to Nigeria (FCO 113142/113152)

Technical Monitor: CDreisbach

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal II.B.: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated
Hormonal II.C.: Strategies to enhance uptake of hormonal methods developed and evaluated.
Hormonal II.D.: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated.

Objective(s): To provide technical assistance to a designated core team of individuals who will take the lead on introducing community-based distribution of injectable contraceptives into Nigeria. FHI's technical assistance will serve to adapt the model implemented in Uganda and Madagascar to the Nigerian context.

Description: This subproject seeks to build on the global effort to scale up community-based distribution (CBD) of DMPA, and to demonstrate that the innovation can be adopted in the Nigerian context. The aim is to increase access for women to hormonal contraceptives and ease provider workloads by shifting tasks to properly trained community-health workers.

This subproject follows on a Feb. 2008 study tour of five Nigerian delegates to Uganda to observe CBD of DMPA programing (funding through FCO 113108).

FHI will provide the following technical assistance (TA) to the Nigerian FMOH, and implementing partner the Association for Reproductive and Family Health (ARFH):

1) Convene stakeholders and a core team to guide the demonstration project; 2) Conduct assessment of proposed implementing sites; 3) Provide support for necessary modifications to the existing monitoring and supervision systems to include the safe provision of injectables; 4) Adapt existing training modules and job aids to Nigerian context; 5) Provide technical assistance in training of CBD agents and supervisors; 6) Assist in drafting a scaling-up strategy, in the event of a successful demonstration project; and 7) Collect data and support monitoring and evaluation of the program.

Subgrantee(s): Association for Reproductive and Family Health (ARFH) (FCO 113152)

Collaborating Agency(s): Association for Reproductive Health (ARFH); Federal Ministry of Health (FMOH), Nigeria

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Activities, Accomplishments, Problems through December 31, 2008

- Approval to implement from USAID was received in October 2008.
- A meeting held with FMOH in July 08 led to the formation of technical working group (TWG) to guide implementation. Members were drawn from the already existing RH working groups.
- FHI convened the TWG of 19 participants, representing relevant stakeholders, to draft guidelines for implementation and monitoring, drawing on the Ugandan experience (Aug 08). C. Dreisbach, TM, for this subproject traveled to Nigeria to finalize the budget and discuss work planning with FHI-Nigeria staff (Oct 08).

- FHI held an initial meeting with the director of ARFH, Dr. Ladipo and ARFH staff to discuss partnership formalization, budgets, subagreements and the scope of work (Dec 08) ARFH developed a draft budget for the subagreement for implementation (Dec 08).

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- An assessment of ARFH's capacity was conducted in collaboration with selected state officials (Feb 09).
- A no-cost extension for this subproject was approved (May 09) The new project end date is April 2010.
- A core team meeting was held (May 09) with ARFH and FMOH to review and finalize the project proposal and subagreement.
- C.Dreisbach was assigned as TM for this project in June 2009.
- A new FHI CBD of DMPA training curriculum was shared with GHAIN in June 2009.

Findings and Outcomes:

- In July 2008, the FMOH requested that the subproject be implemented in two states, but after discussions with ARFH about available funds, implementation will only occur in one site. FHI-GHAIN committed to meeting any funding needs that may exist over and above the CRTU allotted funds (Jan 09). FHI had planned to support a local champion to advocate for national policy change; however, due to project delays and budget constraints, this activity was dropped from the initial year of implementation.

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Planned Activities for July 1, 2009 – April 28, 2010

- FHI will provide TA to ARFH on the following activities: adaptation of existing M&E and supervision strategy for DMPA provision; and adaptation/review of the FHI-FMOH integrated training materials.
- FHI will collect baseline data from selected sites at the request of the CBD of DMPA TWG. TM plans to travel to Abuja in July 2009 to work with GHAIN and ARFH staff to co-facilitate training of trainers (TOT) in Gombe state which will take place in July and August 2009.
- FHI will support monthly data collection efforts, and will convene the TWG on a regular basis to report on the status of implementation. In the event of a positive implementation experience, FHI will support the TWG in planning for scale up. After subproject activities are completed, a final report will be written.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:113142 Jul 2008 113152 Jun 2009
Total Approved Budget:113142	\$ 85,809	Projected End Date: Apr 2010
113152	\$ 65,946	
	\$ 151,755	

Madagascar: Assessment of Late DMPA Client Management (FCO 114113/114137)

Technical Monitor: LDulli

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal II.B.: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated
Hormonal II.D.: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated.

Objective(s): To collect information from contraceptive users and family planning service providers in order to develop interventions that are designed to improve injectable continuation rates.

Specific study objectives were:

Client-level study objectives: 1) to assess the prevalence of lateness among injectable contraceptive clients who return to the clinic for follow-up injections, as well as the degree of lateness (e.g. after the scheduled date, but within the grace period, after the grace period) among women who return for re-injection late; and 2) to assess barriers to receiving timely injections.

Provider-level study objectives: 1) to assess medical barriers to timely re-injection posed by current clinical management of clients who receive injectable contraceptives, such as counseling on when to return for re-injection, and how return visits are scheduled; and 2) to assess current clinic practices regarding management of late clients.

Note: In early 2007, the title of this subproject was amended to that provided above. Its former title was identical to a subproject being conducted in South Africa with somewhat different objectives and a distinction was needed.

Description: Progestin-only injectable contraceptives, such as depot medroxyprogesterone acetate (DMPA), are highly effective hormonal contraceptive methods, provided users receive timely injections. An increasing proportion of women who use a form of hormonal contraception in sub-Saharan Africa are using injectable contraceptives. This fact emphasizes the importance of appropriate clinical management for those who choose injectable contraceptives.

Despite increasing popularity, discontinuation rates for injectable contraceptives remain high. Some studies have shown discontinuation rates for injectable contraceptives as high as 58 percent at 12 months after initiation to 70 percent at 18 months. While the most commonly reported reasons for discontinuation are side effects, including menstrual disturbances and weight gain, it has been suggested that these numbers might be inflated. This perception arises from the fact that, counted among discontinuers are women who return to clinics seeking to continue with the method, but return late (after the scheduled re-injection date) and thus are not given the injection. One study by Potter and colleagues revealed that 20 percent of discontinuers were classified as such because they returned for re-injections after the accepted time period for re-injection. Thus, we do not know the impacts that being late and the clinical management of late clients have on discontinuation rates. In such cases, women might become involuntary discontinuers, and dependent upon how their contraceptive care is managed, at-risk for unintended pregnancy.

This study was designed to assess the degree to which lateness is a problem, how late clients are managed and to use findings from the study to suggest strategies to reduce unintentional DMPA discontinuation due to lateness.

Subgrantee(s): National Institute of Public & Community Health

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- Chin-Quee met with staff of Nicaragua's MOH in May 2006 to propose a study to inform improvement of continuation rates of family planning methods provided by the MOH. The Minister requested that FHI use its service statistics on method use and discontinuation to guide study design and to meet with the Commission on Sexual and Reproductive Health to get input.
- At the time of the meeting, the MOH did not have its service statistics available but the Health Services Research (HSR) and Behavioral and Social Sciences (BASS) groups at FHI proposed a study using a qualitative/quantitative approach to improving continuation rates.
- In August 2006, Chin-Quee and Burke met with the Commission on Sexual and Reproductive Health in Nicaragua. The MOH reported that they now had the service statistics, which showed that there was

not a problem with the continuation rates in Nicaragua, and therefore the Nicaragua-based study was not needed.

- Madagascar was selected as the new site for this study aimed at improving continuation rates.
- The study protocol was significantly revised and approved in September and October 2007.
- The data collection forms were finalized and submitted for review in December 2007.
- The study protocol was amended to include a potential second phase, the need for which will be determined based upon results from the first phase of the study.
- PHSC and Madagascar Ethics Committee approvals were obtained in March 2008.
- Dulli traveled to Madagascar in March-April 2008 to assist in training for data collectors, which was immediately followed by the beginning of data collection activities.
- Data collection was completed in July 2008.
- Data entry, cleaning and analysis was begun in August 2008.
- The second phase of the research study was deemed unnecessary based on preliminary results from phase 1.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Data analysis was completed and a final study report drafted in June 2009. Technical Leadership funds (FCO 114106) will be used to complete the report.
- The FCO was closed in June 2009.

Findings and Outcomes:

- While a full 20% of returning DMPA clients returned after their scheduled date for DMPA re-injection, nearly 3 out of 4 returned within one week of their scheduled injection, and nearly all had returned within 2 weeks. Only 2.7% (n=16) of the 570 returning clients interviewed returned for their reinjection more than 2 weeks after their scheduled date.
- Nearly all returning clients received a re-injection of DMPA, regardless of their lateness status. Only 8 out of 128 late clients did not receive a re-injection, 4 of whom were less than 2 weeks late and 4 of whom were more than two weeks late.
- Most common reasons for returning late included: did not remember appointment date (23%), could not get time off from school or work (23%) or had another commitment (22%).
- Although 74% of the family planning providers interviewed stated that they specified a grace period for returning to the clinic, nearly all limited that grace period to 1 week or less after the scheduled date of reinjection. Few mentioned any grace period for returning prior to the scheduled date.
- Although lateness was a problem in this sample of returning DMPA clients, if the WHO recommended grace period was applied, over 97% of returning clients would have received their DMPA injection at that current visit.
- Despite the fact that 69% of providers stated that they observed a 1 week grace period for DMPA clients, it appears as though the grace period is inconsistently applied, and there was no clear pattern for denying a re-injection to those few late clients who did not receive an injection.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:114113	Apr 2006
		114137	Mar 2008
Total Approved Budget:114113	\$ 184,347	Projected End Date:	Jun 2009
	114137		
	\$ 54,421		
	<hr/>		
	\$ 238,768		

Tanzania: Expanding Access to Hormonal Contraceptives through Drug Shops in Tanzania (FCO 113135/113155)

Technical Monitor: CLasway

Strategy Outcomes(s) to be addressed: Hormonal II.B.: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated

Hormonal II.C.: Strategies to enhance uptake of hormonal methods developed and evaluated.

Hormonal II.D.: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated.

Hormonal II.E.: Policies and service delivery guidelines will be changed in at least one country to reflect new research findings.

Objective(s): To increase access to hormonal contraceptives in Tanzania through drug shops.

Description: Countries have advanced to increase access and demand to hormonals to those underserved by health care facilities through CBD programs. However, without consistent funding or efficient management, these programs face sustainability challenges. Drug shops – already being the first source for medicines for many rural African communities - provide promising solutions to these issues because they are privately owned and tend to support a more sustainable commercial market for health products. However, in the majority of African countries, COCs and DMPA are classified as prescription drugs, and thus, their distribution in these drug shops is not permitted. Such is the case in Tanzania, where there are more than 4,600 drug shops established to serve the rural and peri-urban communities operating under two parallel systems: (i) Duka la Dawa Baridi (DLDBs) – non-accredited drug outlets and (ii) Accredited drug outlets (ADDO shops). ADDO shops are allowed to sell prescribed COCs while DLDBs are not. On the other hand, whilst ADDO shops do sell other injectables, including Quinine, DMPA is not included on the approved list.

FHI, in collaboration with the USAID/Tanzania, as well as T-MARC, PSI, and the Health Policy Initiative, were working to facilitate the amendment of the current national policy to support distribution of COCs by DLDBs. Under this subproject, FHI will provide technical evidence and operational guidance to facilitate policy and practice changes and explore potential opportunities to enhance ADDO's role in the provision of FP which includes: allowing initiation of COCs and the inclusion of DMPA vials on the list. Many of the CRTU evidence-based practices for hormonals, including screening checklists, Contraceptive Effectiveness Chart, COC Strategy Guide will be used in training dispensers to safely provide COCs. In doing so, FHI will provide lessons learned and an example to other countries in Africa with a similar rural infrastructure.

Subgrantee(s): NIMR

Collaborating Agency(s): AED/T-MARC; Futures/Health Policy Initiative Project; Management Sciences for Health (MSH); Ministry of Health and Social Welfare; Tanzania Food and Drug Administration

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Activities, Accomplishments, Problems through December 31, 2008

- Please refer to the 07-08 annual report for accomplishments prior to July 08.
- In Aug. 07, USAID approved this subproject.
- In November 2008, a two-page brief on The Potential of Drug Shops in Maximizing Access to Family Planning in Africa was developed. This brief will be finalized and disseminated once new data from assessments conducted in Uganda and Tanzania has been incorporated.

- In September 2008, staff provided input to developing a strategy with which the new PROGRESS could strengthen the case of drug shops in Family Planning under the legacy area - Maximizing human resources by task shifting and addressing medical barriers to FP services.
- In December 2008, FHI developed a protocol to conduct an assessment of the accredited drug shops for the provision of expanded FP services.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Several stakeholder consultations were held with TFDA, MSH, and RCHS on the goals and objectives of the proposed assessment. A decision was made to postpone the assessment until accreditation of new drug shops was completed in June 2009 so as to have a comparison of FP practices between new and older ADDOs.
- As of June 2009, the assessment protocol was submitted for exemption determination with the FHI PHSC.
- As of June 2009, the National Institute for Medical Research (NIMR) was recruited as the local research organization to conduct data collection, analysis and report writing.

Findings and Outcomes:

- Given the fact that it seems OCs are currently available in ADDOs both on a prescription basis and for initiation using the community-based distribution framework, it seems the original intent of the subproject was not needed. Using ADDO shops to improve access to injectable contraception was also considered as a possible research question, however, it will likely require several different steps, and this process could be enhanced by providing the MOH and TFDA with country-specific evidence.
- Under the recent Global Fund Round 7, Tanzania has been funded to accredit non-accredited drug shops (DLDBs) into ADDOs in the remaining regions. As a result, the mission and partners will discontinue efforts to facilitate policy change to allow for DLDBs to re-supply COCs by the TFDA.

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Planned Activities for July 1, 2009 – April 28, 2010

- Finalize data collection tools for drug shop dispensers and key informants.
- Provide technical assistance to NIMR on the analysis and presentation of results from the assessment.
- Using information collected from the assessment of the drug shops, FHI will host a review, conduct analysis, and strategic planning workshop with key stakeholders to plan the way forward. It is expected that new operations research ideas that could be taken on by PROGRESS, as well as new RU initiatives will arise from this workshop.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 113135 Aug 2007 113155 Aug 2009
Total Approved Budget:	113135 \$ 328,756	Projected End Date: Feb 2010
	113155 \$ 42,942	
	\$ 371,698	

Uganda: Drug Shops and Private Clinics as Sales Outlets for Injectable Contraception (FCO 114131/114149)

Technical Monitor: DChin-Quee

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal II.B.: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated
Hormonal II.C.: Strategies to enhance uptake of hormonal methods developed and evaluated.
Hormonal II.D.: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated.

Objective(s): To assess the suitability of rural drug shops and private clinics as sales outlets for socially marketed injectable contraceptives.

Description: CBD programs have been shown to be effective at extending family planning services to rural areas in Africa, but they are often criticized as being too expensive. One possible alternative to traditional CBD programs would be to make better use of private providers. However, in rural areas, such providers are often low-level nursing aides or auxiliary nurses working in small drug shops. Since these drug shop operators already provide injections in their local communities, including contraceptive injections, they would presumably be simple to recruit and train. Where pills and injectables are socially marketed, their provision of FP services would also be sustainable. Working with Save the Children-Uganda and Uganda's USAID-funded social marketing project AFFORD, we will assess the family planning knowledge, attitudes and practices of rural nursing aides before and after training a cohort of these private providers in contraceptive service delivery skills, including safe injection. If possible, we will also interview recent clients of nursing aides and compare their contraceptive knowledge and outcomes with those of local CBD and clinic clients in an existing local cohort.

Subgrantee(s): Save the Children

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Activities, Accomplishments, Problems through December 31, 2008

- Since the original FCO 114111 for the baseline study was closed in 2008, a new FCO for the follow up, 114131, was established.
- Stanback and Otterness traveled to Kampala, Nakasongola, and Luwero in Uganda in July 2007 to make initial preparations for this subproject.
- Stanback returned to Uganda in November 2007 to work with Save the Children on plans and budgets for the training portion of the study, and to discuss controversial aspects of the research with USAID/Kampala, the AFFORD Project, and the Ministry of Health.
- The study protocol, instruments, and amended subagreement were drafted in June 2008.
- Chin-Quee assumed the duties of Technical Monitor in July 2008 and finalized the protocol and data collection instrument (drug shop operator follow-up survey). Negotiations for a new subagreement with SC were initiated in August 2008. SC's training of drug shop operators was originally scheduled for November 2008, but was changed to February 2009 due to ongoing contract negotiations and protocol review.

- The study protocol and drug shop operator follow-up survey were reviewed in-house and PHSC approval received in December 2008. The protocol and survey were subsequently sent to Dr. Mbonye at the MoH and Martha Bekiita of SC for their review and approval.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Because our current MoU is with Save the Children USA, we were unable to finalize a contract with their Uganda office, which is now managed by Save the Children Norway. We maintained a working relationship with Save the Children in the three study districts, but the FHI Uganda office took over the tasks required to meet study objectives.
- Patricia Wamala at the FHI/Uganda office assumed the role of study coordinator, identified and hired two clinical trainers, and finalized the training curriculum with their assistance. This three-person FHI team trained 43 drug shop operators (not 58, because some drug shop operators from the initial baseline had moved or could not be found and some who had not participated in the pre-test were also trained) from Nakasangola, Nakaseke, and Luwero between June 22nd to 25th.

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Planned Activities for July 1, 2009 – April 28, 2010

- All study documents will be reviewed, finalized and approved by the local IRB, the National Council for Science and Technology--following approval by SC staff and Dr. Mbonye of the Ministry of Health.
- Of the drug shop operators who participated in the pre-test, 34 will be trained before the follow-up survey is administered, and if funds allow, the remaining will be trained after data has been collected.
- The 58 drug shop operators who will receive training will be chosen by simple random selection.
- Follow-up surveys of drug shop operators will be conducted in September 2009 .
- The survey data will be analyzed.
- A report will be written.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:114131 114149	Jul 2007 Jan 2009
Total Approved Budget:	114131 \$ 121,000	Projected End Date:	Apr 2010
	114149 \$ 33,882		
	\$ 154,882		

Nigeria: Evidence-Based Child Spacing Intervention Development for Northern Nigeria (FCO 143104/146001)

Technical Monitor: STsui/JRoss

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal I.I.D.: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated.

Objective(s): To conduct an assessment: 1) to understand the barriers to the uptake of FP methods in northern Nigeria; 2) best practices in promoting family planning in this region, and similar areas (e.g. Sahel countries); and 3) to collect information on young married couples that would identify promising

interventions to improve family planning uptake in this region of Nigeria. Note: Funds were insufficient to launch an intervention; so this work is preliminary to an intervention.

Description: This subproject seeks to identify promising family planning/child spacing interventions in northern Nigeria, a region with low modern contraceptive use and poor reproductive health indicators. Information generated from this effort will add to the knowledge base about how to increase demand for and utilization of family planning services and will directly inform the development of targeted programs to reposition FP in northern Nigeria with a special focus on young married couples (ages 15-30). Note: The subagreement under FCO 146001 was covered with GHAIN funds and FCO 146001 was closed but funds remain for paper writing.

Subgrantee(s): Development Research & Projects Center (dRPC) Society for Family Health

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Activities, Accomplishments, Problems through December 31, 2008

- Review of barriers and best practices in promoting FP in N. Nigeria and similar areas submitted to USAID/Nigeria Dec 2006.
- FHI selected Participatory Learning and Action (PLA) research method with focus on young married people, ages 15-30 (males and females). Discussion/interview guides finalized.
- Study protocol and instruments were submitted to PHSC and USAID/Nigeria. Study was approved by PHSC in Feb 2007.
- FHI, in consultation with USAID/Nigeria, selected Zamfara and Kano States.
- FHI recruited co-principal investigators from a Kano research firm (DRPC) to conduct PLA.
- DRPC and FHI contacted communities in N. Nigeria to conduct the PLA.
- DRPC and FHI initiated field work training, stakeholder workshop, and data collection.
- DRPC conducted key informant interviews at state/local levels, including NGO managers, services providers, and religious and community leaders; mapping exercises with married young people to understand their experiences, attitudes and preferences regarding child spacing; and FGDs in study communities.
- Data collection was completed in April 2007.
- Transcription and translation was completed May 2007.
- FHI received qualitative data from 6 Local Government Areas in two states.
- A draft was provided to the Mission who requested work on recommendations.
- A Nigeria consultant was hired (Dec 2007) to review the report. GHAIN organized an expert meeting to review the draft. Suggestions by Nigerian FP experts, FHI staff in NC and Nigeria, and subcontractor were incorporated.
- The final report was submitted to GHAIN and USAID Mission Jan 4, 2008.
- USAID Mission asked Dr. Kale to review the report. He approved it without revisions.
- Dissemination of study findings and recommendations to key community stakeholders (those who participated in the stakeholder workshop at study start-up) took place April 7, 2008.
- Copies of the final report were re-sent after adding authors.
- Study results were presented at Psychosocial Workshop (April 15, 2008), New Orleans.
- Through the FHI/Nigeria office, FHI disseminated, to USAID/W and to a CA (Georgetown), given possible local interest in introducing the Standard Days Method in N Nigeria.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Due to commitments of Williamson and Tsui, most work on this project was inactive Jan - June 2009, but we will be actively working on the papers in the coming months.

Findings and Outcomes:

- This Nigerian study examined barriers and facilitators to FP and child spacing (F/CS) among young married men and women, age 15-30 years in Kano and Zamfara States in North West Nigeria. Qualitative methods (Participatory Learning and Action (PLA) methods, in-depth interviews, and FGDs) generated information from young married people, community members, and key stakeholders.

The report (M2006-38) emphasizes respondents' thoughts in their own words, quoting from 35 PLA exercises with young men and young women; 43 in-depth interviews with adult stakeholders, and 20 FGDs with adults in the communities. Results:

- Fertility norms (what is meant by a "large", "medium", and "small" family and what is an ideal family size) remained very high, especially for rural men.
- Most young married men and women held positive attitudes towards FP because they understood it to contribute to child spacing (CS). They perceived CS as beneficial for MCH, particularly to avoid "kwanika" – when a woman becomes pregnant before she has finished weaning her child.
- Regarding key sources of information on FP/CS, young married men and women identified radio, peers, health talks, and modern health care providers.
- Regarding communication and decision making on FP/CS, many young married women perceived their husband's attitudes to be negative so they did not talk to them about practicing FP or CS. Men and women believed the husband had the most influence on a couple's decision to practice FP.
- Regarding knowledge and attitudes toward FP methods, young married men and women identified these FP methods- natural: breastfeeding, periodic abstinence, and withdrawal (azi); traditional- guru, karhu, laya, rubutu, local herbs and seeds, goyon ciki; and modern- oral contraceptive pills, injectables, and male condoms. Young married men and women had mixed attitudes towards these methods. They thought modern methods more effective but traditional methods safer and more convenient.
- Although the majority of health care providers perceived FP to be beneficial to MCH, several expressed ambivalence about delivering FP services, especially to married women who were unaccompanied by their spouse.

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Planned Activities for July 1, 2009 – April 28, 2010

- FHI (Williamson/Tsui) will continue to carry out qualitative data analysis and prepare to submit two papers for publication "glimmers of change in N Nigeria among young adults" and another on different results obtained by qualitative and quantitative research on traditional contraceptives.

Funding Source(s):	USAID - US Agency for International Development/USAID: Field Support	FCO Approved:143104 Apr 2006 146001 Mar 2007
Total Approved Budget:143104 \$ 146001	196,016 N/A	Projected End Date: Apr 2010

Worldwide: Pregnancy Provider Checklist & Reference Guide 2005 Update & Implementation (FCO 113107)

Technical Monitor: CLasway

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal II.B.: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated

Objective(s): 1) To update the FHI Pregnancy Checklist in accordance with WHO's 2004 Medical Eligibility Criteria; 2) to revise pregnancy checklist reference materials and to produce and disseminate 2,000 reference guides and 9,000 pregnancy checklists; and 3) to promote the pregnancy checklist to CAs and PVOs, and provide technical assistance for its implementation and use in at least three in-country programs, in an effort to reduce medical barriers and increase access to FP.

Description: In many countries, 25 to 50 percent of women are denied a contraceptive method on their first visit to a family planning clinic because they are not menstruating at the time. The FHI checklist, "How to be reasonably sure a client is not pregnant," provides an easy-to-use screening tool for various levels of health care providers, including physicians in resource-poor settings, pharmacists, or staff stationed at health posts. FHI research in Kenya and Guatemala demonstrated that the pregnancy checklist virtually eradicated the practice of turning away non-menstruating clients. The pregnancy checklist was developed based on WHO Medical Eligibility Criteria and under the CTR, it was both passively and actively disseminated through mailing lists, Network, conferences/workshops, and focused efforts under Research to Practice. It is a simple, low-cost job aid, easily implemented and replicable by in-country program managers with little or no assistance from FHI. FHI believes further outreach to CAs would encourage greater use in USAID-funded programs. Under the CRTU, FHI will work to promote the checklist to pharmacies, VCT clinics, and other non-traditional family planning outlets, to increase access, improve referral mechanisms, and ultimately impact public health.

This subproject will provide support for technical review and update, printing, and dissemination of the Pregnancy Checklist, as well as the development of appropriate background materials in the form of a reference guide to facilitate implementation by programs. A pregnancy checklist promotion strategy will also be developed, outlining focused dissemination and outreach efforts, including global and enhanced focus-country components. It will include a systematic approach for documenting dissemination, follow-up, and (where possible) use of the checklist over a three-year period.

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Activities, Accomplishments, Problems through December 31, 2008

- As of June 2006, a Pregnancy Checklist was developed and printed in five languages: English, Spanish, French, Romanian, and Kiswahili.
- In April 2006, electronic checklists were initially distributed to 12 RH/FP list serves and 5 external non-FHI Websites.
- As of Dec. 2007, FHI responded to 33 user-initiated requests for the checklist (a total of 6,290 disseminated) in Cambodia, Ethiopia, Kenya, Haiti, Mali, Rwanda, Thailand, Zambia, Madagascar, Nigeria, India, Bolivia, Ghana, the Dominican Republic, Romania, South Africa, Swaziland, Tanzania, Uganda, and the USA.
- By July 2007, 6 countries adapted and translated the checklist into their guidelines and distributed it to providers and trainers: Madagascar, May 2006 (FCO 114121); Uganda, June 2006; Romania, Sept. 2006; Kenya, Jan. 2007; Tanzania, April 2007 (by Tanzanian FDA); Senegal, Nov. 2007 (by Intrahealth for the Maternal Neonatal, and Child Health Project).
- Evaluation of dissemination/utilization of the checklist in the Dominican Republic and Uganda was completed in Aug. 2007.
- In May 2008 the checklists were translated and printed in Hindi. Dissemination is on-going and supported under FCO 113132/113136.
- FHI disseminated 835 Pregnancy checklists in response to requests from India, South Africa, DRC, Mali, and the U.S between Jan-June 2008,
- In Feb.-April 2008, 5,000 adapted checklists were re-printed in Kenya and Uganda, respectively. In Uganda, the checklist was included in the national FP basic skills training curriculum.
- In April 2008, 2,000 copies of the English Training and Reference Guide for the Pregnancy checklist were printed, of which 352 copies were disseminated upon request to organizations in Ethiopia, Nigeria, Zambia, Kenya, India, Tanzania, China, Vietnam, Uganda, Fiji, Indonesia, Senegal, Cameroon, Zimbabwe, and the U.S. The French translated version was made available on FHI's and various partner websites and listserves.

- As of June 2008 a report entitled "Measuring the usefulness of family planning job aids following distribution at training workshops" was completed by K. Tumlinson, D. Hubacher, J. Wesson and C. Lasway. It will be submitted to peer-reviewed journals.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Jan-Dec. 2008 938 checklists have been disseminated and 88 service providers have been trained in Kenya.
- The manuscript was submitted for publication and the FCO was closed July 2008.

Findings and Outcomes:

- The pregnancy checklist has been endorsed and co-branded by the Ministries of Health in Uganda, Kenya, Madagascar, Senegal, Tanzania, and Romania.
- The pregnancy, COC, DMPA, IUD checklists have been spontaneously picked up by JSI and independently translated into Romanian and Russian.
- The pregnancy checklist has been included in the new JHUCCP Global Handbook for Family Planning (April 06), and in the WHO Decision-Making Tool.
- Findings from two recent evaluations conducted in Uganda and the Dominican Republic (DR) which measured the usefulness of FHI's family planning provider checklists 7 to 12 months after training workshops in which the checklists were distributed, showed that although providers found the checklists to be useful in their work, training workshops do not lead to high use of job aids. It was concluded that additional dissemination strategies may be needed to ensure high use of job aids, including supportive supervision of job aid integration in the service delivery setting.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2005
Total Approved Budget:	\$ 189,075	Projected End Date:	Jul 2008

Madagascar: Immunization Services as an Entry Point to Family Planning (FCO 114141/114148)

Technical Monitor: LDulli

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal II.B.: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated

Objective(s): The primary goal for this subproject was to increase contraceptive prevalence among postpartum women who desire to either space or limit their pregnancies, thus reducing unmet contraceptive need.

Specific objectives included: 1) To increase knowledge among postpartum women regarding return to fertility and pregnancy risk during the postpartum period; 2) To increase the number of women who can correctly name the three LAM criteria; 3) To increase knowledge among postpartum women regarding their contraceptive options; and 4) To increase provider awareness and knowledge of return to fertility, LAM, pregnancy risk and contraceptive options among postpartum women.

Description: In Sub-Saharan Africa the unweighted average of unmet contraceptive need among women 0-12 months postpartum is 74%, with 55% needing to space and 19% needing to limit. Only 3-8% of women want another child within 2 years of giving birth.

Although few women seek postpartum services, they do seek health services for their infants. Given their timing, immunization (IZ) services are an obvious means to reach postpartum women with FP messages, services and/or referrals. However, such strategies are largely untested.

This current study proposed to evaluate an intervention designed to increase access to postpartum FP by using immunization services as an entry point to the service.

The primary outcomes were to increase contraceptive prevalence and thus reduce unmet contraceptive need among postpartum women. The primary objectives were: 1) To assess the effectiveness of integrating FP into IZ services, measured in terms of increased contraceptive prevalence and reduced unmet contraceptive need among postpartum women attending IZ services; and 2) to evaluate the acceptability and feasibility of implementing the intervention as measured by service uptake, and assessing client and provider perspectives.

The study would have allocated health care facilities into intervention or comparison groups. Pre and post test exit interviews of women at the selected clinics were to be conducted. Given the relatively high uptake of IZ services as compared with other preventive health services, the impact of employing IZ services as an entry or access point for FP services could be quite important. The feasibility of successful integration was supported by the strong Madagascar MOH commitment in addition to FHI's extensive experience in integrating FP services into existing health care services. Replication and scale-up of FP-IZ service integration was supported by the increasing interest among partners and other organizations, such as the CDC, in the possibility of such strategies.

Subgrantee(s): Institut National de la Sante Publique et Communautaire (INSPC)

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Activities, Accomplishments, Problems through December 31, 2008

- The integration intervention was designed, based on findings from an earlier formative study and input from key stakeholders.
- The study protocol was developed and approved through technical review in December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- This study was canceled in Madagascar and moved to Rwanda under PROGRESS FCO 890028 due to the military coup d'état that resulted in USAID suspending all activities in Madagascar.
- The FCO was closed in July 2009.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:114141 Jul 2008 114148 Feb 2009
Total Approved Budget:114141	\$ 272,788	Projected End Date: Jul 2009
114148	\$ 74,153	
	<hr/>	
	\$ 346,941	

Madagascar: Taking Best Practices Package to Scale (FCO 143107)

Technical Monitor: MMalkin/TZan

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal II.B.: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated
Hormonal II.C.: Strategies to enhance uptake of hormonal methods developed and evaluated.

Objective(s): To assist the MOHFP/Madagascar and SantéNet institutionalize the Best Practices Package (BPP) into regular service delivery in appropriate sites.

Description: This subproject builds on earlier efforts in Madagascar under FCOs 123101 and 113115. Scale-up activities will target 90 percent of health facilities in the three districts served by phase one of this project i.e. Alaotra Mangoro, Analamanga and Amoron'i Mania, and 50 percent of health facilities in three additional districts, yet to be determined but in the same regions. It is currently envisioned that an additional 60 providers and program managers will be trained in the implementation and support of the BPP. The original sites, that were part of Phase one of this effort, will also continue to be supported in terms of monitoring and supervision.

Collaborating Agency(s): Ministry of Health and Family Planning, Madagascar

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Activities, Accomplishments, Problems through December 31, 2008

- Approval to implement the scale-up effort was given by USAID in Jan 08.
- FHI staff discussed the pilot study results with NC staff and key stakeholders from the MOHFP. Findings were presented to INSPC and MOH departments in charge of Immunization, STI and HIV/AIDS and Safe Motherhood programs.
- The Best Practices Package (BPP) was one of the key topics discussed at the Mini University in June 08.
- Stakeholders' commitments to support the BPP scale-up program were collected during the Mini-University.
- The MOHFP, FHI and INSPC agreed to set up a steering committee and to hold regular coordination meetings.
- Negotiations took place with MOH and partners on how to translate study findings and commitments for scale-up into programmatic activities.
- A mini-workshop was organized in collaboration with National Leadership Institute in Oct 08 to follow-up on commitments collected during the Mini-University June 08. Partners and the MOH agreed to integrate the BPP into MOH provider trainings and that the involvement of the pilot study sites is critical for quality scale-up.
- 3 regional mini-workshops focusing on the interpretation of the pilot study results were conducted in Moramanga, Ambositra and Antananarivo Sud in Oct 08 for providers and district MOH staff. Strengths, weaknesses and new suggestions were discussed and recommendations from participants were regrouped by INSPC to serve as a reference document. Based on recommendations and on the review of Population Council's guidelines, it was agreed that a new streamlined BPP model should be designed before any scale-up program is implemented and that the efforts should be focused under a uniform leadership in a particular geographic area.

- The steering committee defined the key components of the new BPP model and INSPC developed a draft.
- It was agreed at the RH Coordination meeting in December 08 that the new model of BPP will be implemented solely in the region of Amoron'i Mania because of the personal commitment of the regional director to support the BPP program and the region's relatively low contraceptive prevalence.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Several working meetings were held with INSPC, FHI, and the MOHFP on the new BPP model in January and February 2009.
- In March 2009, Andry Rajoelina, mayor of Antananarivo, took power from President Marc Ravalomanana and put a new government into place. In response, the U.S.—via the State Department and USAID—announced that all non-humanitarian assistance would cease. CRTU activities were suspended, though staff and office are being maintained.
- Discussions with USAID/W and Mission led FHI to transfer remaining funds from CRTU to PROGRESS effective July 1 2009. The CRTU FCO (143107) was closed as of June 30, 2009.

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Planned Activities for July 1, 2009 – April 28, 2010

- This activity is currently on hold pending further guidance from State Department and USAID.

Funding Source(s):	USAID - US Agency for International Development/USAID: Field Support	FCO Approved:	Jan 2008
Total Approved Budget:	\$ 250,952	Projected End Date:	Jun 2009

Madagascar: Scale Up Norms and Procedures (FCO 143108)

Technical Monitor: MMalkin/TZan

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal II.B.: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated
 Hormonal II.C.: Strategies to enhance uptake of hormonal methods developed and evaluated.

Objective(s): To develop and disseminate practical tools and materials to help health care providers navigate and apply the revised, national recommendations.

Description: USAID/Madagascar has allocated field support funds to FHI to assist with the development and dissemination of practical tools and materials to help health care providers. FHI is assisting the MOHFP in ensuring utilization and scale-up of these tools/materials by: developing a training curriculum to roll out the provider tools/materials, supporting the training of providers, and convening stakeholders to garner support for additional regions in Madagascar.

Collaborating Agency(s): Ministry of Health and Family Planning, Madagascar

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Activities, Accomplishments, Problems through December 31, 2008

- The concept paper, approval to implement letter and budget were drafted in Oct 07. USAID approved the subproject in Dec 07.
- FHI staff met with the MOHFP in April 08 to finalize the overall subproject approach and to identify partner involvement.
- A partner's steering committee meeting was held in May 08 to refine the overall plan and outline partner roles and responsibilities.
- A local consultant was hired in May 08 and inventoried existing FP materials and provider tools, evaluated level of use and identified provider needs related to norms/standards as regards provider tools. Consultant suggested changes to existing materials and recommended new ones to MOHFP and key partners.
- Self explanatory adolescent RH materials were developed, approved and 6,000 were printed for use in MOHFP trainings and as reference materials for District Management Teams and 2,500 health centers country wide.
- FHI staff presented the adolescent RH tools and a first draft of the FP provider tools at two regional MOHFP workshops in May 08.
- Participants at the regional workshops confirmed that care providers can use the two tools without additional training. Future evaluations will allow the identification of additional training, if needed.
- The draft FP provider tool was reviewed by FHI staff and the MOHFP based on recommendations from the participants at the two regional workshops.
- Feedback and technical recommendations from HQ were integrated by the consultant into the FP tool for finalization.
- The FP tool was approved and 5,000 copies were printed for use in all 2,500 health centers. A dissemination plan was developed with the MOHFP and the tools were distributed in Dec 08 during the National RH Coordination Meeting.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- In March 2009, Andry Rajoelina, mayor of Antananarivo, took power from President Marc Ravalomanana and put a new government into place. In response, the U.S.—via the State Department and USAID—announced that all non-humanitarian assistance would cease. CRTU activities were suspended, though staff and office are being maintained.
- Discussions with USAID-/W and Mission led FHI to transfer remaining funds from CRTU to PROGRESS effective July 1 2009. The CRTU FCO (143108) was closed as of June 30, 2009.

Funding Source(s):	USAID - US Agency for International Development/USAID: Field Support	FCO Approved:	Jan 2008
Total Approved Budget:	\$ 104,902	Projected End Date:	Jun 2009

Uganda: Advocacy for CBD of DMPA in Uganda (FCO 143115)

Technical Monitor: AAkol

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal II.C.: Strategies to enhance uptake of hormonal methods developed and evaluated.

Hormonal II.D.: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated.

Hormonal IV.B: Results of these evaluations disseminated via professional literature, outreach, technical assistance, client materials, or other means to service delivery partners, normative bodies, USAID, clients, and other interested parties for incorporation into practice and procurement decisions.

Objective(s): 1) To mobilize support from health leaders at national and district levels for CBD of DMPA; 2) to influence the amendment of National RH Policy Guidelines to accommodate provision of DMPA by Community Reproductive Health Workers; and 3) to facilitate the mobilisation of resources from donors and national / international NGOs for further scale up of CBD of DMPA.

Description: A recent cohort study conducted by the MoH in collaboration with FHI and Save the Children in Uganda demonstrate the safety, feasibility, and acceptability of community health worker (CHW) distribution of depot medroxyprogesterone acetate (DMPA) in a rural Ugandan district. Since those results were disseminated, demand for uptake of this approach is increasing. In Uganda, a scale up of six districts has been supported by FHI. Discussions with the MoH have yielded little progress with regard to policy change to facilitate implementation on a wider scale. Partner NGOs that wish to implement CBD of DMPA are awaiting a policy decision from the MoH. There is a pressing need for focused advocacy with the MoH and other regulatory bodies to garner their support for CBD of DMPA through a change in the Uganda RH Policy Guidelines. FHI/Uganda thus proposed, and received field support funding to implement, a subproject to create an enabling environment for the wide scale implementation of CBD of DMPA in Uganda, through the following activities: 1) Advocacy meetings on FP and CBD of DMPA with members of parliament; 2) Conduct study visits of parliamentarians, MoH, donors to CBD of DMPA sites in Uganda and Madagascar to observe CBD of DMPA; 3) Identify and orient FP advocacy champions, fund their advocacy work plans; 4) Advocacy workshops at community level to introduce and promote champions; 5) Support person of influence to make presentations on CBD of DMPA to bodies of influence within the MoH; 6) Orientation meetings on FP and CBD of DMPA for health workers at district levels; 7) Advocacy meetings on CBD of DMPA with regulatory bodies affiliated with the MoH; 8. Advocacy presentations on costs and benefits of CBD of DMPA with development partners and international NGOs; and 9) Produce advocacy support materials.

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Obtained Approval to Implement from USAID in January 2009.
- In January 2009, staff convened the Uganda FP advocacy working group to develop a plan of activities for CBD of DMPA advocacy.
- A draft advocacy strategy for CBD of DMPA was developed by FHI/Uganda staff in March 2009.
- In March 2009, staff met with the leadership of the Uganda Women Parliamentarians and Ministers' advocacy group on maternal health and the Social Services Committee of Parliament to plan for involvement of members of parliament in CBD of DMPA advocacy.
- In April 2009 FHI-Uganda staff presented CBD of DMPA to the Parliamentary Social Services Committee. The Committee was in full support of the initiative and urged the Ministry of Health to do more for family planning in general, and scale up CBD of DMPA. This meeting led to a renewed interest in family planning by the Committee, resulting in a campaign for FP led by MPs.
- In April 2009 FHI/U developed and signed memoranda of understanding with seven districts for implementation of District Champion activities.
- In April 2009, CBD of DMPA implementing districts, in consultation with FHI/U staff selected district family planning champions to lead advocacy activities in the districts. A family planning orientation workshop was held for the seven champions in the same month.
- In May 2009 staff led the development of coordinated response to negative media reporting on DMPA.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

FHI will:

- Conduct study visits of parliamentarians to CBD of DMPA sites in Uganda.
- Provide financial support to district FP champions (To include presentations to district and sub county councils).
- Hold one-on-one meetings and a 1-day seminar on CBD of DMPA with key members of the NDA and Nursing and Midwifery Councils.
- Finalize the development of a guideline for implementation of CBD of DMPA in Uganda.
- Convene a family planning orientation meeting for male members of parliament to encourage their involvement in FP and CBD of DMPA advocacy.
- Staff will be part of a delegation meeting the President of Uganda to advocate for family planning in Uganda.
- Participate in the development of the national village Health Team Manual to ensure the inclusion of CBD of DMPA.
- Convene a stakeholders' meeting to disseminate the CBD of DMPA report documenting outcomes in four districts; and to inform stakeholders on the outcome of the June 2009 WHO/USAID/FHI technical consultation on CBD of DMPA.

Funding Source(s):	USAID - US Agency for International Development/USAID: Field Support	FCO Approved:	Oct 2008
Total Approved Budget:	\$ 200,000	Projected End Date:	Sep 2009

USA: CONRAD: Development of LNG-butanoate (FCO 172014/172015)

Technical Monitor: GPittman

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Hormonal II.B.: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated

Objective(s): To provide funding to CONRAD to manufacture materials for this NICHD-funded clinical trial for development of LNG-butanoate for use in a planned pharmacokinetic study.

Description: This activity is being funded via an interagency agreement with NIH and USAID. FHI has not yet received a full description of the activity; when received it will be added to future reports. However, FHI has no study-related tasks assigned under this activity and upon transfer of funds, the project will continue under CONRAD and future reporting of this activity to USAID will be done by CONRAD.

Subgrantee(s): CONRAD

Collaborating Agency(s): CONRAD; NIH

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- An FCO was established in Dec. 2008.
- The subagreement was drafted in Dec. 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The subagreement was fully executed in February 2009.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- FHI will transfer funds to CONRAD. The activity will continue under CONRAD and future reporting to USAID will be done by CONRAD.

Funding Source(s):	USAID - US Agency for International Development/USAID: IAA; USAID - US Agency for International Development/USAID: Core	FCO Approved: 172014 Dec 2008 172015 Dec 2008
Total Approved Budget: 172014	\$ 212,375	Projected End Date: Apr 2010
172015	\$ 212,375	
	\$ 424,750	

Kenya: Development and Evaluation of a Campaign to Increase Continuation of Hormonal Methods (FCO 113149/116105/116110/146002)

Technical Monitor: HBurke

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal I.I.C.: Strategies to enhance uptake of hormonal methods developed and evaluated.

Objective(s): To develop and evaluate the effect of a communication campaign designed to increase contraceptive continuation among FP users, particularly injectable users.

Description: Despite increases in contraceptive prevalence over the past decades, discontinuation rates are high among women in the developing world. This is especially true in Kenya where 33% of married women are currently using a modern method, but over 19% of contraception users discontinue within 12 months of beginning use, despite still being in need of contraception. The true public health impact of contraception (improved maternal and infant health, quality of life and economic well-being) will not be realized until all women who want to prevent pregnancies are using their method of choice continuously and effectively. Interventions focused on increasing continuation rates are sparse. As a starting point, it is logical to look at interventions that have increased contraception adoption.

Communication campaigns have been successful in increasing contraceptive adoption around the world, including Kenya.

This study will develop, implement and test the effects of a communication campaign on increasing contraceptive continuation rates among injectable users in Nyando District, Kenya. Qualitative research within a theory-driven framework was used to develop the messages communicated in the campaign to contraceptive users and their salient references (male partners, mother-in-laws, providers, and religious leaders). Two rounds of focus groups were conducted with the target groups to determine why women discontinue and the most effective ways to deliver the campaign. Next, extensive product testing refined the final campaign components. To test the effects of the campaign on increasing continuation rates, the treatment site will receive the campaign whereas the control site will not receive the campaign. At each site, 500 new injectable users from the study clinics were enrolled into the study and given baseline interviews. The campaign was implemented in the treatment site beginning April 1, 2009. Participants will be re-interviewed over 9 months to measure continuation rates.

Subgrantee(s): Radio Ramogi; Tropical Institute of Community Health (TICH)

Collaborating Agency(s): Division of Reproductive Health; PATH

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- Approval to implement was received July 2006. Burke then developed a protocol.
- The Nyando District in Kenya was identified as the study site. Burke worked with Dr. Ambasa-Shisanya, FHI-Nairobi, who is responsible for managing the field budget and coordinating study activities with the partners.
- FHI developed a partnership PATH/Kenya whereby FHI would be responsible financially and technically for the formative research and evaluation, and PATH/Kenya for creating and implementing the campaign components.
- FHI entered into a subagreement with the Tropical Institute of Community Health (TICH), Kenya June 1, 2007. The subagreement was terminated February 16, 2009.
- The protocol was approved by PHSC on January 25, 2007 and by the Kenyatta National Hospital Ethics Review Committee (KNH-ERC) in May 2007.
- Burke traveled to Kenya in July 2007, to conduct a 5-day training with TICH staff.
- The first round of focus group discussions (FGD) was conducted by TICH and FHI analyzed the FGD data and provided results to PATH/Kenya in December 2007.
- A baseline pretest component was added to the study to measure discontinuation rates in two study sites before the campaign is implemented in the intervention site. An amendment was submitted to PHSC and KNC-ERC, and a revised subagreement was sent to TICH in December 2007.
- A system was developed to track study participants and data entry programs were developed in Epi Info for entering the pretest questionnaire data.
- FHI and PATH/Kenya developed the preliminary messages based on the data from the first round of focus groups.
- The study was delayed due to post-election violence in Kenya.
- Staff from the FHI/Nairobi office, including the local PI Ambasa, trained the returning RAs, supervisors, and new RAs from March 16-20, 2008 on the FGD Round 2 guide and the pretest activity.
- In April 2008 TICH recruited 500 new injectable users from each of the two study sites for the pretest activity. Data collection for the pretest activity ended in May 2009.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- FHI analyzed the second round FGD data and wrote an internal report based on the data for PATH/Kenya.
- FHI and PATH/Kenya developed the preliminary products for the campaign based on the FGD Round 2 data.
- FHI developed a contract with Radio Ramogi to produce and air 6 radio spots.
- TICH completed enrollment and administration of the baseline interviews with each of the 1000 participants in the pretest activity in August 2008.

- TICH also conducted two of three follow-up interviews with each of the participants in the pretest activity, and conducted FGDs for the media testing activity with each target group on the preliminary products for the campaign.
- In February 2009 FHI ended the subagreement with TICH and hired a consultant to collect data.
- FHI conducted the third follow-up interviews with each of the participants in the pretest activity.
- FHI analyzed the data from the media product testing activity and wrote 2 internal reports specifically for PATH and Radio Ramogi. The communication campaign was finalized based on the results.
- At the end of March the clinic-based campaign components were distributed to Nyando District clinics and PATH/APHIA trained 195 community health workers in Nyando District.
- During May 2009, PATH aired four 30-minute live radio programs about FP, injections, and 2 on male involvement on Radio Nam Lolwe in Nyando District. The 3 PATH funded radio spots will be airing on Nam Lolwe approximately 20 times over a 4 week period.
- FHI conducted baseline interviews of 1,000 participants for the post-test from April to June 2009.
- Data entry screens for the post-test questionnaire data were developed in Epi Info, and data analysis on the pretest data was initiated.

Findings and Outcomes:

- The 1st round of FGDs found that discontinuation of contraceptive use is common and women do not always have control over the use of contraception. Five salient reference groups were identified to influence contraceptive decision making among current contraceptive injectable users (husbands, mother-in-laws, FP providers, community leaders, and long term contraceptive injectable users). Common reasons for discontinuation include side effects, husbands' and mother-in-laws' refusal, myths, stockouts, and lack of cash. The current users of injectables and salient reference groups had a low level of knowledge regarding side effects of contraceptives, especially injectables. Consequently, lack of adequate knowledge about injectables was found as a key factor in discontinuation. This happened either through direct decisions of current users or the influence of salient groups.
- In the 2nd round of FGDs the results indicated that most preliminary messages were understandable and persuasive to their target groups. The only exceptions were messages for service providers and current injectable users that were perceived to be only somewhat persuasive.
- Participants provided invaluable feedback that has been utilized to propose amendments to the messages. Participants identified local radio stations as the most effective mode of disseminating the messages. Non-interactive modes of communication like posters and leaflets were mentioned as well. A 3rd preferred mode of communication involved community interactive strategies such as talks, trainings, drama and skits. These results informed the development of the preliminary media products.
- FHI collaborated with TICH to pre-test preliminary media products that were developed by PATH and Radio Ramogi. Products included: brochures and posters for injectable users, husbands, and providers; 3 radio spots for husbands, mother-in-law, and injectable users; and 6 radio features.
- Two internal reports were written by FHI to present the results from the product testing activity. The preliminary media products were well received by target groups, and found to be acceptable and very persuasive. A summary of specific recommendations were provided.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- FHI will analyze quantitative data from the pretest.
- FHI will conduct 3 or 4 follow-up interviews (depending on time/funding) with the post-test participants.
- FHI will analyze quantitative data from the post-test evaluation to determine the effect of the communication campaign on contraceptive continuation rates against a control.
- FHI will write manuscripts based on study findings.
- FHI will conduct in-country dissemination of study findings.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: Field Support	FCO Approved: 116105 Jul 2006 116110 Mar 2007 113149 Nov 2008 146002 Mar 2009
Total Approved Budget:	116105 \$ 413,556 116110 \$ 258,946 113149 \$ 51,993 146002 \$ 30,000 \$ 754,495	Projected End Date: Apr 2010

Africa Regional: Increasing Family Planning Uptake among Postpartum Women: Testing Supply and Demand Solutions (FCO 112137/114128/890030)

Technical Monitor: GVance

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal II.B.: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated
Hormonal II.C.: Strategies to enhance uptake of hormonal methods developed and evaluated.
Hormonal II.D.: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated.

Objective(s): For FCO 114128: (1) To test whether supplying free pregnancy tests in low resource family planning clinics increases contraceptive uptake. (2) To test whether a demand-generation intervention among new mothers attending immunization clinics increases the likelihood of their using contraception at 9-12 months postpartum.
For FCO 112137: The 2007 Ghana National Family Planning Protocols require that before giving DMPA, a family planning provider must be reasonably certain that the client is not pregnant. To make the determination of reasonable certainty, these guidelines recommend that the provider ask the woman a series of questions, and depending on the answers to those questions, possibly administer a pregnancy test. However, pregnancy tests in this circumstance may not be highly accurate. The purpose of this study is to assess the accuracy of this approach to ruling out pregnancy and to evaluate alternate approaches. The study was canceled because of concerns about the possibility that a woman could be pregnant despite a negative pregnancy test; a smaller than anticipated number of women eligible for the study; and the study clinics were not well equipped to host a randomized trial.

Description: Two strategies aimed at increasing the uptake of family planning among postpartum women will be tested in a 3-armed study. Health facilities in Ghana and Zambia will be randomized to one of the three arms. Arms one and two will constitute the intervention arms and arm 3 will be the control arm of the study.

The first intervention tested will be the provision of free pregnancy tests in family planning clinics. It is theorized that the provision of the tests, will result in an increase in the proportion of new clients who receive a method immediately, compared to clients randomly allocated to control clinics. With the second intervention strategy, researchers will assess whether family planning messages for new mothers attending immunization clinics increases the likelihood that immunization clients 9-12 months postpartum are using contraception.

Note: The FCO was originally entitled "Do Pregnancy Tests Increase Family Planning Uptake? However, the scope of the study was enlarged and therefore the title changed to "Increasing FP Uptake Among Postpartum Women - Testing Supply and Demand Solutions" to more accurately describe the study.

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Activities, Accomplishments, Problems through December 31, 2008

- The FCOs were assigned and the approval to implement letter for both components was sent to USAID in June 2007.
- Site assessment trips were made to Kenya and Ghana on November 2007. Ghana was selected as an appropriate site for the study.
- Stanback and Vance made site visits to Ghana and Zambia to prepare for the enlarged scope of the study that now includes a research component at immunization clinics in March 2008.
- The protocol, study instruments, and informed consent statements were approved by PHSC on July 27, 2008.
- The research was approved by the Ghana Health Service Ethics Review Committee on November 2, 2008.
- The protocol was submitted and reviewed by an ethics committee in Zambia. On December 11, 2008, the committee provided written notice for reasons not to approve the research.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- In Ghana, research assistants were recruited and trained as data collectors during the last week of January 2009.
- Baseline data collection began in both FP and Immunization clinics on 2 February 2009.
- Baseline data collection ended in both immunization and FP clinics around the 31st of May 2009 (the actual end date varied by clinic).
- During the month of June 2009, the study coordinator introduced all of the interventions in the study sites.
- In Zambia, scientific and ethical approval was granted by the local IRB on 17th March, 2008.
- Research assistants were recruited and trained as data collectors for one week during April, 2009.
- Baseline data collection began on 22 April 2009 in both immunization and family planning clinics.
- Baseline data collection paused for approximately 1 month due to a nurses strike and resumed on 29 June 2009.
- Funding for the completion of the study in Zambia was secured under the PROGRESS project, FCO 890030.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Baseline data collection in FP and immunization clinics is scheduled to end July 31, 2009 in Zambia.
- During the month of August 2009, the study coordinator in Zambia will introduce the interventions in all of the study facilities.
- In Ghana and Zambia, the interim assessment portion of the protocol will be carried out. Note: The interim assessment is to occur after the job aid is introduced in immunization clinics in order to confirm that providers are using the job aid as intended. If not, additional follow-up and training will be completed by the study coordinator.
- The qualitative component of this study was submitted as a year 5 proposal under the CRTU, and was approved by USAID. However, to implement the planned changes, the protocol must be updated and approved by PHSC, and the local ethical committees.

- For the qualitative piece, research assistants capable of completing in-depth interviews with providers must be recruited in both Ghana and Zambia.
- The qualitative research should commence before the end of the calendar year.
- The data analysis plan will be completed and approved for the study.
- Preliminary data entry and analysis will be completed. It is expected that preliminary results will be available for the first study objective.
- From August 2009 to April 2010 the CRTU will support all work in Ghana, all work related to the qualitative component of the study in Ghana and Zamiba, and HQ time that is not specific to meeting PROGRESS administration requirements through April 2010.
- PROGRESS will support all field work in Zambia.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:112137 May 2007 114128 Jun 2007 890030 Jun 2009
Total Approved Budget:	112137 \$ 69,171	Projected End Date: Apr 2010
	114128 \$ 448,026	
	890030 \$ 141,509	
	<hr/> \$ 658,706	

HIV/AIDS AND CONTRACEPTIVE SERVICES

GOALS	OUTCOMES
<p>I. To improve understanding of safety and effectiveness of contraceptive methods for women at high risk of HIV and HIV infected including women on ART</p>	<p>A. At least two clinical studies of the safety and effectiveness of hormonal contraceptives and ART completed.</p> <p>B. At least two studies on the safety, effectiveness, and health benefits of contraceptives for women at high risk of HIV or HIV infected women completed.</p>
<p>II. To increase access, improve quality and expand use of contraceptives to safely prevent unintended pregnancies among people at high risk of HIV and HIV infected, including women on ART</p>	<p>A. At least two scalable and appropriate models given the CPR, HIV prevalence, and available services for integrating family planning and HIV services designed, evaluated and introduced in up to five countries.</p> <p>B. At least three strategies to meet demand of specific populations identified, implemented by HIV and/or FP providers and evaluated, and introduced into programs in five countries.</p> <p>C. Research evidence provided to at least four countries to inform policy reviews and strengthen policies focused on increasing contraceptive use in HIV programs to avert HIV-positive births.</p> <p>D. International recommendations for contraceptive use by people at risk of HIV and HIV-infected, including women on ART changed or strengthened; and international recommendations used in country guidelines and program documents.</p> <p>E. Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.</p>

FHI/NC subprojects fully or partially funded by USAID's CRTU Agreement:

DRC:	Integration of FP Services into Counseling and Testing Sites (FCO 143106/143112/143113/143114/143121/143122/143123)
Haiti:	Increase Family Planning Uptake in Designated Locations in Haiti (FCO 143105)
Tanzania:	Implementing and Evaluating FP and VCT Services Integration (FCO 114115)
Kenya:	Improving Use of Family Planning in VCT (FCO 114104/153103)
Kenya:	Understanding Fertility Desires and Demand for Contraceptive Use of Women on Antiretroviral Therapy in Comprehensive Care Centers (FCO 153134/156100)
Kenya	Integration of Family Planning into Comprehensive Care Centers (FCO 114114/124104)

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- South Africa: Family Planning & HIV Service Integration: South Africa Network of Champions (FCO 113127/153130)
- South Africa: Expansion of Strengthen Linkages Between HBC, FP, ARV (FCO 153128/153129/153138)
- South Africa: Developing and Testing Family Planning Programs for PMTCT Clients in South Africa, Phase 2 (FCO 114144/114145)
- South Africa: Enhancing PMTCT Performance (FCO 153104)
- Kenya: FP/PMTCT Integration Assessment (FCO 144101/154101)
- Worldwide: Country Assessments: Documenting Promising Family Planning-HIV Integration Models (FCO 114124/114135/124106/124107/124108)
- Worldwide: Monitoring Status FP/HIV Integration Efforts (FCO 114143/184000/114153)
- Tanzania: Facilitated Referrals to Promote FP Access Among HIV-Positive Women at HIV Care and Treatment Centers (FCO 114136/114151)
- Madagascar: Increasing Access to Postpartum Family Planning Services (FCO 114116/114132)
- Worldwide: Prospective Evaluation of Contraceptive Dynamics in Women (FCO 112127)
- Kenya: Examining the Family Planning Needs of Women Traditionally Targeted for HIV/STI Services (FCO 124100/124105)
- Africa Regional: Assessing Provision of Family Planning and Reproductive Health Services in Commercial Sector HIV/AIDS Programs (FCO 124102)
- Worldwide: Tool Kit to Increase Access to Appropriate and Effective Contraception for Clients with HIV (FCO 113106)
- Worldwide: Providing Global Leadership to Family Planning and HIV Integration Efforts (FCO 113104/123100)
- Kenya: Scale-up and Global Dissemination of Kenya's FP/VCT Integration Package (FCO 113126/123102)
- Africa Regional: FP in Context of HIV: Supporting Evidence-Based and Promising Practices (FCO 113131)
- Worldwide: Interactions between Hormonal Contraceptives and ARV (FCO 112139/112145/112146/112147)
- Kenya: Safety of Implant Use among Women on ARVs (FCO 112136/112141)
- Kenya: Risk of HIV and Feasibility Research Among House Girls in Nairobi (FCO 154100/154102/154104/154105)
- Worldwide: Program Guidance for Integrating FP/HIV Services (FCO 113147)
- Kenya: Youth Integrated FP and HIV Service Delivery Models (FCO 114130)
- Kenya: Strengthening RH Counseling for Youth Seeking Post Abortion Care Services (FCO 114146)
- South Africa: Collaborative Study of Hormonal Contraception and HIV Disease Progression for Women before and after Initiating Antiretroviral Therapy (FCO 172010)

South Africa: Hormonal Contraception and HIV Acquisition Analysis of the Carraguard Dataset (FCO 112138/132129)
South Africa: Integrated Community Palliative Care Project (ICPC) (FCO 153122/153123/153124/153125/153126/153127/153136/153139/153140/153142/153143)
Uganda: Understanding Concurrent Partnerships in Uganda (FCO 156103)
Worldwide: Journal Supplement on Family Planning and HIV (FCO 113151)

Dem Rep of Congo: Integration of FP Services into Counseling and Testing Sites in DRC (FCO 143106/143112/143113/143114/143121/143122/143123)

Technical Monitor: JWesson

Strategy Outcomes(s) to be addressed: HIV/FP II.A.: At least two scalable and appropriate models given the CPR, HIV prevalence, and available services for integrating family planning and HIV services designed, evaluated and introduced in up to five countries.

HIV/FP II.E.: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Objective(s): 1) To incorporate family planning content into the existing CT counseling services supported by FHI/DRC; 2) to provide limited family planning methods and/or refer for initiation/re-supply in CT sites; 3) to promote family planning as an effective HIV prevention strategy; 4) to create an enabling environment that supports family planning/CT integration; and 5) to improve the future expansion of family planning into current and future CT sites in the DRC.

Description: This subproject will aim to increase the use of family planning through the integration of family planning services into counseling and testing (CT) services in the Democratic Republic of Congo (DRC). Building on existing programmatic efforts, FHI proposes to integrate family planning services into the RESA+ CT sites, including community-based and integrated sites in Matadi and Lubumbashi. FHI/DRC's primary partners will be those already operational under the RESA+ project –AMO-Congo/CSR Mvuzi in Matadi and AMO-Congo/HGR Kenya in Lubumbashi.

Subgrantee(s): AMO-Congo (Matadi and Lubumbashi); Centre de Référence Mvuzi (Matadi); Hôpital Général de Référence Kenya (Lubumbashi)

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- Staff reviewed existing DRC FP policies and training curricula.
- Field visits (Drs. Yacobson and Dulli/FHI/NC and Mr. Tegang, FHI/AFRO/Nairobi) were conducted in December 2007.
- Meetings were held with key stakeholders in-country along with CO staff to solicit buy-in for the project and commitment to strengthening the integration of family planning and HIV services.
- The draft 2008 work plan was developed.
- The protocol for the Baseline Assessment was developed and in March 2008 a fact finding assessment was conducted to inform the development of the intervention.
- A full-time family planning coordinator was hired for the DRC office.
- Training materials were translated into French.
- A workshop was conducted by the National Reproductive Health Program with support from FHI in order to bring DRC national FP training materials up to date.
- Trainers were identified for the training of providers.
- The FHI FP officer and the head of the FP division at the National Program for Reproductive health attended the International Technical meeting on FP Services Integration with HIV in Addis Ababa in July 2008.
- 57 VCT counselors were trained on FP/HIV integration with the new training module in both Matadi and Lubumbashi in August and October 2008. Integrated services began in October 2008.

- Pamphlets regarding FP methods, and reference cards were developed and distributed to integration sites.
- Subagreements with all three subgrantees (see above) were signed in November 2008.
- 1221 VCT clients received family planning counseling from the completion of counselor training until the end of December 2008. 565 of these clients accepted a contraceptive method from the FP service.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- From January-March 2009, a total of 52% (3155/6091) HIV counseling and testing clients had been counseled on FP in the four project sites. Among those counseled, 41% (1295) initiated contraceptive methods: 525 in the affiliated FP sites and 770 in the CT sites themselves.
- The Provincial office of the National Programme for Reproductive Health (PNSR) offices and four health districts (Matadi, Nzanza, Kampemba and Kenya) received computers and office supplies to improve their data management and facilitate regular reporting.
- Monthly monitoring visits were conducted in all four sites. These visits are conducted jointly with the Provincial PNSR, the Provincial office of the National AIDS Control Program (CNLS) and FHI.
- J. Wesson visited Kinshasa in May 2009 to review progress and determine next steps for the subproject, including whether additional data collection efforts were required to evaluate the project. The team agreed that currently collected service statistics and the mid-term review meetings would serve as a good gauge of progress and advise future steps. In consultation with USAID/DRC, the budget was revised to transfer money from evaluation activities to implementing subagreements to establish 10 more integration sites. The number of sites included in the second phase of the subproject is limited by the small number of functioning VCT center in DRC.
- Mid-term review meetings were held with stakeholders in Matadi and Lubumbashi in June 2009 to review lessons learned from implementing integrated FP and VCT services, and to discuss a scale-up of the intervention into other sites in DRC. A report is forthcoming.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Develop subagreements and extend activities to an additional 10 sites in Matadi, Lubumbashi and Kinshasa.
- Continue monthly supervision visits at all integration sites in coordination with the National Program on Reproductive Health and the National AIDS Control Program.
- Provide institutional support to intervention health zones to build capacity and ensure regular supervision of the integrated sites.
- Provide updates to community stakeholders in the intervention health zones regarding the integration process.

Funding Source(s):	USAID - US Agency for International Development/USAID: Field Support	FCO Approved: 143106 143112 143113 143114 143123 143121 143122	Oct 2007 Aug 2008 Aug 2008 Aug 2008 Aug 2009 Aug 2009 Aug 2009
Total Approved Budget: 143106	\$ 940,004	Projected End Date:	Apr 2010
143112	\$ 14,375		
143113	\$ 14,375		
143114	\$ 30,646		
143123	\$ 13,435		
143121	\$ 13,435		
143122	\$ 13,435		
	<hr/>		
	\$ 1,039,705		

Tanzania: Implementing and Evaluating FP and VCT Services Integration in Tanzania (FCO 114115)

Technical Monitor: JBaumgartner

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.A.: At least two scalable and appropriate models given the CPR, HIV prevalence, and available services for integrating family planning and HIV services designed, evaluated and introduced in up to five countries.

Objective(s): To implement and evaluate the integration of FP and VCT services on FP uptake in selected ANGAZA (AMREF's VCT program) sites in Tanzania.

The specific study objectives were: 1) to measure the level of unmet need for contraception among VCT clients; 2) to determine the effectiveness and cost of adding FP to VCT; 3) to determine the effect of adding FP on quality of care for VCT; and 4) to measure FP uptake among VCT clients with unmet contraceptive need.

Description: Integration of family planning (FP) services into existing voluntary counseling and testing (VCT) sites has gained credibility as a viable strategy to increase access to contraception and augment the prevention potential of VCT services, particularly in low-income countries with poor reproductive health indicators such as Tanzania. FHI has recently demonstrated in neighboring Kenya that VCT clients are at risk of unintended pregnancy and that integration of services was both feasible and acceptable to providers and clients. Demonstrating whether or not FP-VCT integration results in increased FP uptake and continuation among VCT clients with identified unmet need is an important research gap that FHI and Tanzania partners wanted to address.

The proposed subproject involved an intervention component funded by AMREF, and an operations research component funded by FHI.

Collaborating Agency(s): African Medical and Research Foundation and Infectious Disease Centre (Dar es Salaam, Tanzania)

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Activities, Accomplishments, Problems through December 31, 2008

- The concept was prepared and reviewed within FHI in the fall of 2006.
- The FCO was assigned in November 2006 when the ATI letter was prepared. This subproject's approval was sought outside of the normal workplan cycle because AMREF/Tanzania was able to fund the integration intervention, provided most of the work was done by summer 2007. In addition, EngenderHealth was willing to provide TA for the FP components in Tanzania but their ACQUIRE project ended in December 2007.
- USAID/W gave its approval for FHI to implement the subproject on December 5, 2006.
- The TM, in collaboration with AMREF and FHI/Tanzania, coordinated the first FP/VCT technical working group meeting in Tanzania in February 2007.
- During the trip to Tanzania in May 2007, the TM identified Muhimbili University Health & Allied Sciences (MUHAS) as an implementing partner to conduct the research.
- An MOU between FHI and AMREF was drafted and signed by both parties in May 2007.
- In conjunction with AMREF, the preliminary identification of study clinic sites and a FP-VCT integration strategy was completed in June 2007.

- Finalizing selection of study clinics and the basic integration intervention strategy occurred when the TM visited Tanzania in November 2007. It was anticipated that these decisions could be made over email and conference calls with AMREF but this was not the case.
- Muhimbili University of Health and Allied Sciences (MUHAS, previously MUCHS) was selected as the implementing partner in June 2008.
- The study protocol was drafted.
- A revised MOU between FHI and AMREF was drafted and sent for review in June 2008.
- The protocol was sent to AMREF for review and comments were delayed pending finalization of the MOU.
- The revised MOU between FHI and AMREF was not finalized.
- This study was cancelled on August 2008.

Findings and Outcomes:

- TM met with AMREF in Tanzania in July 2008. After many months of negotiation & multiple meetings between FHI & AMREF, it was mutually agreed upon to end the collaboration. AMREF had competing pressures and was no longer interested in the study as originally designed.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Nov 2006
Total Approved Budget:	\$ 329,716	Projected End Date:	Aug 2008

Kenya: Improving Use of Family Planning in VCT (FCO 114104/153103)

Technical Monitor: DChin-Quee

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.A.: At least two scalable and appropriate models given the CPR, HIV prevalence, and available services for integrating family planning and HIV services designed, evaluated and introduced in up to five countries.

Objective(s): 1) To determine the effect of adding a strengthened (or "full") family planning intervention to VCT centres compared to control facilities on the intention to use a method among female VCT clients at risk of unintended pregnancy; 2) to determine the added value of training providers and conducting supportive supervision compared to advocacy and sensitization and introduction of a monitoring and evaluation (M&E) tool alone; 3) to calculate the incremental costs and cost-effectiveness ratios of scaling up the M&E and full models; 4) to determine the difference in VCT session length, client waiting time, and VCT counseling content between intervention groups and the control group; and 5) to assess men's fertility desires and providers' ability to address men's fertility desires.

Description: This subproject, which is co-funded with CRTU core and Kenya PEPFAR funds, will strengthen the provision of integrated FP/VCT services in a subset of VCT centers in Kenya and evaluate the effect of integrated services on contraceptive uptake. The development and implementation of an enhanced integration intervention was funded by PEPFAR (FCO 153103), CRTU core funds (FCOs 113126 and 123102), and the APHIA II project. Core components of the intervention will include: holding provincial- and district-level sensitization meetings to orient managers and other health personnel to the integration

effort; training VCT providers in a subset of VCT centers who were not previously trained in FP/VCT integration; implementing revised VCT client cards that include family planning M&E indicators; and conducting support supervision for trained providers. (Note: FCOs 113126 and 123102 fund the production and dissemination of Kenya's national FP/VCT materials and, therefore, contribute to the intervention by making materials available and advocating their use. FCO 153103 was obligated \$83,000 by USAID/Kenya, but the ATI was written for only \$52,900. Approximately \$73,000 was ultimately spent.)

CRTU core funds (FCO 114104) will be used to conduct research activities including: testing the effectiveness of the enhanced integration intervention and collecting monitoring and evaluation data. The effectiveness of the intervention will be measured by assessing the proportion of VCT clients at risk for unintended pregnancy who intend to use a method of contraception. We will rely on a two group, post-test only design, where we will collect data from a subset of clinics receiving strengthened integration activities and in a group of control clinics. Monitoring data will be collected from a VCT client card that has been modified to include family planning indicators. All activities under this subproject will be implemented in collaboration with the Kenya Ministry of Health.

Collaborating Agency(s): Ministry of Health, Kenya

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Activities, Accomplishments, Problems through December 31, 2008

- Meetings were held with representatives from the MOH in Nov. 2005 to agree on the sequence and timing of subproject activities.
- Four one-day dissemination/sensitization/advocacy meetings were held with a total of 58 VCT counselors and 71 VCT supervisors and MOH managers representing seven provinces in March 2006.
- FHI called two FP-VCT subcommittee meetings, in Feb. and in May 2006, to get buy-in from committee members on planned activities.
- Two trainings were held in Busia and Mombasa for 47 VCT providers co-funded by AMKENI & FHI.
- A FP-VCT integration subcommittee meeting was held in June 2006 to work on the FP-VCT training manual and in February 2007 to finalize the training intervention.
- An FP-VCT training was held for 18 VCT providers in Mombasa, July 24-28, 2006 (funded by UNFPA and led by the MOH).
- Results of FP-VCT integration (formerly FCO 9390) were presented at the APHA annual meeting in December 2005, at the PEPFAR Annual Meeting in Durban, South Africa in June 2006, and at a meeting on family planning and HIV linkages in Addis Ababa, Ethiopia on Oct. 9-10, 2006.
- Protocol and draft data collection instruments were submitted to Kenyatta National Hospital's Ethical Review Committee in Feb. 2007 and FHI's PHSC in May 2007 and were approved by both bodies.
- APHIA held training of trainer (TOT) updates with 25 participants in March 2007; four provincial level advocacy and sensitization meetings with FHI staff in Rift Valley and Coast Provinces in May-June 2007 (157 participants total) (see FCO 113126/123102); and provider trainings with FHI participation in May-August 2007 (123 participants total in 95 facilities).
- M&E orientations for Rift Valley were conducted in August 2007 with 47 participants and in Coast in September 2007. Implementation began in October and monitoring occurred in November.
- The supportive supervision tool was approved by the MOH in October 2007.
- Supervision visits were delayed due to political unrest, but were eventually conducted in May and June, 2008.
- Post test data collection took place in October 2008 and M&E data were tallied, with all data arriving in NC in November 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- A new TM (Chin-Queue) was assigned to this project in January and a new timeline for completion of remaining study activities was drafted in February 2009.
- An analysis plan was developed and analyses conducted on a subset of the data (indicators of program effectiveness), the results of which were presented at the dissemination seminar in Nairobi on June 25th, 2009, 53 people attended.

Findings and Outcomes:

- Based on our definition of unmet need, no more than 26% of clients were at risk for unintended pregnancy. Nevertheless, most VCT clients were not using a contraceptive method.
- Analyses of indicators of program effectiveness (provision/referral of FP methods, counseling on key messages) demonstrated that providers trained in FP-VCT integration were more likely to counsel their clients on HIV transmission/testing, condoms and other FP methods, as well as assess clients' FP needs than their counterparts in the control and partial intervention (advocacy/sensitization and use of M&E tool only) groups.
- While provision and referral for FP methods was very low overall, providers trained in FP-VCT were more likely to provide these services to their clients than providers in the control and partial intervention group.

2009—2010 WORKPLAN**Planned Activities for July 1, 2009 – April 28, 2010**

- Comprehensive analyses of the data will be conducted and added to the findings on indicators of program effectiveness
- A final report and/or publication including results from the full study will be prepared and submitted prior to April 2010.

Funding Source(s):

	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/PEPFAR	FCO Approved:153103 Sep 2005 114104 Sep 2005
Total Approved Budget:	153103 \$ 52,900	Projected End Date: Apr 2010
	114104 \$ 446,239	
	\$ 499,139	

Kenya: Understanding Fertility Desires and Demand for Contraceptive Use of Women on Antiretroviral Therapy in Comprehensive Care Centers (FCO 153134/156100)

Technical Monitor: JAlaii

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.B.: At least three strategies to meet demand of specific populations identified, implemented by HIV and/or FP providers and evaluated, and introduced into programs in five countries.

Objective(s): 1)To investigate the prevalence and reproductive decisions of fertility desire, contraceptive use, and condom use of HIV+ women on ART, compared to reference groups of HIV+ women not on ART and HIV- women; 2) to explore provider attitudes on reproductive desires of HIV+ women, their perceptions of contraceptive methods for HIV+ women, and the acceptability of providing family planning (FP) services in

an ART setting; and 3) to use findings to inform the development of a training module for ART providers to offer FP services.

Description: More than half of the people living with HIV in Sub-Saharan Africa are women of childbearing age. As availability of and access to antiretroviral therapy (ART) continues to rapidly expand, it is essential to understand and address the fertility desires and FP needs of HIV+ women eligible for ART. This study will support efforts in Kenya to integrate FP into ART settings, such as Comprehensive Care Centres (CCCs). This study seeks to characterize: fertility desires; current contraceptive use and condom use of HIV+ women on ART, compared to HIV+ women on HIV Care and HIV- women; and provider attitudes and acceptability of providing FP services in the CCC in Nakuru Provincial General Hospital (NPGH). Findings will be used to inform the development of a training module for ART providers and the module will be integrated into an existing National ART Curriculum.

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Activities, Accomplishments, Problems through December 31, 2008

- The study protocol was submitted to PHSC in January and approved in February 2007. It was submitted to KNH-ERC in the same month; approval was received in June 2007.
- BIOS approved the data analysis plan in April 2007.
- Data collection training materials were developed and study training and pre-test of data collection instruments occurred from June 18-22, 2007.
- Data were collected by four trained research assistants from June 25, 2007-December 7, 2007.
- CRTU received COP07 continuation funds to train an additional 100 CCC providers.
- In November 2007, this study was integrated with FCO 114114/124104, an evaluation study to inform intervention development.
- Preliminary data on unmet contraceptive needs of female CCC clients were shared at the CRTU Management Meeting in December 2007.
- MoH contacts were identified in December 2007 to facilitate collaborative development of an FP-ART integration module.
- Preliminary analysis findings were shared with MoH and National RH-HIV integration committee in April-May 2008.
- FHI worked with the MoH on the study research brief and slides for dissemination meetings and then jointly held provincial and national disseminations with 35 and 70 participants respectively in July 2008.
- The RH-HIV integration committee (FHI is a member) drafted a provider Orientation Package (OP), and conducted a national FP-ART ToT workshop in July-August 2008.
- The RH-HIV integration stakeholders and USAID APHIA II planned provider orientation-cum-field tests of the OP in September-October 2008.
- The RH-HIV integration committee explored opportunities for incorporating monitoring systems in existing CCC registers to generate strategic data in August-December 2008.
- Study findings were presented at the APHA October 2008 conference.
- FHI and USAID APHIA II Rift and Coast matched initial provider orientation-cum-field testing schedule to facilities included in FCO 114114/124104 study.
- We worked with USAID APHIA II and MoH to field-test the OP with 28 and 33 providers in Coast and South Rift provinces respectively in November-December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- We worked with USAID APHIA II Rift and the MoH to further field-test the OP with 30 providers in North Rift in January 2009. We also collaborated with NASCOP and the RH-HIV integration committee to revise the draft OP using comments from November/December 2008 field testing sessions.
- We continued exploring opportunities to incorporate monitoring systems into existing CCC registers to generate strategic information on the effect of the orientations on service provision and the extent of integrated services.
- We provided TA at a second workshop for 20 ToTs (funded by Jhpiego) to facilitate roll out of service provider training in provinces in February 2009.

- We worked with USAID APHIA II Rift and Gold Star Network (GSN) to train 30 private sector providers in March 2009.
- We collaborated with MoH and USAID APHIA II Rift and Coast in monitoring progress with integrated FP-ART service provision in FCO 114114/124104 study sites in May 2009.
- We worked with USAID APHIA II Rift to train 30 public service providers in North and South Rift respectively. CRTU hired an FP consultant to support trainings in June 2009.
- We secured NASCOP commitment that they would work with Provincial Directors in Nyanza, Western, Eastern, North Eastern, Central, and Nairobi provinces to facilitate FHI-supported provider trainings, all to be done by September 2009.
- We secured USAID APHIA II Rift and Coast commitment that they would work with the respective Provincial Directors to facilitate FHI-supported provider trainings in sites outside APHIA II coverage areas.
- We completed the final study report in June 2009 (M2009-13) and submitted a scientific manuscript to AIDS Supplement on May 1, 2009 (PP2009/024).

Findings and Outcomes:

Key formative assessment findings include:

- The majority of women did not want to get pregnant within 2 years; there was substantial unmet need which was also evidenced by high rates of unintended pregnancies.
- Limited FP services were offered at CCC and screening on fertility intention was not systematic; very few learned about FP interactions with ARVs (a frequently asked question by women); majority did not receive a FP method, or referral for FP services.
- The majority of clients wished to talk to a provider about how to prevent a pregnancy, and to receive FP services on site.
- FP services offered to women on ART are much less than services offered to women not on ART. However, data suggests that fertility intentions among recently sexually active women are not very different. There is a need to address this bias with providers.
- Providers identified a need for refresher training on the latest available methods and on how to provide FP services in the context of HIV/AIDS.
- CCC providers should be sensitized on contraceptive demand from HIV+ clients (i.e. unmet need, unintended pregnancy rates).
- Screening on fertility intention of HIV+ women should be systematic, regardless of their ART status. There is a need to address misconceptions that women on ART are not sexually active.
- CRTU achievements with FP-ART provider orientations include:
 - Ensuring utilization of research evidence and field test experiences in developing the orientation package;
 - Providing TA during development of the National RH-HIV strategy, and TA at 2 Jhpiego –supported National TOT workshops in August 2008, and February 2009 respectively;
 - Supporting training (funds and TA) of 149 public service ART providers in Coast and Rift Valley between November 2008 and June 2009;
 - Providing TA at Jhpiego-supported provider training of 30 providers in Coast in December 2008;
 - Providing TA at International Centre for Reproductive Health (ICRH) training of 60 municipal council providers in Coast in January 2009;
 - Providing TA and supported printing of manuals towards training of GSN providers in Rift; and
 - Collaborating with USAID APHIA II and PMO's offices in Rift and Coast in supportive supervision in selected public and private facilities offering integrated FP-ART services.
 - Sharing feedback from the supervisory visits to inform selection of providers for further training, including ensuring to invite site supervisors (nursing officers in charge, etc) for future trainings.

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Planned Activities for July 1, 2009 – April 28, 2010

We will:

- Work with NASCOP and FHI NC to produce 5,000 CD copies of the OP as soon as the MoH endorsement is obtained. We will also print 5,000 copies of the OP in July-August 2009;
- Work with NASCOP and Health Policy Initiatives (USAID HPI) to cost-share the launch of National RH-HIV integration strategy and the OP. We will also cost-share printing for the strategy document in July-September 2009;
- Work with NASCOP to meet commitment to train providers in Nyanza, Western, Eastern, North Eastern, Central, and Nairobi provinces in July-September 2009;
- Work with USAID APHIA II Rift and Coast to meet commitment to train providers in sites outside APHIA II coverage areas in July-October 2009;
- Explore with NASCOP, DRH, and USAID APHIA II Coast and Rift opportunities to support training of 10 ToTs in each of non-APHIA coverage areas to support cascading of service provider training in the regions.
- Support a key NASCOP contact to attend the WomenLead in Repositioning RH workshop in Washington DC in September 2009, as part of TA;
- Collaborate with the MoH to share RH-HIV integration experiences at the November 2009 International FP Conference in Kampala;
- Continue to apply strategic information generated from FY 2007 and FCO 114114/124104 to continue to refine models for FP delivery in ART settings;
- Draft a report on achievements and experiences from FP-HIV integration training, implementation, and monitoring in July – November 2009. We will also work with FCO 114114/124104 to cost the intervention; and
- Provide TA to the MoH towards development of 10 CCCs as centers of excellence for training in provision of FP to HIV+ women and couples in July – November 2009, based on the outcomes of May – June 2009 monitoring visits.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR	FCO Approved:156100 153134	Jan 2007 Dec 2008
Total Approved Budget:	156100 \$	500,000	Projected End Date: Nov 2009
	153134 \$	50,000	
	\$	550,000	

Kenya: Integration of Family Planning into Comprehensive Care Centers (FCO 114114/124104)

Technical Monitor: ESutherland

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.A.: At least two scalable and appropriate models given the CPR, HIV prevalence, and available services for integrating family planning and HIV services designed, evaluated and introduced in up to five countries.

Objective(s): 1) To test whether family planning services in Comprehensive Care Centers (CCCs) increase female clients' use of family planning methods over time; 2) to measure whether CCC providers are more likely to provide family planning services as a result of the intervention; 3) to measure the effect of the intervention on how CCC services are delivered; 4) to understand how CCCs can better support male CCC clients with their and their partners' family planning needs; and 5) to determine if the intervention is worth scaling up.

Description: This study will rely on a one group, pre-and post-test design where baseline and post-intervention data on contraceptive use will be collected. In order to assess contraceptive use, the number of comprehensive care clients accepting to use contraceptive methods during their visits will be documented. Further, important information about provision of family planning services in these settings can be obtained through routine monitoring and evaluation (M&E). Special attention will be paid during the research to factors that facilitate or detract from providers' ability to implement the intervention. This information will inform future integration efforts. The study will be conducted in 16 CCCs in Coast and Rift Valley. The number of study participants is 192 HIV+ women for a cohort study, 400 HIV+ men for a descriptive study (includes pre- and post-test), 800 HIV+ women and men for a patient flow analysis (includes pre- and post-test), 128 providers (includes pre- and post-test), and 32 supervisors (includes pre- and post-test).

Collaborating Agency(s): Ministry of Health, Kenya

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Activities, Accomplishments, Problems through December 31, 2008

- The protocol was finalized in December 2006.
- Numerous discussions with the FHI APHIA team, APHIA partners, and the Ministry of Health (MOH) confirmed their interest in the intervention and support for this study.
- Exploratory data from CCCs was obtained in March 2007 to inform sample size calculations.
- The protocol was approved by PHSC in May.
- Data collection forms were drafted.
- A baseline data analysis plan was developed in June 2007.
- The protocol was approved by Kenyatta National Hospital's Ethical Review Committee in July 2007.
- A protocol amendment was submitted in December 2007 to include a pre-intervention CCC assessment.
- PHSC and KNH-ERC renewal of ethical approval was sought and obtained in June 2008.
- The fieldwork budget was updated in June 2008 to reflect changing field expenses and fluctuating exchange rates.
- A draft research assistant training manual was completed in July 2008.
- Additional funds for Year 5 of the CRTU were secured.
- Ongoing conversations with the MOH, the FHI APHIA team, and the APHIA partners confirmed continued support for this study, but required delaying study launch until partners were ready to proceed with the planned intervention. The study launch proceeded in September 2008.
- RAs were trained and baseline data collected in September 2008.
- A participant tracking database was designed in coordination with the Data Management Group in anticipation of following up with the study cohort. The database was finalized in September 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Interim Client Contacts were completed in March 2009
- Data collection forms and informed consent forms were revised and finalized in May - June 2009.
- RAs were trained and follow up data collection began in June 2009.

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Planned Activities for July 1, 2009 – April 28, 2010

- Follow up data collection will be completed in July 2009.
- Data entry and data cleaning will be completed in August 2009.
- A data analysis plan will be finalized in October 2009.
- Preliminary data analysis will be completed in November 2009.

- Data analysis will be completed, an in-country dissemination meeting held, and a manuscript completed and submitted for publication by April 2010.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: GLP	FCO Approved: 114114 Jul 2006 124104 Jul 2006
Total Approved Budget:	114114 \$ 675,693	Projected End Date: Apr 2010
	124104 \$ 134,000	
	<hr/> \$ 809,693	

South Africa: Family Planning & HIV Service Integration: South Africa Network of Champions (FCO 113127/153130)

Technical Monitor: SPilusa

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.E.: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Objective(s): To establish and provide technical support to a network of individuals in the South African Department of Health who are working to advance the integration of family planning and HIV service delivery.

Description: To bolster HIV prevention efforts nationally, South Africa's National Department of Health (NDOH) has requested support from FHI to establish a network of FP/HIV integration Champions. The network includes nine provincial Champions located in each provincial DOH, and one full-time staff person seconded to the NDOH by FHI to provide technical assistance to the Champions and their activities. These Champions are committed to strengthening the integration of FP and HIV services in South Africa in order to better meet the contraceptive needs of HIV-infected clients. The prevention of unintended pregnancies among these women, in turn, will result in the prevention of HIV-positive births. The Champions serve as key links between the health research community, policy makers and service delivery sites, and work to bring evidence supporting FP/HIV integration into practice.

In November 2007, FHI received PEPFAR funding to continue the work of the Champions project. With this funding, FHI will support NDOH and provincial staff in Mpumalanga, KwaZulu-Natal, Northern Cape, Limpopo and Gauteng provinces. FHI will help the NDOH to revise the current sexual and reproductive health curriculum to include guidelines for HIV-infected couples, including those on ARVs, and will provide TA to the NDOH on implementing the new curriculum, training trainers and service providers and integrating HIV and FP services.

Collaborating Agency(s): National Department of Health

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Activities, Accomplishments, Problems through December 31, 2008

- The RH/HIV Integration Advisor and the provincial Champions hosted workshops in each province to develop activity plans for strengthening RH/HIV service integration in the province. By June 2007, activity plans for 3 of the provinces had been developed.
- An article on the Champions' subproject was developed for the March 2007 FHI newsletter, "Family Health Research."
- Between July and September 2007, the baseline assessment survey was completed in Mpumalanga, Northwest, and Limpopo Provinces.
- A provincial project launch was held in Gauteng Province in July 2007.
- In August 2007, FHI staff presented the Champions network at a quarterly NDOH meeting on FP/HIV integration for multidisciplinary managers. By September 2007, activity plans for strengthening FP and HIV integration were developed in 5 provinces (Limpopo, Free State, Gauteng, Northern Cape and Mpumalanga).
- The national workshop was held in March 2008 for Champions from all nine provinces including directors of Maternal Child and Women's Health to give feedback on and to discuss the progress of the Champions project.
- Starting in April 2008, FHI assisted the provincial departments to review the SRH training curriculum.
- In August 2008, FHI facilitated a training of trainers in Eastern Cape using the SRH curriculum and conducted a training on SRH and the integration of FP and HIV/AIDS services in November 2008 in Eastern Cape (25 trainers trained).
- In July 2008, representatives from FHI/SA and the NDOH participated in the first FHI Global Technical Meeting on Family Planning and Integration with HIV/AIDS Programs in Addis Ababa, Ethiopia.
- FHI participated in data collection and monitoring of data collection for the 5-country FP/HIV integration study. Study Title: Country Assessments: Documenting Family Planning-HIV Integration Models, Protocol M070933 Implementing Organization: FHI, USA and SA (Susan E. Adamchak and Dirk Tajaard).
- In December 2008, FHI and NDOH conducted provincial visits to Mpumalanga and North West Provinces to introduce the new Technical Monitor for the Champions project and to provide support to the provincial Champions by reviewing work plans and developing future plans.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- FHI conducted training on SRH and integration of FP and HIV services in January, March and June 2009 in North West (11 trainers and 18 service providers trained), Mpumalanga Province (26 trainers and 5 service providers trained) and Northern Cape Province (27 trainers trained), respectively.
- Needs assessments were conducted in facilities in 2 of the 18 priority districts.
- FHI developed a tool to conduct the needs assessments.
- Provincial meetings in 4 provinces were conducted to provide technical support and mentoring to the provincial Champions and their counterpart through reviewing work plans, identifying challenges and developing future plans. Western Cape February 19, 2009
- A meeting with NDOH was held in January to give feedback on the activities of the Champions project and discuss future plans.
- FHI participated in the Western Cape quarterly SRH committee meeting (February 2009) and the North West Reproductive Health partners meeting on the 27 February 2009 in order to provide feedback on activities undertaken in the provinces and to identify other opportunities to support the provinces
- In response to the request from NDOH, FHI SA developed a pamphlet on all contraceptive methods available in the government facilities.
- FHI developed a supervision tool that promotes the integration of FP and HIV/AIDS services.
- FHI provided feedback to Eastern Cape province and NDOH in June 2009 on the findings of the DMPA study conducted by FHI in the Eastern Cape.
- The National Network of Champions workshop took place in May 2009 and was linked up with the FHI end of Project meeting that took place in South Africa.
- FHI hosted the End of Project (EOP) meeting for the CRTU Network of Champions subproject in Nigeria, Tanzania, Uganda, and Zambia, May 2009.

- The National integration indicators were modified by FHI during the National Network of Champions workshop, and are now ready to be used for integration data collection.

Findings and Outcomes:

- Baseline survey reports on FP and HIV integration were completed for five provinces.
- Five provincial activity plans were developed and are to be used for strengthening FP and HIV integration.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- FHI will continue to provide technical assistance to the NDOH and facilitate the process of developing national integration guidelines.
- FHI will provide technical assistance to the provinces and ensure that integration activities are planned, implemented, and monitored.
- FHI will work with the NDOH to train 100 trainers and 300 service providers using the updated SRH curriculum. Workshops have been scheduled and confirmed for NC, EC, FS and KZN.
- FHI will monitor utilization of the latest available CRTU literature and tools, and document successes and lessons learned.
- As requested by the NDOH, FHI staff will continue to work on the provincial level to revise the Sexual and Reproductive Health Training Curriculum to include evidence-based information on contraception for HIV-infected women, including those on ARV therapy.
- FHI will continue to monitor FP and HIV integration through monitoring of the data collection using the new integration indicators.
- FHI will rollout the dissemination of the DMPA study results to the provinces using the champions forums, e.g. training workshops and other seminars.
- FHI will continue to support service providers through the distribution of provider tools including the medical eligibility criteria for contraceptive use, checklists on screening for pregnancy and screening for use of IUD, oral contraceptives and injectables.
- The training for IUD insertion has not been budgeted for in COP 08; however, FHI has begun collaborating with Population Council to explore ways to collectively address this need. In addition FHI is conducting IUD insertion/removal training for a PMTCT-FP study undertaken in the Western Cape.
- FHI will assist the provinces in completing their work plans: the development of district work plans will be incorporated during the trainings to strengthen FP/HIV integration in the districts. These district work plans will together contribute to forming the provincial work plans.
- FHI will help the NDOH to revise the national contraception service delivery guidelines and the national contraception policy guidelines.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR; USAID - US Agency for International Development/USAID: Core	FCO Approved: 113127 Aug 2006 153130 Jan 2008
Total Approved Budget: 113127	\$ 129,005	Projected End Date: Apr 2010
153130	\$ 358,293	
	\$ 487,298	

South Africa: Expansion of Strengthening Linkages Between HBC, FP, ARV in South Africa (FCO 153128/153129/153138)

Technical Monitor: SPilusa

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.A.: At least two scalable and appropriate models given the CPR, HIV prevalence, and available services for integrating family planning and HIV services designed, evaluated and introduced in up to five countries.

Objective(s): 1) To build the communication and referral skills of HBC volunteers regarding family planning as an effective PMTCT approach; 2) to build the skills of HBC volunteers to provide basic information about and referrals for VCT and ARV services, and to assist HBC clients to adhere to the treatment regimen; 3) to strengthen referral mechanisms between HBC programs and FP, VCT, and ARV services; and 4) to increase access to integrated HIV and RH services through four mobile service units (MSU) in Mpumalanga (MP), Kwa-Zulu Natal (KZN) and the Limpopo Provinces (LP).

Description: With funds received from the President's Plan for Emergency Relief (PEPFAR) in November 2007, FHI will expand access to integrated reproductive health (RH) and HIV services for HIV-infected/affected individuals by enhancing palliative care programs and strengthening the linkages between home-based care (HBC), RH, voluntary counseling and testing (VCT), antiretroviral (ARV) services, and other essential services for comprehensive treatment, care and support. Tighter links between palliative care, VCT, ARV and RH services, in particular, afford men and women the opportunity to improve their overall quality of life, but also make informed decisions about their fertility. This subproject is an expansion of "Strengthening Linkages between HBC, FP and ARV Services" (FCO 153105). In this new subproject, FHI will continue to strengthen access to integrated services as part of a comprehensive care package for persons living with HIV and AIDS and their families.

Subgrantee(s): Project Support Association of Southern Africa (PSA SA)

Collaborating Agency(s): National Department of Health

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Activities, Accomplishments, Problems through December 31, 2008

- FHI leveraged government and partner resources by working with PSA/SA to build/strengthen formal referrals between HBC projects and FP clinics, VCT sites and ARV providers.
- FHI continued to support the MSU by providing integrated HIV/RH services to 58 HBC projects in Mpumalanga, Kwa-Zulu Natal, Eastern Cape and Limpopo provinces.
- In May 2007 and March 2008, FHI conducted trainings for 36 FP and ARV providers on contraception for HIV-infected couples.
- In March 2008, FHI trained 20 PSA/SA trainers and 63 coordinators on palliative care services, including FP and the establishment of referral networks.
- By March 2008, PSA/SA provided comprehensive care in households to 3160 males and 6681 females, and trained 312 HBC volunteers.
- In May 2008, FHI launched the MSU project in Greater Thaba Chweu Municipality with Dr. Al Siemens, FHI's CEO. Media coverage was extensive – Dr. Siemens was interviewed on SAFM, SABC International and Capricorn FM; an article called "Moving Mountains with Mobile Clinics" ran in the

Sunday Times; and a FHI SPO and the Project Director were interviewed on Ikwewezi FM and Capricorn FM, respectively.

- FHI negotiated with NDOH in KwaZulu-Natal, Mpumalanga, Limpopo and the Eastern Cape to provide the MSUs with tests kits, FP methods, sputum collection, and medications for minor ailments. The Eastern Cape MSU receives additional medication for chronic illnesses.
- MOUs and offices were established in all four provinces.
- FHI revised the MSU management protocol in December 2008.
- 26 staff members were recruited from July-December 2008 including an SPO, PO, M&E Officer, 4 Provincial Project Coordinators, 4 Health Promoters, 12 Professional Nurses and 3 trainers.
- In December 2008, Eastern Cape FHI Provincial Office established and provided training to HBC groups consisting of 30 volunteers.
- In December 2008, FHI/SA Country Director, Sonja Pilusa, was interviewed on SAFM and Metro FM on World AIDS Day and FHI activities.
- By December 2008, a functional M&E system was in place to improve data collection and capturing.
- In December 2008, FHI provided MSU staff with training on Aerobic Laughter Therapy (ALT) for the caregivers program.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- By March 2009, 463 HBC and community care workers were trained on ALT. The program is in Limpopo and Kwa-Zulu Natal, and being rolled out to Mpumalanga and Eastern Cape.
- From February-May 2009, 36 HBC caregivers were trained on basic HBC skills in Eastern Cape, where an HBC program was previously nonexistent. Additional trainings in Limpopo on palliative care were conducted for 117 HBC groups.
- MSU showcased FHI's work in Kwa-Zulu Natal and shared best practices with partners in February 2009.
- An additional MSU was procured in May 2009 to meet increased health service demands on Mpumalanga MSU and cater to other disadvantaged geographically dispersed communities in Pixley KaSeme district. It will be launched in August 2009.
- MSU partnered with Ramotshinyandi HIV/AIDS Youth Guide in Limpopo, who aim to increase access to youth friendly health services and publicize MSU services including VCT and SRH/FP to the youth. A June 2009 pilot for the 2010 World Cup Event publicized the package of services provided by MSU. 374 adults and youth were trained on life skills, ABC and STIs.
- The MOU between FHISA, Kwa-Zulu Natal and Mpumalanga was renewed. FHI negotiated with NDOH in the four provinces to provide MSUs with both minor ailment and chronic medications.
- By January 2009, MSU staff was recruited including: PO, KZN project coordinator, 2 professional nurses and a health promoter; project coordinator and 3 professional nurses in Limpopo and a health promoter in the Eastern Cape.
- In May 2009, the MSU submitted an abstract titled: Integrated RH/HIV Mobile Service Units as a Source of Modern FP Methods in Underserved Areas: The Example of FHI-SA and the DoH MSU project in South Africa
- In May 2009, FHI M&E unit trained MSU staff on the new data entry program and data quality management.
- In April 2009, FHI finance unit trained MSU staff on FHI F&A procedures.
- In June 2009, University of Pretoria trained MSU professional nurses on effective management of TB.

Findings and Outcomes:

- There is a lack of support given to People Living with HIV (PLWHA). This calls for stronger support groups to be formed or strengthened for VCT clients who test positive in the mobile clinics.
- There is a need by FHI to facilitate a continuum of care in the mobile service units. This will ensure that clients experience seamless and/or comprehensive health service (e.g. after HIV testing). FHI SA has a professional responsibility to provide a "one stop shop service" as accessible as possible by extending the scope of services rendered to include WHO clinical staging, CD4 testing and proper referral for treatment if required.
- There is a need for a proactive clinical management plan for emergencies. This include medical emergencies, basic level trauma management, and emergency deliveries for women in labor.

- The government needs to provide MSU's with referral pathways/guidelines and/or policies. This will enhance partnership and better working relations between FHI and the government, and enhance timely referrals for effective management.
- Improved partnership and support for the mobile service unit has resulted from improved stakeholder management and communication
- There is a need to ensure inter-sectoral collaboration. Due to a number of socio-economic determinants of health in the communities that the MSU serves, there is a need for a multi-disciplinary approach and multi-focal development projects to work with the MSU to address, mainly, the water and poor sanitation problem in order to break the cause and effects related disease determinants.
- Available resources should be utilized to maximize project outputs. FHI SA has been innovative to identify available resources and working with key gatekeepers within communities including chiefs, the community, etc. This has been achieved by supporting community mobilization activities that seek to encourage communities to utilize MSU services.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- The launch of the Mpumalanga MSU has been scheduled to take place in August 2009
- FHI will conduct a FP training workshop for nurses in the MSU. The training will update their knowledge on recent FP methods used.
- A dispensing license training for MSU Professional Nurses have been scheduled for September 2009
- FHI will conduct a well being (i.e. ALT program for the HBC Carers) working closely with the MSU in Eastern Cape and Mpumalanga.
- Benefiting HBC clients, family members and caregivers and FHI will continue to provide TA to HBC volunteers to identify FP, VCT, and ARV needs in the household and to refer to appropriate services; and to train HBC volunteers to assist clients in initiation of ARV therapy and to monitor client adherence.
- In close collaboration with NDOH, FHI will expand access to quality integrated services for individuals in HBC programs by continuing to support four MSUs to provide FP, ARV, VCT, and STI services in rural, underserved areas.
- FHI will continue to oversee the quality of FP services and counseling, VCT, STI testing, and ARV screening on the MSUs.
- FHI will continue to work with local HBC care groups to ensure HBC volunteers in MSU service sites provide referrals to their area MSU for FP, VCT, STI and ARV referrals services.
- FHI will continue to conduct outreach to HBC projects and communities through household visits and the use of IEC materials.
- FHI will continue to ensure that CRTU materials are used by each of the service providers being trained and supported. This will include monitoring the use of all CRTU materials and resources.

Funding Source(s):	USAID - US Agency for International Development/USAID: Field Support; USAID - US Agency for International Development/USAID: GLP	FCO Approved: 153128 Jan 2008 153129 Jan 2008 153138 Apr 2009
Total Approved Budget:	153128 \$ 624,604 153129 \$ 765,426 153138 \$ 1,179,971 \$ 2,570,001	Projected End Date: Apr 2010

South Africa: Developing and Testing Family Planning Programs for PMTCT Clients in South Africa, Phase 2 (FCO 114144/114145)

Technical Monitor: THoke

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.A.: At least two scalable and appropriate models given the CPR, HIV prevalence, and available services for integrating family planning and HIV services designed, evaluated and introduced in up to five countries.

Objective(s): 1) To evaluate the influence of a LAPM promotion intervention on knowledge regarding the IUD and sterilization among Child Health Services clients who participated in PMTCT services.
2) To evaluate the influence of an LAPM promotion intervention on knowledge regarding the IUD and sterilization among Child Health Services clients who have not participated in PMTCT services.
3) To assess the impact of training and technical support on service providers' knowledge, attitudes, and counseling practices with respect to IUD and sterilization.
4) To assess the impact of strengthened IUD and female sterilization services on Child Health Services clients' attitudes towards those methods, their intentions to use them, and their actual uptake.

Description: The study will be conducted in 5 resource-constrained sites in Western Cape Province that offer PMTCT services, that are a subset of the 10 PEPFAR-supported sites. Each site will have a high volume of PMTCT clients, and each will offer family planning services and have the potential to provide IUD services, in terms of necessary infrastructure and staffing. The intervention will include provider training to counsel all their clients (PMTCT or otherwise) on the availability of their contraceptive options, with a strong focus on the IUD and female sterilization. Mechanisms to capitalize on multiple contact points with PMTCT clients will be incorporated.

The primary objective will be measured by conducting repeated cross sectional interviews (pre- and post-intervention) with women attending Child Health Services who attended antenatal care and delivered within the past 6 months, all within the same facility. Pre-intervention interviews will be conducted with 500 clients approximately 2 months before all intervention components are in place, and post-intervention interviews with 500 clients will be conducted approximately 7 months after full introduction of the intervention. Additionally, in the post-intervention period individual in-depth interviews with providers who have been exposed to the study intervention will be conducted. Approximately 20 providers will be interviewed. To our knowledge, no intervention study examining promotion of contraception to PMTCT clients has included a concerted effort to ensure LAPMs are included among the choices offered. Research is needed to examine the effect of a package of interventions designed to improve promotion of and access to methods like the IUD and sterilization. The findings of such research will guide development of explicit policies and service delivery guidelines that require providers to counsel HIV+ women on the range of reproductive options available to them, including the full range of contraceptive methods.

Subgrantee(s): Women's Health Research Unit (WHRU), University of Cape Town

Collaborating Agency(s): Western Cape Provincial Department of Health

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Activities, Accomplishments, Problems through December 31, 2008

- Beginning in August 2008, FHI/South Africa colleagues joined WHRU collaborators in talking repeatedly with provincial officials and visiting health centers to select study sites.

- The subagreement with WHRU was approved and initiated in November 2008.
- The WHRU study coordinator was hired December 1, 2008.
- FHI/NC research utilization specialists collaborated continuously with field staff in planning multi-component intervention to strengthen LAPM services.
- Data collection staff were recruited and hired in December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Pre-intervention interviews were completed with 538 child health service clients in February – April 2009.
- The technical monitor traveled to South Africa in March 2009 to work with WHRU and FHI/South Africa on advancing plans for the PMTCT-LAPM study intervention.
- FHI/NC research utilization specialists continued to collaborate with field staff in preparing the multi-component intervention to strengthen LAPM services. A Research Utilization Senior Program Officer traveled to Cape Town in May 2009 to collaborate with WHRU and FHI/South Africa on these efforts.
- Pre-intervention data were entered and cleaned by WHRU data management specialists.
- A consultant was recruited to train clinicians in IUD insertion and removal. Another was recruited to serve as the PMTCT Coach, reinforcing the instruction provided in the PEPFAR-funded training on PMTCT with special focus on family planning.
- FHI/South Africa and WHRU representatives met with Western Cape Province and Cape Town City health officials to provide study updates and enlist their support in implementing the PMTCT-LAPM intervention.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- IUD insertion training will occur in July 2009, and additional LAPM promotion supports will be implemented in July and August 2009.
- Training in safe, effective family planning for HIV positive women will take place in July and September 2009.
- The PMTCT Coach will work with clinic staff in the 5 sites to strengthen promotion of postpartum family planning, including LAPM, within antenatal care, post-delivery, and child health services.
- Pre-intervention data will be analyzed and a manuscript presenting baseline findings will be prepared.
- It is anticipated the study will be transferred to a new Agreement effective December 1, 2009.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 114144 Aug 2008 114145 Aug 2008
Total Approved Budget:	114144 \$ 197,141	Projected End Date: Dec 2009
	114145 \$ 165,049	
	\$ 362,190	

South Africa: Enhancing PMTCT Performance in South Africa (FCO 153104)

Technical Monitor: SPilusa

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.E.: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Objective(s): 1) To provide technical assistance to 60 sites in South Africa (SA) to design, develop, and implement high quality, comprehensive and cost effective PMTCT programs, with an emphasis on strengthening family planning (FP) counseling and referral; 2) to expand upon lessons learned from previous FHI projects in PMTCT and FP/HIV integration (FCOs 3449, 9403, and 3447); and 3) to assist the provincial departments of health as needed with the development and finalization of provincial PMTCT protocols and training manuals.

Note: Sites mentioned in objective no. 1 have been expanded from 30 sites to 58 sites in COP 07 with the following additional provinces: North West, Free State and Western Cape.

Objective 3 was separated out from the general technical assistance since the DOH has directly asked FHI for this support.

Description: The goal of this subproject is to improve overall performance of selected PMTCT sites, with an emphasis on promoting FP counseling and referrals through training and technical assistance. This subproject follows the PMTCT study initiated in 2003 with USAID field support funds (FCO 9403), the TA project implemented under the South Africa COP 04 funding cycle (FCO 3449) in two provinces (LP and Northern Cape), and in Northern Cape in the COP 05 (FCO 153104) funding cycle. Following on to COP 06 activities, FHI is providing support to 58 service outlets in five provinces – 10 in Northern Cape, 13 in Limpopo, 13 in Western Cape, 10 in North West and 10 in Free State provinces – to strengthen PMTCT services by providing the minimum package of PMTCT services according to South African and international standards. FHI SA's current activities build on the FY 2006 and FY 2007 program in which FHI developed human capacity by refining the current training course for auxiliary nurses and lay counselors and equipping them with the knowledge and skills necessary to strengthen PMTCT services, including: (1) counseling and testing; (2) provision of ARV prophylaxis; (3) counseling and support for safe infant feeding practices; and (4) counseling on FP.

Evidence from an assessment (FCO 9403) indicates that family planning is an underdeveloped or neglected component of most PMTCT packages. In 2005, these evaluation findings were shared with the National Department of Health (NDOH) PMTCT program managers in South Africa. Technical assistance is currently being provided via the COP 07 to help apply the lessons learned in efforts to strengthen basic PMTCT services by focusing on family planning and ensuring the quality of existing site.

Collaborating Agency(s): National Department of Health

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Activities, Accomplishments, Problems through December 31, 2008

- In March 2006, FHI conducted a rapid needs assessment of 21 PMTCT sites and pilot tested the training curriculum in Northern Cape.
- Upon receiving FY 2006 and FY 2007 funding, the subproject expanded to 56 sites in 5 provinces (North West, Limpopo, Free State, Western Cape and Northern Cape).
- A baseline assessment was conducted in NC, LP, FS, and NW sites and feedback was provided on these results.
- In Western Cape Province, discussions took place regarding strengthening PMTCT/FP in PEPFAR sites as well as in 5 sites selected to participate in the second phase LAMP CRTU core-funded study sites (see FCO 114103).
- 647 health providers have been trained since FY 2006.
- Requested by NDOH, FHI helped to finalize the new PMTCT guidelines (Dual Therapy), and further provided guidance on utilization of these guidelines at the service level.
- As a member of National PMTCT Steering committee, FHI provided TA support and guidance in strengthening PMTCT and MCWH service delivery through attendance of quarterly meetings held in February, April, August and Nov 2008.

- FHI selected 13 PEPFAR PMTCT sites in WC including 5 LAPM second phase study sites. All sites were visited in July 2008 and the first training was conducted in August 2008. In NW 10 sites were identified in Bophirima district in June 2008 and the first training was conducted in July and Aug 2008.
- In November 2008, the FHI and NW provincial and district team held a meeting to review activities conducted in 2008 and created an implementation plan for 2009 activities.
- FHI continued working closely with NDOH to finalize the PMTCT training manual incorporating new PMTCT dual therapy guidelines to ensure utilization of the guidelines at the service level. These inputs have been discussed at Quarterly PMTCT Steering Committee meetings held in Feb, May, July and Nov 2008.
- All trainings conducted from March 2008 and forward ensure that new guidelines are incorporated according to the country PMTCT accelerated plan, aimed at scaling up coverage and improving the quality of PMTCT to reduce MTCT to less than 5% and broadening existing PMTCT services and integrating FP and other maternal and child health care services.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- FHI SA was involved in provincial meetings that review progress made with regard to strengthening integration of FP and implementation of new guidelines. One meeting was held in Limpopo in January 2009. During these discussions FHI SA together with other NGOs supporting the province contributed and gave inputs to the Provincial 2009 Comprehensive Operational Plan that is inclusive of all partners aligned to the National Strategic Plan 2008 -2013.
- Further PMTCT/FP integration training was conducted in Limpopo province in February, March and June 2009. A total of 86 health care providers were reached.
- 237 health care providers attended training session in various districts within the provinces to strengthen their knowledge and skills.
- In NW, FHI conducted the PMTCT/FP integration training in January, 21 nursing assistants and lay counselors were trained. In FS, FHI conducted the PMTCT/FP training in January for Thabo Mofutsanyane district. During this training, 31 nurse assistance and lay counselors were trained. Another HIV/PMTCT and FP training was conducted for 28 clinic managers in March 2009.
- FHI SA continues to support 5 LAPM study sites in WC through provision of capacity building and technical assistance. During March 2009, 18 professional nurses were trained on PMTCT/FP training. Ten of these participants came from 5 LAPM study sites.
- FHI SA has been providing capacity building and mentoring to PMTCT service providers and managers in NC DOH since FY 2006. In February 2009, they conducted PMTCT/FP training reaching 30 health care workers (HCW). FHI SA provided guidance and training material for this training. This is the model that FHI SA is marketing within the other 4 provinces as part of its sustainability plan. Further, 24 participants were trained by FHI SA in June 2009 in Naqwa district.

Findings and Outcomes:

- FHI provided training and technical assistance to 56 PMTCT service outlets which provide the minimum package of PMTCT services according to South African standards. FHI incorporated the new PMTCT guidelines (Dual Therapy) within these trainings.
- 260 health workers have been trained and provided with TA from October 2007- Sept 2008.
- Nationally, FHI provided technical support during the quarterly National PMTCT steering committee meetings where strategies to improve quality on HIV/PMTCT and Maternal health services were discussed.
- FHI contributed to the finalization of the new PMTCT/FP guidelines that will improve successful provision of PMTCT dual therapy. These new guidelines were signed by the Health Minister on 13 February 2008.
- Training, mentoring and coaching in the 56 PMTCT sites contributed to the increased number of women provided with HIV counseling and testing for PMTCT/FP and received results at those sites. A total of 5449 clients received HIV counseling and testing for PMTCT and received their results in the selected sites, representing 91% of the indirect target figure (6000). This 91% excludes data from the Western Cape and North West provinces, since training started in August 2008 in these provinces due to provincial government delays in signing the MOUs, approving workplans, etc.
- FHI exceeded the target on pregnant women provided with complete course of ARV prophylaxis – this is also seen as an improvement given the availability of trained and mentored staff in these facilities.

- PMTCT National training manual is currently under revision and FHI, as an expert in reproductive health and Family Planning, made contributions to the module on contraceptives for HIV+ women and couples.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

Staff will:

- Train of health care workers in the provision of PMTCT/FP services according to national and international standards; Conduct 5 day PMTCT/FP integration training in 5 provinces (NW, WC, LP, FS and NC). Target group auxiliary nurses and lay counselors.
- Train, guide, counsel local and provincial trainers by involving them during training sessions so that they are able to cascade information on their own.
- Provide TA to all Health workers including managers and supervisors in the 5 provinces at the 58 sites; Conduct facility visits to provide mentoring, coaching, and on-job inservice training.
- Provide technical advice to the Provincial Managers that supervise the provision of PMTCT/FP services.
- Support the sites in the development of M&E plans and communicate M&E strategies to sites (e.g. targets & indicators; assist and support sites in quality data collection and collation).
- Provide feedback on progress within the sites at different levels of management;
- Review program workplans and compile relevant reports according to PEPFAR requirements and share results with partners.
- Ensure capacity building/training to continue to reach the target of 400 health providers as per FY 2008 plan.
- Expand sites from 58 to 70 (12 additional sites) according to needs assessment in provinces.
- Continue to provide TA to Provincial Managers who supervise the provision of PMTCT/FP services.
- Support strategies to ensure male involvement at all levels of health care by encouraging couple counseling; ensuring access during partner treatment or management (e.g. during ANC and labor and delivery); establishing partner friendly facilities including FP services; and supporting workshops, awareness, and open days to promote male involvement in all health care services.
- Provide support to the LAPM study in Western Cape in the 5 selected PMTCT sites.
- The manual will be field tested in July 2009 and FHISA has been requested to be make contribution during that process.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR	FCO Approved:	Sep 2005
Total Approved Budget:	\$ 1,261,511	Projected End Date:	Sep 2009

Kenya: FP/PMTCT Integration Assessment in Kenya (FCO 144101/154101)

Technical Monitor: JLiku

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.B.: At least three strategies to meet demand of specific populations identified, implemented by HIV and/or FP providers and evaluated, and introduced into programs in five countries.

HIV/FP II.E.: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Objective(s): To conduct a formative assessment in order to better understand the program opportunities for and potential barriers to the successful integration of FP into the wider scope of PMTCT plus services for both fecund and recently postpartum HIV+ women. This subproject also aims to develop or modify existing training materials as needed on the provision of FP services for HIV+ women.

Description: FHI will partner with the National AIDS and STD Control Program (NASCO) and the Division of Reproductive Health (DRH) to implement this subproject. The assessment will utilize cross-sectional survey interviews with the whole constellation of potential PMTCT plus service providers (including physicians, nurses, dietitians, and counselors) at 20 sites. These sites will be concentrated in FHI's APHIA II provinces (Coast and Rift Valley) and will represent a subset of 60 "typical" service sites targeted by FHI/CRTU's COP05 activities. Provider surveys will seek to identify circumstances in which providers might appropriately screen for unmet need for contraception and how FP services might be made available when needed. Client interviews will seek to identify when and why fecund and recently postpartum HIV+ women access health services for themselves or their children, and how these services might better meet unmet care and support needs, including unmet need for contraception. Also, a stakeholder meeting with PMTCT policymakers and program administrators will be conducted to assess their perspectives on opportunities for and challenges to successful PMTCT-FP integration in Kenya. Strategic information generated by the assessment and stakeholder meeting will inform the development of potential training materials and/or messages on the provision of FP services for HIV+ women and couples in Kenya, particularly within the context of PMTCT plus services. Assessment findings will be widely disseminated so that experiences and successes documented during the study can be used by PMTCT program managers, supervisors and providers beyond the 20 sites included in the assessment. Furthermore, this subproject will provide information to assist the National PMTCT Technical Working Group to strengthen provision of integrated FP/PMTCT services as part of a comprehensive risk reduction strategy.

Collaborating Agency(s): Division of Reproductive Health; National AIDS Control Program; National PMTCT Technical Working Group (TWG)

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Activities, Accomplishments, Problems through December 31, 2008

- FCOs 144101 (field support funds) and 154101 (PEPFAR) were approved on January 24, 2007.
- A protocol was developed, reviewed, and submitted for PHSC and Kenyatta National Hospital Ethics Review Committee approvals between May-June 2007.
- PHSC approved the protocol in July and Kenyatta approved it in August 2007.
- Data collection forms were developed and reviewed in December 2007.
- Research Assistant recruitment and training, and data collection form piloting took place in April 2008.
- Data collection took place in May 2008.
- Data analysis began in June 2008.
- FCO 144101 was closed in June 2008.
- Data analysis was completed and verified in December 2008.
- An in-country dissemination meeting was held with 25 stakeholders to present findings in December 2008. A research brief was prepared and shared during dissemination

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- An updated literature review on family planning for PMTCT was completed in February 2009.
- A review of assessment results and preparation of brief project description was completed in April 2009.
- The activity protocol was finalized in April 2009.
- A link was established with PMTCT Technical Working Group to introduce FP-PMTCT project activities in March 2009.
- Dr. Masaba and TM met and shared activity protocol with NASCO point persons in May 2009 and agreed with NASCO on FHI support for two meetings to finalize training materials/tools.

- Project budget was prepared in April 2009 and a review of materials/tools was started in June 2009.
- Study sites were selected and site visits were conducted in Coast & R. Valley provinces in June 2009 (Bamburi Health Centre, Chaani Health Centre, Coast Provincial General Hospital, Kisauni Health Centre, Likoni Health Centre, Mwembe Tayari Health Centre, Reitz District Hospital, Shimo La Tewa Health Centre, Tudor Health Centre, Kongowea Health Centre, Bondeni Maternity, Chebaraa HC, Kabatini HC, Kapkures HC, Kuresoi HC, Lanet HC, Nakuru PGH, Olenguruone SDH, Rongai Health Center, and Solai HC).
- 20 Research Assistants were hired and trained in June 2009.
- Baseline data collection started (service statistics) in June 2009.
- A PMTCT TWG meeting was held on June 17, 2009.

Findings and Outcomes:

Clients:

- Demonstrated a high need for FP knowledge and services among women interviewed and reported a low frequency of FP discussions with clinic staff.
- Knowledge of LAM criteria for natural family planning is low, particularly breastfeeding exclusively and the appropriate post-partum period.
- Fear of partner disapproval and/or disclosure of FP is a motivating factor in non-use.

Providers:

- Demonstrated need for further FP training/refresher especially in regards to FP specifically for HIV+ clients.
- Provider knowledge of LAM criteria is high, but is not being passed on to clients.
- Providers favor integration of FP counseling and referral into existing services but voice some concerns about confidentiality and space limitations in regards to direct FP provision.
- Providers do not always know clients' HIV status, thus, targeting only HIV+ clients may be difficult and/or undesirable – hence the need for generalized provision of FP services in these service units (ANC, PNC, CWC).
- There were approximately 25 people who attended the dissemination meeting in December 2008.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Update training materials for antenatal care, postnatal care, and child welfare clinic providers as needed to strengthen expertise on family planning service provision for HIV positive women and couples as well as HIV negative women and couples in July/Aug 2009.
- Pre-test the updated provider training materials in July/August 2009.
- Pre-test/field test training materials (conduct orientation for TOTs/program managers & train service providers) in July/Aug 2009.
- Monitor FP uptake – collect service statistics after service provider training in Aug-Oct 2009.
- Results of pretest of updated provider training materials and indicated revisions will be prepared for presentation to the TWG in Sept/Oct 2009.
- Updated materials will be submitted for approval by the MOH by Nov/Dec 2009. Data entry and cleaning (service statistics) will take place in Oct-Nov 2009.
- Data analysis in Dec 2009 to Jan 2010.
- Preparation of slides for dissemination & research brief in Feb 2010.
- Dissemination in Feb/Mar 2010.
- Final report writing in Mar 2010.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR; USAID - US Agency for International Development/USAID: Field Support	FCO Approved: 144101 Feb 2007 154101 Feb 2007
Total Approved Budget: 144101 \$	49,958	Projected End Date: Apr 2010
154101 \$	400,132	
\$	450,090	

Ethiopia: Country Assessments: Documenting Promising Family Planning-HIV Integration Models (FCO 114124/114135/124106/124107/124108)

Technical Monitor: SAdamchak

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.A.: At least two scalable and appropriate models given the CPR, HIV prevalence, and available services for integrating family planning and HIV services designed, evaluated and introduced in up to five countries.

Objective(s): 1) To describe the range of integrated or linked FP/HIV activities being carried out in the PEPFAR focus countries, including the approach to integration for each activity, scale of implementation, and evaluation results; and 2) to gather rigorous, in-depth information about FP-VCT, FP-ART, and FP-HIV integration models in five countries (Kenya, Uganda, South Africa, Ethiopia and Rwanda) to describe how these models are being implemented, their impact on client intentions to use (or in FP clinics, those who are already using) contraception, their cost-effectiveness in reaching HIV-positive women with FP services, and their potential for scale-up.

Description: Rather than funding an unfocused research and program agenda that initially concentrates on pilot projects, we implemented a strategic approach that systematically identified and evaluated integrated models that have the most potential to reach the largest number of people at risk of HIV, living with HIV or on ART with family planning services at reasonable costs. Our approach consisted of two phases: In the first phase, we conducted a rapid assessment in PEPFAR focus countries to create an inventory of integration models. Phase II consisted of a situation analysis in a subset of five countries (Kenya, Uganda, South Africa, Ethiopia and Rwanda) to describe how FP-VCT, FP-ART, and FP-HIV models are implemented, their association with client contraceptive use, their cost-effectiveness in reaching HIV-positive women, and their potential for scale-up. Phase I consisted primarily of a desk review. The activities in Phase II included interviews with policy makers and key informants, as well as facility-level interviews with mid-level managers, providers, and clients. We also conducted structured observations of facilities. The outcome of Phase I and Phase II was to systematically identify integrated or linked models, define the programmatic inputs that make up an integrated model, document the organizational and policy support for the models, and determine the additional inputs and resources needed for these activities. This subproject informed two activities: a dissemination of lessons learned and capacity

building activities with CAs and in-country partners to prepare for scale-up and operations research on promising models.

Subgrantee(s): Ethiopia: Macro International; South Africa: Progressus Research and Development Consultancy CC; Uganda: Department of Population Studies, Institute for Statistics and Applied Economics

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Activities, Accomplishments, Problems through December 31, 2008

- FCO 114124 was approved within FHI on February 19, 2007; Approval to Implement was received March 7, 2007.
- Preliminary Phase I results and plans for Phase II were presented to the USAID's internal FP-HIV integration working group and key CA partners on May 1, 2007.
- As per USAID's request, Phase I was expanded from 7 to 15 PEPFAR countries; the data collection for Phase I was completed at the end of June 2007.
- Protocol and data collection instruments for Phase II were finalized and submitted to PHSC in August 2007.
- The protocol for Phase II was reviewed by local IRBs in Uganda and S. Africa in September 2007; in Kenya in October 2007; and submitted for review in Ethiopia in December 2007. A presentation of the protocol was made to the National Committee for the Fight against AIDS in Rwanda in December 2007 and to the MOH Ethics Review Board in Rwanda in January 2008.
- Training of the data collection team in Uganda occurred in October 2007, and data collection at 22 sites was completed in November. (FCO 114135).
- Training of the Kenya data collection team took place in October-November 2007, and data collection at 30 sites was completed in December 2007.
- In-depth interviews and fieldwork planning took place in South Africa in November 2007, including developing a subagreement with a local data collection firm (FCO 124107). Data collection began in April 2008.
- In-depth interviews, field work planning and budget preparation took place in Rwanda in December 2007. Training of the Rwanda team occurred in January, and data collection began immediately.
- Data collection, coding, and data entry began in Ethiopia in January 2008 (FCO 124108) and was completed in April.
- A report of preliminary data was prepared during July 2008, and was sent to participating FHI country offices.
- Results of the assessment were presented at the Integration Working Group meeting in October 2008 in Washington, DC.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Work in South Africa was completed. The subproject was closed in February 2009 when final payment was made to the contractor. The final report will be completed under FCO 114143.

Findings and Outcomes:

- Analysis of data from 5 countries demonstrate very different client profiles among women attending FP, VCT and Care and Treatment (C&T) services. Notably, women attending VCT are younger, less likely to be married and more likely to report having a partner, and more apt to have no children than their FP or C&T counterparts. Women attending C&T services are older than the others, and are less likely to report being married than women attending FP services.
- Fewer than one-third of the FP clients report being screened for HIV risk behaviors or condom use, and fewer than one-quarter report discussing dual method use with a provider. Comparatively higher proportions of C&T clients report being screened for fertility desires and current FP method use, but many report not discussing methods other than condoms, and fewer than 40% had help in starting a FP method during C&T.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: GLP; USAID - US Agency for International Development/USAID: GLP/HIV & FP	FCO Approved: 114124 Feb 2007 114135 Oct 2007 124106 Nov 2007 124107 Nov 2007 124108 Nov 2007
Total Approved Budget:	114124 \$ 459,470	Projected End Date: Feb 2009
	114135 \$ 49,467	
	124106 \$ 375,400	
	124107 \$ 42,042	
	124108 \$ 159,008	
	\$ 1,085,387	

Worldwide: Monitoring Status FP/HIV Integration Efforts (FCO 114143/114153/184000)

Technical Monitor: SAdamchak

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.A.: At least two scalable and appropriate models given the CPR, HIV prevalence, and available services for integrating family planning and HIV services designed, evaluated and introduced in up to five countries.

Objective(s): 1) To conduct an assessment to document promising practices in existing or newly implemented integrated FP-PMTCT programs or programs designed to reach postpartum PMTCT clients with FP;
 2) to organize a session at the 2009 PEPFAR Implementers Meeting to discuss the importance of reaching HIV+ women with FP services and to review promising programmatic and implementation practices and lessons learned in integration;
 3) to provide streamlined tracking of the placement, scale, and implementation approaches of FP/HIV integration programs worldwide;
 4) to conduct in-depth monitoring of FP/HIV integration programs in a sub-set of countries, including the technical program activities and evaluation findings;
 5) to track changes in the policy environment, funding trends, government support, and other factors that may influence integration in the same sub-set of countries; and
 6) to conduct ongoing analysis of the data from the FP-HIV in-depth situation analysis.
 7) to conduct a qualitative assessment of the barriers providers face in delivering integrated services.
 Note: Objective 1 was changed to include drafting of a discussion paper on FP-PMTCT, and its use as the foundation of a technical meeting to be held in Washington DC in October 2009. Objective 2 was not

completed as the proposed session was not included in the meeting agenda. Objective 3 was dropped by USAID. Objective 7 was added as a follow-on study of the five-country FP-HIV integration assessment.

Description: FHI prepared a literature review of recent publications describing models of FP-PMTCT integration, and conducted interviews with policy makers and key informants to document activities, facilitators and barriers to FP-PMTCT integrated programs.

To meet the second objective an abstract was submitted reporting on the results of the 5-country assessment of FP-HIV programs; it was not accepted by session organizers. A second abstract was submitted and accepted by the IAS.

To meet the third objective, FHI proposed developing a tracking matrix to monitor integration programs worldwide. Staff were to regularly track published and grey literature, attend meetings or review relevant conference proceedings, and liaise with in-country contacts to stay abreast of FP/HIV integration activities in the field. This activity was dropped following the compilation of a comprehensive literature file in preparation for the October 2008 Integration Working Group meeting.

For objectives 4 and 5, FHI will monitor the status of integration efforts in Kenya and Rwanda. This subproject will track the type of FP/HIV integration programs funded by the USG and other organizations to determine whether programs have increased and improved integration efforts in the time since the 5-country assessment was conducted; a particular focus will be on the barriers confronting providers in offering integrated services..

Monitoring activities will be coupled with ongoing data analysis from the situation analysis of integrated programs recently completed in 5 countries (objective 6), and preparation of at least two conference abstracts and one manuscript for publication. To capitalize on USAID's investment, this subproject will support additional data analysis to maximize the lessons learned and generate recommendations for integration programs, including considerations for replication, scale-up, and future research.

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Activities, Accomplishments, Problems through December 31, 2008

- The FCO was opened in July 2008.
- The Technical Monitor held several discussions with USAID colleagues to determine countries to include in the monitoring data base.
- Data analysis of the FP-HIV in-depth situation analysis took place, including a presentation of results at the October 2008 meeting of the USAID-supported Integration Technical Working Group. Countries included in the assessment were Ethiopia, Kenya, Rwanda, South Africa and Uganda. Data collection took place between October 2007 and June 2008 under FCOs 114135, 124106, 124107, and 124108.
- Preparation of the final report of the FP-HIV Integration situation analysis started.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Fieldwork for the monitoring activity started in three countries in May 2009.
- A consultant was engaged to conduct the PMTCT-FP literature review and in-depth interviews.
- In collaboration with external partners, 2 countries were identified in which to carry out fieldwork for the study of providers and barriers to delivering integrated services.
- Data analysis of the FP-HIV in-depth situation analysis was continued in preparation for conference presentations and manuscript writing. Three conference abstracts were submitted, and a manuscript prepared for a supplement to the journal AIDS.
- The final report of the FP-HIV Integration situation analysis was completed in June 2009.

Findings and Outcomes:

- In all countries, early FP-HIV integration efforts appear weak: providers lack training and job aids, they are biased against oral contraceptive and IUCD use by HIV+ women. While they strongly advocate condom use among women with HIV, they do not view it as a protective measure for use by women who are HIV negative. Few women report being offered family planning services or referrals.
- Data from client interviews from Kenya, Rwanda and Uganda for two integration models: family planning in counseling and testing (CT) and family planning in care and treatment (C&Tx) will be presented at IAS in July 2009. Women differed on key characteristics: women in CT are younger, more likely to be

childless, to have a partner and to have been recently sexually active. Unmet need for modern contraception is lower among women in C&Tx than among women in CT. In most programs the condom is the most commonly used method; there are substantial differences in condom use at last sex. For both types of clients, except among CT clients in Uganda, at least half reported that they had been told three key HIV messages. CT and C&Tx providers in Kenya were similar in the frequency with which they screened for unmet family planning need, while C&Tx providers in Rwanda and Uganda were more likely to have screened for unmet need compared to their CT counterparts. Women in C&Tx were more likely to report they received information about methods than were CT clients; few received a method, with the condom provided most often. Few clients were referred elsewhere for services. Findings highlight a fundamental paradox confronting service providers: how do they promote use of other modern contraceptive methods while still persuading women to use condoms?

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Planned Activities for July 1, 2009 – April 28, 2010

- A research protocol will be submitted to PHSC and local IRBs in July 2009 to conduct field work with providers in Kenya and Rwanda.
- Data collection instruments were developed as part of the protocol amendment process, and will be finalized in July 2009. Data collection is anticipated to be done during August-September.
- A single subcontract will be negotiated with a local research firm to conduct in-depth interviews with providers in both countries
- FHI will assist USAID in organizing a technical meeting on FP-PMTCT integration to be held in October 2009.
- Data analysis of the provider study will be conducted in October 2009.
- Two manuscripts will be developed using data from the Five Country FP-HIV Integration Assessment.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 184000	Jul 2008
		114143	Jul 2008
		114153	Sep 2009
Total Approved Budget: 184000	\$ 200,000	Projected End Date:	Apr 2010
	\$ 455,005		
	\$ 17,788		
	<u>\$ 672,793</u>		

Tanzania: Facilitated Referrals to Promote FP Access Among HIV-Positive Women at HIV Care and Treatment Centers (FCO 114136/114151)

Technical Monitor: MGreen

Strategy Outcomes(s) to be addressed: HIV/FP II.A.: At least two scalable and appropriate models given the CPR, HIV prevalence, and available services for integrating family planning and HIV services designed, evaluated and introduced in up to five countries.

Objective(s): The primary goal is to evaluate the feasibility and effectiveness of “facilitated referrals” on the uptake and continuation of FP among female clients attending HIV Care and Treatment Centers (CTC) sites who have unmet need for contraception.

Specific research objectives are to: 1) Measure the level of unmet need for contraception among clients at CTC sites; 2) assess the feasibility and acceptability of implementing “facilitated referrals” to FP services

within CTCs; 3) determine the effect of adding facilitated referrals to FP on the quality of care at CTCs; and 4) measure same day FP uptake among CTC clients with unmet need for FP.

Description: Given the need for effective models of HIV services that meet women's needs for family planning (FP), FHI proposes to test a new "facilitated referral" intervention for FP services. Facilitated referrals are enhanced referrals that consist of specific actions to encourage completion of a referral and include some combination of the following at the client's CTC visit: active counseling by CTC counselor on need for referral to FP (or pre-PMTCT) services; inquiry about barriers to referred services; linking to financial support or transport if needed; CTC counselor accompanies client to FP clinic or a FP staff person (FP facilitator) links to client during CTC session; informed choice counseling on contraception; CTC counselor offers some FP methods immediately; CTC counselor provides referral slip; referral recorded in register; and monitoring and follow-up of referrals.

Monthly CTC counseling sessions address psycho-social issues, adherence and prevention education. Counselors can be trained in FP issues; however, since most CTC sites have co-located FP clinics, it would be most efficient to refer for FP services. The benefit of the facilitated referral is to more effectively ensure linkage to contraceptive services and to decrease delays or barriers to the referred service.

The intervention (funded and implemented by FHI/Tanzania) will likely include the following activities: development of the FP-CTC integration model and guidelines, revision of the CTC counseling curriculum, training for CTC & FP staff and establishing supportive supervision for CTC & FP providers.

Subgrantee(s): Muhimbili University of Health and Allied Sciences (MUHAS)

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Activities, Accomplishments, Problems through December 31, 2008

- The approval to implement letter was signed in January 2008.
- The Technical Monitor met with the FHI/Tanzania point person for the project in NC in May 2008 to discuss key issues regarding program intervention and study design.
- The TM visited CTC sites in Tanzania in July 2008.
- The TM applied for and secured funds for the program intervention (to be implemented by FHI/Tanzania) from the Tides Foundation (funding from October 2008 through September 2009)—FCO 16535.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The TM finalized the study protocol in consultation with the FHI/Tanzania office.
- The protocol received PHSC approval in March 2009.
- The TM participated in a Technical Workshop in Morogoro, Tanzania in April 2009 with key stakeholders to orient them on the proposed integration intervention (and associated materials such as curricula and job aids) and the planned evaluation.
- The protocol received approval from the National Institute of Medical Research (NIMR) in June 2009.
- The protocol was initially reviewed by the MUHAS ethics committee and not approved pending responses to reviewer comments. It is currently under re-review.
- The subagreement with MUHAS was approved and the first payment went through in June 2009.

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Planned Activities for July 1, 2009 – April 28, 2010

- Research assistants will be trained in July and baseline data collection will be collected in August 2009.
- While the program partner (FHI/Tanzania) implements the intervention, baseline data will be entered and analyzed.
- The project will be transitioned from CRTU to PTA in December 2009.
- Follow-up data collection will be collected in January 2010.
- Data will be entered, cleaned and analyzed by April 2010.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 114136 Jan 2008 114151 Mar 2009
Total Approved Budget: 114136	\$ 280,425	Projected End Date: Apr 2010
114151	\$ 86,197	
	<hr/> \$ 366,622	

Madagascar: Increasing Access to Postpartum Family Planning Services (FCO 114116/114132)

Technical Monitor: LDulli

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.B.: At least three strategies to meet demand of specific populations identified, implemented by HIV and/or FP providers and evaluated, and introduced into programs in five countries.

Objective(s): To increase use of postpartum family planning by women. To achieve this goal, this subproject conducted an assessment of immunization services to generate strategies to reach postpartum women with family planning messages, services and/or referral. Specifically, this study described: 1) how immunization services are typically organized in a country with high levels of immunizations; 2) the characteristics of mothers and infants attending immunization services, particularly contraceptive use, breastfeeding practices, and HIV status (as appropriate); and, 3) provider and client perspectives on the feasibility and acceptability of a strategy to link mothers to family planning services.

Description: Many postpartum women have an unmet need for family planning services. In Sub-Saharan Africa, the unweighted average of unmet need among women 0-12 months postpartum is 74%, with 55% having a need to space and 19% needing to limit. Few women seek postpartum family planning services, although they are seeking health services for their infants. By their infant's first birthday, the majority of women in most countries have sought an immunization against the measles as well as the third polio or the third DPT immunization for their infants. Immunization services are an obvious area to reach postpartum women with family planning messages, services and/or referrals. Strategies to reach postpartum women with their infants in immunization services, however, have been largely untested. One study demonstrated that even a simple, unobtrusive family planning referral message in immunization services was associated with an over 50% increase in the number of family planning clients. This study seeks to identify testable strategies to reach women with postpartum family planning messages. This was a cross-sectional assessment of immunization clinics as potential sites for integration of family planning activities. The study involved structured interviews with immunization clinic managers, service providers and with women who bring their children to receive immunization clinic services. Additionally, a review of clinic service statistics, structured clinic observations and activity sampling within the clinics provided data on immunization service facility organization and capacity for service integration.

Collaborating Agency(s): Population Services International (PSI)

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Activities, Accomplishments, Problems through December 31, 2008

- In May 2007, Dulli traveled to Madagascar to present and gain support for the proposed study. During this visit, MOH officials gave verbal support/approval for the study and will appoint one individual from within the MOH to serve as a co-investigator.
- USAID/Madagascar gave their verbal support for the subproject.
- Dulli also met with the Director General of the National Institute of Public Health who has extensive experience collaborating with agencies such as PSI and the University of North Carolina on research projects and has both the expertise and capacity to handle on-the-ground implementation of the studies. The Director General agreed to be a co-investigator and to coordinate all field activities for the study.
- Dulli also met with representatives from Santénet, the USAID bilateral, and PSI to discuss potential collaboration for results dissemination and utilization.
- Study documents were finalized and received approval from both FHI and Madagascar ethics committees in August 2007.
- Data collector training took place in September 2007 and data collection began the same month.
- Data collection was completed in January 2008.
- Data entry was completed in February and analyses completed in May 2008.
- A stakeholder's meeting with the MOH and partners was conducted in June 2008 at which time ideas for an intervention to be tested were developed.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- A final project report was drafted in June 2009 and will be using Technical Leadership funds, FCO 114106, to complete.
- The FCO was closed in June 2009.

Findings and Outcomes:

- Findings from the formative feasibility and acceptability assessment indicate that contraceptive prevalence among women up to 12 months postpartum was low (17%), and unmet contraceptive need was 71% among married or sexually active respondents who did not meet the criteria for LAM. Nearly half (49%) of the respondents met the criteria for LAM (< 6 months postpartum, amenorrheic, and exclusively breastfeeding), but only 0.5% reported using the method. 82% of women who were not currently using a contraceptive method reported that they intended to do so in the future. 44% of women stated that they did not want any additional children, yet use of long-acting or permanent methods was low (5.5% among current users). The majority of women said that they would like to receive information, education and counseling about contraceptive methods during the immunization clinic visit.
- Most immunization service providers (73%) and service managers (89%) thought that offering family planning services to women at the same time as the immunization service was a good idea and that it would save women time by not having to travel back and forth from their homes. However, many stated that they would need an additional person to reorganize services to meet the needs of both the infants and the mothers at the same time because immunization services are usually offered in a large room with no privacy and little time is spent with each client.
- Health care facilities and immunization services provider observations revealed that immunization clients generally arrive early in the morning, client flow is heavy from about 9 AM to 11 AM and most clients have left by noon. Providers' afternoons are largely spent doing administrative tasks or in non-work-related activities.
- Over all, both clients and providers expressed interest in combining all or some aspects of family planning services with infant immunization services, but the strategy and level of integration will need to be tailored to different clinic settings based on the number and training of staff.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 114116	Nov 2006
		114132	Aug 2007
Total Approved Budget: 114116	\$ 125,983	Projected End Date:	Jun 2009
114132	\$ 64,124		
	\$ 190,107		

Worldwide: Prospective Evaluation of Contraceptive Dynamics in Women (FCO 112127)

Technical Monitor: KNanda

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.B.: At least three strategies to meet demand of specific populations identified, implemented by HIV and/or FP providers and evaluated, and introduced into programs in five countries.

Hormonal II.D.: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated.

Objective(s): 1) To describe patterns and dynamics of hormonal contraceptive use including discontinuation, method switching, and dual use using prospective data collected across countries and regions (Africa, Asia); 2) to examine the relationship between method discontinuation or switching and baseline reproductive health characteristics, reasons for method discontinuation, and condom use and sexual partnership characteristics over time; and 3) to examine, in a prospective study, the effect of HIV diagnosis (and possibly need for antiretroviral (ARV) treatment) on hormonal contraceptive discontinuation, initiation, switching, and dual use patterns.

Description: More than 100 million women worldwide use hormonal contraceptive methods. Both oral and injectable contraceptives comprise large proportions of the contraceptive method mix for women in low-resource settings, including those at high risk for, or infected with, HIV. However, almost 50% of women, many in low-resource settings, discontinue these methods during the first year of use.

In addition to women who discontinue, some women considered discontinuers in fact switch to another method, which may lead to unintended pregnancy if the method is less effective or if the switching results in a lapse in contraceptive coverage. It is estimated that over one million unintended pregnancies are related to misuse or discontinuation of hormonal contraceptives.

Another area of concern is use of contraception by women who are HIV-infected. Global efforts are currently underway to expand HIV prevention and care programs, and to integrate contraceptive services into these programs as a key HIV prevention strategy. To optimize integration, knowledge of contraceptive behavior once a woman knows she is HIV-infected, and other factors that influence her reproductive decision-making, is needed. Furthermore, it is important to understand how similar or different her contraceptive use might be from those of non-infected women.

We propose to use data from the large prospective Hormonal Contraception and Risk of HIV Acquisition (HC-HIV) Study to estimate frequency of contraceptive discontinuation, switching, and initiation in women using DMPA, combined oral contraceptives (COCs), and condoms. We will also specifically examine the effect of HIV diagnosis and other factors on contraceptive dynamics.

Such data are important in counseling women, in developing programs, and in informing public policy, particularly for the development of optimal strategies for using contraceptive methods to prevent both pregnancy and HIV.

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Activities, Accomplishments, Problems through December 31, 2008

- The concept proposal was approved in early 2006; FCO 112127 was assigned on October 31, 2006; and this subproject was approved with the 2006-07 workplan.

- The analysis plan was finalized and data analysis was completed.
- The study team met to discuss the results and assign manuscript tasks.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- FHI staff continued to work on the manuscript.

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Planned Activities for July 1, 2009 – April 28, 2010

- The manuscript will be submitted for publication and the FCO/subproject will be closed.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Oct 2006
Total Approved Budget:	\$ 132,799	Projected End Date:	Dec 2009

Kenya: Examining the Family Planning Needs of Women Traditionally Targeted for HIV/STI Services (FCO 124100/124105)

Technical Monitor: ESutherland

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.B.: At least three strategies to meet demand of specific populations identified, implemented by HIV and/or FP providers and evaluated, and introduced into programs in five countries.

Objective(s): To identify strategies for heightening sex workers' consistent use of highly effective family planning methods by: 1) exploring sex workers' fertility desires, knowledge, attitudes and practices related to contraception; 2) examining obstacles sex workers face in accessing family planning services; and 3) gathering sex workers' views on how family planning services could be adapted to optimally meet their needs.

Description: Sex workers are commonly targeted for STI/HIV prevention interventions, but far less attention has been directed toward sex workers' family planning needs. Addressing sex workers' family planning needs is essential since they are at very high risk of unintended pregnancy, given frequent sex with multiple partners. Preventing unplanned and undesired pregnancies can reduce multiple health risks for both the mother and the newborn. Additionally, in sex worker populations with high HIV prevalence, provision of family planning services to sex workers not desiring pregnancy is a means of preventing vertical HIV transmission, by reducing risk of unplanned pregnancy in HIV-infected women.

This cross-sectional study was conducted in two sites in Kenya that have benefited from HIV/STI prevention interventions for sex workers. Data collection consisted of a survey conducted with a representative sample of sex workers (n= 300 women per site). The sampling strategy included stratification by type of sex worker (bar-based, home-based, street-based), which captured some of the socio-economic diversity of the population. The survey included questions on reproductive history; fertility desires; knowledge, attitudes, and practices related to contraception; and experiences accessing family planning services. Focus group discussions (FGDs) were conducted to gather sex workers' views on how family planning services could be configured to meet the needs of this special population. The study results were shared in a one-day

workshop with program managers responsible for interventions targeting populations at high risk for STI/HIV. Workshop participants were guided in drawing conclusions from the study results and developing possible strategies for addressing unmet need for family planning services targeting those populations, and sex workers in particular.

Subgrantee(s): International Center for Reproductive Health

Collaborating Agency(s): Lifebloom Services International

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Activities, Accomplishments, Problems through December 31, 2008

- A literature review was completed in June 2006 as background material for the study protocol.
- The technical monitor collaborated with FHI/Nairobi in order to identify field partners who could provide access to two sex worker populations: Lifebloom Services International, which works in Naivasha, and the International Centre for Reproductive Health, which intervenes with sex workers in Mombasa.
- The technical monitor traveled to Kenya in November 2006 and met with field partners regarding study objectives and methods. Next steps, partner responsibilities, and a study timeline were developed. As part of this trip, visits were made by the technical monitor to research sites in Naivasha and Mombasa, Kenya.
- In December 2006, the technical monitor for this study changed from THoke to ESutherland.
- The study protocol was approved by PHSC and the National Council for Science and Technology in May 2007.
- Data collection instruments were drafted and reviewed.
- In June 2007, a Memorandum of Agreement was established with Lifebloom Services International.
- In August 2007, a subagreement was established and signed with International Center for Reproductive Health (FCO 124105). Research Assistants were trained and the study launched simultaneously in the two study sites (Changamwe and Naivasha).
- In August-December 2007, data collection continued in both sites and was completed in late December.
- Data entry ended in January 2008.
- In February-March 2008, data cleaning took place and the data analysis plan was finalized.
- Preliminary data analysis took place in April-May 2008.
- Preliminary findings were presented at the International AIDS Conference in Mexico City, July 2008.
- Data analysis was completed and verified in December 2008.
- An in-country dissemination meeting was held in December 2008. It was attended by approximately 25 representatives of stakeholders.
- Final payments were issued to subgrantees in December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- FCO 124100 was closed in January 2009.
- An initial draft of a publication was completed and reviewed in June 2009. A final paper draft will be completed and submitted to a peer-reviewed journal in lieu of a final report using Technical Leadership funds, FCO 114106.

Findings and Outcomes:

- Results indicate that inconsistent condom use and unintended pregnancies are significant issues for FSW. Approximately 80% of participants report using a condom at last sex with a client. However, 60-70% reported that negotiating condom use is difficult and that clients' dislike of condoms is a "big problem" for them personally. Despite these difficulties, only half of women reported currently using a modern method other than condoms. 62% of respondents reported having experienced an unintended pregnancy and 46% admit to having at least one induced abortion. Our study results indicate that FSW continue to have unmet contraceptive needs which have resulted in unintended pregnancies and may contribute to the number of infants born with HIV. Current HIV/STI prevention interventions are not addressing the broader reproductive health needs of FSW. The results of this study can help to identify intervention strategies for addressing their unmet need for contraception.

Funding Source(s):	USAID - US Agency for International Development/USAID: GLP	FCO Approved: 124100 124105	Jan 2006 Aug 2007
Total Approved Budget: 124100	\$	189,518	Projected End Date: Jan 2009
124105	\$	79,784	
	\$	269,302	

Africa Regional: Assessing Provision of Family Planning and Reproductive Health Services in Commercial Sector HIV/AIDS Programs (FCO 124102)

Technical Monitor: DMcCarraher

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.C.: Research evidence provided to at least four countries to inform policy reviews and strengthen policies focused on increasing contraceptive use in HIV programs to avert HIV-positive births.

Objective(s): 1) To assess if commercial sector workplace HIV/AIDS programs also provide family planning, reproductive health and child health services; 2) to document how family planning, reproductive health and child care services are paid for (private insurance, services contracted out or work-based clinics) and the beneficiaries of them; 3) to document obstacles to providing these services; and 4) to prepare one or more case studies that highlight the commercial sector's interest in the provision of family planning as an HIV/AIDS prevention tool. These studies will highlight commercial sector HIV/AIDS programs that also provide family planning, reproductive health and child health services or those programs that could be easily expanded to include these services.

Description: The commercial sector is an important partner for the expansion of HIV care and treatment efforts in countries with a generalized HIV epidemic. Some commercial sector businesses provide HIV/AIDS prevention and care services to their employees. These services include the provision of condoms, voluntary counseling and testing and antiretroviral treatment. However, these efforts have not been uniformly documented or synthesized. In addition, it is unknown if commercial HIV/AIDS programs provide integrated services including the provision of family planning (FP), reproductive health care (antenatal care, delivery care, PMTCT), and child health services (immunizations and sick child visits) to their employees as well. For those programs that do provide FP and other services, the reasons for doing so, as a way to prevent HIV or as a way to improve maternal and child health, are unknown as well.

Using PEPFAR funds, Abt Associates planned to: a) conduct a literature review of commercial sector HIV/AIDS initiatives; b) survey commercial sector HIV/AIDS programs in PEPFAR African countries; and c) prepare case studies highlighting successful commercial sector programs. Taking advantage of this opportunity, FHI worked with Abt to develop the survey to include questions related to FP, reproductive health (RH), and child health services. Information derived from the survey will tell us if commercial sector HIV programs are viable targets for future FP/HIV integration efforts. In addition, our GLP funding was used for the development of case studies that highlight successful commercial sector programs that already

include FP, RH, and child health services or programs that are suitable for future HIV/FP integration activities.

Collaborating Agency(s): Abt Associates

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Activities, Accomplishments, Problems through December 31, 2008

- March-May 2006, McCarraher worked with Abt Associates to: a) finalize the study protocol; b) develop a hard copy questionnaire that would be used when companies failed to complete the web-based survey; and c) pre-test the web-based survey and the questionnaire.
- June 2006, the web-based survey was sent to a convenience sample of private-sector companies that received donor support or technical assistance to implement work-place based HIV programs in Namibia, Kenya, Ethiopia, and Zambia. In each country, approximately 50 companies were identified. The companies had 5 days to complete the survey and then were called up to five times to complete the hard copy survey. Data collection was completed on June 23, with responses received from 121 companies, yielding a response rate of about 63%.
- December 2006, the Nairobi office conducted in-depth interviews with nine companies that participated in the survey to write a case study highlighting why companies should consider adding family planning to their workplace-based HIV programs.
- FHI/NC submitted the Kenya case study entitled "Opportunities for employees to provide family planning services in Kenya" that highlights the role family planning can have in preventing HIV in workplace-based HIV programs.
- In January and March 2007, FHI/NC sent two memos to Abt outlining issues that needed to be resolved in the final report. A final version of the report was received from Abt in June. It did not however address all the comments raised in previous correspondence.
- In August, FHI staff made the decision to have FHI's role be mentioned in the acknowledgment section instead of being listed as authors.
- The person at Abt in charge of this project left the company; Abt informed FHI that there would be a delay in the final products.
- April 2008, we received the final products from Abt. These products included: a report that contains both a literature review of the role of private sector companies in meeting the HIV needs of their employees and results of the survey. In addition, fact sheets were finalized for each country using the survey data.
- A final dissemination meeting was held in Kenya in August 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The FCO was closed June 30, 2009.

Findings and Outcomes:

- We received the finalized versions of the report and country fact sheets in July 2008.
- The main findings of the report include:
- Of all the companies, 69% reported that they provide HIV testing and counseling either by offering it on-site or by financing it in some other way (insurance, contracting out, etc); 42% financed ART services; and more than 60% paid for testing and treatment related to tuberculosis and opportunistic infections. Home based care services and prevention of mother-to-child transmission projects were less likely to be financed by companies.
- Significant variations in company size and multinational affiliation were found with large companies; those affiliated with a multinational firm being more likely to finance HIV services.
- For the majority of companies the HIV services paid for by companies were benefits extended to employees only and not their dependents.
- Half of the companies interviewed financed family planning methods other than condoms for their employees. Similarly about half of companies also financed antenatal care, delivery services, and post-partum services.
- When asked why contraception and other maternal health services were not financed, the companies reported that these needs were being met by public services or that they would not be utilized by their employees (several companies employed large percentages of men).

- FHI disseminated these results in Nairobi on August 28, 2008. FHI supported the attendance of representatives from all 24 companies in Kenya that participated in the workplace survey. Overall, the companies were generally interested in contraception as an HIV prevention strategy. Large companies have found it necessary to actively support family planning since current national employment policies place great emphasis on employee benefits and welfare, including 14 days paternity and 3 months maternity leaves. There were a lot of questions regarding breastfeeding and HIV transmission, and the official MOH policy was explained to the attendees.

Funding Source(s):	USAID - US Agency for International Development/USAID: GLP	FCO Approved:	Mar 2006
Total Approved Budget:	\$ 114,599	Projected End Date:	Jun 2009

Worldwide: Tool Kit to Increase Access to Appropriate and Effective Contraception for Clients with HIV (FCO 113106)

Technical Monitor: IYacobson

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.D.: International recommendations for contraceptive use by people at risk of HIV and HIV-infected, including women on ART changed or strengthened; and international recommendations used in country guidelines and program documents.
HIV/FP II.E.: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Objective(s): 1) To synthesize information on current practices and interventions being used in integrated programs to address the RH/FP needs of women and couples with HIV; and 2) to develop a Toolkit that will include a tailored training package and other tools and job aids to increase access to contraception for women and couples with HIV.

Description: As of 2005, increased access to antiretroviral (ARV) therapy and the resulting improvements in health are giving many clients with HIV a renewed optimism. Demand for contraception among clients with HIV, especially those on ARV therapy, is expected to increase. Use of effective contraception reduces the risk of pregnancy, giving women with HIV a wider range of ARV drugs. Contraception can also play a role in PMTCT of HIV by preventing unintended pregnancy. While the evidence on "best practices" for integration of HIV/FP services is limited, it is important to offer guidance to programs/providers to move integration efforts forward. In order to do that, information on current practices and interventions will be collected through literature reviews and communication with staff in country programs implemented by FHI and possibly other partners. Additionally, rapid assessments of provider and client needs, as well as challenges in integrated programs, were conducted in several countries with ongoing FP/HIV integration activities. This information was used to develop a Toolkit, it does include and adapt for worldwide audience FHI's module Contraception for Women and Couples with HIV developed in collaboration with EngenderHealth with support from USAID/REDSO/ESA. It also included training materials tailored to providers with different technical backgrounds, needs assessment tools, facility readiness checklists, job aids for providers, and

others. EngenderHealth and the Center for Communication Programs contributed to the development of additional resources.

The training materials were tested in at least two countries among HIV/AIDS care and treatment providers and FP providers. Following the testing and expert review of the Toolkit, a final package was produced and distributed in digital/CD-ROM format to CAs and other partners involved in integrating FP and HIV services, as well as FHI's country programs where FP/HIV integration takes place.

Collaborating Agency(s): EngenderHealth; Johns Hopkins/CCP

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Activities, Accomplishments, Problems through December 31, 2008

- In the final quarter of 2005, a literature search was conducted to identify existing materials related to FP/HIV integration and learn about program experiences with integration.
- Materials were identified that could be complimentary to the Toolkit.
- A needs assessment questionnaire was developed for providers involved in integration efforts.
- FHI networked with other CAs also involved in integration efforts to share and coordinate efforts (e.g. Policy Project, HIPNET, FP/HIV integration working group, EngenderHealth)
- A rapid assessment in Kenya, Thailand and Zimbabwe was conducted in the fall of 2006 to get providers' perspective on integration activities in their countries and explore what type of information, training materials, job aids, tools, client materials, or other items would be useful to them as they provide integrated FP/HIV services.
- The content and outline of the Toolkit was finalized and a first draft of the training curriculum was developed, including objectives, training activities and session design. A draft was circulated to EngenderHealth for their comments and a second draft was finalized incorporating their suggestions.
- Presentations were developed on individual contraceptive methods to be used as part of the training curriculum and to compliment FP/HIV specific information provided in the existing module, "Contraception for Women and Couples with HIV."
- A flip chart for counseling clients with HIV was developed.
- The Toolkit was field-tested in South Africa (Feb. 2007) with two different types of providers (FP and HIV providers). It was revised based on the results of the field-testing and was again circulated to EngenderHealth. Final changes to the Toolkit were made and the collateral materials included in the Toolkit were finalized.
- The CD-ROM layout and cover were designed and the Toolkit materials were copy-edited, including curriculum, facilitator guide, participants' handbook and flip chart.
- Staff incorporated changes from the WHO expert meeting in April 2008 into Toolkit materials.
- The CD-ROM layout was finalized, and 5000 copies of the Toolkit CD were printed.
- The subproject and the FCO were closed October 31, 2008.

Findings and Outcomes:

- To inform the development of the Toolkit, a quick needs assessment was conducted in Kenya, Thailand and Zimbabwe. The assessment offered providers' perspective on integration activities in their countries and identified what type of information, training materials, job aids, tools, client materials, or other items would be useful to providers as they offer integrated FP/HIV services. As a result of this assessment, the following needs were identified:
- Simple educational materials for providers; training on FP/HIV counseling; check lists for contraindications of each contraceptive method.
- Updated information on risks and benefits of contraception for HIV+ patients and FP methods and ARVs; a manual on contraception for clients with HIV that is suitable for non-medical persons/volunteers.
- Short and simple educational materials (i.e. pamphlets and flip charts) for clients on the safety/needs of HIV infected clients, and on the need for contraception and condom use; AV materials for clients to promote safer sex, responsibility, self esteem, and knowledge about contraception and prevention of HIV transmission.
- Many of these items were addressed in the Toolkit. No formal report was generated as this assessment was done solely for development purposes.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2005
Total Approved Budget:	\$ 360,972	Projected End Date:	Oct 2008

Worldwide: Providing Global Leadership to Family Planning and HIV Integration Efforts (FCO 113104/123100)

Technical Monitor: RWilcher

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.C.: Research evidence provided to at least four countries to inform policy reviews and strengthen policies focused on increasing contraceptive use in HIV programs to avert HIV-positive births.

HIV/FP II.D.: International recommendations for contraceptive use by people at risk of HIV and HIV-infected, including women on ART changed or strengthened; and international recommendations used in country guidelines and program documents.

HIV/FP II.E.: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Objective(s): 1) To strengthen support for family planning as an HIV prevention intervention; 2) to promote dissemination and utilization of the latest scientific evidence and programming tools on FP/HIV integration and contraception for HIV-infected and at-risk women; 3) to establish partnerships and collaborations with other organizations working on HIV and contraception activities; and 4) to facilitate strategic placement of new HIV and contraception research and programs in the field.

Description: Since 2003, FHI has become increasingly involved not only in research and programs designed to increase contraceptive use in the context of the HIV/AIDS epidemic, but also in leadership efforts to garner support for such research and programming. By establishing and coordinating USAID's Family Planning and HIV/AIDS Integration Working Group, hosting key events at international HIV/AIDS and RH conferences, and facilitating country-level integration efforts, FHI has been at the forefront of efforts to expand access to and use of contraceptives by HIV-infected and at-risk women.

This subproject will support a number of activities that will allow FHI to build on the leadership role it has established in the arena of HIV and contraception and continue to advance research and programming. First, FHI will continue to participate in and provide leadership to the Family Planning and HIV/AIDS Integration Working Group. Second, FHI will host satellite sessions on HIV and contraception-related topics at high-profile international HIV/AIDS and/or RH conferences. Third, FHI will maintain involvement in and operation of field-based working groups addressing HIV and contraception issues. Finally, FHI will leverage and work with its Research-to-Practice Network of Champions to foster local partnerships and collaborations on integration activities and identify field-based opportunities to apply emerging research findings.

All of these activities will contribute to: increased awareness of the importance of contraception as an HIV prevention intervention; improved dissemination and utilization of the latest scientific evidence on FP/HIV integration programming and contraception for HIV-infected and at-risk women; and the strategic placement of more integration research and programming in the field.

This subproject was approved for continuation in Years 4 and 5 of the CRTU, with an increase to the original budget.

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Activities, Accomplishments, Problems through December 31, 2008

- Nov 05, May 06, and Oct 08, FHI staff participated in the meetings of the USAID-led FP/HIV Integration Working Group.
- USAID's approval to implement was obtained in Feb 06.
- Dec 06 and Feb 08, FHI staff participated in meetings on integrating RH into Global Fund proposals.
- Jan 06 and Feb 07, FHI/Kenya staff provided TA at RH/HIV integration workshops in Nigeria.
- In Feb 07, a brief summarizing the evidence on contraception as HIV prevention and encouraging application of this evidence in FHI's HIV programs was sent to FHI's 36 country and field directors.
- Staff carried out 15 interviews with FHI country directors as part of an assessment of FP within FHI's HIV programs. In Feb 08, findings were disseminated to FHI's 36 country and field directors.
- FHI staff gave FP/HIV-related presentations at the following conferences: APHA (Dec 05); USAID's Mini-University (Oct 05 and 06); International AIDS Conference (Aug 06); conferences on RH/HIV integration in Ethiopia (Oct 06) and India (Feb 07); the 3rd National HIV/AIDS Research Conference in Rwanda (March 07); the 1st International Workshop on HIV Treatment, Pathogenesis, and Prevention Research in Resource-Poor Settings in Uganda (May 07); the annual HIV Implementer's Meeting in Rwanda (June 07); Global Health Council (June 07); ISSTD (July 07); CSIS-sponsored meeting on RH/HIV integration and PEPFAR reauthorization (Oct 07); the 5th African Conference on Population in Tanzania (Dec 07); ICASA (Dec 08); and the International AIDS Conference (Aug 08).
- In Dec 07, FHI/Tanzania staff hosted a technical meeting on FP/HIV integration. As a result of the meeting, the MOH formed a technical working group and appointed FHI the secretariat.
- Staff worked with CEDPA to integrate content on contraception for HIV+ women into the "Africa Regional Workshop: Women's Leadership in HIV/AIDS." In May 2008, FHI/Kenya staff facilitated the session on this topic.
- In July 2008, FHI hosted a technical meeting on "Family planning and Integration with HIV/AIDS Programs" for more than 80 FHI field staff and MOH partners from 13 countries.
- FHI staff gave a series of presentations on FP/HIV integration to World Bank staff in Dec 08.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Staff continued to provide input into the UN-led "Global Strategy for Accelerating PMTCT Scale-Up," including supporting the development of an FP M&E indicator.
- A survey was administered to FHI field staff represented at the July 2008 FP/HIV technical meeting to assess progress and technical support needs in advancing FP/HIV integration.
- In April 2009, W Cates sent an email to FHI Country Directors encouraging them to explore opportunities to integrate FP activities into this year's PEPFAR COPs.
- Also in April, R Wilcher presented on FP/HIV integration at the Consultation on Family Planning in HIV Prevention Trials, sponsored by the Global Campaign for Microbicides.
- An advocacy brief on integrating FP into HIV services provided by faith-based organizations was developed in collaboration with Christian Connections for International Health (CCIH), and distributed at the CCIH annual conference in May 2009.
- Also at the CCIH conference, FHI staff hosted a workshop on increasing access to contraception for clients with HIV for 25 participants, most representing faith-based organizations.
- In May 2009, a paper by R Wilcher and W Cates, "Reproductive Choices for Women with HIV," was accepted for publication in the Bulletin of the World Health Organization.
- The World Bank published a technical brief on FP/HIV integration in May, which was developed collaboratively with FHI.
- Staff continued developing a set of standardized indicators on FP/HIV for FHI field programs; drafts of the indicators were presented at the SI meeting in May 2009.
- R Wilcher served as a guest expert during a JHU-sponsored e-forum on FP/HIV integration in June 2009.

- Also in June, R Wilcher gave a presentation on FP/HIV integration at the UNFPA-sponsored meeting, "Reducing Inequities: Ensuring Universal Access to Family Planning"
- Key FHI articles and tools on contraception as HIV prevention were shared with JSI staff and included on the AIDSTAR-One website.

Findings and Outcomes:

- The following publications were supported by this subproject:
- Reynolds HW, Wilcher R. Best kept secret in PMTCT: contraception to avert unintended pregnancies. Glob AIDSLink 2006 May-Jun; (97): 8, 16. (FHI Pub 2006-30).
- Contraception is the best kept secret for prevention of mother-to-child HIV transmission (letter) Petruney T, Robinson E, Reynolds H, Wilcher R, Cates W. Bull World Health Organ 2008 Jun. 86 (6) : B (FHI Pub 2008-60, FCO 113131).
- From effectiveness to impact: contraception as an HIV prevention intervention. Wilcher R, Petruney T, Reynolds HW, Cates W. Sex Transm Infect 2008 Oct. 84 (Suppl II) : ii54-60 (FHI Pub 2008-101).
- Contraception to prevent HIV-positive births: current contribution and potential cost savings in PEPFAR countries. Reynolds HW, Janowitz B, Wilcher R, Cates W. Sex Transm Infect 2008 Oct. 84 (Suppl II) : ii49-53 (FHI Pub 2008-100).
- A letter on family planning as HIV prevention by W Cates, R Wilcher and T Petruney was published in the International Herald Tribune (int'l edition of New York Times) on Dec 5, 2008.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Staff will host a follow-up field-based technical meeting on FP/HIV with FHI staff and MOH representatives in November 2009.
- Staff will develop, produce, and disseminate an advocacy package on FP/HIV that synthesizes information on the FP/HIV evidence base, policy support, and programmatic experience and resources.
- FHI staff will provide leadership to an M&E sub-group of the WHO-led working group on SRH/HIV linkages.
- Staff will work with the Ethiopia office to write up a detailed case study of their RH/HIV integration experience.
- Staff will pilot test and, ultimately, institutionalize a set of standardized FP/HIV indicators within monitoring systems for FHI field-based HIV programs.
- The TM will liaise with USAID regarding FHI's portfolio of FP/HIV research and RU activities.
- As opportunities arise, staff will publish articles and letters and give presentations on contraception for HIV prevention.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: GLP	FCO Approved:113104 Sep 2005 123100 Jan 2006
Total Approved Budget:	113104 \$ 655,270	Projected End Date: Apr 2010
	123100 \$ 175,000	
	\$ 830,270	

Kenya: Scale-up and Global Dissemination of Kenya's FP/VCT Integration Package (FCO 113126/123102)

Technical Monitor: RWilcher

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.E.: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Objective(s): 1) To finalize and launch within Kenya, MOH-approved documents and tools to support the integration of family planning (FP) services into VCT centers; 2) to package, disseminate, and promote utilization of the Kenyan FP/VCT integration documents and tools by other countries and programs interested in integrating FP and VCT services; and 3) to provide technical assistance to the Ministry of Health in Kenya to roll-out the integration of FP services into VCT sites.

Description: In 2002, FHI began working with the Kenya National AIDS and STD Control Programme (NAS COP) and the Division of Reproductive Health (DRH) in the Ministry of Health (MOH), as well as with other partners, to integrate FP services into VCT centers in Kenya and to test the effectiveness of these efforts. Since then, these partners have examined the feasibility and acceptability of integrated services, developed a national strategy for integration based on the findings, developed training, IEC and other materials to support implementation of the strategy, advocated for integration at various levels, documented the process and evaluated the effectiveness and costs of implementing the strategy (FCOs 9390, 9490, and 3445). The experience gained, lessons learned, and materials developed from integrating FP and VCT services in Kenya to-date needed to be shared with other countries and programs initiating integration efforts. This subproject allowed FHI to support the MOH to finalize the tools and materials that had been drafted to support FP/VCT integration, and to promote global dissemination and utilization of the tools and lessons learned. This subproject built on the FP/VCT work completed under the CTR (FCOs 9490, 9390, and 3445) and was closely linked to CRTU FCO 114104.

Collaborating Agency(s): Ministry of Health, Kenya

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Activities, Accomplishments, Problems through December 31, 2008

- In October 2006, FHI supported the MOH in implementing an FP/VCT integration training with 18 VCT providers.
- 4,000 copies of "Integrating Family Planning into HIV Voluntary Counseling and Testing Services in Kenya: Progress to Date and Lessons Learned," were printed.
- 5,000 copies of the client brochure on FP/VCT integration were re-printed.
- The 3 FP/VCT briefs were re-designed using the FP/VCT design theme and copy edited; 1,000 copies of each were printed.
- The national FP/VCT integration strategy was finalized in Aug 2007 and 500 copies were printed.
- The national FP/VCT integration training manuals were finalized; 500 copies of the trainer's manual were printed and 2,000 copies of the participant's manual were printed.
- FHI/Kenya staff gave presentations on the FP/VCT RtoP process at the Joint Scientific Conference of the National Institute for Medical Research in Tanzania; the East African Community Health and Scientific Conference in Uganda; and the First Regional Forum on Best Practices in Health Care in Tanzania. The presentations reached 100 participants.

- Between May-July 2007, the MOH, FHI and APHIA II partners held 5 FP/VCT advocacy meetings for Coast, Rift Valley, Western/Nyanza, Central/Eastern, and Nairobi provinces. 207 participants attended.
- In July 2007, FHI/Kenya staff oriented a visiting delegation from the Nigeria MOH to the FP/VCT integration process and disseminated the materials to them.
- In October 2007, FHI/Kenya staff oriented a visiting delegation from the Capacity Project (IntraHealth) in Rwanda to the FP/VCT integration process and disseminated the materials to them.
- In July 2008, the package of FP/VCT materials was launched at a national meeting hosted by the MOH and sponsored by FHI and the Population Council. Approximately 90 individuals attended the launch, including representatives from the MOH, USAID, CDC, APHIA II partners, local and international NGOs and other collaborating agencies.
- The FP/VCT package was disseminated to FHI colleagues based in South Africa, Nigeria, Rwanda, Tanzania, Madagascar, Mozambique, Uganda, and Zimbabwe.
- The subproject was closed in September 2008.

Findings and Outcomes:

- This subproject resulted in the production of a package of MOH-supported FP/VCT integration materials. This package includes the following documents:
 - 1) Report: "Integrating Family Planning into HIV Voluntary Counseling and Testing Services in Kenya: Progress to Date and Lessons Learned" (M2006-52)
 - 2) Policy: "Strategy for the Integration of Family Planning and HIV Voluntary Counseling and Testing Services"
 - 3) Client IEC brochure: "Family Planning Information and Services at the VCT Centre"
 - 4) Brief: "Preparedness of Voluntary Counseling and Testing Centers in Kenya to Provide Family Planning"
 - 5) Brief: "Integrating Family Planning and Voluntary Counseling and Testing Services in Kenya"
 - 6) Brief: "Evaluating the Integration of Family Planning and Voluntary Counseling and Testing in Kenya"
 - 7) Trainer's Manual: "Family Planning Training for Voluntary Counseling and Testing Providers: An Integrated Approach to Counseling and Service Provision"
 - 8) Participant's Manual: "Family Planning Training for Voluntary Counseling and Testing Providers: An Integrated Approach to Counseling and Service Provision"
- In July 2008, the package of FP/VCT materials was launched at a national meeting hosted by the MOH and sponsored by FHI and the Population Council. Approximately 90 individuals attended the launch, including representatives from the MOH, USAID, CDC, APHIA II partners, local and international NGOs and other collaborating agencies.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: GLP	FCO Approved:123102 Jun 2006 113126 Jun 2006
Total Approved Budget:123102	\$ 88,628	Projected End Date: Jun 2008
113126	\$ 146,001	
	\$ 234,629	

Africa Regional: FP in Context of HIV: Supporting Evidence-Based and Promising Practices in Africa (FCO 113131)

Technical Monitor: TPetrunev

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.C.: Research evidence provided to at least four countries to inform policy reviews and strengthen policies focused on increasing contraceptive use in HIV programs to avert HIV-positive births.

HIV/FP II.D.: International recommendations for contraceptive use by people at risk of HIV and HIV-infected, including women on ART changed or strengthened; and international recommendations used in country guidelines and program documents.

HIV/FP II.E.: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Objective(s): 1) To promote family planning (FP) services as central to HIV prevention efforts; 2) to improve the knowledge and attitudes of key HIV program decision-makers worldwide regarding the role of FP in preventing vertical transmission of HIV; 3) to compile and disseminate information on integration of FP into HIV programs; and 4) to provide technical assistance to Ministries of Health and/or other implementers in increasing access to FP services for HIV-infected and at-risk women and couples in three target countries, with the aim of facilitating policy and program change.

Description: Use of contraception by HIV-positive individuals can avert the birth of HIV-positive infants, reducing the burden of the epidemic and contributing to public health. However, most HIV prevention, care and treatment programs, including VCT, PMTCT and ART services, do not include FP information and services. In October 2006, an international meeting on FP and HIV integration was held in Addis Ababa, Ethiopia. One of the key challenges identified at this conference was ensuring that existing research findings are applied in policies and programs. This subproject represents a systematic effort to follow up on the Addis meeting to market the evidence available on the contribution of contraception to HIV prevention efforts, and to provide technical assistance in three target countries to increase access to contraceptive services among HIV-infected and at-risk women and couples. Through this subproject, FHI will support targeted follow-up activities with policy makers and program managers from select country teams who may have attended this meeting with individuals that make funding decisions (in the U.S., including PEPFAR officials, and donors in Europe) including scientists and advocates who sit on the boards of funding organizations as well as with government officials who set policies and make broad decisions about HIV programs in developing countries.

Collaborating Agency(s): Ministry of Health, Rwanda

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Activities, Accomplishments, Problems through December 31, 2008

- Approval to implement was obtained in May 2007.
- Communications component (aka Tipping Point Project): A PowerPoint and summary of subproject aims was developed and presented to FHI/US staff (Oct 07). Staff wrote several advocacy letters (published in N&O, WHO Bulletin), and attended global conferences on FP/HIV integration. Staff used systematic methods to identify 500+ key HIV stakeholders. Four senior staff and WHO categorized each individual into Tipping Point categories.
- TA component: Tanzania, Rwanda, and Uganda were identified as target countries for the TA activities.

- In Tanzania an introductory integration meeting was held in Dec 07 with key stakeholders (covered by 113104); FHI assisted the MOH in developing and finalizing a TOR for the TWG (April - Oct 08); mobilized NACP and secured their participation as co-chairs; and technically reviewed national FP/HIV curricula (July 08); HQ staff completed two desk reviews of HIV & FP policies; coordinated and facilitated the official two-day launch of the National FP/HIV TWG (Nov 08) with 67 participants; initiated the 2009-2010 term for FHI's Secretariat role for the TWG.
- In Rwanda, a partner integration meeting was hosted in Dec 07 at which Dr. Maggwa presented on integration; a National FP/HIV Coordinator was hired (Jul 08), and visits to the USAID/WHO InterAgency Working Group for Integration and FHI HQ were made; AFRO technical advisor visited Rwanda to lead a 2-day TA session for strategic planning (Oct 08). HQ staff traveled (Nov 08) to support development of a national integration workplan for 2009, presented on FP/PMTCT integration, and attended an FP TWG meeting.
- In Uganda, in collaboration with 113113, a joint session of the PMTCT and FP/HIV TWGs was held (Apr 08); the FHI/Ug Country Director and MOH PMTCT Coordinator were supported to attend FHI's Technical Meeting on FP/HIV (Jul 08). Staff hosted a national dissemination of FHI's FP/HIV Country Assessments (114124), attended by 37 stakeholders; a letter on FP and PMTCT was published in Uganda's daily newspaper (Nov 08).

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- **Tipping Point:** A qualitative analysis of 22 key informant interviews was completed and informed the development of an advocacy/communications intervention. 455 letters (55 of which were highly personalized and tailored) were sent to the individuals identified as the most influential global stakeholders in HIV/AIDS, sent by W Cates and which advocated for supporting FP as HIV prevention, asked each person to broach the subject within HIV prevention discourse, named specific individuals within their social and professional circles to whom they might talk, and provided a set of supportive information and resources. Country-level individuals were provided with a hard copy of the Toolkit "Increasing Access to Contraception for Clients with HIV".
- The paper "Increasing support for contraception as HIV prevention: Stakeholder mapping to identify influential individuals and their perceptions" was submitted to AIDS and AIDS & Behavior (May-June 2009). Its abstract was accepted for oral presentation to APHA 2009
- **Technical Assistance:**
- In Rwanda, a cost-sharing agreement was secured between the CRTU and PROGRESS to extend the contract for seconding the National FP/HIV Coordinator in Rwanda from FHI to the MOH in FY2010 (113131/113104); TA was provided by HQ staff for the 2009 workplan.
- In Tanzania an agreement was reached with WHO-Geneva to direct funding for a national Rapid Assessment of SRH/HIV Linkages to FHI's Tanzania office, who will lead the assessment. FP/HIV training was held for 20 "Master Trainers" representing 7 regions of Tanzania, using the Toolkit "Increasing Access to Contraception for Clients with HIV", with staff from HQ and AFRO attending and providing TA.
- In Uganda 2 of 3 three-day FP trainings of 168 HIV/AIDS service providers conducted in 7 FHI supported districts was supported by 113131.

Findings and Outcomes:

- FP was included in an Oct 07 presentation on PEPFAR and the Global AIDS Response, following our contact with OGAC. FHI/Tanzania's appointment as Secretariat of the FP/HIV TWG represents successful promotion of the topic at the policy level in one CRTU focus country.
- An advocacy letter to the Editor was published in Bulletin of WHO in June 08. An FP/HIV bibliography was shared at a Global Fund meeting in Feb 08, and expanded and adapted for FHI's Technical Meeting on FP/HIV in Addis July 08.
- In the Uganda TA component, promotion of FHI as an expert and resource in the field of integration has been necessary due to tight compartmentalization from the Mission to have all integration activities led by EngenderHealth (who is really focused on PMTCT in targeted areas).
- A potential collaboration with HCI may have been missed in May 08 due to this focus from the Mission and points to the need for enhanced efforts to advocate for FHI's relevancy and niche. The national

dissemination of FHI's 5 Country FP/HIV Assessment results in Nov 08 helped build support from the Mission for FHI as a key partner for FP/HIV.

- In Tanzania, months of interpersonal advocacy proved necessary to secure NACP's support of the FP/HIV TWG, and similar regional efforts could apply this as a lesson learned. A significant outcome of the TWG launch was the agreement from the MOH to develop a "National Strategic Framework for FP/HIV Integration in Tanzania". Another was that even with existing policy support for integration, without proactive dissemination of policies and follow-through by MOH, integrated services will not be designed or implemented.
- The approach in Rwanda is unique and innovative, and the end results and measure of progress achieved will inform regional efforts as well.
- A letter promoting FP as HIV prevention was published in the Int Herald Tribune Dec08.
- Key informant interviews suggest that obstacles to linking FP and HIV/AIDS include the need for resources to integrate family planning and HIV services, infrastructure or capacity to provide integrated services at the facility level, national leadership and coordination, and targeted advocacy to key decision-makers.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- In Tanzania, staff will support FHI's role as the Secretariat of the National FP/HIV TWG, namely hosting a workshop and follow-on efforts to develop a National Strategic Framework for FP/HIV Integration, and funds will help cost-share WHO Rapid Assessment for SRH/HIV Linkages.
- In Rwanda, staff will continue to provide TA and guidance to the National FP/HIV Coordinator and identify specific items in the 2009 National Workplan to provide financial support and TA.
- Staff will be supported to attend FHI's second Technical Meeting on FP/HIV Integration in Ethiopia (November 2009) and to present at APHA 2009 (Philadelphia, November).
- A comprehensive package of FP/HIV materials will be produced and cost-shared with 113104.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Dec 2006
Total Approved Budget:	\$ 470,858	Projected End Date:	Apr 2010

Worldwide: Interactions between Hormonal Contraceptives and Antiretroviral Therapies (FCO 112139/112145/112146/112147)

Technical Monitor: KNanda

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP I.A.: At least two clinical studies of the safety and effectiveness of hormonal contraceptives and ART completed.

Objective(s): 1) To evaluate the effects of common ARV regimens on COC effectiveness; 2) to validate a new method of detecting ovulation suitable for low-tech settings; and 3) to evaluate possible effects of hormonal contraceptives on safety and effectiveness of common ARV regimens.

Description: Pharmacokinetic data suggest that some ARV agents may affect the metabolism of contraceptive steroids, but it is not clear whether these interactions actually result in a loss of contraceptive efficacy. However, many authorities recommend that women taking ARVs either use a back-up method with oral contraceptive pills or increase the dose. Both of these recommendations create potential issues for women, in particular the impracticality of using a back-up, presumably barrier, method of contraception. Information on contraceptive efficacy of oral contraceptive pills in women taking ARVs is important so that HIV infected women using ARVs can be properly advised about their options for preventing pregnancy. This will be an open-labeled, non-randomized, non-blinded clinical trial. Initially, we planned to validate a new method of detecting ovulation suitable for low resource settings in a small group of women. However, the new method was deemed not feasible upon further exploration. For this study we plan to enroll approximately 370 reproductive age women who have been receiving a standard regimen of ARV treatment for at least one month and who are taking or are willing to take oral contraceptive pills for six months. As a control group we will enroll women who are HIV+ and who are not yet medically eligible for ARVs and who are willing to take oral contraceptive pills for six months. Each woman will be followed for six cycles. We will take blood at various intervals to look for evidence of ovulation, test for pregnancy, and collect data on side effects. Participants will be enrolled at two sites. We will provide the contraceptive method and appropriate compensation to the study participants for their efforts in participating in the study, but not for taking the ARV treatment.

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Activities, Accomplishments, Problems through December 31, 2008

- In October 2007, USAID granted approval to implement the study.
- Study progress was delayed due to lack of FHI staff time and competing priorities.
- Additional staff were identified to assist with study implementation.
- Potential study sites in South Africa, Uganda and Ghana were identified.
- Staff drafted the first versions of the study protocol, informed consent forms and study case report forms.
- A site evaluation visit took place to Uganda and South Africa in September 2008.
- The protocol v2.0 and the generic ICF v2.0 was approved by PHSC on November 7, 2008.
- Case report forms were reviewed.
- The study manual was drafted.
- The monitoring plan was finalized.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Site initiation training was conducted at the RHRU (South Africa) site in March 2009.
- We received USAID approval and Mission concurrence for all three sub-agreements in April 2009.
- The data management plan was finalized in April 2009.
- The CRFs were finalized in April 2009.
- The South Africa consent forms and CRFs were submitted and approved by PHSC in May 2009.
- The RHRU site began enrolling participants in June 2009.
- The Makerere University (Uganda) informed consents and other study documents were translated into Luganda and submitted to the Uganda IRB for approval in June 2009.

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Planned Activities for July 1, 2009 – April 28, 2010

- Laboratory SOPs will be finalized for the Uganda site.
- The informed consent forms, protocol and other study documents will be approved by the Uganda IRB. The informed consent forms, translation certifications, and recruitment documents will be submitted to PHSC in July 2009.
- Initiation training will take place at the Uganda site in July 2009.
- The Uganda site will begin enrollment in August 2009.
- The study monitor will conduct 2 monitoring visits at each study site. The first interim monitoring visit to RHRU site will be conducted in August 2009.

- The following activities will be conducted until April 2010 (under the CRTU) and beyond under another funding agreement if approved: complete participant follow up visits at sites, closeout sites, analyze data, draft manuscript and submit for publication.
- Note that FHI has proposed transitioning some of this activity to another agreement. If approved, the projected end date will be extended.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 112139	Sep 2007
		112145	Dec 2008
		112147	Feb 2009
		112146	Jan 2009
Total Approved Budget:	112139 \$	532,380	Projected End Date: Apr 2010
	112145 \$	244,089	
	112147 \$	52,293	
	112146 \$	149,474	
	\$	978,236	

Kenya: Safety of Implant Use among Women on ARVs (FCO 112136/112141)

Technical Monitor: DHubacher

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP I.A.: At least two clinical studies of the safety and effectiveness of hormonal contraceptives and ART completed.

Objective(s): To monitor changes in CD4 counts (a common indicator of the effectiveness of ARV therapy) among two groups of ARV patients: those using implants and those not using hormonal contraception. Pregnancies will also be monitored and compared across groups.

Description: HIV-infected women using antiretroviral (ARV) therapy need safe and effective forms of birth control to prevent unintended pregnancy and possible maternal-to-child transmission of HIV. Concomitant use of hormonal contraception and ARVs is not well studied and because both medications are metabolized in the liver, simultaneous use may decrease the effectiveness of one or the other. Some research suggests that effectiveness of combined hormonal contraception and ARV therapy may be compromised when taken simultaneously. Nothing is known about whether progestin-only contraceptive implants compromise the effectiveness of ARVs.

A prospective study with one year of follow-up and 120 ARV patients (60 implant and 60 non-hormonal) will determine whether CD4 counts in the implant group remain equivalent to the non-hormonal group. This cohort study will be conducted at Kenyatta National Hospital in Nairobi. Women receiving ARVs in the Comprehensive Care Clinic will be offered an opportunity to use Jadelle (a 2-rod levonorgestrel implant). A comparison group of ARV patients who are not using hormonal contraception will be enrolled; this group will be matched on age, time on ARVs, and CD4 counts. Over a one-year period, data on CD4 counts will be transcribed from existing records for analysis. Incidence of HIV-related disease will be collected and tallied. In addition, prospective information on changes in contraceptive method and any pregnancies will be collected.

Subgrantee(s): University of Nairobi Institute of Tropical and Infectious Diseases (UNITID)

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Activities, Accomplishments, Problems through December 31, 2008

- FCO 112136 was assigned in May 2007.
- FHI staff made a site visit to Kenya to select the site and draft the protocol. Protocol development was complicated by the difficulty in gathering information from partners at the government hospital.
- Political conflict in Kenya related to the elections led to additional delays and interrupted necessary effort for shaping the subproject.
- The protocol was approved by FHI's PHSC in November 2007 and the Kenya IRB in March 2008.
- The forms were pretested in April 2008.
- The subagreement with University of Nairobi Institute of Tropical and Infectious Diseases (UNITID) was signed in June 2008.
- The study manual that the nurse will use was prepared.
- FHI staff turnover and time required to competitively hire a study nurse caused delays on these subprojects.
- UNITID hired a study nurse for the project in November 2008.
- Recruitment began in December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Recruitment was suspended for three months during March-May 2009 due to dismissal of study nurse.
- A new study nurse was hired in June 2009.
- A total of 15 participants were enrolled during the period January-June 2009.

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Planned Activities for July 1, 2009 – April 28, 2010

- FHI has proposed transitioning some of this activity to a new agreement. If approved, the new projected end date will be June 30, 2011.
- Recruitment of implant participants will be completed by January 2010.
- Data entry will begin when completed forms become available.
- Data analysis programs will be written and tested in January 2010.
- Site closeout activities will begin in February 2011.
- A draft manuscript with table shells will be written in March 2011.
- Final data queries will be issued in January 2011.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 112136 May 2007 112141 Mar 2008
Total Approved Budget: 112136	\$ 298,252	Projected End Date: Apr 2010
112141	\$ 91,146	
	\$ 389,398	

Kenya: Risk of HIV and Feasibility Research Among House Girls in Nairobi (FCO 154100/154102/154104/154105)

Technical Monitor: JAlaii

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.B.: At least three strategies to meet demand of specific populations identified, implemented by HIV and/or FP providers and evaluated, and introduced into programs in five countries.

Objective(s): In FY 2005: 1) to map house girls' knowledge of HIV/AIDS, sexual experiences, behaviors and sexual networks; 2) to determine the feasibility of an intervention study with house girls; 3) to use study findings to develop an appropriate intervention for house girls; and 4) to develop a protocol for an add-on intervention study.

In FY 2006: 1) to implement a program to raise awareness among Bahati PCEA Church members and Nairobi community about house girls' vulnerability to HIV and unwanted pregnancies; 2) to implement an education program and support for a group of house girls in Bahati area; and 3) to conduct a baseline survey of house girls in Bahati.

In FY 2007, to continue to gather strategic information and identify lessons learned to support scale up of the intervention. In FY 2008, to continue to gather strategic information and identify lessons learned to support integration of the activity with partners including USAID APHIA II.

Description: Female domestic workers in Kenya, house girls, are a potentially high-risk population due to circumstances of their employment, young age, and low educational levels. There are many unknown factors concerning their risk level, and degree and nature of sexual relationships, if any. Also, it is not clear what kind of intervention would be feasible with house girls, particularly due to their little freedom of movement outside their work places.

In FY 2005 the study involved: 1) in-depth interviews with house girls to explore risk behavior and experience with non-consensual sex and/or violence, and to map sexual networks; 2) key informant interviews with church leaders and HIV community workers; and 3) interviews with house girls' employers to develop a feasible strategy to conduct the project.

In FY 2006, we conducted a follow up survey among house girls whose employers attend Bahati PCEA Church. A radio talk show and 60 hours church-based pilot training intervention was launched in November 2007 to raise community awareness about the vulnerability of house girls and to increase house girls' life skills.

In FY 2007 and 2008 the project continued to gather strategic information and identify lessons learned to support scale up of the intervention, and integration of activities with USAID APHIA II partners for sustainability. Targets include 1) expanding the intervention to two additional faith-based institutions in Nairobi, and provision of technical assistance (TA) to five others; 2) training 50 peer educators to reach 500 housegirls with HIV and unwanted pregnancy prevention messages; 3) expanding the media campaign through national radio stations to air HIV and unintended pregnancy prevention messages to reach 10,000 housegirls; 4) disseminating lessons learned, including providing TA to USAID APHIA II partners to apply those findings within their activities; and 5) beginning to develop and implement a transition plan with the subgrantee to promote sustainability.

Subgrantee(s): Kenyatta University

Collaborating Agency(s): P.C.E.A Bahati Martyrs Church, Nairobi

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Activities, Accomplishments, Problems through December 31, 2008

- August 2005-June 2006: Conducted a formative assessment, findings were shared with stakeholders, and a draft referral guide for house girls developed.
- December 2006: Signed a sub-agreement with Kenyatta University and developed Phase II work plan and budget.
- February-October 2007: Completed baseline survey protocol, collected, processed and analyzed data.
- July 2007: Internal review of formative phase report.
- July-December 2007: Continued engagement with church members for community endorsement, pilot intervention development, and mobilization of house girls for training.
- November-December 2007: 20 of 28 housegirls enrolled in First Aid class successfully completed training.
- February-March 2008: We drafted training curriculum outline, oriented consultants at a two-day workshop and developed lesson plans.
- March-May 2008: Aired six interactive radio sessions on a Kameme Radio.
- April 2008: Made a presentation at University of Nairobi Annual STD Collaborative Meeting.
- April-June 2008: Enrolled 48 house girls for trainings.
- May 2008: Submitted a sub-agreement budget amendment for the 2008-2009 work plan, and the change of project end date to August 2009.
- June 2008: Pre-tested a tool to monitor project outputs and document progress.
- July-October 2008: Offered training to 48 house girls on sexual violence, and financial savings.
- Financial audit of sub-agreement requested after consultation with NC.
- August 2008: The project monitoring tool was deployed with graduating house girls.
- Awarded certificates to 54 house girls as per specific modules completed. 28 girls completed the full course. 41 and 42 girls completed STI/HIV&AIDS prevention and SRH modules respectively.
- September 2008: Developed scale up phase activity timeline; criteria for sites selection; and strategy for mentoring and monitoring peer educators.
- October 2008: Reviewed draft baseline survey report.
- November-December 2008: Aired four interactive Kiswahili radio sessions on Citizen Radio. Received in total, 6 calls during two sessions, and 28 text messages during the 4 sessions.
- Recruited two project assistants to provide hands on field support in scale up phase.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Produced a project brief in the Family Health Research, Kenya newsletter (Feb 2009: Vol 3, Issue 1).
- February-March 2009: Confirmed 5 of 7 sites for scale up phase and mobilized fellowship groups there; explaining project goals and scale up plans.
- Printed 1000 copies of the "Reference Guide: Essential services for female domestic workers in Nairobi"
- March 2009: Posted a brief; "FHI Project Empowers Kenya's House Girls" on the FHI website http://www.fhi.org/en/countryprofiles/kenya/res_house_girls.htm.
- Produced a feature article "Is your househelp HIV-savvy" in the Daily Nation Newspaper, Wednesday, March 25th 2009.
- March-April 2009: Confirmed 2 additional sites for scale up.
- April 2009: Finalized baseline survey report.
- Began shooting a 10-minute project documentary featuring house girls from the pilot phase.
- Project activities covered in IRINPlus News feature "Kenya-Domestic workers often do more than housework" in IRIN Africa English reports, 5/26/2009.
- April-June 2009: Explored opportunities for further media outreach to air HIV and unintended pregnancy prevention messages to reach 10,000 house girls.
- May 2009: Submitted abstract to International Conference on Urban Health (Nairobi, October 2009).

- May 29, 2009: Resolved outstanding audit findings with KU management and transferred direct administration of subgrant funds to FHI Nairobi.
- Conducted 6 peer education training sessions for 30 housegirls from pilot phase.
- Identified volunteer (support) trainers at 4 confirmed scale up sites.
- Confirmed consultant TOTs to provide support during scale up.
- June 2009: Finalized project brochure, developed a project logo, and sent package for typesetting.
- Hired 2 project assistants to support FHI TM, and 1 additional assistant to support KU.

Findings and Outcomes:

- Formative assessment from Phase I results indicate that:
- House girls are at significant risk of acquiring HIV/AIDS and unintended pregnancies because of: 1) their socioeconomic background; 2) isolation and lack of social support; 3) the low status of their work; and 4) their previous experiences with sexual coercion and violence.
- House girls have some knowledge of modes of transmission and prevention of HIV/AIDS, but knowledge and use of contraception and condoms is low.
- House girls would like to be involved in training, and feel that the best time and place for this is Sundays after church.
- Employers were generally favorable about an intervention with house girls, but they would need to have all of the information about the program first. Furthermore, they were not sure other employers would agree.
- Finally, the Presbyterian Church of East Africa (P.C.E.A.) in Bahati has expressed its interest in being part of such an intervention.
- Results of the cross-sectional survey conducted in 2007 corroborate those of the preceding qualitative study conducted in 2005.
- About two-thirds (64.5%) of the girls had attained only primary education. The girls had worked for an average of two years and earned an average monthly salary of Ksh. 1627.6 (approximately \$25).
- The level of knowledge of reproductive health was low, despite half of the girls ever having had sex in their lifetime. Less than 15% of the girls were aware of the period of the menstrual cycle when they are most at risk of conceiving and that they could get pregnant the first time they had sex.
- Among the 77 house girls who reported ever having consensual sex, 75.3% (n= 58) reported ever using a condom. Forced sex within the employer's house was reported by 7.5% (n=6) of the sexually active girls (n=80).
- The successful intervention seems largely dependent on good employer-house girls relations and political stability. We have observed that regular attendees enjoy good relations with employers and only miss classes on an expressed genuine need to provide support to employers. Post-election crisis in Kenya resulted in inability to trace back some previously enrolled house girls.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- July 2009: Conduct a 2-day TOT orientation workshop for trainers from pilot phase and a 3-day workshop for TOTs to train support trainers for scale up phase.
- Conduct pre-training assessment of RH-HIV related knowledge and experiences using 2007 baseline survey questionnaire
- Finalize information package including brochure and documentary and produce DVDs for use in media outreach.
- Produce peer educators kit including branded T-shirt, umbrella, bag, cap, "leso".
- July-November 2009: Air HIV and unintended pregnancy prevention messages on popular local radio to reach 10,000 house girls.
- July-December 2009: Conduct training activities with housegirls at 2 scale-up sites, and provide TA on site specific priority activities in 5 other sites.
- Link up with USAID APHIA II partners for integration of lessons learned in their project sites.
- August 2009: Begin monthly peer educator mentoring meetings after training.
- Finalize project information package (documentary, brochure)
- Progressively work with KU on transitioning the project to be managed fully by KU.

- October–November 2009: Undertake an end-term review and begin to develop a terminal project report.
- November–December 2009: End term review data entry and cleaning.
- January–March 2010: Data analysis and use of findings in terminal project report.
- Project wrap up activities as appropriate including final financial and progress reporting, update on progress of transitioning with KU and APHIA II.
- February 2010: Hold stakeholder dissemination.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR; USAID - US Agency for International Development/USAID: Add-On; USAID - US Agency for International Development/USAID: IAA	FCO Approved: 154100 Jul 2005 154102 Feb 2007 154104 Apr 2009 154105 Jul 2009
Total Approved Budget:	154100 \$ 448,107	Projected End Date: Apr 2010
	154102 \$ 434,894	
	154104 \$ 42,747	
	154105 \$ 157,253	
	\$ 1,083,001	

Worldwide: Program Guidance for Integrating FP/HIV Services (FCO 113147)

Technical Monitor: RWilcher

Strategy Outcomes(s) to be addressed: HIV/FP II.E.: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Objective(s): 1) To create a publication that provides evidence-based technical guidance on designing, implementing and evaluating integrated FP/HIV service delivery programs. 2) To disseminate the technical guidance publication and other key FP/HIV research findings to international RH and HIV/AIDS organizations, in-country implementing partners, and FHI country offices. 3) To provide technical assistance to select partners/programs in applying the guidance contained in the publication.

Description: As awareness of the importance of addressing the contraceptive needs of HIV-infected women increases, many programs are responding by attempting to integrate family planning services into vertical HIV programs. However, limited evidence of effective integrated FP/HIV service delivery models currently exists, and “how to” programmatic guidance is urgently needed to assist program managers to plan, implement and evaluate integrated FP/HIV services. In collaboration with WHO, FHI will develop technical guidance that can help improve current FP/HIV integration programs, and inform the design of new, promising programs. The guidance will be informed by the latest research findings and build on recommendations that emerge from USAID’s FP/HIV Integration Technical Experts’ Meeting in October 2008. Once the programmatic guidance has been produced, FHI will identify 2-3 programs that might benefit from technical assistance in applying the guidance.

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

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Activities, Accomplishments, Problems through December 31, 2008

- Beginning in July 2008, several FHI staff members participated on expert panels formed by USAID to review the literature and develop technical recommendations for field-based programs implementing FP/HIV integration activities. R. Wilcher was the facilitator of the panel focusing on FP/HIV care and treatment integration.
- Approval to implement was obtained from USAID in October 2008.
- October 2-3, 2008, FHI hosted a retreat for a core group of panel members to review the evidence and recommendations put forth by the panels and discuss how they should be translated into programmatic guidance.
- Following the retreat, R. Wilcher produced a first draft of the programmatic guidance.
- October 20-22, 2008, R. Wilcher and other FHI staff participated in a technical workshop sponsored by USAID during which a draft of the programmatic guidance was reviewed and commented on by more than 80 experts in FP/HIV integration. R. Wilcher presented an overview of the guidance at the workshop.
- R. Wilcher, in collaboration with a core working group consisting of representatives from USAID, WHO, EngenderHealth and Pathfinder revised the guidance based on feedback received at the workshop.
- A second draft of the guidance was submitted for review by key staff at USAID, CDC, and WHO.
- R. Wilcher revised the guidance and in December 2008, a third draft was submitted to all participants at the October workshop for their review.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- R. Wilcher revised the guidance based on feedback from workshop reviewers and a fourth draft was sent for final review by USAID, WHO, and CDC.
- R. Wilcher revised the guidance based on feedback from USAID, WHO, and CDC reviewers and, in March 2009, a final draft of the guidance was submitted to WHO to undergo the final clearance process necessary for the WHO logo to appear on the document.

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Planned Activities for July 1, 2009 – April 28, 2010

- Incorporate any final revisions from the WHO clearance process and submit for copy-editing.
- Work with a graphics designer on the layout of the guidance.
- Finalize programmatic guidance and prepare to print.
- Disseminate and promote utilization of guidance to key stakeholders globally and at country-level, including at the technical meeting on FP/HIV integration for FHI field staff and MOH partners in November 2008.
- Provide technical assistance to 2-3 field-based programs in implementing the programmatic guidance. (For example, in Tanzania, FHI will provide support to the MOH in using the guidance to inform the development of a National FP/HIV Integration Framework.)
- Work with USAID to prepare 2-3 companion briefs on topics related to the programmatic guidance.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Jul 2008
Total Approved Budget:	\$ 200,000	Projected End Date:	Apr 2010

Kenya: Youth Integrated FP and HIV Service Delivery Models (FCO 114130)

Technical Monitor: JBaumgartner

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.B.: At least three strategies to meet demand of specific populations identified, implemented by HIV and/or FP providers and evaluated, and introduced into programs in five countries.

Youth I.B.: Up to two integrated services models for youth evaluated, including one using the YouthNet counseling/testing manual.

Objective(s): 1) To examine how the characteristics of facilities, available services, providers, and clients vary across a variety of FP-VCT integrated clinics that serve youth; and 2) to understand the facility, including provider characteristics that are associated with a) same day uptake or intention to use contraception after the VCT session and b) the level of contraceptive use three months after the VCT session among youth clients, taking into account the characteristics of clients who seek VCT services. Note: The objectives have changed from that originally proposed, based on discussions with USAID.

Description: One potential strategy to address the dual contraception and HIV prevention needs of youth is through integrated contraceptive-HIV services. Kenya has been the global leader integrating FP services into VCT services. A large proportion of clients seeking VCT services are youth, i.e., 24 years old and younger, and high levels of unmet contraceptive need among VCT clients in Kenya have been documented. In Kenya youth seek VCT and integrated FP-VCT services in youth clinics and general population VCT centers. Only a small number of studies have evaluated the effectiveness of youth clinics for their impact on behavior change. There is still a need to understand how the characteristics of services, such as services that are tailored to youth or integrated services, affect behavior, such as contraceptive uptake. The purpose of this study is to identify facility and provider level characteristics that are associated with uptake of contraceptives among youth VCT clients. This is a descriptive cross-sectional and cohort study. The primary outcome is 'the proportion of youth VCT clients using contraception at three months.' We will include 20 facilities in the study, a number which is determined by logistic and budget constraints. FHI has identified 12 youth clinics and 86 general population VCT clinics that are eligible to participate in the study. We will randomly select 10 of the 12 youth clinics and randomly select 10 from the general population VCT clinics. We will conduct provider and client interviews (n=260) and facility structured observations. Clients will be interviewed three months after their VCT session to find out about their contraceptive use. We will test the relationship between facility and provider characteristics and client contraceptive use using structural equation modeling, specifically a path analysis, to test the main relationships.

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Activities, Accomplishments, Problems through December 31, 2008

- The approval to implement letter was signed by USAID on July 26, 2007.
- Information was sought about the type of youth VCT services available in an effort to identify the high performing youth clinics to inform protocol development.
- USAID/Kenya approved this study in February 2008.
- The protocol and data collection instruments were drafted, reviewed and submitted to KEMRI IRB on June 30, 2008 (for the July 15, 2008 meeting).

- The protocol was submitted to and approved by FHI's PHSC in August 2008, and by KEMRI in October 2008.
- Sites were randomly selected and staff conducted phone calls to ensure appropriateness of sites to include in the study.
- After study sites were confirmed, staff conducted site visits to gain Ministry of Health approval for the study in November and December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Time 1 (baseline) and Time 2 (follow-up) data were collected in February and May, respectively.
- By June 2009, all data were entered and cleaned and data analysis had begun.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Data analysis will be completed by July 2009.
- A manuscript for submission to a peer-reviewed journal will be prepared and submitted.
- Local/regional dissemination activities for country stakeholders will occur by December 2009.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Jun 2007
Total Approved Budget:	\$ 264,101	Projected End Date:	Apr 2010

South Africa: Collaborative Study of Hormonal Contraception and HIV Disease Progression for Women before and after Initiating Antiretroviral Therapy (FCO 172010)

Technical Monitor: CMorrison

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP I.A.: At least two clinical studies of the safety and effectiveness of hormonal contraceptives and ART completed.
HIV/FP I.B.: At least two studies on the safety, effectiveness, and health benefits of contraceptives for women at high risk of HIV or HIV infected women completed.

Objective(s): Primary objective: To develop and seek funding for a study to evaluate whether the use of specific hormonal contraceptive methods including DMPA, COC and progestin-only implants, alters HIV disease progression among women taking and not taking antiretroviral therapy, when compared to the use of a non-hormonal method, the copper IUD.

Secondary objectives: 1) To evaluate the effectiveness of hormonal contraceptives (i.e. pregnancy rates) in HIV-infected women before and after antiretroviral treatment has been initiated; 2) To compare contraceptive method choices, continuation rates and side effect profiles before and after antiretroviral treatment has been initiated; 3) To evaluate differences in ARV-related side effects and toxicities according to use of different contraceptive methods, including use of concomitant treatments for opportunistic infections (OIs). Ability to meet the secondary objectives is dependent upon securing funding.

Description: This subproject aims to develop and obtain funding for a prospective cohort study. The study would follow women every 12 weeks for 3-4 years. In the disease progression cohort, we would enroll 1,600 women (400 women using each of the four contraceptive methods of interest) at four African research sites. During the follow-up period, women who meet WHO criteria for initiation of ARVs, would be offered ART. The current criteria are having Stage 4 (or multiple Stage 3) disease, or CD4 lymphocyte count < 200 cells/mm3. These criteria many change over time, however. They are already revised for pregnant women and women with pulmonary TB. Women who begin ART would be offered admission into the ART initiator cohort. We would anticipate following 400-500 women for one year on ART to determine differences in HIV disease progression, as well as ART associated toxicities and side effects, for women using hormonal contraception compared to women using a copper IUD. This subproject is funded by an Interagency Agreement between NIH and USAID (NIH # 8142).

Collaborating Agency(s): WHO/UNFPA SPP

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Activities, Accomplishments, Problems through December 31, 2008

- FHI staff met with project staff in Geneva (Farley, Rees, Blumenthal, Chen, Meirak, Kapp) in October 2007 to make key decisions about critical aspects of the research study (contraceptives to be studied, number of sites, research objectives, etc.).
- A study concept proposal was drafted and circulated to the study team for comments.
- Team members discussed strategies for seeking funding for the study and initial contacts were made with potential study funders.
- Comments were received from reviewers and the concept proposal was revised as of December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- No activities took place on the subproject during the period January 2009 through June 2009.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- The study concept proposal will be finalized and shared with potential funders.
- Decisions about the protocol writing process will be made.

Funding Source(s):	USAID - US Agency for International Development/USAID: IAA	FCO Approved:	Feb 2008
Total Approved Budget:	\$ 74,000	Projected End Date:	Mar 2010

South Africa: Hormonal Contraception and HIV Acquisition Analysis of the Carraguard Dataset (FCO 112138/132129)

Technical Monitor: CMorrison

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP I.B.: At least two studies on the safety, effectiveness, and health benefits of contraceptives for women at high risk of HIV or HIV infected women completed.

Microbicides II.H.: Programmatic and biomedical lessons learned from research synthesized, and results of these evaluations disseminated via professional literature, outreach, technical assistance, client materials, or other means to service delivery partners, normative bodies, USAID, clients, and others for incorporation into practice and procurement decisions.

Objective(s): Primary Objective: To evaluate the effect of COCs, DMPA and NET-EN on the risk of HIV acquisition.

Secondary Objectives: 1) To examine whether the relationship between hormonal contraception and HIV acquisition is altered by the age or by the risk status of women. 2) To evaluate the effect of combined oral contraceptives (COC), DMPA and NET-EN on the risk of acquisition of chlamydial and gonococcal infections.

Description: The Carraguard trial is a Phase III, two-arm, randomized, parallel group, placebo controlled, double-blind, efficacy trial of Carraguard® gel to prevent HIV acquisition. The trial was conducted by the Population Council at three sites in South Africa. Data collection was completed in March 2007 and study results were made public by the end of 2007. The study enrolled 6,203 women and about 280 women became HIV-infected during the study. The study had a mix of contraceptive methods, including: 481 women using COCs; 1,573 women using DMPA; 1,110 women using NET-EN; and 3,030 women not using hormonal methods. There are large numbers of young women who participated in the study (2,289, or 37%, of the women were less than 25 years old— including 511 women ages 16-18 years).

We will conduct an analysis similar to that conducted for the NICHD-funded HC-HIV study with several notable exceptions. As in the HC-HIV study, we will calculate HIV incidence rates for each contraceptive method (COC, DMPA, NET-EN, and non-hormonal) based on time-varying contraceptive exposure. In contrast to the HC-HIV study, we will evaluate a third contraceptive group (NET-EN in addition to COC and DMPA) and we will base our primary analysis upon the majority contraceptive use within the visit segment as opposed to any (hormonal) contraceptive use within the segment. The primary analytic method will be multivariate modeling using Proportional Hazards modeling of time to HIV infection. Sensitivity analyses will include recalculating models when censoring person-time starting at the time of the first contraceptive method switch or the first pregnancy. We will also evaluate whether age or risk category modifies the effect of hormonal contraception on HIV acquisition. If so (p-value for interaction <0.05), we will present separate models for young vs. older age and/or for low vs. high-risk groups.

Collaborating Agency(s): Population Council

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Activities, Accomplishments, Problems through December 31, 2008

- As of December 2007, FHI staff had reviewed the Carraguard Study case report forms and requested data files from the Population Council.
- An analysis plan was drafted.
- The analysis plan was circulated to co-authors (including Population Council staff) and was finalized in October 2008.
- The profile dataset was created and various analyses were run in November-December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The primary data analysis for this subproject was completed.
- An abstract was submitted, accepted and presented at the ISSTD Conference in London in June 2009.

Findings and Outcomes:

- Although DMPA was associated with increased HIV acquisition risk in univariate analysis, none of the contraceptive methods (DMPA, COC or Net-En) were associated with increased HIV risk in multivariate analysis.
- There was some indication of an increase in HIV risk among young women (16-24 years) who used DMPA compared to women not using hormonal contraception (HR=1.54; 95% CI 0.90-2.61; p=0.11).

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Additional primary analysis of the HC-HIV relationship using the Carraguard dataset will be done at FHI.
- A manuscript will be drafted, circulated to co-authors and revisions will be made. The goal is to have the manuscript submitted by April 2010.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides; USAID - US Agency for International Development/USAID: Core	FCO Approved: 112138 Sep 2007 132129 Sep 2007
Total Approved Budget: 112138 \$	166,405	Projected End Date: Apr 2010
132129 \$	166,405	
	<hr/>	
	\$ 332,810	

South Africa: Integrated Community Palliative Care Project (ICPC) in South Africa (FCO 153122/153123/153124/153125/153126/153127/153136/153139/153140/153142/153143)

Technical Monitor: SPilusa

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.A.: At least two scalable and appropriate models given the CPR, HIV prevalence, and available services for integrating family planning and HIV services designed, evaluated and introduced in up to five countries.

Objective(s): 1) To improve access to comprehensive palliative care (PC) services including family planning (FP) for clients and family members receiving PC in select communities in all the four ICPC sites; and 2) to improve the provision of integrated PC and family planning in Johannesburg Hospital through the expansion of the Palliative Care Team (PCT) and through education in PC and FP.

Description: With funds from PEPFAR, FHI will continue to expand access to integrated FP/RH and HIV services for HIV-infected/affected individuals by enhancing PC programs and strengthening the linkages between HBC, FP/RH, PC, ARV, and other essential services for comprehensive treatment, care and support. Under the IMPACT project, FHI's primary mandate had been to support the National Department of Health (NDoH) by responding to its priority areas which include comprehensive and community PC. In FY06, with PEPFAR funds available through the CRTU, FHI began to integrate FP/RH within the ongoing FHI-supported PC programs, which are administered on the basis of the World Health Organization (WHO) definition of PC: the active, total care of a patient whose disease is not responsive to curative treatment. FHI will continue to support the Johannesburg Hospital Palliative Care Team (HPCT) in a tertiary hospital as well as the district-level Integrated Community Palliative Care (ICPC) pilot model within primary health care sites and selected districts in Limpopo and Northern Cape provinces. The Johannesburg Hospital Palliative Care Team (HPCT) provides comprehensive PC services to all wards and disciplines in a public tertiary hospital through the provision of pain management and PC across the spectrum of illnesses. ICPC is characterized

by family-centered care throughout the entire health system, including: primary health care facilities and their multidisciplinary teams; ART sites and their interdisciplinary care teams; community home based care (CHBC) groups; support groups; and the community and families themselves.

Subgrantee(s): Evelyn Lekganyane Home Based Care, Non-Profit Organization; Evelyn Lekganyane Home based care , Non profit Organization FCO 153126; Johannesburg Hospital Palliative Care Team; Johannesburg Hospital Palliative Care Team FCO 153124 & 153136; Makhudu Thamaga Umbrella (NGO); Makhudu Thamaga Umbrella (NGO) FCO 153127 & 153143; Nightingale Hospice; Nightingale Hospice FCO 153123 & 153140; South African Red Cross Society; South African Red Cross Society FCO 153125 & 153142

Collaborating Agency(s): Limpopo Departments of Health; National Department of Health; Northern Cape Departments of Health

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Activities, Accomplishments, Problems through December 31, 2008

- The approval to implement was submitted to USAID Washington in August 2007.
- The subagreements for all five implementing sites (SICP, CICPC, FICPC, PICPC, and JHPCT) were developed and USAID approval was received. The other four subagreements were sent to the DOH in both provinces which took more than four months before they were signed. This delayed the implementation of activities which should have started in August 2007.
- Two 2-day provincial referral network workshops were conducted in September 2007 in Limpopo and the Northern Cape provinces with 48 participants from all the sites, including representatives from the HPCT and Project Support Association (PSA). The workshop's objective was to develop a referral network for the HIV/AIDS program in each district. Each site developed a referral network work plan for six months.
- In October 2007, FHI provided technical assistance to JHPCT to strengthen the linkages with FP/RH services.
- A meeting was held in January 2008 between FHI, Wits Health Consortium and JHPCT to discuss the following new development: PC services in three hospitals (Johannesburg, Baragwanath and Helen Joseph) were integrated by the Provincial Government into the Gauteng Centre of Excellence for Palliative Care, an umbrella PC service which affects the JHPCT.
- Two intra-provincial workshops were conducted in the Northern Cape (September 2007) and Limpopo (October 2007), to discuss progress reports, share lessons learned and orient the site service providers on integration of FP/HIV services.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Meetings were held between FHI/SA and Limpopo and Northern Cape DOHs in April 2008 to inform them about the ICPC project and to secure their buy-in into the project.
- Two trainers were hired to conduct training on integrating FP into ICPC services and programs.
- In May 2008, FHI/SA started planning an inter-provincial workshop to be held in Sept 2008 to discuss progress, share lessons learned and assess the readiness of the project to move from the pilot sites to full roll-out in the provinces.
- In May 2008 the DOH and FHI/SA identified the potential step-down facilities for PC in Northern Cape Province and are planning its roll out.
- Project management teams within the sites were reconvened in May 2008 and meet on a monthly basis. The multidisciplinary teams are also meeting weekly to discuss patient management.
- FHI/SA trained 150 health care professionals, 90 community health care workers and 35 traditional healers and pastors on Integrating FP into PC Programming. Elements of FHI's module on "Contraception for HIV-positive Women and Couples" were used in the trainings, particularly for the service providers.
- FHI/SA developed a PC manual that includes FP integration into PC in Feb 2008.
- The FHISA trained 363 health care professionals, community health care workers, pastors, traditional leaders and healers on integrating FP into PC services and programs.
- All ICPC sites were visited for follow up support to ensure implementation of services.
- FHI/SA participated in the quarterly NDoH PC stakeholder review meetings.

- FHI/SA is facilitating the integration of FP into the NDoH PC guidelines in quarterly review meetings and during site visits.
- FHISA is busy reviewing the Palliative care training manual for accreditation; a service provider has been identified to manage the process of accreditation.
- All sub partners submitted quarterly reports and are busy compiling Sept data to complete the annual reports by the 7th Oct 2009.

Findings and Outcomes:

- A baseline assessment was conducted in 2007 in all ICPC sites; a report is available.
- FHI developed a PC training manual in 2007 that includes FP integration into PC. The manual used a number of elements from FHI's module on "Contraception for HIV-positive Women and Couples."
- An abstract was accepted and presented by FHI/SA's Activity Manager at USAID, Malik Jaffer, at the PEPFAR partners meeting in June 2007.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

FHI staff will:

- Establish a step-down facility in each of the two provinces for PC.
- Strengthen the management structures of the project at the site level.
- Develop a roll-out strategy and plan for the project.
- Conduct Monitoring and evaluation training to ensure submission of quality reports
- Conduct training on ICPC and FP integration for health workers in ART sites.
- Complete the accreditation process of the ICPC training manual.

Funding Source(s):

USAID - US Agency for International Development/PEPFAR;	FCO Approved: 153122	Jun 2007
USAID - US Agency for International Development/USAID: IAA	153123	Jun 2007
	153124	Jun 2007
	153125	Jun 2007
	153126	Jun 2007
	153127	Jun 2007
	153136	Feb 2009
	153143	Apr 2009
	153142	Apr 2009
	153140	Apr 2009
	153139	Apr 2009

Total Approved Budget: 153122	\$	757,873	Projected End Date:	Dec 2009
153123	\$	32,463		
153124	\$	197,948		
153125	\$	53,868		
153126	\$	36,092		
153127	\$	71,756		
153136	\$	225,000		
153143	\$	33,000		
153142	\$	23,500		
153140	\$	40,000		
153139	\$	695,627		
	\$	<u>2,167,127</u>		

Uganda: Understanding Concurrent Partnerships in Uganda (FCO 156103)

Technical Monitor: GGuest

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Objective(s): To generate strategic information on factors that contribute to the extent and pattern of concurrency in sexual partnerships.

Description: In high prevalence areas, spread of sexually transmitted infections (STIs), including HIV, is much more rapid under conditions of concurrent partnerships, that is, when one sexual partnership has not ended before a second one is initiated. The pattern of concurrency, the duration of overlap, and the frequency of sexual relations with each partner, also have significant implications for the spread of the epidemic. This assessment will be conducted among 2 groups likely to be engaged in concurrency- male truck drivers and female market vendors. Qualitative methods will be used primarily to identify and understand factors that influence persons' decisions to engage in concurrent partnerships. We aim to conduct 30 in-depth interviews and 500 surveys with each group to explore social, cultural, and economic characteristics that influence concurrency, including family influences, social networks, characteristics of "sexual marketplaces," community norms, cultural expectations such as bride wealth or dowry, job and housing markets, and public policies. This information will be useful to better understanding partnership dynamics, their relationship to STI/HIV risk, and the factors that assist individuals in choosing and navigating relationships in ways that reduce risk. It will directly contribute to development of enhanced STI and HIV-prevention interventions, particularly among most-at-risk populations (MARPs) in Uganda. In addition, lessons learned will inform ongoing activities through the Regional Outreach Addressing AIDS through Development Strategies (ROADS) project to strengthen HIV prevention programming with MARPs along high-prevalence transport corridors, including Busia, Malaba and Katuna.

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Activities, Accomplishments, Problems through December 31, 2008

- In November 2008, approval to implement this subproject was sought and the study protocol was developed.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- USAID signed the approval to implement letter on January 5, 2009.
- On January 17, 2009, the study received approval by the FHI PHSC.
- From February 23 to March 6, 2009, Dr. Guest and Ms. Succop traveled to Uganda to conduct data collection training with the Uganda team.
- From March 27 to April 2, 2009, the field team conducted observations of the study areas and developed sampling lists for recruitment.
- On June 18, 2009, the study received conditional approval by the National HIV/AIDS Research Committee in Uganda. The committee required a change in consent procedures, from oral to written.
- A revised protocol and informed consent form were submitted to the Uganda IRB on June 25 and to PHSC on June 29, 2009.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- We will obtain final Uganda IRB approval, as well as PHSC approval for the study amendment.
- Focus group discussions will begin in July 2009.

- Based on the focus group data we will make any adjustments to survey and in-depth interview instruments and data entry screens.
- Further data collection will follow; all qualitative data will be transcribed, translated, entered and sent to FHI/NC for analysis.
- All data analysis should be completed by December 31, 2009, with report and manuscript preparation completed by March 31, 2010.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR	FCO Approved:	Oct 2008
Total Approved Budget:	\$ 250,000	Projected End Date:	Mar 2010

Kenya: ESD: Integrated Services for Women Seeking Postabortion Care in Kenya (FCO 114146)

Technical Monitor: EEvens

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: HIV/FP II.B.: At least three strategies to meet demand of specific populations identified, implemented by HIV and/or FP providers and evaluated, and introduced into programs in five countries.

Objective(s): The goal of this study is to provide data to decision-makers about whether and how to scale-up the Postabortion Care (PAC) services package developed by the ESD (Extending Service Delivery) Project, including PAC job aids. The study objectives are: 1) To document the ESD PAC service package including: the provision of services, client satisfaction with those services and provider attitudes towards PAC services; 2) To examine any differences in implementation of the ESD PAC services package for youth and adult clients; and 3) To assess the usefulness of the five Youth-Friendly PAC Job Aids.

Note: The study title has been changed to reflect the inclusion of participants older than 24 years and the partnership with the ESD project. The original study objectives (assessing risk for unintended pregnancy and STI/HIV, delivery of integrated counseling messages, contraceptive uptake, and referral/utilization of VCT/STI services) will be addressed. However, due to limitations in the length of the data collection period and the expected sample size, the changes in contraceptive uptake and referral/utilization of VCT/STI services after the distribution of the job aids will not be evaluated.

Description: In 2007, Pathfinder received private funding to improve PAC services for adolescents in eight sub-Saharan countries. In Kenya, these activities were implemented in clinic sites supported by the AIDS, Population and Health Integrated Assistance (APHIA II) project located in Central Province and Nairobi. PAC providers in these facilities were trained using Pathfinder's youth friendly (YF) PAC curriculum. This subproject demonstrated the need for information, education, and communication materials and The Extending Service Delivery (ESD) project developed job aids for PAC providers. Despite the potential for PAC services to serve as an opportunity to provide counseling on other sexual and reproductive health services, little evidence exists regarding the impact of counseling on PAC patients' use of these services. This study will both document the usefulness of the job aids and document the effect of PAC services on clients' utilization of other SRH services.

The study is a post-intervention only descriptive study. Approximately three months of data will be collected following the distribution of the job aids in eight study health facilities. Telephone interviews with approximately 300 PAC clients, interviews with PAC providers and facility checklists will be performed. Results of this study will be used to inform the scale-up of the PAC intervention and the job aids to other APHIA II facilities in Nairobi and Central, and potentially to other APHIA II sites in Kenya, as well as countries where PAC and YFPAC services are provided.

Collaborating Agency(s): Pathfinder International

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Activities, Accomplishments, Problems through December 31, 2008

- The FCO was approved in September 2008.
- ESD agreed to produce and distribute the job aids in October 2008.
- Approval to implement the subproject was obtained in October 2008.
- A project development trip was taken and the study design was finalized in consultation with stakeholders from FHI-Nairobi, APHIA II, Pathfinder and the Kenyan Ministry of Health's Division of Reproductive Health in November 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- A plan for testing the feasibility of phone interviews with PAC clients was developed in January 2009 and implemented in 6 health facilities; feasibility confirmed in April 2009
- The study protocol was developed and approved by the PHSC in February 2009.
- Data collection forms were developed and translated.
- The protocol was approved by the local IRB in May 2009.
- Study sites were finalized.
- Job aids were finalized in collaboration with Pathfinder and the Kenyan Ministry of Health.
- Estimates for printing job aids were procured.
- A draft plan for printing and disseminating job aids to study facilities and providers was made in collaboration with APHIA II.
- A study coordinator was hired in June 2009.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- The study coordinator will be oriented and trained
- The timeline for data collection will be finalized with Pathfinder and the MOH.
- ESD/Pathfinder will print the job aids.
- Job aids will be distributed to study facilities and providers will be oriented to their use by Pathfinder and FHI staff.
- The data collection tools will be pre-tested.
- Baseline data collection should begin in August 2009.
- Data collection will be completed by fall 2009.
- Data analysis and report writing will be conducted in fall/winter 2009-2010.
- Dissemination of findings will be completed by April 2010.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2008
Total Approved Budget:	\$ 248,355	Projected End Date:	Apr 2010

Kenya: Male Involvement in FP through Male Circumcision Services (FCO 114147)

Technical Monitor: RHoman

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.B.: At least three strategies to meet demand of specific populations identified, implemented by HIV and/or FP providers and evaluated, and introduced into programs in five countries.

Barriers II.B.: Training and supervision approaches and job aids that heighten family planning or HIV service providers' capacity to promote barrier methods (most immediately, male and female condoms) developed, tested and implemented in at least three countries.

Objective(s): 1) To describe the sociodemographic characteristics of the population of men seeking MC services for HIV prevention in terms of age, occupation, education, religious and ethnic background; 2) to describe the sexual relationships of these men and the nature of those relationships, such as, marital status, number of sexual partners and whether their partners are long-term partners or casual partners; 3) to assess current condom use, as well as knowledge, attitudes and interest in dual protection and family planning, including men's perspectives on their role in FP; and 4) to explore men's perspectives on barriers to condom use and male involvement in FP, as well as strategies to overcome these barriers.

Description: This formative study proposes to explore the characteristics of men who consider adult MC for HIV prevention in order to determine whether this sub-population of men is an appropriate group to target with counseling on dual protection and male involvement in family planning.

This will be a cross-sectional study of men who seek MC counseling in VCT clinics that serve as entry points into MC services in Kenya supported by the Male Circumcision Consortium (MCC), which includes FHI, the University of Illinois at Chicago (UIC) and EngenderHealth, with funding from USAID and the Bill and Melinda Gates Foundation. When a male VCT client is deemed eligible for MC (HIV negative and uncircumcised) he will be referred for counseling on MC. Structured interviews will be conducted with a sample of these men who undergo MC counseling. Additionally, focus groups will be conducted with defined sets of these men to explore the topics of male involvement in FP, barriers and strategies to overcome these barriers in greater detail. Results from the study will serve to inform intervention FP strategies targeting men who seek MC to prevent HIV.

Collaborating Agency(s): EngenderHealth; University of Illinois at Chicago

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Activities, Accomplishments, Problems through December 31, 2008

- The FCO was assigned in November 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Development of the protocol and data collection forms was completed in March 2009.
- PHSC and local IRB approval to implement was obtained in May 2009.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Quantitative and qualitative data collection will begin in July 2009.
- Analysis is expected to begin in October 2009.
- Report writing and dissemination will be completed by April 2010.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Nov 2008
Total Approved Budget:	\$ 145,500	Projected End Date:	Apr 2010

LONG-ACTING & PERMANENT METHODS

<p>I. To promote feasible, evidence-based models for revitalizing under-used LAPMs and/or introducing new LAPMs.</p>	<p>A. At least two replicable approaches to improve provider performance or increase demand for LAPMs identified and evaluated.</p> <p>B. At least three programmatic approaches to improve access to or assure supply of LAPMs identified and evaluated.</p> <p>C. Evidence-based LAPM programming approaches institutionalized and implemented by at least three service-delivery organizations and at least four countries through information dissemination, technical assistance, and collaboration with partners.</p>
<p>II. To develop a safe, effective, and acceptable method of non-surgical female sterilization ready for introduction into FP programs within ten years.</p>	<p>A. An FDA-regulated Phase II clinical trial of a nonsurgical female sterilization method will be underway and negotiations with a private sector licensee will be initiated.</p>
<p>III. To increase male acceptance, support for, and uptake of LAPMs (including vasectomy).</p>	<p>A. Evidence provided from two or more demonstration projects (in partnership with service delivery organizations) on effective approaches to increasing male involvement in FP and uptake of vasectomy.</p> <p>B. At least one spermicidal agent that could prove effective in hastening azoospermia after vasectomy evaluated.</p> <p>C. The effectiveness of more easily reversible methods of vasectomy, such as the Shepherd IVD (intra-vas device), and their impact on method uptake evaluated. <i>(NB: As of 2005-06 USAID considers this to be a lower priority outcome.)</i></p>
<p>IV. To substantially expand IUD use by decreasing medical and other access barriers, as well as increasing demand and contraceptive choice. <i>(USAID noted this goal could be combined with Goal I above.)</i></p>	<p>A. New IUDs and IUS evaluated for effectiveness, uptake, continuation rates, and side effects, with emphasis on special populations such as nulliparous women, and introduced in at least three countries. <i>(NB: USAID considers this to be a low priority outcome due to poor feasibility.)</i></p>

FHI/NC subprojects fully or partially funded by USAID's CRTU Agreement:

- Worldwide: USAID Financial Support of Female Nonsurgical Sterilization Development (FCO 2271/112107)
- Worldwide: Maximizing Access and Quality (MAQ) IUD Subcommittee, and FHI's IUD Checklist Production and Dissemination (FCO 113112)
- India: IUD Revitalization (FCO 113136/114138/143111/113150/114150)
- Kenya: IUD Revitalization - Transition Phase and M & E (FCO 113111)
- Kenya: Improved Counseling on Implants to Reduce Unintended Pregnancy (FCO 112129/112140)
- Worldwide: Assessing Implant Provision in Various Service Delivery Settings (FCO 112124)
- Worldwide: Collaborative Research on Implants (FCO 112125/112135)

India: Vasectomy Acceptability among Clients and Providers in Uttar Pradesh (FCO 116100/116111)
India: RCT of Three Vasectomy Techniques (FCO 12098/112128)
Malawi: Using Male Educators to Increase Family Planning Use among Young Married Couples in Malawi (FCO 116108/116109)
Uganda: Repositioning Family Planning: Revitalizing LAPMs (FCO 113110)
Worldwide: Global Advocacy & Stakeholder Engagement for LAPMs (FCO 113109)

Worldwide: USAID Financial Support of Female Nonsurgical Sterilization Development (FCO 2271/112107)

Technical Monitor: DOWen

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: LAPM II.A.: An FDA-regulated Phase II clinical trial of a nonsurgical female sterilization method will be underway and negotiations with a private sector licensee will be initiated.

Objective(s): To support the development of a method of non-surgical female sterilization.

Description: FHI received a grant from a private foundation to develop a nonsurgical female sterilization method; this foundation only pays 15% of FHI's overhead (G&A) expenses. Under this subproject, USAID will provide financial support to cost share the G&A expenses for FCOs 1656, 1340, 1330 and 1663. These FCOs include activities related to: 1) the development of erythromycin as a means of female nonsurgical sterilization; and 2) the operations of a consumer advisory committee which provides oversight of the overall female nonsurgical sterilization program. As a management FCO, this subproject will not routinely be reported.

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Activities, Accomplishments, Problems through December 31, 2008

- After a private foundation informed FHI that they would only pay 15% overhead, a request was made by FHI Senior Management to USAID for financial support. USAID agreed to pay the difference in overhead effective March 2001.
- A letter was sent to USAID in November 2001 requesting written approval for the use of USAID core funds to pay FHI's portion of the overhead. Approval was granted in December 2001.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Updates for this FCO were summarized in EIS reports for FCO 1656, 1658, 1339, 1340 and 1390.
- In summary, the NSS program strategy has been revised, with a short term goal of determining efficacy of EY in a baboon animal model and investigating dose effect via in vitro/ex vivo studies. Further clinical development of EY as a method of female non-surgical sterilization is on-hold indefinitely.

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- This FCO will provide support overhead (15%) for the studies that are outlined in the new FCOs TBD. FCOs 1656, 1340, 1330 and 1663 will be closed.
- Note that FHI has proposed transitioning some of this activity to PROGRESS. If approved with the PROGRESS Year 2 Workplan, the projected end date will be extended.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 2271 Apr 2002 112107 Jul 2005
Total Approved Budget: 2271	\$ 156,619	Projected End Date: Apr 2010
112107	\$ 351,445	
	<hr/> \$ 508,064	

Worldwide: Maximizing Access and Quality (MAQ) IUD Subcommittee, and FHI's IUD Checklist Production and Dissemination (FCO 113112)

Technical Monitor: SHarlan

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: LAPM I.C.: Evidence-based LAPM programming approaches institutionalized and implemented by at least three service-delivery organizations in at least five countries through information dissemination, technical assistance, and collaboration with partners.

Objective(s): 1) To support FHI's participation in a key global technical leadership group that promotes knowledge-sharing and use of best practices related to the IUD; 2) to increase accessibility of key IUD-related resources, including job aids, assessment tools, scientific articles, and advocacy materials for field-based partners; and 3) to increase dissemination and uptake of evidence-based reproductive health practices related to IUD provision (e.g., use of FHI's IUD checklist or other job aids).

Description: Recognizing that access to the IUD has the potential to expand method choice, increase the economic sustainability of family planning programs, and reduce unwanted or mistimed pregnancies, the reproductive health community has increased its focus on revitalizing the IUD. A key component of these efforts is dissemination of accurate programmatic and clinical information on IUD use. To this end, USAID has established an IUD Subcommittee as part of its Maximizing Access and Quality (MAQ) Initiative. Co-chaired by Roberto Rivera (consultant, Family Health International) and Roy Jacobstein (EngenderHealth/ACQUIRE Project), and with secretariat support from FHI's Research to Practice Initiative, the Subcommittee's mandate is to develop collaborative CA-based projects designed to enhance global IUD use. Its membership includes a wide range of CAs with expertise in training, research, service delivery, advocacy and marketing, logistics, and communications, thus promoting a holistic approach to IUD revitalization. This subproject will support: FHI's participation in the MAQ IUD Subcommittee, including ongoing secretariat support and staff participation at MAQ meetings. FHI's coordination of the collection and review of documents for an "IUD toolkit". The toolkit is a natural extension of the ongoing work of the Subcommittee and has been identified as a major component of the Subcommittee's workplan for the next two years. FHI's contribution to the IUD toolkit, such as FHI Briefs, PowerPoint presentations, advocacy briefs, assessment tools, and in particular, the development of background information for the FHI IUD Checklist.

Collaborating Agency(s): Indian Council of Medical Research, New Delhi; Jhpiego; State Innovations in Family Planning Services Agency (SIFPSA); The Futures Group

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- For accomplishments prior to 2008, please see the 2007-2008 CRTU annual report.
- Approval to implement was received from USAID in Jan. 2006.
- In Feb. 2008, a training on FHI's checklists was conducted in Mali during a Child Survival and Technical Support Plus Project (CSTS+) workshop (FCOs 113138, 113114).
- In March 2008, FHI and EngenderHealth organized a one-day MAQ IUD Subcommittee. The group discussed progress on promotion of the IUD Toolkit and possible content revisions, and shared project information between partners on IUD activities. 26 people attended, from 13 different organizations, including eight representatives from USAID. V Bukusi presented (with EngenderHealth) on the IUD/LAPM activities in Kenya; E McGinn presented (with Jhpiego) on the new IUD activities in India, and S Harlan presented (with INFO) on the dissemination and use of the website and CD ROMs.
- In April 2008, FHI reprinted 5,000 copies of the Uganda adapted IUD checklist.
- The Training and Reference Guide for a Screening Checklist to Initiate the Copper IUD was printed in English and French, and was posted to www.fhi.org. A dissemination plan for the guide was developed and implemented in May 2008.
- A paper was drafted by K. Tumlinson (et al.) on the dissemination/utilization of FHI checklists in the Dominican Republic and Uganda, and submitted to WHO Bulletin (status pending, FCO 113114).
- Between May 2007-June 2009, more than 600 copies of the IUD Toolkit CD-ROM have been distributed as a result of requests. Additionally, over 300 copies were distributed at meetings and conferences.
- Between June-Dec. 2008, a dissemination plan was implemented for the IUD Checklist (in English, French and Spanish) and the Training and Reference Guide for the IUD checklist (in English). During this same period, 625 IUD Checklists were distributed (449 in English, 146 in French, and 30 in Spanish), as were 67 IUD Training and Reference Guides (all in English). These materials were distributed in the following countries: Kenya, India, Nigeria, Tanzania, Indonesia, Ethiopia, Uganda, Madagascar, Zambia, Jamaica, and the U.S.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Staff worked with EngenderHealth and JHUCCP, staff to complete updates to the IUD Toolkit website (www.iudtoolkit.org). They reviewed new materials to add, completed meta-data pages for new materials, and coordinated with JHUCCP regarding posting items.
- Staff worked with EngenderHealth and JHUCCP to finalize a new section for the IUD Toolkit on the LNG-IUS, and posted these (and other new materials).
- New toolkit material on the LNG-IUS, as well as updated information on the copper IUD, was translated into Sp. and posted to the toolkit. Material was also translated into Fr., and editing is underway.
- A dissemination plan for the new toolkit material was discussed (it will be implemented in FY10).
- From Jan. to June 2009, staff disseminated 439 IUD checklists in Eng., 57 in Sp. and 61 in Fr., in US, Kenya, Rwanda, Nigeria, and Mali. Staff also disseminated 130 Training and Reference guide CDs in Eng. (which includes the guide for the IUD) at US conferences.
- 100 IUD Toolkit CD-ROMs were distributed at meetings and conferences. Additionally, 25 CD-ROMs were mailed as a result of requests. Staff also responded to roughly 20 emails on behalf of the IUD Toolkit team.
- From Jan. to June 2009, the IUD Toolkit website received 43,191 unique visitors from 175 countries and territories for a total of 46,652 total visits to the site. Of the total visits to the site: 72% of the visits were from developed countries and 28% were from developing countries.
- There were a total of 69,962 page views on the IUD Toolkit website. Most frequently viewed pages were: Frequently Asked Questions about Intrauterine Devices (IUDs) (accounting for 25% of the

page views); Management of Side Effects for IUDs (accounting for 15% of the page views); Different Types of IUDs, Spanish version (accounting for 10% of the page views); Frequently Asked Questions, Spanish version (accounting for 9% of the page views); and Essential Knowledge about the Copper IUD (accounting for 3% of the page views).

Findings and Outcomes:

- IUDToolkit.org launched Oct 2006. Between October 2006 and June 2009, it received over 243,000 visitors. By June 2009, nearly 30% of the visitors were from developing countries. Over 175,000 files have been downloaded, the most popular being related to interview guides, training, and marketing.
- In 2007-2008, over 60,000 individuals were reached through general and targeted dissemination of the Toolkit (including e-forums and listservs); over 50 websites have linked to the Toolkit.
- By June 2009, we have disseminated: 770 CD-ROMs (523 to CAs for trainings and conferences, and 247 were sent on request, almost all to developing countries).
- By June 2009, we have disseminated 549 Training and Reference Guides (in Africa, Asia, the Caribbean, and the U.S.).
- The IUD Checklist and accompanying material was included in Population Reports, The Latest on IUDs, Series B, No.7.
- The IUD checklist was translated and produced by JSI for use in Romania, and by IntraHealth in Senegal.
- Pathfinder adapted the IUD checklist into their IUD training manual; 1000 copies were disseminated worldwide. The checklist was included in the Jhpiego IUD Guidelines for FP Service Programs. Staff from the Society for Family Health (PSI/Nigeria) reported using the IUD Checklist.
- In Aug 2008, JSI used the Toolkit in Tajikistan to develop clinical practice guidelines for the IUD. JSI distributed CD-ROMs at 3 IUD trainings.
- The IUD checklist was translated into Hindi, and will be used by State Innovations in Family Planning Services Project Agency to use in trainings in Uttar Pradesh (UP), the government of UP in three districts (Bareilly, Gorakhpur and Lucknow), and the Hindustan Latex Family Planning Promotion Trust with their MerryGold private franchises. The Federation of Obstetric and Gynaecological Societies of India will promote the checklists to members. The checklist has also been disseminated to Prerna, Catholic Relief Services, Find Your Feet, Population Research Centre Lucknow University, Dept. of Social and Preventive Medicine King George Medical Univ, PSP-One, Clinton Foundation, Family Planning Association India- Lucknow Branch, UP Voluntary Health Association and UP Network of People Positive. See FCO 113132/36 for more details.

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- The IUD Toolkit will be migrated from the MaqWeb server to the Knowledge for Health server, and the website will be modified. FHI staff will work with JHUCCP staff as they migrate all toolkit materials to the new site.
- Staff will incorporate changes to the new LNG-IUS section, based on feedback from the MAQ IUD Subcommittee (including staff from Population Council, USAID, and others).
- Editing of French LNG-IUS material will be completed, and material will be added to the IUD Toolkit.
- Staff will notify the members of the MAQ IUD Subcommittee of the new platform, roll out dissemination plan for its promotion, and will also promote a new section on LNG-IUS.
- Staff will roll out dissemination plan for promotion of the new platform, and will promote the new section on the LNG-IUS to a wide audience.
- Staff will continue to co-chair the USAID MAQ IUD Subcommittee and provide both technical and secretariat support to its activities. Staff will also work with JHUCCP and EngenderHealth to discuss IUD Toolkit changes, updates, etc.
- With USAID and others, FHI will continue to discuss the future of the MAQ IUD Subcommittee and possible ways to roll this group into USAID's larger LAPM strategy group. FHI will discuss with EngenderHealth the transition of secretariat support for the MAQ IUD committee from FHI/CRTU to EH/RESPOND in 2009.

- Staff will continue to fill requests for the IUD Checklist and the Training and Reference Guides for the IUD Checklist, and will look for additional opportunities to disseminate these materials.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2005
Total Approved Budget:	\$ 401,115	Projected End Date:	Apr 2010

India: LAPM Revitalization in India (FCO 113136/113150/114138/114150/143111)

Technical Monitor: MSingh

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: LAPM I.C.: Evidence-based LAPM programming approaches institutionalized and implemented by at least three service-delivery organizations in at least five countries through information dissemination, technical assistance, and collaboration with partners.

Objective(s): To increase support for LAPMs provision among policymakers, health care professionals and clients; and 2) to increase the quality of LAPM services. With research being conducted under 114138, the focus was broadened to include LAPMs generally and also injectables, not IUDs specifically. The title was changed from "IUD Revitalization in India" to "LAPM Revitalization in India" to reflect this change.

Note: Originally the objectives were specific to IUDs with research being conducted.

Description: There is a substantial unmet need for contraception in India. India's family planning program is characterized by high discontinuation rates, low use of contraceptives among both married and unmarried adolescents, and the predominance of female sterilization. The intrauterine device (IUD) in particular is highly underutilized (likewise are injectables), even though it has been part of the national family planning program since the 1960s and different types of copper-bearing IUDs are available.

Invited by USAID and in collaboration with a number of local partners, FHI seeks to revitalize IUD use in both public and private sectors within four districts in Uttar Pradesh. Uttar Pradesh was selected as the geographic region of interest because of its large population, poor reproductive health indicators, low CPR and the existing relationships with the state government.

Uttar Pradesh (UP) is the most populous state in India, with an estimated population of about 170 million as of March 2000. According to the 2005-06 National Family Health Survey (NFHS-3), contraceptive prevalence among currently married women in the state is 43.6% for any method and 29.3% for any modern method.(1) The most commonly used modern method of family planning is female sterilization (17.3%) followed by the condom (8.6%) and the rhythm method (11.3%). Unmet need for family planning in the state is 21.2% among currently married women, with 9.1% reporting unmet need for spacing methods, and 12.1% reporting unmet need for limiting. While the percentage of married women using a modern family planning method rose over the period 1998-2005 from 22 to 29%, IUD prevalence remained largely unchanged at about one percent. However, while use of the

IUD is low, awareness of the method among currently married women in Uttar Pradesh is relatively high (88%), and higher than the national average (74%).

Subgrantee(s): ORG Centre for Social Research

Collaborating Agency(s): State Innovations in Family Planning Services Agency (SIFPSA)

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- A symposium to develop a comprehensive strategy for IUD repositioning was held in Lucknow, UP (Oct. 2007). The planning committee included representatives from the MOHFW, the Government of UP, Constella Futures, Population Council, ICMR, SIFPSA and FHI.
- FHI received \$200K in field support funds from USAID/India in support of this subproject (FCO 143111). With core and field support funds, the Mission asked FHI to conduct a research study on the role of the private sector in IUD provision in UP, conduct a desk review of agencies working in RH in India, and develop two IUD strategies: national and UP state.
- In UP the IUD checklist was introduced to the members of the Federation of Obstetrics and Gynecology Societies of India (FOGSI). UP further disseminated the checklists to three district service provider centers namely Bareilly, Gorakhpur and Lucknow. See outcomes section for more information.
- Development of a National IUD strategy was discussed with key officials in the Ministry of Health and Family Welfare (MOHFW) as well as with USAID India (April-May 08).
- A protocol for the private sector study was developed and approved by the key partners (HLFPPT, SIFPSA, UP) in August 2008.
- A draft of the National IUD strategy was shared with key stakeholders (MOHFW, USAID) in August 2008 and distributed to experts at a National Advocacy workshop in September 2008. FHI received approval from UP to initiate the development of an IUD strategy, including calling the IUD Working Group meeting.
- Paperwork for the study to receive approval from the Indian Health Ministries Screening Committee (HMSC) was submitted in October 2008. The study received approval from PHSC and a local Indian IRB in December 2008.
- Study instruments were drafted.
- In UP, IUD checklists were introduced to professional organizations like FOGSI, Indian Medical Association (IMA) and King George Medical College, Lucknow.
- A new CRTU Program Manager, based in UP, was hired (Nov 2008) and oriented to the CRTU in India.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- FHI provided technical assistance to ICMR on 'Pre-program introduction of Cyclofem and NET EN contraceptives through District Hospitals and NGO clinics'. As a part of this, in June 2009 FHI developed a report on "Impact of introducing injectables on modern contraceptive use in India" and shared it with ICMR Task Force members. The findings of the report will inform the country position paper that establishes the case for introducing a new contraceptive method (Cyclofem and NET EN injectables) into the national program with the policy makers.
- Also FHI participated in a two-day workshop organized by Packard and Concept Foundation to i) develop conceptual understanding of WHO recommended framework for introducing new contraceptive methods; ii) adapt this framework to the Indian context with specific reference to Cyclofem in public and private sector; and iii) to define the preparatory activities to roll-out ICMR pre-introductory Cyclofem study in 31 district hospitals and nine NGO clinics.
- FHI hired a new Research Director, Anjali Widge, who will join FHI full time from July 2009 and will be cost-shared between CRTU and PROGRESS.
- FCO 114138 and 114150: The research agency ORG Centre for Social Research was selected and contracted during Q1 2009 to conduct the field activities for the private sector study.
- Approval for the research study was received from the Health Ministries Screening Committee in March 2009.

- Study instruments and training materials for Phase One were finalized April-June 2009.
- Data collector training for Phase One, including units on research ethics and methodology, was conducted in June 2009.

Findings and Outcomes:

- FHI provided technical assistance to the MOH and Family Welfare (MOHFW) to develop new national training guidelines for medical officers, ANMs and health workers, titled "IUD Reference Manual for Medical Officers." This manual was distributed to about 75 participants who attended the IUD symposium in Oct. 2007.
- A joint review paper titled "IUD Repositioning in the FP Program" was prepared with Population Council (2007).
- FHI provided background information for an expert group meeting, led by the MOHFW to discuss introducing the Multiload 375 (apart from the existing TCu 380 A) in the National Program (contrary to evidence that the Multiload is not a superior product).
- In 2008, the IUD checklist (along with the COC, DMPA, and Pregnancy checklists) was translated into Hindi under FCO 113132/113136. They have been shared with State Innovations in Family Planning Services Project Agency (SIFPSA). It is expected that SIFPSA will reprint and use these in trainings in Uttar Pradesh (UP). Also, the government of UP has shown interest in taking all the checklists forward in the three districts of Bareilly, Gorakhpur and Lucknow. The Hindustan Latex Family Planning Promotion Trust (HLFPPT) has agreed to take all four checklists forward with their Merry Gold/ Silver and Tarang Clinics (private franchisees). HLFPPT has also agreed to reprint and take forward the pregnancy checklist to the 120,000 ASHA's in the state. The checklist has also been disseminated to Prerna, Catholic Relief Services, Find Your Feet, Population Research Centre Lucknow University, Department of Social and Preventive Medicine King George Medical University, PSP-One, Clinton Foundation, Family Planning Association India Lucknow Branch, UP Voluntary Health Association (UPVHA) and UP Network of People Positive (UPNP+).
- FHI is one of the key organization of the task force working on ICMR pre-program introduction of Cyclofem and NET EN injectable contraceptives through the public sector in India.

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- FHI will sign a subagreement with Family Planning Association of India to undertake preparatory activities that are required to ensure smooth initiation of the ICMR pre- program introduction of Cyclofem and Noristerat injectable contraceptives through 31 District hospitals and 9 NGO clinics in India
- Data collection for Phase One of the private sector study will commence in the four study sites in July 2009, and regular monitoring visits will be made during July and August 2009. Study instruments and training materials for Phase Two will be developed and finalized during August and September 2009.
- Data collection for Phase Two will commence in September 2009 in all four study sites. The UP CRTU Program Manager will monitor the four sites during this period.
- Study analysis and report writing are expected in Q4 2009 with a dissemination meeting held in January 2010. Both will highlight the key findings and recommendations for further utilization of the study findings.
- The private sector study will involve regular stakeholder engagement to discuss the progress of the study, identify obstacles faced and possible strategies and solutions to these obstacles
- The Government of UP and local and international regulatory authorities will be regularly updated on the progress of the study .
- The IUD checklist (and other FHI job aids) will continue to be promoted to relevant organizations and technical assistance will be provided as needed.
- FHI will disseminate the study results and recommendation of the private sector study with key stakeholders in UP.
- FHI will organize a two-day national conference on healthy timing and spacing including IUD post partum contraception to bring renewed focus to family planning including maternal and child health in India

- FHI will revive the UP IUD expert group and provide technical assistance on UP population policy operational Workplan to ensure the IUD is addressed.

Funding Source(s):	USAID - US Agency for International Development/USAID:	FCO Approved: 113136	Aug 2007
	Core; USAID - US Agency for International Development/USAID: Field Support	114138	Mar 2008
		143111	Oct 2007
		114150	Feb 2009
		113150	Aug 2009
Total Approved Budget:	113136 \$	450,000	Projected End Date: Apr 2010
	114138 \$	330,591	
	143111 \$	200,000	
	114150 \$	54,527	
	113150	N/A	
	\$	1,035,118	

Kenya: Kenya IUD Revitalization - Transition Phase and M & E (FCO 113111)

Technical Monitor: SClapp

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: LAPM I.B.: At least three programmatic approaches to improve access to or assure supply of LAPMs identified and evaluated.

LAPM I.C.: Evidence-based LAPM programming approaches institutionalized and implemented by at least three service-delivery organizations in at least five countries through information dissemination, technical assistance, and collaboration with partners.

Objective(s): 1) To develop and implement FHI's exit strategy from the Kenya IUD Revitalization Initiative (ongoing); 2) to provide technical assistance to the Kenya MoH and other partners during the leadership transition; 3) to provide focused advocacy and outreach at the national level to program managers and professional associations to disseminate the new Kenya FP Guidelines and FHI's IUD Provider Checklist; and 4) to inform the design of future IUD and LAPM revitalization efforts by comparing and contrasting the various interventions that have recently taken place in Kenya.

NOTE: The fourth objective has been broadened to include a comparative assessment of all IUD reintroduction activities in Kenya.

Description: In 2002, the Kenya Ministry of Health (MOH) initiated a national effort to improve contraceptive choice and promote a sustainable method mix, with a focus on revitalizing IUD use, termed the Kenya IUD Rehabilitation Initiative. In addition to providing technical support and capacity development to the MOH, FHI has collaborated with several partners on this activity, including AMKENI (EngenderHealth-led bilateral), JHPIEGO, DFID, Kenya Obstetrics and Gynecology Society, Family Planning Association of Kenya, GTZ, PRIME/INTRAH, Africa Population Advisory Committee, and the Population Council. FHI and AMKENI have successfully increased IUD use in pilot sites by

approximately 200% (see FCO 3022/3432 under the CTR). Now, several organizations are scaling up the service delivery and demand creation components of the IUD Rehabilitation project. For example, EngenderHealth has received funding to expand IUD services to non-AMKENI sites, and Marie Stopes is experimenting with social marketing and franchising of IUD supplies and services.

Under this subproject, FHI will develop and implement its exit strategy. FHI has played a pivotal secretariat and coordinating role for the MOH and partners. As IUD rehabilitation in Kenya becomes main-streamed, FHI will focus its attention on technical assistance and monitoring and evaluation. Of particular need is evaluation of the effect of the various interventions thus far at a national level.

Collaborating Agency(s): AMKENI; EngenderHealth; Marie Stopes Kenya; Ministry of Health, Kenya

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- Approval to implement was obtained Jan 10, 2006.
- Please refer to the 06-07 annual report for accomplishments prior to July 07.
- Data from the comparative assessment was analyzed and a draft report developed Oct 2007.
- A stakeholders meeting was held by the MOH, in collaboration with FHI, EngenderHealth and Marie Stopes/Kenya on Nov 14, 2007. The LAMP comparative assessment, as well as programmatic lessons learned, were discussed. There were 56 participants with MOH representation from all 8 provinces and representation from the collaborating agencies, RH coordinators from APHIA II, donors, and institutions of higher education. One outcome was the request to develop an LAMP Strategy; FHI has taken on this responsibility.
- The Comparative Assessment workshop report was finalized and presented to the MOH; a two-page summary brief was developed and disseminated through FHI's Information Programs/Research to Practice activities.
- A draft National LAMP strategy was developed and presented to a small MOH-led working group for comments (February 2008).
- Results of the comparative assessment were presented at the 2nd East African Community International Health and Scientific Conference, in Arusha, Tanzania in February 2008 (M Solomon) and at the IUD MAQ working group in Washington DC in March 2008 (V Bukusi). The comparative assessment study report was finalized in June 2008.
- A national advocacy strategy for LAMPs (including dissemination of the LAMP assessment) was developed for implementation July – December 2008 under FCO 113109.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Violoet Bukusi will be presenting at the From Data to Impact Symposium in Arusha, TZ in January 2009, "Revitalizing the IUCD: Kenya's Experience".
- Remaining "New Look at IUCD" pamphlets and 80 "Translating Research into Practice: Reintroducing the IUD in Kenya" will be shipped to the FHI Nairobi Office.
- The comparative assessment will be finalized by the HQ and Kenya staff from EngenderHealth and FHI, and submitted to the MOH for sign-off.
- The assessment will then be printed and disseminated as per MOH's request.

Findings and Outcomes:

- The MOH's effort to revitalize the IUD has provided a wealth of programmatic experience. Since 2003, Uganda and Tanzania have, with ACQUIRE, followed suit— though at a smaller scale; IUD revitalization was included in Senegal's bilateral (Intrahealth, 2006); India initiated IUD revitalization efforts (2008, FHI and JHPIEGO); Malawi visited Kenya for an IUD study tour; and there is a general revival of interest in IUDs as Hewlett commissioned a report on opportunities to expand use of IUDs in Africa (2006), and PSI has initiated a 14-country effort on IUDs and implants (2008).
- 2000 Advocacy toolkits "A New Look at IUDs" were disseminated in Kenya, Nigeria, India, Bangladesh, Egypt, Yugoslavia, Ghana, Pakistan, Turkey, and Madagascar. 2500 copies of "Translating Research into Practice: Reintroducing the IUD in Kenya" were disseminated, primarily within Kenya to members of KOGS and the FP working group, but also to Nigeria, Tanzania,

Nepal, Uganda, Ethiopia, Ghana, Philippines, Cameroon, and Madagascar. These publications were also distributed at international conferences in the US.

- The IUD Advocacy Kit was so popular the Population Council adapted it for the Ghana Health Services and produced 500 copies. The IUD Advocacy toolkit became a new template for FHI and was followed by two additional advocacy kits, one on CBD of DMPA (FCO 113108, another on LAPMs (113109).
- The Kenya experience has helped crystallize EngenderHealth's Supply-Demand-Advocacy model which is the foundation of their approach to LAPMs under their new Project RESPOND (awarded 6/08).
- With respect to improved services in Kenya, the APHIA II bilateral project has integrated IUD revitalization efforts into their workplan, under MoH leadership. Between July 2007 – June 2008, 8 additional districts adopted the IUD revitalization model in Eastern and Western provinces, and 115 additional providers were trained on IUD provision in secondary trainings.
- The assessment of IUD/LAPM interventions in Kenya completed in 2008 (M2008-34) has fed into a national MOH LAPM strategy. FHI assisted with the dissemination of this strategy and engaged in LAPM advocacy July – December 2008 under FCO 113109.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2005
Total Approved Budget:	\$ 300,548	Projected End Date:	Apr 2009

Kenya: Improved Counseling on Implants to Reduce Unintended Pregnancy (FCO 112129/112140)

Technical Monitor: DHubacher

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: LAPM I.A.: At least two replicable approaches to improve provider performance or increase demand for LAPMs identified and evaluated.

LAPM I.B.: At least three programmatic approaches to improve access to or assure supply of LAPMs identified and evaluated.

Objective(s): 1) To measure the percent distribution of the contraceptive method chosen by the participants (implants, DMPA, and oral contraceptives); 2) to compare the percentage of women in each group who get pregnant over the 18 month period: implant group versus the DMPA/oral contraceptive group; 3) to measure the continuation rates of the different contraceptives methods; and 4) to assess the acceptability of implants through in-depth interviews.

Description: Because of possible ambivalence toward future pregnancy, many young women have vague or initial short-term contraceptive needs (4-12 months) when they seek services. They do not naturally request long-acting implants for pregnancy protection and instead, self-select toward short-term methods; this often sets them on a path toward unintended pregnancy. Short-term methods are difficult to use consistently and correctly; when side effects arise and/or when actions are needed to continue using these methods, ambivalence toward pregnancy can prevail and lead to early method discontinuation. Unintended pregnancies in this population can limit educational opportunities for life,

affect desires to gain employment outside the home, and prevent realization of other goals. This subproject will involve an observational study of directed counseling to test the appropriateness of offering implants to young women who would normally receive DMPA for short- or indefinite-term contraceptive needs. In a single clinic, providers will recruit 300 women with the following characteristics: aged 18-24, seeking DMPA, having vague or short-term contraceptive needs (4-12 months), willing to participate in a prospective study. Women will be followed prospectively for 18 months regardless of whether they switch methods; continuation rates and pregnancies are the primary and secondary outcomes, respectively. In-depth interviews will be conducted with a small number of implant users who complete 12 months of use without discontinuation. These interviews will examine young women's acceptability of implants versus shorter-term methods and how method use may have affected other aspects of their lives. In-depth interviews with implant continuers might provide further evidence that the method is acceptable and enables young women to achieve other life goals.

Subgrantee(s): University of Nairobi Institute of Tropical and Infectious Diseases (UNITID)

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- As part of the Workplan process, the concept proposal was prepared and submitted to USAID for consideration as a "fast track proposal" in December 2006.
- The original proposal was changed per the request of USAID.
- The preliminary approval to implement letter was received from USAID in June 2007.
- USAID gave final approval in September 2007.
- FHI staff made a site visit to Kenya to select the site and draft the protocol.
- The protocol was submitted and approved by FHI's PHSC on November 9, 2007 and the Kenya IRB in February 2008.
- Political conflict in Kenya related to the elections led to additional delays and discussions about changing countries.
- Protocol amendments were approved in April and May 2008.
- Lang'ata Health Centre was selected to be the site for the study since the previous site, Kenyatta National Hospital, was found to be inadequate.
- The subagreement with University of Nairobi Institute of Tropical and Infectious Diseases (UNITID) was signed in June 2008.
- Donated Jadelle implants were received from USAID and shipped to Nairobi.
- The study manual that the nurse will use was prepared and tested.
- FHI staff turnover and time required to competitively hire a study nurse caused some delays; UNITID hired a study nurse for the project in October 2008.
- The first participant was enrolled in November 2008. It has been slower than expected, given previously documented/ verified site information and analysis.
- Data entry systems were created and tested.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Data from the admission forms were analyzed in April 2009 to detect errors and initiate queries.
- Recruitment was completed in June 2009.
- Follow-up interviews at one- and six-months were completed for most eligible participants, depending on date of enrollment.
- This subproject was approved in June 2009 for transitional funding through PROGRESS, (to begin May 1, 2010).

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Planned Activities for July 1, 2009 – April 28, 2010

- Data entry will continue as completed forms become available.
- Data analysis programs will be written and tested.
- Data querying and cleaning will be an ongoing process.

- By June 30, 2010, all 400 participants will have completed at least one year in the study and approximately 60 participants will have completed the full 18 months in the study.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 112129 Nov 2006 112140 Mar 2008
Total Approved Budget: 112129 \$	407,039	Projected End Date: Dec 2010
112140 \$	88,593	
	<u>495,632</u>	

Worldwide: Assessing Implant Provision in Various Service Delivery Settings (FCO 112124)

Technical Monitor: MSteiner

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: LAPM I.A.: At least two replicable approaches to improve provider performance or increase demand for LAPMs identified and evaluated.

LAPM I.B.: At least three programmatic approaches to improve access to or assure supply of LAPMs identified and evaluated.

Objective(s): 1) To explore the role three sectors (private for profit, private not for profit and public sector) are currently playing in implant provision as we start to prepare for the introduction of lower cost implants should they become available; 2) To assess whether the private sector can provide implants with sufficient quality and in a sustainable manner; specifically, to determine at what unit cost is sustainable private sector provision of implants feasible.

Description: Despite the high current price of implants, some programs are relying heavily on this method. According to an Implant Situation Analysis conducted in Kenya (FCO 112122), about 75,000 Jadelle and Implanon implants were inserted during CY 2005. Users are increasingly switching from OCs and DMPA to implants. Most implant insertions are being performed in NGO and public sector facilities where cost recovery is often not a priority. However, IntraHealth, in collaboration with the Kenya Ministry of Health, recently trained 172 private sector service providers on implant provision. Of acute interest is to learn more about the potential of cost recovery of implant provision in the private sector.

We propose to build on the findings from the Kenya situation analysis and design a study to help guide policy. Our specific objective is to explore the role the private sector could play in providing lower cost implants should they become available.

In Kenya we will sample approximately 50 private sector providers from unique facilities. We will select matched providers from public sector facilities as well as NGO facilities (total number of facilities assessed per country=150).

At each facility, we will: 1) conduct structured interviews with staff; 2) review service statistics; 3) take inventories of supplies; 4) observe insertions and removals; and 5) conduct client interviews with women who have received insertions at the facility.

These data will be used to compare private sector facilities to public sector and NGO facilities across the following outcomes: 1) price charged for insertion and removal; 2) fully loaded cost of insertion and removal; 3) current volume of implant insertion and removal; 4) quality of service provision including

barriers of access to removal; 5) quality of staff training; and 6) ability and willingness of clients to pay for services.

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Activities, Accomplishments, Problems through December 31, 2008

- A mail/telephone survey was conducted with 112 private sector providers trained by IntraHealth in preparation for writing a protocol in August 2006.
- The approval to implement letter was signed by USAID in October 2006.
- The retrospective cohort of implant users to be interviewed was identified in April 2007.
- The protocol was approved by PHSC in February 2007 and by the local IRB in June 2007.
- The data collection instruments were finalized in May 2007.
- A data monitoring plan was finalized in June 2007.
- An analysis plan was drafted in June 2007.
- The first participant was enrolled in October 2007.
- Data collection was completed in December 2007.
- Data entry was completed in February 2008 and data analysis began the same month.
- Sino-implant (a generic version of Jadelle) was registered in Kenya in August 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The key study results related to study objectives were presented at the Sino-Implant launch meeting in January 2009, including: 1) price charged for insertion and removal; 2) fully loaded cost of insertion and removal; 3) current volume of implant insertion and removal; 4) quality of service provision including barriers of access to removal; 5) quality of staff training; and 6) ability and willingness of clients to pay for services.

Findings and Outcomes:

- The mail/telephone interview had a response rate of 58% with a majority of recently trained private sector providers (79%) saying they currently provide implants. These facilities charge US\$2.80—28.00 per insertion with about a quarter (27%) charging US\$7 and 15% charging US\$14.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Key study-staff from the Kenya office will be retained to help facilitate the Sino-Implant product launch using their experience from this study. Advocacy events and networking with stakeholders will continue.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Jul 2006
Total Approved Budget:	\$ 384,592	Projected End Date:	Apr 2010

Worldwide: Collaborative Research on Implants (FCO 112125/112135)

Technical Monitor: DHubacher

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: LAPM I.A.: At least two replicable approaches to improve provider performance or increase demand for LAPMs identified and evaluated.

Objective(s): The objectives of this subproject are: 1) to provide financial support for a WHO clinical trial to allow continued follow-up of Implanon users through five years; 2) to provide partial support for data management; and 3) to monitor all the clinical trial sites.

Description: Implants are highly effective and acceptable contraceptives. The 2-rod, 5-year Jadelle and the 1-rod, 3-year Implanon implants have been approved by numerous drug regulatory authorities. To date, implant contraception has been limited by the relatively high up-front costs. However, several options could increase the potential of implants becoming a lower-cost, sustainable method: e.g. if Implanon was shown to last longer than the existing three-year labeling; if greater price competition was created between the manufacturers of Implanon and Jadelle; or if new, lower-cost alternatives were to become available.

There are no published studies comparing Jadelle and Implanon. Furthermore, all Implanon data come from studies sponsored by the company that developed and marketed it. As a result, donors, national family programs, and individual providers are shifting from Norplant to Jadelle/Implanon. Therefore the WHO initiated a comparative study on the contraceptive effectiveness and acceptability of these two products. The study has enrolled 2,979 women randomized to Implanon or Jadelle, and 1,000 age-matched women chose to initiate use of copper-IUDs. The last site to complete enrollment was Thailand, on January 31, 2008. The latter group will provide comparative data on incidence of common non-reproductive complaints in users of longer-term reversible contraceptive methods. The trial is being conducted in seven WHO collaborating centers in seven countries.

Unfortunately, support for this study has been severely affected by funding limitations at WHO. In addition, as WHO requested an extended follow-up for more than three years for Implanon users, through a subproject, FHI has been able to provide financial support to the WHO clinical trial to allow continued follow-up of Implanon users through five years. CREP, the data monitoring center is in charge of data management, though FHI provides partial support. FHI staff monitors the clinical trial sites.

Subgrantee(s): World Health Organization

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Activities, Accomplishments, Problems through December 31, 2008

- Markus Steiner visited WHO in August 2006 to discuss future FHI involvement in this ongoing trial.
- An approval to implement letter was signed by USAID in October 2006.
- Technical assistance was provided in October 2006 with the transferring of the database from WHO to the data center in Argentina where the data will be processed.
- A subagreement was signed by all parties in November 2006.
- By March 2007, all seven sites were visited in a first wave of initial site status evaluations.
- A Monitoring Plan was finalized, and monitoring trips were made in May 2007.
- A second wave of monitoring visits to Hungary and Turkey using the newly approved Monitoring Plan began in June 2007.
- In October 2007, Joy Coker became an additional monitor for all sites except Thailand.
- GCP training of the study staff in the Dominican Republic was held in October 2007.
- An Investigators' Meeting was held in Argentina in November 2007.
- An updated Study Manual was finalized in November 2007.
- In December 2007, Dr. Kelly Culwell took over from Dr. Nuriye Ortayli as project manager of the study.
- GCP training of the study staff in Thailand was held in December 2007.
- By December 2007, all seven sites were visited in a second wave of monitoring visits.
- In January 2008, Dr. Culwell joined FHI monitors on Hungary and Turkey site visits.

- In March 2008, the monitoring plan was updated to v2.0, which focuses monitoring on overall study compliance, key endpoint data, informed consents, and regulatory documents.
- In May 2008, CREP implemented the automatic querying system and sent six of the seven sites queries regarding missing forms.
- Important informed consent violations found in Brazil, Turkey, and Zimbabwe were addressed with Dr. Culwell who raised them with the WHO Specialist Panel during a meeting held in July 2008.
- Monitoring visits were completed in Brazil in July 2008, Hungary and Turkey in August/September 2008, Thailand in September and December 2008 and the Dominican Republic in December 2008.
- Dr. Olav Meirik began writing the first study publication in September 2008.
- The first wave of data queries were completed in December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- A second project newsletter was issued to investigators in January 2009.
- Some staff changes at WHO, CREP, and the Chile site occurred.
- Monitoring visits were completed during the period January 2009 through June 2009 in Hungary-March, Turkey-April, Thailand-May, Brazil-June, Chile-June.
- Follow-up data querying activities continued.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- A final wave of queries will be completed for missing data on forms.
- Final FHI monitoring visits will be conducted by April 2010, unless more funding becomes available to extend FHI involvement in this WHO project.
- Note that FHI will propose transitioning some of this activity to PROGRESS. If approved in the PROGRESS Year 3 Workplan (beginning July 1, 2010), the projected end date will be extended.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 112135 Sep 2006 112125 Jul 2006
Total Approved Budget:	112135 \$ 166,294	Projected End Date: Apr 2010
	112125 \$ 893,758	
	<hr/>	
	\$ 1,060,052	

India: Vasectomy Acceptability among Clients and Providers in Uttar Pradesh (FCO 116100/116111)

Technical Monitor: PAlleman-Valez

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: LAPM I.A.: At least two replicable approaches to improve provider performance or increase demand for LAPMs identified and evaluated.
LAPM III.A.: Evidence provided from two or more demonstration projects (in partnership with service delivery organizations) on effective approaches to increasing male involvement in FP and uptake of vasectomy.

Objective(s): To establish evidence-based guidelines for improving vasectomy uptake in Uttar Pradesh and other states of India, as well as other countries within the region. This subproject will expand upon previous vasectomy research work done in other regions, and ultimately improve understanding of the barriers to vasectomy uptake.

Description: Over the past decade, calls have been made on several fronts to involve men more in matters of reproductive health and family planning. One way to better involve men in family planning is to promote male-oriented methods of contraception thereby giving couples more contraceptive choices. Vasectomy has long been recognized as a highly effective method of contraception. Compared to female sterilization, vasectomy is more convenient, less expensive, and safer. Despite the many benefits of vasectomy, it remains an under-utilized method of contraception in most countries. Sterilization is the most widely used contraceptive method worldwide, yet female sterilization accounts for the majority of procedures, more than five times that of vasectomy. Vasectomy accounts for only 7% of all modern contraceptive use at the global level. In the majority of less-developed countries, this figure drops to less than 1%. In India, female sterilization outnumbers male sterilization by a factor of 18 to 1 nationwide, and in Uttar Pradesh, this ratio is more than 100 to 1.

This subproject will be a collaborative venture between FHI and EngenderHealth, and will take place in two geographically distinct districts of Uttar Pradesh - Ballia and Meerut. The study will investigate vasectomy acceptability from both the supply and demand sides of the equation and will collect data from vasectomy clients and their wives, potential vasectomy clients and their wives, tubal ligation clients and their husbands, family planning providers, and public health stakeholders.

The study methodology includes: secondary data analysis and synthesis, focus groups, in-depth interviews and observation. The study will involve approximately 285 participants. The analytical approach will triangulate all data sources. Findings from this study will be given to government officials of Uttar Pradesh to be fed into the design of ongoing programs.

Subgrantee(s): EngenderHealth

Collaborating Agency(s): EngenderHealth

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Activities, Accomplishments, Problems through December 31, 2008

- A draft protocol was written in November 2005.
- Guest and Bunce traveled to India December 7-16, 2005 and met with government officials, the USAID mission, local research organizations, and representatives from various family planning stakeholders (UNFPA, SIFPSA, Population Council).
- A local implementing agency, EngenderHealth (EH), was identified to do the research.
- The protocol was revised based on information obtained during the December trip.
- USAID signed the approval to implement letter on March 31, 2006 (India Mission) and April 10, 2006 (DC office).
- The protocol was submitted to PHSC and obtained conditional approval (dependent on local IRB approval) on April 12, 2006.
- A subagreement was signed with EngenderHealth India in May 2006.
- A protocol was submitted to the local IRB (CEHAT) in July 2006. Additional information requested by the IRB was provided.
- Alleman became the technical monitor of study in December 2006.
- Due to the unforeseen requirement to obtain Health Ministry Screening Committee (HMSC) approval, initiation of data collection was delayed by approximately 6 months. CEHAT and HMSC approval for pretesting of study instruments was received in January 2007.
- Alleman conducted a training in ethics, data collection and study management in April 2007; a study stakeholder meeting was also conducted.

- Pretest data collection began in April 2007; instruments and the protocol were revised per results in April 2007.
- Renewal approval was received from PHSC in April 2007.
- Pretest study results and revised instruments were submitted to CEHAT in May 2007 and the protocol obtained final approval from CEHAT on May 13, 2007.
- Alleman drafted a data analysis plan in November 2007.
- In November 2007, a study monitoring visit was conducted on site by PI and FHI/India staff. In June 2008 Alleman conducted a training of five EH staff on qualitative data analysis and a training of 12 FHI India staff on qualitative research method and proposal development.
- Data collection was completed in August 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- On 22 September 2008 a Dissemination Meeting was held in Lucknow. There were 30 participants from national, state and community levels. There were participants from the Uttar Pradesh Government, King George Medical College, Urology-NSV Unit, EngenderHealth and State Innovations in Family Planning Services Project Agency (SIFPSA), and the Ministry of Health and Family Welfare.
- Alleman left FHI in February 2009. Prior to her departure she completed a first draft of the final report for the study.
- McCarraher assumed the role of technical monitor.
- After an internal review of the final report, it was decided that further analysis was necessary.
- McCarraher began the search for an independent consultant to rewrite the final report which will include re-analyzing some of the data that were collected in order to answer the primary study objectives.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- An independent consultant will be identified and hired to complete the final report.
- The final report will be sent to the FHI India office for dissemination.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 116100 Jul 2005 116111 Jul 2005
Total Approved Budget:	116100 \$ 222,710	Projected End Date: Apr 2010
	116111 \$ 103,106	
	\$ 325,816	

India: RCT of Three Vasectomy Techniques (FCO 12098/112128)

Technical Monitor: DSokal

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: LAPM I.A.: At least two replicable approaches to improve provider performance or increase demand for LAPMs identified and evaluated.

LAPM III.A.: Evidence provided from two or more demonstration projects (in partnership with service delivery organizations) on effective approaches to increasing male involvement in FP and uptake of vasectomy.

Objective(s): To compare the effectiveness of three vas occlusion techniques, all using the no-scalpel vasectomy approach for isolation of the vas.

Description: Vasectomy is one of the safest and most effective methods of contraception, but in low-resource settings as many as 1 in 20 couples (5%) may conceive a pregnancy after vasectomy when ligation and excision is used as the method of vas occlusion (Wang, 2002; Nazerali, 2003). This proposed research is a randomized, controlled multicenter trial, to be conducted by the Indian Council of Medical Research (ICMR), New Delhi, with technical assistance from Family Health International. The study will compare the effectiveness of three vas occlusion techniques, all using the no-scalpel vasectomy (NSV) approach for isolation of the vas: 1) ligation and excision of about 1 cm of the vas, with fascial interposition; 2) thermal cautery with excision of about 1 cm of the vas; and 3) thermal cautery with excision of about 1 cm of the vas, and with fascial interposition.

The study will also compare the frequency of early spontaneous recanalization, surgical difficulties and the safety of the three techniques. Each of 1,500 participants will be randomized to one of the three groups and will be followed for 12 months, with semen analyses beginning 8 weeks after the vasectomy.

Fascial interposition is considered technically difficult and time consuming by many surgeons, so it would be extremely useful to know whether cautery without fascial interposition is more effective than ligation and excision with fascial interposition. Thermal cautery of the vas can be performed using small, low-cost, hand-held units powered by AA alkaline batteries, but this technique is not currently used for vas occlusion in low-resource settings. Depending on the results of this study, thermal cautery devices could be recommended for use in low-resource settings.

Collaborating Agency(s): Indian Council of Medical Research, New Delhi; PATH

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Activities, Accomplishments, Problems through December 31, 2008

- Notification of study approval by the Indo-US grant committee was received.
- Discussions began with USAID and NIH on arranging funding from NIH. Approval was received from USAID in December 2006 for funding to complement NIH monies.
- The study protocol was approved by FHI's PHSC in February 2007. In the same month it was reviewed with Prof. Kaza and other key researchers at the annual meeting of the No-Scalpel Vasectomy Surgeons of India in Amritsar. Expedited review was obtained in June 2007.
- PATH of Seattle obtained USAID funding to help prepare vasectomy training materials for the study, including videos of each method to be studied for external review prior to study initiation. PATH staff met with Prof. Kaza and Dr. Shekhar in Delhi in May 2007 to define tasks and agree on a timeline.
- FCO 12098 was opened with funding from CONRAD, originating with NIH, in July 2007.
- A fifth investigator and site were identified by ICMR in Amritsar.
- FHI sent the revised protocol to ICMR for review by Indian investigators and for submission to local IRBs in June 2007.
- CRFs were finalized and sent to ICMR for review.
- IRB approvals were obtained in October 2007 at two of the five Indian sites: Maulana Azad Medical College (Prof. Kaza); and St. Stephen's Hospital (Dr. Grover).
- FHI staff visited ICMR in November and December 2007 and revised the data management plan in consultation with ICMR staff.
- Prof. Kaza completed the video sessions to document the surgical techniques to be used.
- FHI staff visited ICMR in May 2008, and reviewed the data management plan and CRF's in consultation with ICMR staff.

- CRF's were revised (mostly changes to the format requested by ICMR); revised versions were sent to ICMR.
- PATH completed editing of Prof. Kaza's video work, and sent the videos on DVDs to two independent reviewers. A summary/consensus document was prepared after discussions by e-mail and a teleconference with Professor Kaza.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- A study initiation meeting was held in January 2009, and a study manual and training materials were prepared
- The questionnaire was revised based on comments at the study initiation meeting.
- Following the study initiation meeting, the study was withdrawn from consideration by FHI's PHSC, due to lack of further USAID funding. Ethical oversight responsibility will rest with ICMR and the local hospitals.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- ICMR has adequate funding to implement the study, and is planning to initiate enrollment in August or September 2009.
- ICMR Co-PI Dr. Chander Shekhar will seek Government of India funding to permit additional technical assistance from FHI's GCP trainer, Belinda Irsula, to help with monitoring of the study and staff training.

Funding Source(s):	CONRAD/Private; USAID - US Agency for International Development/USAID: Core	FCO Approved: 112128 Nov 2006 12098 Jul 2007
Total Approved Budget:	112128 \$ 250,000	Projected End Date: Jun 2012
	12098 \$ 55,209	
	\$ 305,209	

Malawi: Using Male Educators to Increase Family Planning Use among Young Married Couples (FCO 116108/116109)

Technical Monitor: GGuest

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: LAPM III.A.: Evidence provided from two or more demonstration projects (in partnership with service delivery organizations) on effective approaches to increasing male involvement in FP and uptake of vasectomy.

Objective(s): To test the effectiveness of an intervention that involves utilizing "male motivators" to increase contraceptive uptake among 400 young married couples.
To obtain female partners' perspectives about the intervention.

Description: This is a randomized controlled trial that will test the effectiveness of an intervention that involves utilizing "male motivators" to increase contraceptive uptake among 400 young married couples. Study participants will be adult men in committed relationships with women under the age of 25. It is important to know if/how educating men will have an effect on contraceptive uptake.

Participants will be given a baseline survey - documenting contraceptive attitudes, use history, and access - and then randomized to either a control condition or the intervention arm (200 men per arm). The intervention consists of training 40 male exemplars to provide family planning information and gender equity training over an 8 month period (6 visits, about 1 month apart). A follow-up survey will be administered to all participants after the intervention is complete. A randomly selected subset of 15 men in the intervention arm will be chosen for a qualitative interview at the time of the follow-up survey.

This subproject is being carried out in collaboration with Save the Children. Save the Children will be responsible for developing the intervention and implementing the research on the ground.

Subgrantee(s): Save the Children

Collaborating Agency(s): Save the Children

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Activities, Accomplishments, Problems through December 31, 2008

- Staff worked with Save the Children to develop a protocol.
- The approval to implement was approved by USAID on January 18, 2007.
- The protocol was approved by PHSC on February 20, 2007.
- A subagreement with Save the Children was executed in February 2007.
- Intervention and training materials were developed.
- FHI staff traveled to Malawi in late May/early June 2007 to train field staff.
- Field staff recruited male educators as well as eligible couples for the intervention.
- Field staff pre-tested and revised the survey.
- The baseline survey was completed in December 2007, with 398 enrolled.
- Baseline survey data were cleaned and entered into the database.
- Field staff completed training for the male educators.
- Male educators completed the intervention.
- An experience-sharing workshop for male educators was held by field staff in Malawi.
- The endline survey was completed in September 2008.
- Eighteen in-depth interviews were completed in October 2008.
- An extension of the subproject was approved by USAID on 01/05/2009, to conduct 30 in-depth interviews with female partners of the study.
- Data analysis began in November 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Primary data analysis was completed in March 2009.
- A manuscript was submitted to Studies in Family Planning on May 20, 2009, titled "Using Male Educators to Increase Family Planning Uptake among Young Couples: The Malawi Male Motivator Project."
- PHSC approval was received on February 24, 2009 for an amendment to the study that adds 30 in-depth interviews with women.
- A protocol amendment was submitted to the Malawi IRB on June 24, 2009.

Findings and Outcomes:

- After the intervention, contraceptive use differed significantly between the two groups: Intervention 78%, Control 59% ($p < .01$).

- Quantitative and qualitative data indicate that communication within couples influenced uptake (p < .01), condoms were the most frequently selected family planning method, and selection of method was based on ease of use and limited number of side-effects.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Malawi IRB approval will be obtained for the amendment.
- The field team will begin data collection for the 2nd phase of the study (30 in-depth interviews).
- The second phase of the study (30 in-depth interviews) will be conducted.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 116108	Dec 2006
		116109	Feb 2007
Total Approved Budget:	116108 \$	143,190	Projected End Date: Mar 2010
	116109 \$	86,057	
	\$	<u>229,247</u>	

Uganda: Repositioning Family Planning: Revitalizing LAPMs (FCO 113110)

Technical Monitor: EMcGinn

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: LAPM I.C.: Evidence-based LAPM programming approaches institutionalized and implemented by at least three service-delivery organizations in at least five countries through information dissemination, technical assistance, and collaboration with partners.

Objective(s): 1) To provide technical assistance and support to the Uganda Ministry of Health (MoH) in order to mobilize in-country stakeholders to undertake a revitalization of long-acting and permanent methods (LAPMs), particularly the IUD; and 2) to provide technical assistance to the MoH and in-country partners (e.g., ACQUIRE/EngenderHealth) in implementing evidence-based LAPM activities, and adapting and implementing lessons learned from the Kenya IUD Rehabilitation Initiative 2002-2005.

Note: Two additional objectives added in 2007-2008 are: (1) to conduct three additional CMEs at the district level; and (2) to provide technical assistance to EngenderHealth/ACQUIRE on assessing the costs of LAPM revitalization activities.

Description: Ever use of contraceptives by women in Uganda increased four-fold between 1988 and 2001, from around seven percent to 35 percent. Today, pills, condoms, and injectables dominate the method mix, and fewer than seven percent of contraceptive users have ever used IUDs, female sterilization, or vasectomy. Yet around a quarter of urban women, and a third of rural women, indicate an unmet need to space or limit births.

In response to these needs, this subproject engaged in LAPM activities (focused on the IUD) in Uganda. These were considered continuing activities which were initiated in January 2005 (see FCO

3007), when the MoH requested FHI's technical assistance with expanding IUD access in Uganda, in collaboration with EngenderHealth's ACQUIRE Project (which received funding in October 2004 to undertake IUD revitalization activities within the context of promoting LAPMs). FHI initiated this collaboration by: 1) providing assistance to the MoH to establish a national "Repositioning Family Planning Working Group," composed of in-country stakeholders and EngenderHealth/ACQUIRE and FHI; 2) developing an addendum to the 2001 national family planning guidelines providing an evidence-based update on eligibility criteria for all methods; and 3) providing technical assistance to EngenderHealth on costing and monitoring and evaluation of their LAPM activities in the district of Mayuge, which informed scale up in other districts.

Collaborating Agency(s): EngenderHealth; Ministry of Health, Uganda

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Activities, Accomplishments, Problems through December 31, 2008

- For additional RY 2005-06 accomplishments please see the CRTU Annual Report (2006-2007) and Workplan (2007-2008).
- Four continuing medical education (CME) workshops were conducted (Mubende, Luwero, Arua, and Lira) in April 2006. During these workshops, staff promoted and distributed the National RH Guidelines addendum and FHI's Checklists to approximately 175 providers.
- FHI agreed to provide costing TA to ACQUIRE/EngenderHealth's work on LAPM revitalization in four districts in Uganda. FHI developed a costing instrument which could be implemented by local staff.
- Dr. Blaakman worked with EngenderHealth staff (Kakande and Wiltshire) to begin to obtain preliminary cost data estimates for these districts.
- Following requests from the MoH, two additional CME workshops were held in July 2006 for approximately 80 RH trainers from nursing training institutions and medical colleges. Apart from a knowledge update on the WHO Medical Eligibility Criteria for Contraceptive use, the workshops were used as a forum to disseminate the National Guidelines addendum, FHI's DMPA, COC, IUD, and Pregnancy Checklists.
- FHI supported the MOH in its efforts to establish a Repositioning FP Working Group and coordinated several meetings in 2005-06. By 2007, these meetings were being conducted with limited FHI intervention, reflecting institutionalization of this forum.
- Distribution of the FHI IUD checklist was ongoing; 300 checklists were sent to Pathfinder International (5/25/07) and 70 to RH trainers and service providers (5/3/07). See FCO 113107 and 113112.
- In August 2007, FHI completed an "Evaluation of Uganda CME workshops. Final report" (M2007-42). As a result of this evaluation, the MOH requested 3 additional CMEs from FHI. FHI delivered to EngenderHealth a brief report on preliminary cost estimates of scaling up LAPMs in the districts of Mayuge and Hoima.
- Additional funds and an extension were requested in order to complete additional TA and 3 CMEs.
- In March 2008 FHI conducted a CME for 28 FP service providers in Nakaseke district.
- In June 2008 3 additional CMEs were conducted in Kanungu, Bugiri and Busia districts.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Due to staffing turnover issues, FHI was unable to complete and provide a final report on the costing analysis for EngenderHealth. EngenderHealth was understanding and felt the preliminary costs estimates were adequate for their internal use. No additional follow-up is planned.

Findings and Outcomes:

- The quarterly family planning working group meetings served as a forum to bring together key stakeholders in reproductive health and discuss ways to synergize efforts aimed at revitalizing family planning. This forum has been institutionalized within the FP/RH community, and will continue beyond this subproject.
- Findings of the CME evaluation include: participants found them extremely useful and reported they influenced their work; the CMEs seemed to be instrumental in influencing community

representatives' attitudes about FP; it may be useful to separate clinical and non-clinical audiences to tailor key messages appropriately; not enough job aids/tools were available for all participants; future M&E efforts should consider testing knowledge of providers to see if they are retaining the information learned in the workshop. As a result, the Ministry of Health requested FHI conduct three additional CMEs in 2007-2008.

- The additional CME conducted in 2008 supported ongoing efforts by FHI to promote CBD of DMPA by updating the skills of FP providers in the CBD of DMPA districts.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2005
Total Approved Budget:	\$ 219,351	Projected End Date:	Jul 2008

Worldwide: Global Advocacy & Stakeholder Engagement for LAPMs (FCO 113109)

Technical Monitor: TZan

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: LAPM I.C.: Evidence-based LAPM programming approaches institutionalized and implemented by at least three service-delivery organizations in at least five countries through information dissemination, technical assistance, and collaboration with partners.

Objective(s): 1) To broaden advocacy messages beyond IUDs, and to ensure that "Repositioning Family Planning" efforts include a revitalization of LAPMs based on evidence and best programming practices; and 2) to engage in-country stakeholders on revitalization of LAPMs and support champions for south-to-south learning of best practices on LAPM revitalization efforts.

Description: Despite the Cairo goal to provide couples with a "full range" of family planning methods, many couples in Sub-Saharan Africa (SSA) still lack choices regarding contraception. For instance, although LAPMs are safe and cost-effective contraceptive choices, they are used less often in SSA than in other developing countries. The most underused LAPMs include IUDs, vasectomy, and implants. The aim of this subproject is to effectively influence global, regional, and national key change agents and stakeholders towards revitalizing uptake of underutilized LAPMs in SSA. A broad advocacy effort on underused LAPMs will be carried out at both global and country levels. At the global level, activities will include developing evidence-based advocacy messages on LAPMs, and launching a series of advocacy briefs on a variety of LAPM topics over a period of eight weeks culminating in an electronic forum discussion over the IBP electronic communication system (ECS). The electronic forum will be designed to provide participants with up-to-date and state-of-the-art information on what is happening in the field and will provide an opportunity for synergy between sharing global best practices and country-based experiences. Furthermore, in November 2006, an expert consultation on vasectomy was organized to discuss future programmatic and non-clinical research needs to improve success of such programs.

At country level, the focus will be on key policy makers, health and development professionals, and the private sector to not only raise their awareness and influence them to revitalize LAPMs, but also to

work with in-country service delivery partners to assist them in developing a strategy for LAPM revitalization. These efforts will also be complimented by South-to-South exchanges and technical assistance geared to promote knowledge transfer and adoption of best practices.

Collaborating Agency(s): EngenderHealth; Management Sciences for Health (MSH)

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Activities, Accomplishments, Problems through December 31, 2008

- For prior accomplishments during the period of July 2005-June 2007, please see CRTU Annual Reports.
- In Aug '07, FHI provided input to the technical brief "Linking CBFP with Long Acting Methods," managed by CSTS+ and circulated to CAs working on community-based family planning.
- In Oct '07, a Global Health Technical Brief on Implants was developed and posted on the MAQ website.
- In Nov '07, the report of the Vasectomy experts' consultation was finalized and circulated to meeting participants.
- In Jan '08, the LAPM Advocacy Package was launched. The French version was released in April '08. A total of 1083 English and 241 French copies were disseminated in '08. It was also posted in the USAID Repositioning in Action E-Bulletin - April 2008.
- FHI, with EngenderHealth and MSH, hosted a 5-day GEN forum on Effective Programming for LAPMs in April '08. 91 people participated with 196 logins and 50 postings.
- Kenya: A country advocacy plan was developed and implementation began in June/July '08. In Dec '08, Kenya's national LAPM strategy, developed with support from FHI, was finalized and endorsed by the Ministry of Health's Division of Reproductive Health. From July-Dec '08, 200 LAPM Advocacy Packages were distributed in-country.
- Uganda: In Oct '08, the Uganda advocacy plan was finalized and in Nov '08, FHI staff held three meetings in three regions to discuss scaling up use of LAPMs. 131 LAPM Advocacy Packages were distributed. Each region developed action plans.
- Tanzania: In Oct '08, FHI presented to 30 participants on the use of champions to facilitate changes in policy and practice at a workshop. FHI also authored a chapter in a larger document on the Guidelines and Recommendations for Identifying and Recruiting Family Planning Champions.
- In Oct '08, a new Checklist for Screening Clients Who Want to Initiate Use of Contraceptive Implants was developed and launched. Electronic checklists were initially distributed to 16 RH/FP list serves, 4 external Web sites, and 6,000 persons from the FHI Online Rolodex. As of Dec '08, 792 Implants checklists were disseminated in 18 countries.
- In Nov '08, the WHO MEC chart was updated and Implants were included.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- 262 English and 13 French copies of the LAPM Advocacy Package were distributed globally between January-June 2009.
- The Training and Reference Guide for a Screening Checklist to Initiate Use of Contraceptive Implants was finalized and 1,000 copies were printed (with accompanying CD) as well as 500 additional CDs for global dissemination.
- In Kenya: A national launch for LAPM strategy was held with support of MOH and partners and over 80 attendants resulting in press coverage; conducted 2 regional advocacy meetings on LAPMs were conducted, distributing LAPM strategy, comparative assessment, and advocacy package; a total of 2,000 copies of LAPM strategy and 1,000 copies of comparative assessment were distributed in-country.
- There were no additional activities in Uganda; there is a possibility for continuation in Yr 5.
- In Tanzania: a consultant was hired to coordinate the Advocacy Package for Champions Initiative in Repositioning Family Planning. As part of the activity, the following documents were developed in collaboration with the MOH and key stakeholders (including EngenderHealth): framework/guidance for champions, orientation package for champions, and advocacy package for champions (Cost-share with FCO 113148).

Findings and Outcomes:

- The vasectomy experts' consultation meeting held in November 2006 identified several priorities and recommendations for investments in vasectomy programs, advocacy, and research, some of which include the following: 1) efforts should focus on settings in which vasectomy services are already available and where vasectomy revitalization efforts are most likely to succeed ("low-hanging fruit"); 2) prevalence should not be the only indicator of success in a vasectomy program. Programs should measure incidence, by provider as well as by population, to give a better indication of vasectomy's contribution to FP; 3) further research is needed to address questions on: a) the cost of vasectomy programs and how to provide cost-effective services; b) the effectiveness and feasibility of vasectomy techniques (e.g. Why aren't providers using better techniques? What kind of training is required to ensure adoption, mastery, and sustained use of new techniques?); c) how to create and sustain demand and acceptability of vasectomy; and d) how to create demand for vasectomy and build support for vasectomy programs.
- The GEN forum on Effective Programming for LAPMs had a high posting to participant ratio, indicating active participation. The primary themes that emerged during the forum discussion were: the need for a diverse group of stakeholders for LAPM revitalization, the importance of other Ministries beyond the MoH, such as the Ministry of Finance in the process, as well as champions at multiple levels. In addition, the central importance of the influence of supply side factors in driving demand came up, including contraceptive security and avoiding stockouts of LAPM commodities, equipment and supplies, reducing provider bias and other medical barriers.
- Districts in Uganda are aware of the benefits of LAPMs, but their efforts to scale up use and access are hampered mainly by unavailability of funds and shortage of staff.
- In December 2008, Kenya's MOH endorsed a national LAPM strategy developed with support from FHI.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Kenya: Hold 2 more regional advocacy meetings to disseminate the LAPM strategy, comparative assessment and advocacy package; continue disseminating the LAPM advocacy package as opportunities arise.
- Uganda: Support select action items in regional work plans to facilitate LAPM revitalization. Possible action items could include: integrating LAPMs into CMEs; conducting orientations for district councils on LAPMs; community awareness-raising; outreach by hospital staff to rural health facilities.
- Tanzania: Print and disseminate Advocacy Package at the zonal level in select areas.
- Support new efforts identified in the three countries where in-country advocacy is on-going.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2005
Total Approved Budget:	\$ 587,665	Projected End Date:	Apr 2010

USA: Non-Invasive Approaches to Male Sterilization (FCO 172012/172013)

Technical Monitor: DSokal

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: LAPM III.C.: The effectiveness of more easily reversible methods of vasectomy, such as the Shepherd IVD (intra-vas device), and their impact on method uptake evaluated.

Objective(s): To administer a grant to Prof. Nate Fried at the University of North Carolina (UNC) Charlotte to study non-invasive methods of male sterilization. The objective are to: 1) show that the vas deferens can be thermally occluded safely and effectively in a canine model; 2) confirm the mechanism of vas deferens occlusion; and 3) conduct long-term azoospermia ejaculation studies in canines to determine whether or not there is permanent male sterilization without recanalization.

Description: The overall objective of the proposed research is to study noninvasive methods for thermal occlusion of the vas deferens with the long-term goal of developing a completely noninvasive approach to male sterilization. In the absence of progress on the development of a male birth control pill, the next most effective method of male contraception is male sterilization. Male sterilization (vasectomy) has a higher success rate, lower complication rate, is less expensive, and is easier to perform than female sterilization (tubal ligation). Fear of complications related to vasectomy (e.g. incision, bleeding, and potential for infection) was most frequently cited as the primary reason for couples choosing tubal ligation over vasectomy. Since male sterilization is currently an elective procedure, any improvement in the method of the procedure which eliminates these male concerns has the potential to greatly increase the popularity of the procedure. A completely noninvasive method of male sterilization would eliminate incision, bleeding, and potential infection associated with conventional vasectomy. Preliminary experiments in our laboratory have demonstrated that it is possible to use therapeutic focused ultrasound to noninvasively target the vas deferens for thermal coagulation, scarring, and occlusion. This method has the potential to be developed into a completely noninvasive method of male sterilization.

This project will conduct fundamental studies in dogs that should significantly advance our understanding of the mechanism by which thermal energy occludes the vas deferens, and should lead to the optimization of the treatment parameters for successful vas occlusion, and provide long-term pre-clinical results demonstrating safety and efficacy of this completely noninvasive, incision-less method of male sterilization.

Funding provided by an NIH IAA for FHI to administer a grant for Prof. Fried at UNC Charlotte, and for David Sokal to monitor the progress of the research.

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Activities, Accomplishments, Problems through December 31, 2008

- Administrative arrangements began shortly after the funding was agreed upon in October 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Administrative arrangements were finalized, and a subcontract was signed in March 2009.
- In May 2009, FHI informed Dr. Fried of potential collaborators in the private sector who are also looking at high intensity focused ultrasound (HIFU) for the vasectomy indication.
- Dr. Fried has hired staff and begun implementing project activities, including a trip to the Hopkins labs in June 2009 to coordinate the work there.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Conduct animal studies to achieve objective 1.
- Two site visits will be conducted, one at UNC-Charlotte and one at Johns Hopkins.
- Dr. Fried will give a talk at FHI describing his research.
- Funding under the CRTU will end for Dr. Fried's subagreement on February 28, 2010; a new IAA will fund an extension under PROGRESS.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: IAA	FCO Approved: 172012 Dec 2008 172013 Dec 2008									
Total Approved Budget:	<table border="0" style="margin-left: 20px;"> <tr> <td style="text-align: right;">172012</td> <td style="text-align: right;">\$</td> <td style="text-align: right;">12,925</td> </tr> <tr> <td style="text-align: right;">172013</td> <td style="text-align: right;">\$</td> <td style="text-align: right;">209,425</td> </tr> <tr> <td></td> <td style="text-align: right;">\$</td> <td style="text-align: right; border-top: 1px solid black;">222,350</td> </tr> </table>	172012	\$	12,925	172013	\$	209,425		\$	222,350	Projected End Date: Apr 2010
172012	\$	12,925									
172013	\$	209,425									
	\$	222,350									

MICROBICIDES

GOALS	OUTCOMES
<p>I. To develop, evaluate and seek approval for microbicides with and without contraceptive effects</p>	<ul style="list-style-type: none"> A. Five pivotal trials of topical microbicides completed. Results will submitted to the FDA, other regulatory bodies, and other interested parties as appropriate. B. Through Phase I trials in collaboration with CONRAD, the initial safety of three new microbicide candidates determined. Results will submitted to the FDA, other regulatory bodies, and other interested parties as appropriate. C. Five new sites for pivotal microbicide trials established, qualified, and functioning, with appropriate stakeholder involvement. D. Two new approaches for evaluating the safety or effectiveness of topical microbicides developed and validated. Results will be shared with other research organizations, funding agencies, and other interested parties. E. A new multistage, interdisciplinary paradigm based on lessons learned from Phase I, II and III microbicide trials developed. Results will be shared with other research organizations, funding agencies, and other interested parties. F. Two new delivery systems/methods of administration for topical microbicides evaluated. Results will submitted to the FDA, other regulatory bodies, and other interested parties as appropriate. G. One pivotal trial comparing oral versus topical microbicides implemented. Results will submitted to the FDA, other regulatory bodies, and other interested parties as appropriate. H. Social and behavioral components and/or ancillary studies within microbicide clinical trials conducted to provide information on: sexual relationships and practices, the social and cultural context for microbicides, potential for covert use, and community support and policies. I. Innovative strategies to increase retention and reduce product interruptions in trials developed and tested.
<p>II. To inform microbicide introduction by research and information dissemination to stakeholders</p> <p><i>(NB: This goal and its outcomes are lower priority until such time that a microbicide is approved.)</i></p>	<ul style="list-style-type: none"> A. Acceptability of at least three different formulations or microbicide delivery systems assessed in at least three regions. B. In collaboration with various stakeholders (potential users, providers, women's groups, ministries of health, and service delivery programs), a plan to determine appropriate population and service delivery targets for the introduction of the first available microbicides developed. C. Acceptability and feasibility of integrating microbicides into STI and VCT clinics and other services used by individuals at high risk for HIV acquisition evaluated. D. Messages and materials for microbicides in various service delivery settings developed and evaluated. E. The impact of microbicide introduction and use (contraceptive and non-contraceptive) on family

GOALS	OUTCOMES
	planning use and pregnancy evaluated. F. Clients' willingness to pay for microbicides assessed. G. At least one pre-introductory study of effectiveness, extended safety and acceptability conducted while product regulatory approval is pending. Results will support local approvals and help further guide product introduction once approval is obtained. H. Programmatic and biomedical lessons learned from research synthesized, and results of these evaluations disseminated via professional literature, outreach, technical assistance, client materials, or other means to service delivery partners, normative bodies, USAID, clients, and others for incorporation into practice and procurement decisions.
III. To introduce microbicides and enhance current consistent use of microbicides by populations with greatest need	A. Uptake (actual use) and impact of microbicide use among the first target population assessed <i>as products become available</i> . B. Product quality assurance methodologies for testing and analyzing candidate microbicides adopted and further refined, if necessary, promoting independent quality assurance of microbicides.

FHI/NC subprojects fully or partially funded by USAID's CTR and CRTU Agreement:

- Worldwide: Expert Meeting on Microbicide Adherence and Its Measurement (FCO 136110)
- USA: MRI Studies of New Microbicide Formulations with CONRAD (FCO 132112)
- USA: Phase I Safety Study of Q-2 Vaginal Gel (FCO 132148)
- USA: UC-781 PK Study (FCO 132147)
- USA: Male Tolerance Study of UC-781 Gel with CONRAD (FCO 132111)
- South Africa: CAPRISA Case-Control Study (FCO 136104/136107)
- Nigeria: Savvy Phase III RCT, Nigeria (FCO 2277/132104/132126/132127/132128/132139)
- Ghana: Savvy® Phase III RCT, Ghana (FCO 2278/132105/132121/132140/132141/132144)
- Africa Regional: Truvada Phase III Clinical Trial (FCO 12302/12322/12341/132146/132157/132158/132159/132168/132169/132170/132179/132180)
- South Africa: Truvada Study: Site Preparedness (FCO 12331/12332/12333/12334/12335/12336/136105/136106/136108/136111/136112)

Africa Regional: Truvada Study: Social, Behavioral & Community Activities (FCO 12354/12355/136109/136117/136121/136122)

South Africa: RCT of Tenofovir Gel (FCO 132108/132119/132120)

Nigeria: Randomized Controlled Trial of Cellulose Sulfate (CS) Gel and HIV in Nigeria (FCO 2266/132100/132122/132123/132124/132125/132143)

USA: New Delivery Device for Vaginal Microbicides (FCO 1844/2290/132103/132178)

Madagascar: Diaphragm Plus Microbicide: Expansion study of STDs (FCO 132150/132151)

India: Sustained Acceptability of Vaginal Microbicides: Male and Female Perspectives (FCO 9386/136100/136102)

USA: Assessment of Soluble and Cellular Markers of Inflammation after Vaginal Product Use (FCO 132109)

Worldwide: Independent Monitoring of CONRAD Collaborative Studies (FCO 2285/132101)

Worldwide: Site Identification, Assessment & Development (FCO 1041/132113/132118/132145/132152/132153/132154/132155/132156/132160/132161/132162/132163/132164/132165/132166/132167/132171/132172/132173/132174/132175/136114/136116/136118)

Worldwide: Use of DHS Data for Site ID Recruitment (FCO 136103)

Worldwide: Assuring Stakeholder Involvement at New Microbicide Research Site (FCO 136115)

Worldwide: Tool for Local Lexicon to Explain Difficult Informed Consent Terms (FCO 136101)

Worldwide: Good Microbicide Communication Practice (FCO 133101)

Africa Regional: Evaluating Informed Consent Comprehension (FCO 136113)

USA: Statistical Support - Microbicides (FCO 139101)

USA: Biomarkers of Semen Exposure Study (FCO 132149)

Africa Regional: Improving Measurement of Pregnancy Intentions (FCO 134000/134001)

Africa Regional: Sociobehavioral Research and Community Planning to Develop Site-Specific Pilot Intervention Plans for PrEP Rollout (FCO 136123)

Worldwide: Expert Meeting on Microbicide Adherence and Its Measurement (FCO 136110)

Technical Monitor: BTolley

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.H.: Social and behavioral components and/or ancillary studies within microbicide clinical trials conducted to provide information on: sexual relationships and practices, the social and cultural context for microbicides, potential for covert use, and community support and policies.

Objective(s): 1) To apply a "Mixture Models for Estimating Developmental Trajectories" approach to a subset of Savvy Ghana adherence data and document procedures and outcomes; 2) if the approach provides insight, to share procedures with other trial implementing agencies and request that they prepare similar analyses; 3) to work with Alliance to finalize the agenda and list of agencies/individuals to attend the meeting; 4) to assist in meeting implementation; and 5) to write a "white paper" on meeting proceedings.

Description: For a microbicide trial to successfully determine effectiveness, participants must be exposed to HIV and adhere to product use. Many sub-studies indicate inconsistent product adherence and inaccurate reporting of sexual and product behavior. Consequently, better methods are needed to improve adherence and its measurement. These two broad issues were examined.

FHI collaborated with the Alliance for Microbicide Development organization to plan and implement an Expert Meeting on Adherence and Its Measurement.

Improving Adherence: To date, microbicide researchers have not systematically reviewed or tested approaches to maximize adherence within their trials. Some potential strategies might include shortening trial follow-up or incorporating adherence-related interventions, for example, motivational interviewing, the development of adherence messages tailored to individual circumstances, or the use of peer motivators to increase compliance. However, there are trade-offs to these various approaches.

Improving Its Measurement: The Microbicide Development Strategy (MDS) report identified the lack of clarity on behavioral measurement as one of the critical gaps in clinical trial research. While more and more clinical trial researchers acknowledge the need to measure adherence, many methodological issues remain. For example, there is no consensus on how to measure the frequency, timing and nature of sexual behavior, as well as gel and condom use in trials. In addition, trials have varied in terms of whether and/or how they measure types of sex and sexual partners. There have also been discussions about the need to develop biomarkers of adherence and one trial has evaluated the use of applicator lavage as a surrogate for gel use. The recent closures and completions of the Savvy, CS, MIRA, and Carraguard trials create an opportunity to examine and compare actual adherence-related data from this range of different trials in order to draw some concrete lessons.

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Activities, Accomplishments, Problems through December 31, 2008

- Dr. Tolley presented the subproject idea to USAID in September 2006. A CRTU Concept proposal was developed, submitted in October 2006, and re-submitted in February 2007.

- In March 2007, Dr. Tolley contacted Dr. Polly Harrison of the Alliance for Microbicide Development (AMD) and obtained her collaboration on the proposed meeting.
- Dr. Tolley worked with Dr. Harrison and other staff at the AMD to develop the meeting agenda, identify and provide guidance to presenters, finalize the participant list and communicate with participants.
- Approval to implement the subproject was obtained in September 2007.
- Between September and December 2007, Dr. Tolley worked with Ms. Tsui and Dr. Weaver to analyze Savvy, CONRAD CS and Pune acceptability datasets to present at the meeting.
- The Meeting on Adherence and Its Measurement was held from December 18-19, 2007 in Washington, D.C. It was attended by approximately 70 individuals. Over two days and six substantive sessions, presentations examined the following: 1) Patterns of Adherence; 2) Validating Self-Reported Measures of Adherence; 3) Approaches to Gaining Adherence in Microbicide Trials; 4) Technologies and Approaches on the Horizon; 5) External Views and Approaches from HIV Prevention & Treatment Programs; and 6) Perspectives from Biostatisticians and the FDA.
- A final report (M2008-21) was drafted by the AMD and reviewed and finalized with FHI input.
- Dr. Tolley provided an overview and report on findings and next steps at the Microbicides 2008 Conference in February 2008.
- Under a separate FCO (058), a Task Force was assembled in June 2008 to prepare a peer-reviewed paper summarizing the meeting presentations and providing a set of recommendations for future trials.
- The draft will be completed by January 2009 (PP2009/006) and submitted to either JAIDS or PLoS by end of February 2009.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- This subproject ended and the FCO was closed September 30, 2008.

Findings and Outcomes:

- Adherence data have multiple uses in microbicide trials: aiding explanations of heterogeneity of effects across sites, making determinations about whether adherence was too low to identify an effective product, and generating new hypotheses from trial data. However, intent-to-treat (ITT) analysis is a more realistic description of the impact of a new medicine, and thus should be the standard for evaluating the efficacy of the tested product.
- Women who use gel but are inconsistent condom users are the most informative group for establishing effectiveness but, so far at least, these women appear to account for a small percentage of participants
- Data have shown differential condom use in the control and intervention arms, suggesting that study arm assignment can influence behavior, possibly due to prevention misconceptions or partner negotiation.
- Not all microbicide trials are measuring the same thing, nor is there clarity or consensus about what should be measured and why, though there is agreement on the need for more investment in methods for getting accurate data and how to adapt those methods for different populations.
- Trajectory analysis suggests that associations of baseline characteristics with adherence trajectories could be used in association with future trials to select high compliers for future enrollment or to identify women needing more product support or intensive counseling. Differences among adherence trajectory groups suggest potential ways to monitor adherence in future trials.
- Factors that might predict adherence (including motivation, context, and partner involvement) could be used to identify and enroll participants most likely to adhere to a future study protocol. Standardizing adherence measurement across trials might also be helpful but is challenged by the complexities of inter- and intra-trial variations, contextual differences, and needs to fine-tune data collection methods for specific populations.

- Misunderstanding among site staff of key messages, and difficulty conveying adherence messages, may lead to low adherence levels by study participants.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:	Aug 2007
Total Approved Budget:	\$ 55,000	Projected End Date:	Sep 2008

USA: MRI Studies of New Microbicide Formulations with CONRAD (FCO 132112)

Technical Monitor: GPittman

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.B.: Through Phase I trials in collaboration with CONRAD, the initial safety of three new microbicide candidates determined. Results will be submitted to the FDA, other regulatory bodies, and other interested parties as appropriate.

Objective(s): To provide data management and analysis support to a CONRAD-led study designed to examine the spreading characteristics of new microbicide formulations.

Description: FHI will provide data management and analysis support to this CONRAD-led single center, comparative, randomized study. The tentative study design proposes that women will be randomized to separate groups to apply their assigned microbicide formulation to the vagina twice daily for 6 days. Cervicovaginal lavages and colposcopy will be carried out at baseline, after the fifth dose, after the last (eleventh) dose, and 3 days after the last dose. Biopsies will be done before product use and one day after the last use. The biopsies will be carried out at the same point in each of two subsequent cycles. Quantitative estimates of coverage will be assessed using three imaging techniques (fiberoptic probe, gamma scintigraphy, and MRI). Spreading, as seen when the woman does not ambulate after insertion, will be compared with spreading as seen when she does ambulate after insertion. Studies completed by CONRAD and others have demonstrated differences in spreading characteristics of different products, even under conditions of simulated coitus. It is assumed that a product which covers more of the cervicovaginal surface area prior to or early in intercourse will afford greater protection than one which covers less. It is also assumed that the correlation of imaging results with in-vitro physical testing and clinical efficacy testing will allow products to be "designed" to have optimal spreading characteristics.

Collaborating Agency(s): CONRAD

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Activities, Accomplishments, Problems through December 31, 2008

- No significant activities occurred under this FCO during the January 2007 - December 2008 time period.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- No significant activities occurred under this FCO during the January – June 2009 time period.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Based on communication from CONRAD, this study will not undergo further development during the current FY (July 2009 - April 2010).
- The FCO will be closed. It may be resubmitted at a later date.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:	Jun 2006
Total Approved Budget:	\$ 98,306	Projected End Date:	Apr 2010

USA: Phase I Safety Study of Q-2 Vaginal Gel with CONRAD (FCO 132148)

Technical Monitor: GPittman

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.B.: Through Phase I trials in collaboration with CONRAD, the initial safety of three new microbicide candidates determined. Results will be submitted to the FDA, other regulatory bodies, and other interested parties as appropriate.

Objective(s): To provide data management and analysis support to a CONRAD-led study designed to assess and compare the effect of 14 days of twice-daily vaginal applications of Q-2 (3.5ml) or the HEC-based "universal placebo" (3.5 ml) on symptoms and signs of irritation of the external genitalia, vagina, and cervix.

Description: This CONRAD-led single center, Phase I, randomized, closed label study will seek to enroll healthy sexually abstinent women. The tentative study design proposes that participants will apply 3.5 ml of their assigned product (Q-2 or the HEC-based "universal placebo") twice daily for 14 days. Symptoms and signs of irritation of the external genitalia, vagina, and cervix as seen on naked eye exam after 7 and 14 days of use will be recorded. Any disruption of the epithelium and blood vessels as seen on colposcopy after 14 days of use will also be noted. Secondary objectives will be to assess and compare differences in vaginal health by evaluating the results of wet mounts, pH, gram stains (Nugent score and neutrophil counts),

soluble and cellular markers of innate immunity and inflammation after 7 and 14 days of use, and vaginal cultures after 14 days of use. In addition, acceptability of the study products after 14 days of use will be assessed.

Unlike many off-the-shelf polymers used in microbicide formulations, Q-2 was the first polymer rationally designed and optimized to be the main carrier of a vaginal contraceptive/microbicide combination (Brode, 1998 and Brode et al., 2000). The main advantages of Q-2 over other polymeric carriers currently used in microbicide formulations are its enhanced bioadhesiveness (long-lasting potential) and its compatibility with both hydrophobic and hydrophilic active agents such as NNRTIs and entry inhibitors. Q-2 has not been studied in humans. Initial human studies are permitted by FDA using preliminary formulations to determine pharmacokinetics, so drug selection and formulation optimization can be performed quickly and correlated to in vitro and animal data. This approach will be used by CONRAD.

Collaborating Agency(s): CONRAD

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- No significant activities occurred under this FCO during the January 2007 - December 2008 time period.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- No significant activities occurred under this FCO during the January - June 2009 time period.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Based on communication from CONRAD, this study will not undergo further development during the current FY (July 2009 - April 2010).
- The FCO will be closed. It may be resubmitted at a later date.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:	Jul 2007
Total Approved Budget:	\$ 176,680	Projected End Date:	Apr 2010

USA: UC-781 PK Study with CONRAD (FCO 132147)

Technical Monitor: GPittman

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Objective(s): To provide statistical analysis and data management support for a CONRAD study designed to assess the local absorption and concentration of UC-781 in the female genital tract after a single dose and after 14 days of once-daily dosing. Note: This FCO will also serve to provide data management support for a CONRAD-led pilot study to prepare for the planned

PK/PD/safety study of UC781. The pilot study will use OpenClinica, which is an open-source data entry software. FHI will assist with data management, but is not otherwise involved in the pilot study.

Description: This will be a CONRAD-led Phase I trial designed to assess local absorption and concentration of UC-781 in the female genital tract after a single dose and after 14-days of once-daily dosing.

Collaborating Agency(s): CONRAD

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Activities, Accomplishments, Problems through December 31, 2008

- No significant activities occurred under this FCO during January 2007- December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- No significant activities occurred under this FCO during the January – June 2009 time period.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- The FHI Research Informatics team will work with CONRAD and site study staff to provide training and implementation of the OpenClinica database for the UC781 Pilot study at EVMS.
- FHI will develop and validate OpenClinica error-checking for this study.
- BIOS will review the study report.
- The FHI team will work with CONRAD while the PK study design is further developed, and will provide review of the protocol to be written by CONRAD.
- FHI will work with CONRAD to develop, review, finalize, and print the case report forms.
- CONRAD will initiate the study at US site(s) to be determined.
- Recruitment will begin.
- Funding for the Pilot and PK studies will continue under a new FCO to allow for ongoing study activities.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:	Jul 2007
Total Approved Budget:	\$ 291,420	Projected End Date:	Apr 2010

USA: Male Tolerance Study of UC-781 Gel with CONRAD (FCO 132111)

Technical Monitor: GPittman

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.B.: Through Phase I trials in collaboration with CONRAD, the initial safety of three new microbicide candidates determined.

Results will be submitted to the FDA, other regulatory bodies, and other interested parties as appropriate.

Objective(s): To provide biostatistical and data management support to a CONRAD-led Phase I male tolerance study of UC-781 gel versus a universal placebo gel.

Description: FHI provided data management and analysis support to this CONRAD-led single-center, randomized Phase I study comparing the effects of UC-781 gel and universal placebo gel on the penis. UC-781 is a non-nucleoside reverse transcriptase inhibitor of HIV that is being developed as a potential microbicide.

Thirty-six healthy, circumcised and uncircumcised men who were willing to be sexually abstinent for the length of the study were recruited. Participants were randomly assigned to product groups in a 2:1 ratio. Each applied seven consecutive daily doses of their assigned study product to the penis and left it on for 6-10 hours. Safety was assessed with reports of symptoms and examination findings involving the genito-urinary system. Acceptability was assessed by questionnaire as a secondary endpoint.

Results from this study will be used to further the development of a promising microbicide. In a completed Phase I study, the safety and acceptability of UC-781 gel versus placebo control gel was assessed after a single administration and five additional consecutive daily doses in 48 healthy, sexually abstinent women. The conclusion of that study was that UC-781 is safe for use once daily for 6 days in sexually abstinent women and is appropriate for future study. A male tolerance study with UC-781 will help to ensure that male partners of the female participants in the CDC expanded safety study of UC-781 gel will not be subjected to an undue risk of penile irritation as a result of exposure to the product.

Collaborating Agency(s): CONRAD

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- The FHI study team worked with CONRAD on the development of the protocol during the second half of 2006.
- The protocol was initially reviewed and approved in January 2007 and amendment #1, v2.0, was done in February 2007.
- FHI worked with CONRAD to develop a review of the case report forms. These were finalized and printed in July 2007.
- During the June 2007 site initiation visit conducted by the CONRAD monitor, questions arose that necessitated further discussion with the FDA. It was determined another protocol amendment was needed and amendment #2, v3.0, was approved in September 2007.
- The Data Management Plan was finalized in October 2007.
- Enrollment began in October 2007.
- Analysis programming was set up in November 2007.
- In December 2007 the analysis plan and table shells were sent for CONRAD review and the data management system was set-up and made ready to receive data in December 2007.
- Data entry and querying was done during the January – June 2008 time period.
- Recruitment ended in July 2008 with 36 participants enrolled.
- The analysis plan was finalized and approved in August 2008.
- A closeout visit was conducted at the study site by the CONRAD monitor in September 2008.
- All data were received in-house at FHI in September 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Data entry and querying was completed and the final data freeze was done in January 2009.
- The statistical report was completed in late April and sent to CONRAD in early May 2009.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- FHI will provide review of the final clinical report and manuscript as requested by CONRAD.
- The subproject will end, study documents will be archived, and the FCO will be closed.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:	Jun 2006
Total Approved Budget:	\$ 131,579	Projected End Date:	Apr 2010

South Africa: CAPRISA Microbicide Case-Control Study (FCO 136104/136107)

Technical Monitor: SSuccop

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.H.: Social and behavioral components and/or ancillary studies within microbicide clinical trials conducted to provide information on: sexual relationships and practices, the social and cultural context for microbicides, potential for covert use, and community support and policies.

Objective(s): 1) To statistically model the relative risk of HIV infection for women in the experimental arm of the CAPRISA 004 Tenofovir Gel RCT (FHI Study 9946) compared to those in the placebo arm, controlling for behavioral variability in gel use patterns; and (2) to qualitatively evaluate patterns of gel use behavior among participants, and the extent to which those patterns vary by infection status and study arm.

Description: The CAPRISA 004 Tenofovir Microbicide Trial seeks to assess the safety and effectiveness of tenofovir gel, a candidate vaginal microbicide, in sexually active women at risk for HIV infection in South Africa. The complexity of the gel-use message for the trial creates challenges for accurately measuring compliance and, hence, evaluating the potential contribution of behavioral variability to the effectiveness outcome. To address this measurement challenge, we will conduct a case-control study in parallel with the CAPRISA 004 trial. Data collection centers on in-depth interviews with seroconverters (a target of 92 cases) matched 1:3 to a random sample of uninfected controls, for a goal of 272 interviews overall. Both qualitative and quantitative data are being collected. Formative research was conducted to ensure enrollment strategies are sensitive and ethically appropriate. Strategies to reduce bias in self-reported data are incorporated, for example, cognitive framing techniques and multiple measures. The interviews focus on behavior related to gel use, sexual behavior, and partners since enrollment or in the previous three months, whichever is less. This study is collaboratively implemented with the Center for the AIDS Programme of Research in South Africa (CAPRISA), University of KwaZulu-Natal, Durban, South Africa.

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Activities, Accomplishments, Problems through December 31, 2008

- In November 2007, ethics approvals for the study protocol were received from FHI's Protection of Human Subjects Committee and the University of KwaZulu-Natal's Biomedical Research Ethics Administration.
- Key members of the CAPRISA research team were identified including a PI, study coordinator, research assistant, and interviewers. Some difficulties were encountered in identifying team members; this delayed study implementation by several months.
- The CAPRISA research team was trained in study procedures and research ethics in November 2007.
- Modifications to consent forms and data collection instruments were made based on feedback during the CAPRISA training. Modified materials were submitted to the FHI and CAPRISA ethics committees in December 2007.
- Formative work, including interviews and focus group discussions, was completed between January and March 2008. Participant enrollment for the main study began at the end of March 2008.
- In March 2008 a monitoring visit was conducted and a study procedures manual was completed.
- A quantitative data entry and management system was completed in April 2008. Quantitative data entry has since continued with no significant issues.
- Processing of interview transcripts has been time-consuming and challenging due to staffing issues in the field, but participant recruitment and data collection continues on schedule.
- Team members began work on drafting qualitative and quantitative data analysis plans in May 2008; this work is on-going.
- Monitoring trips were completed in March and June of 2008.
- Additional staff were added on site in May 2008 to assist with processing of transcripts.
- Summary statistics were derived in November 2008 based on current data in the quantitative database and shared with team members.
- As of mid-December 2008, 155 women were enrolled in the study.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Participant recruitment and enrollment remains on-target. As of end of June 2009, 224 women had been enrolled in this study and 229 interviews had been conducted (5 participants were interviewed twice, first as controls and later as cases).
- The CAPRISA 004 clinical trial received approvals to continue participant follow-up for the trial until 92 endpoints were reached (increased from 68 endpoints). CAPRISA 104 was also granted ethics approvals to continue enrollment until the CAPRISA 004 trial reaches 92 endpoints.
- Team members have continued to work on developing quantitative and qualitative analysis plans.
- Processing of interview transcripts is ongoing and transcripts are being completed in a faster time period with the assistance of a full-time staff member dedicated solely to transcription.
- Quantitative data entry has been ongoing.
- Two monitoring visits were held in February 2009 and June 2009. Study SOPs underwent a full review and new SOPs were developed for transcribing Adherence Support Program notes and for completing/transcribing Interviewer Feedback Forms.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Three more monitoring visits and a close-out visit are planned for the upcoming year. Additionally, the FHI Study PI will visit the site in July 2009 for progress and data analysis planning meetings with CAPRISA 004 and CAPRISA 104 project leaders.

- Based on current projections for when the 92 endpoints for the 004 trial will be reached, participant recruitment and data collection for the 104 study will continue until approximately mid-February 2010.
- Interview transcript processing and quantitative data entry will be ongoing and are projected to continue until June 2010.
- The team will continue reviewing quantitative data and qualitative data coding and analysis. Data analysis will be ongoing until approximately June 2010.
- At least one manuscript outlining the main findings of the study is expected to be completed by September 2010 under a new microbicides award.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:136104 May 2007 136107 Aug 2007
Total Approved Budget:136104 \$	285,300	Projected End Date: Jul 2010
136107 \$	243,972	
	<hr/>	
	\$ 529,272	

Nigeria: Savvy Phase III RCT, Nigeria (FCO 2277/132104/132126/132127/132128/132139)

Technical Monitor: PFeldblum

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.A.: Five pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate.

Objective(s): To assess the effectiveness of Savvy vaginal gel in preventing HIV among Nigerian women at high risk.

Description: This subproject entailed a Phase III placebo-controlled, randomized, triple-masked study. A total of 2,153 uninfected women, aged 18-35 at high risk for acquiring HIV, were recruited over 12 months at study sites in Ibadan and Lagos, Nigeria. Women who consented to be in this study were randomized into either a condom/Savvy or condom/placebo group and were followed for 12 months. After completion of the study, incidence rates of HIV-1 and HIV-2 infection were compared between the two groups.

This subproject was supported by USAID microbicide funding. Biosyn, Inc., the developer of Savvy, supplied the Savvy and placebo gels for the study.

NOTE: After negotiations with the USFDA and deciding on a final study design, USAID requested 12 months of follow-up time for each study participant and to drop gonorrhoea and chlamydia as secondary endpoints. FHI amended the protocol to reflect the new study design and obtained all necessary approvals.

Subgrantee(s): Association for Reproductive and Family Health (ARFH); Association for Reproductive and Family Health, Inc.; College of Medicine, University of Ibadan; Health Matters Inc.; Health Matters, Inc. (HMI); Nigerian Institute of Medical Research; Nigerian Institute of Medical Research (NIMR); University College Hospital, University of Ibadan

Collaborating Agency(s): Biosyn, Inc.

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Activities, Accomplishments, Problems through December 31, 2008

- Preliminary approval was granted by USAID for the study in Sept. 2002.
- Please refer to the Annual Report dated July 2006 – June 2007 for cumulative results that took place during the period of Jan. 2003 to Dec.2006.
- A closeout plan and budget was developed and approved by the site investigators.
- An FHI Auditor audited the Lagos study site in Nov. 2006 and the Ibadan study site in Jan. 2007.
- Data for the annual safety report was submitted to CONRAD in Jan. 2007.
- All remaining CRFs were entered, and all data queries were resolved.
- All final data tables were produced by FHI's Biostatistics Group.
- The study team completed the final report in Aug.2007, which was submitted to CONRAD along with all corresponding appendices.
- All remaining study logs and tools that FHI requested from the study sites were shipped and received at FHI for filing.
- In Dec.2007 the study team submitted a manuscript to the open-access journal of Public Library of Science (PLoS) ONE reporting on the main SAVVY study results.
- The main study results were published in PLoS ONE in January 2008 (FHI Pub 2008-13) and presented at the Microbicides 2008 Conference in New Delhi in Feb.2008.
- All logs and tools shipped by study sites to FHI were labeled and filed in central files.
- Discussions were held at FHI regarding possible secondary analysis of SAVVY data for additional papers, mostly pooled with data from the CS trials.
- Discussions were held with the site investigators regarding best means to disseminate the main study results in Nigeria.
- Dissemination meetings were held with stakeholders and study participants in Lagos and Ibadan in Sept. and Oct. 2008.
- Approximately 200 study participants attended both the Lagos and Ibadan dissemination meetings.
- Also in attendance at the meetings were representatives of the state Ministries of Health (MOH), the State Action Committees on AIDS Control (SACA), the national drug regulatory agency (NAFDAC), and a key advocacy group for prevention technologies (NHVMAG).
- Secondary analysis papers were written using SAVVY Nigeria data pooled with data from the SAVVY Ghana, CS Nigeria and CS Multi-country trials.
- The subproject was closed on June 30, 2009.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Secondary analysis papers were written using SAVVY Nigeria data pooled with data from the SAVVY Ghana, CS Nigeria and CS Multi-country trials.
- The subproject was closed on June 30, 2009.

Findings and Outcomes:

- The main study results were published in PLoS ONE. Feldblum PJ, Adeiga A, Bakare R et al. SAVVY vaginal gel (C31G) for prevention of HIV infection: a randomized controlled trial in Nigeria. PLoS ONE 2008; 3(1): e1474 doi:10.1371/journal.pone.0001474. (FHI Pub 2008-13)
- The abstract is as follows: The objective of this trial was to determine the effectiveness of 1.0% C31G (SAVVY) in preventing male-to-female vaginal transmission of HIV infection among women at high risk.

- **Methodology/Principal Findings:** This was a Phase 3, double-blind, randomized, placebo-controlled trial. Participants made up to 12 monthly follow-up visits for HIV testing, adverse event reporting, and study product supply. The study was conducted between September 2004 and December 2006 in Lagos and Ibadan, Nigeria, where we enrolled 2153 HIV-negative women at high risk of HIV infection. Participants were randomized 1:1 ratio to SAVVY or placebo. The effectiveness endpoint was incidence of HIV infection as indicated by detection of HIV antibodies in oral mucosal transudate (rapid test) or blood (ELISA), and confirmed by Western blot or PCR testing. We observed 33 seroconversions (21 in the SAVVY group, 12 in the placebo group). The Kaplan-Meier estimates of the cumulative probability of HIV infection at 12 months were 0.028 in the SAVVY group and 0.015 in the placebo group (2-sided p-value for the log-rank test of treatment effect 0.121). The point estimate of the hazard ratio was 1.7 for SAVVY versus placebo (95% confidence interval 0.9, 3.5). Because of lower-than-expected HIV incidence, we did not observe the required number of HIV infections (66) for adequate power to detect an effect of SAVVY. Follow-up frequencies of adverse events, reproductive tract adverse events, abnormal pelvic examination findings, chlamydial infections and vaginal infections were similar in the study arms. No serious adverse event was attributable to SAVVY use.
- **Conclusions/Significance:** SAVVY did not reduce the incidence of HIV infection. Although the hazard ratio was higher in the SAVVY than the placebo group, we cannot conclude that there was a harmful treatment effect of SAVVY.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:	2277	Aug 2002
			132104	Jul 2005
			132126	Oct 2006
			132127	Oct 2006
			132128	Oct 2006
			132139	Oct 2006
Total Approved Budget:	2277	\$	4,395,997	Projected End Date: Jun 2009
	132104	\$	7,886,312	
	132126	\$	2,274,205	
	132127	\$	1,948,939	
	132128	\$	259,776	
	132139	\$	54,205	
		\$	16,819,434	

Ghana: Savvy® Phase III RCT, Ghana (FCO 2278/132105/132121/132140/132141/132144)

Technical Monitor: ATroxler

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.A.: Five pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate.

Objective(s): To assess the effectiveness of Savvy vaginal gel in preventing HIV among Ghanaian women at high risk.

Description: This study was designed as a Phase III placebo-controlled, randomized, triple-masked study. A total of 2,142 uninfected women, aged 18-35 at high risk for acquiring HIV, were recruited over 15 months at study sites in Accra and Kumasi, Ghana. Women who consented to be in this study were randomized into either a condom/Savvy or condom/placebo group. The planned follow-up period was 12 months.

This subproject is supported by USAID-designated microbicides funds. Biosyn, Inc. is the developer of Savvy and supplied the Savvy and placebo gels for the study.

Subgrantee(s): Care and Love Mission; Komfo Anokye Teaching Hospital (KATH); Noguchi Memorial Institute for Med Research (NMIMR); Noguchi Memorial Institute for Medical Research (NMIMR); Virtual Access (VA)

Collaborating Agency(s): Biosyn, Inc.

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- Preliminary approval was granted by USAID in Sep. 2002.
- In Nov. 2002, the protocol was approved by PHSC and sites were visited.
- In May 2003, site investigators and coordinators attended Good Clinical Practices training by The RAN Institute in Accra; in-country monitors also attended a monitoring training.
- Site training took place in early 2004.
- Clinical supplies were shipped in Feb. 2004 and enrollment began in Mar. 2004.
- Monitoring visits took place in May, July, and Nov. of 2004 and Feb., June, and October of 2005.
- A contract between FHI and Focus Technologies for in vitro testing of study gel was executed in June 2004.
- The local IRBs granted annual approvals in Oct. 2004. PHSC granted annual approval in Nov. 2004.
- Enrollment ended in June 2005 with 2,142 women recruited.
- In June and Sep. 2005, the DMC met to review interim data and approved study continuation at both meetings.
- Annual approval was granted by the Noguchi IRB in Sep. 2005, by the KATH IRB in Oct. 2005, and by PHSC in Nov. 2005.
- The DMC met in Nov. 2005 to review the study data to date and concluded that the study would be unable to evaluate the effectiveness due to low incidence in the study population. Based on the DMC recommendation, a joint decision between FHI and Cellegy Pharmaceutical Inc. was made to stop the study.
- Participants were seen for a final follow-up visit by mid-Feb 2006.
- The close-out monitoring visit was conducted and data were cleaned in Mar. 2006.
- A database lock was completed in Apr. 2006.
- The analysis was completed in May 2006.
- The final report was submitted to CONRAD in Nov. 2006.
- Contracts with local NGOs were executed to provide care for seroconverters.
- Comments were received from PLoS ONE and a revised manuscript submitted in May 2007.
- The manuscript, "Savvy (C31G) Gel for Prevention of HIV infection in Women: Phase III, Double-blind Randomized Placebo-controlled Trial in Ghana" was published in PLoS ONE Dec. 19, 2007 (FHI Pub 2007-111).
- From Dec. 2007 to Dec. 2008, care and treatment was provided to seroconverters that accessed services from our contract NGOs.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Local HIV treatment providers in Kumasi and Accra provided access to care and treatment services for seroconverters during the period of January through June 2009. Secondary analysis also continued during this period.

Findings and Outcomes:

- Complex design and operational issues (such as lower than expected HIV incidence rates, high pregnancy rates, and low product adherence) emerged from the Savvy trials that exceeded the traditional clinical trial challenges of recruiting participants and maintaining protocol adherence. They also are relevant for other HIV prevention technologies.
- Skoler S, Peterson L, Cates W. Our current microbicide trials: lessons learned and to be learned. *Microbicide Q* 2006 Jan-Mar; 4 (1):1-6 (FHI Pub 2006-27) was supported under this subproject.
- From the PLoS ONE primary publication (FHI Pub 2007-111): The study was conducted March 2004 — February 2006 in Accra and Kumasi, Ghana. We enrolled 2142 HIV-negative women at high risk of HIV infection, and randomized them to SAVVY or placebo gel. Main outcome measures were the incidence of HIV-1 and HIV-2 infection as determined by detection of HIV antibodies from oral mucosal transudate specimens and adverse events. We accrued 790 person-years of follow-up in the SAVVY group and 772 person-years in the placebo group. No clinically significant differences in the overall frequency of adverse events, abnormal pelvic examination findings, or abnormal laboratory results were seen between treatment groups. However, more participants in the SAVVY group reported reproductive tract adverse events than in the placebo group (13.0% versus 9.4%). Seventeen HIV seroconversions occurred; eight in participants randomized to SAVVY and nine in participants receiving placebo. The Kaplan-Meier estimates of the cumulative probability of HIV infection through 12 months were 0.010 in the SAVVY group and 0.011 in the placebo group ($p = 0.731$), with a hazard ratio (SAVVY versus placebo) of 0.88 (95% confidence interval 0.33, 2.27). Because of a lower-than-expected HIV incidence, we were unable to achieve the required number of HIV infections (66) to obtain the desired study power.
- Conclusions: SAVVY was not associated with increased adverse events overall, but was associated with higher reporting of reproductive adverse events. Our data are insufficient to conclude whether SAVVY is effective at preventing HIV infection relative to placebo.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Secondary analysis will be completed.
- FCOs 132121 and 132144 will remain open; they relate to subagreements that cover the costs of seroconverter care.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: Microbicides	FCO Approved: 2278 Aug 2002 132105 Jul 2005 132121 Jan 2007 132140 Oct 2006 132141 Oct 2006 132144 Jun 2006
Total Approved Budget:	2278 \$ 6,767,839 132105 \$ 7,551,240 132121 \$ 16,540 132140 \$ 1,990,576 132141 \$ 1,559,782 132144 \$ 14,703 \$ 17,900,680	Projected End Date: Apr 2010

Africa Regional: Truvada - FEMPrEP Phase III Clinical Trial (FCO 12302/12322/12341/132146/132157/132158/132159/ 132168/132169/132170/132179/132180)

Technical Monitor: ATroxler

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.A.: Five pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate.

Microbicides I.G.: One pivotal trial comparing oral versus topical microbicides implemented. Results will be submitted to the FDA, other regulatory bodies, and other interested parties as appropriate.

Objective(s): To determine the effectiveness and safety of daily Truvada™ compared with placebo for HIV prevention among HIV-uninfected women who are at higher risk of becoming HIV infected through sexual intercourse.

Secondary objectives include: 1) To compare viral load, viral set point, CD4 and T cell counts, and frequency of FTC and tenofovir phenotypic and genotypic drug resistance among participants who seroconvert while receiving Truvada versus placebo; 2) To determine, in a subset of participants, the effects of co-administration of Truvada and DMPA (depot medroxyprogesterone acetate) on bone mineral density over time and compare to the effects with placebo and DMPA; 3) To evaluate the effects of administration of Truvada versus placebo during early pregnancy on pregnancy outcome; 4) To assess adherence to once-daily pill taking; 5) To describe the effect of potential pre-exposure prophylaxis on risk disinhibition; and 6) To compare sexual behaviors between participants who seroconvert and matched HIV negative participants.

Description: This Phase III, double-blind, randomized, placebo-controlled trial will enroll an estimated 3900 HIV-negative women from 6 sites in 4 countries (Kenya, Malawi, Tanzania and South Africa). The study population includes HIV-antibody-negative women between the ages of 18-35 who are at higher risk of HIV acquisition through sexual intercourse.

Each participant will take either a daily single oral tablet of Truvada, which is a fixed-dose combination of emtricitabine (FTC; 200 mg) and tenofovir disoproxil fumarate (TDF; 300 mg), or an identical placebo. All participants will receive risk reduction counseling and condoms. Women must be using a study-approved effective non-barrier contraceptive method at the time of enrollment and will receive contraceptive counseling throughout the study. Any diagnosed, treatable STI will be treated free of charge.

Study duration is approximately 37-40 months per site; participant screening and enrollment is anticipated to take approximately 12-16 months. After enrollment, each participant will be followed every 4 weeks for 52 weeks on study drug. All participants will be followed for an additional 4 weeks after study drug has been stopped. Participants at risk for HBV flare will be followed for every 4 weeks for at least 12 weeks after stopping study product. Participants who acquire HIV infection during the study will be followed for 52 weeks post HIV diagnosis and will be referred for care and treatment. Participants who become pregnant will stop study drug but will continue follow-up visits.

After the study, incidence rates of HIV infection will be compared between the two groups (active and placebo). The Independent Data Monitoring Committee (IDMC) will review the study at

strategically chosen points to determine whether the study should continue, be modified or be discontinued.

Related subprojects include site preparedness FCO 136108 and social and behavioral component FCO 136109. The trial has been named FEM-PrEP.

Subgrantee(s): Bio-Imaging Technologies, Inc.; IMPACT Research and Development Organization; Institute for Tropical Medicine (ITM); Institute of Tropical Medicine (Antwerp, Belgium); SCT Consulting; Synexus Clinical Research South Africa Pty Ltd; Synexus Clinical Research South Africa Pty Ltd.; University of Cape Town, Women's Health Research Unit

Collaborating Agency(s): Gilead Sciences; Gladstone Institute of Virology and Immunology

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- In Jan. 2007, FHI submitted the study proposal to USAID for funding. Work on the protocol began and potential study sites were contacted.
- In June 2007, FHI received preliminary approval from USAID to begin spending CRTU microbicide funds.
- A grant proposal for additional study funds was submitted to Bill & Melinda Gates Foundation in July 2007.
- In Oct. 2007, Lut Van Damme joined FHI as the Clinical Principal Investigator of the Truvada study.
- The Investigators' Meeting was conducted on Oct. 24-26, 2007 in Nairobi, Kenya.
- In Dec. 2007, the protocol was sent for review to the IDMC members, Protocol Advisor Committee, USAID, Gates and FHI formal reviewers.
- The first IDMC meeting was held in Jan. 2008. The final plan v1.0 was approved in June 2008.
- PHSC approval was received in Mar. 2008.
- The monitoring plan, v 1.0 was approved in Apr. 2008.
- The protocol, ICs and required Case Report Forms (CRFs) were submitted to all local institutional review boards (IRBs), Kenya Poisons Board, South Africa Medicines Control Council (MCC) and Tanzania Food and Drug Authority (TFDA). Local IRB approvals were received for the following sites: Bondo, Pretoria, Cape Town and Arusha.
- The first shipment of study product from Gilead Sciences, Inc. arrived at FHI in May 2008.
- Good Clinical Practices (GCP), laboratory and core protocol training was conducted by FHI and ITM for the Bondo site in July 2008.
- An IND was submitted to the U.S. FDA in Aug. 2008. U.S. FDA clearance was received on Sept. 26, 2008.
- A data management (DM) plan, v 1.0 was finalized in Sept. 2008.
- CRFs were approved in Nov. 2008.
- A statistical analysis plan, v 1.0 was approved in Nov. 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The Bondo site initiation training was conducted in April 2009. Participants screening started in May 2009. The first participant was enrolled on June 11, 2009.
- Good Clinical Practices (GCP), laboratory and core protocol training was conducted by FHI and ITM for the Pretoria site in June 2009.
- Study drug and supplies were shipped to Bondo in April 2009 and to Pretoria in June 2009.
- As of July 7, 2009, there were 124 participants screened and 12 enrolled.
- A site in Mazabuka, Zambia, has been added to the trial. Negotiations are ongoing with potential other sites.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Subcontracts will be finalized with the study sites.
- Local IRB and regulatory approvals will continue to be sought where pending.
- Pretoria initiation will occur in the 2nd quarter 2009.
- Monitoring visits will begin at each site 4-6 weeks after the first participant is enrolled. The first monitoring visit for Bondo will be conducted in July 2009 and in Pretoria in September 2009.
- For all sites monthly monitoring visits will be conducted by in-country monitors. A monitor from FHI NC will join the monitoring visit once per quarter.
- A second Investigators' Meeting is scheduled for August 2009.
- For Arusha and Mazabuka, study drug and other supplies will be shipped to the sites when all approvals have been received.
- Re-supply of study drug from Gilead scheduled for 4th Q 2009.
- Site re-supply of study drug and supplies will take place as needed at each site.
- Good Clinical Practices (GCP), laboratory and core protocol training will be conducted for the Arusha site in September 2009 with site initiation in November 2009.
- Mazabuka site Good Clinical Practices (GCP), laboratory and core protocol training is scheduled for 1st Q 2010, with site initiation occurring by 2nd Q 2010.
- At least one additional site will be identified.
- It is anticipated that this study will continue under a new agreement.

Funding Source(s):	Gates Foundation, Bill and Melinda/Private; USAID - US Agency for International Development/USAID: Microbicides; Gates Foundation, Bill and Melinda/Foundation; Gates Foundation, Bill and Melinda/PEPFAR	FCO Approved:	12302	Jun 2007
			132146	Jul 2007
			12322	Jul 2007
			12341	Jul 2007
			132157	Apr 2008
			132158	Apr 2008
			132159	Apr 2008
			132168	Aug 2007
			132169	Jun 2008
			132170	Jun 2008
			132180	Mar 2009
			132179	Mar 2009
Total Approved Budget:	12302	\$	27,890	Projected End Date: Apr 2010
	132146	\$	15,545,753	
	12322	\$	735,197	
	12341	\$	617,453	
	132157	\$	3,505,367	
	132158	\$	4,170,398	
	132159		Canceled	
	132168	\$	1,646,411	
	132169	\$	342,971	
	132170	\$	281,490	
	132180	\$	6,436,122	
	132179		N/A	
		\$	<u>33,309,052</u>	

South Africa: Truvada - FEM-PrEP Study: Site Preparedness (FCO 12331/12332/12333/12334/12335/12336/136105/136106/ 136108/136111/136112)

Technical Monitor: ACorneli

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.C.: Five new sites for pivotal microbicide trials established, qualified, and functioning, with appropriate stakeholder involvement.

Objective(s): 1) To identify and map areas and establishments within the study catchment area where people meet sex partners; 2) to identify and map community-based and other support organizations who are interested in the welfare of women at higher risk of HIV exposure and in the implementation of the future pre-exposure prophylaxis clinical trial; 3) to foster partnerships with civil society/community stakeholders and to maintain community involvement throughout all phases of the clinical trial process, from design of study procedures through dissemination of results; 4) to improve understanding of and trust in clinical trial research among community-level stakeholders; and 5) to gather data to inform: a) strategies for recruiting women at higher risk of HIV exposure into a pre-exposure prophylaxis clinical trial; b) strategies to ensure high product use, such as: retention strategies, strategies for contraception provision and for encouraging consistent use; c) counseling messages on risk reduction; and d) the explanation of the pre-exposure prophylaxis clinical trial in the informed consent documents.

Description: The purpose of the study is to prepare for the implementation of an HIV pre-exposure prophylaxis clinical trial using oral Truvada for women at higher risk of HIV exposure and to involve civil society/community stakeholders in the research process from the design of study procedures through dissemination of results. This is a qualitative descriptive study, including community mapping, observations, in-depth interviews, and focus group discussions. Activities will be conducted in two phases: a socio-behavioral and community (SBC) site preparedness phase prior to clinical trial initiation and an SBC on-going phase after the clinical trial has begun. The on-going phase will be captured under FCO 136109. The data will provide examples of whether the proposed clinical trial meets the needs of the community and how to engage the community. Data gathered will be used to inform clinical trial procedures on recruitment; retention; counseling on adherence, contraceptives, and HIV risk reduction; and informed consent.

The overall study was renamed FEM-PrEP in early 2008.

Subgrantee(s): Kilimanjaro Medical Center; UNC; Univ. of Zimbabwe; University of California San Francisco; University of Cape Town; University of Limpopo; University of Malawi

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Activities, Accomplishments, Problems through December 31, 2008

- The SBC preparedness protocol received final approval on June 12, 2007 after minor modifications.
- In August 2007, the Bondo and Kibera teams received training for the preparedness activities. The two sites completed site preparedness activities in February 2008. However, due to civil unrest after the Kenyan presidential elections, the Kibera site was closed at the

end of February. The Bondo data were analyzed and incorporated into materials for clinical training held July 2008.

- In October 2007, FHI learned funding from the Bill & Melinda Gates Foundation had been secured.
- The Lilongwe and Blantyre Malawi sites received training in October 2007. They completed data collection in April 2008. The data analysis for the Malawi sites was put on hold in mid-2008 when the local IRB did not approve the clinical trial. We are awaiting a reply to a second appeal before determining how to proceed.
- Minor amendments were approved by PHSC, including changes in leadership for the clinical team at FHI and the sites, site initiation documents, and increasing the sample size for community mapping activities.
- In December 2007, FHI determined that Zimbabwe would no longer be a study site due to challenges stemming from the political and economic situation in the country.
- In January 2008, the Pretoria and Cape Town, South Africa sites received training. They completed data collection in October 2008.
- In April 2008, the Arusha site was trained to conduct the site preparedness activities. The site was expanded to include the neighboring town of Moshi in late 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Arusha/Moshi site restarted data collection February 2009 after it was halted in November 2008 due to a minor protocol violation. Both research and community activities are continuing.
- Cape Town, South Africa site conducted dissemination of findings with community in May and June 2009. The site was closed in June 2009 and will not continue with the FEM-PrEP clinical trial due to financial reasons.
- The Pretoria, South Africa data were analyzed and incorporated in materials for clinical training held June 2009
- The protocol was submitted to the local IRB for the Mazabuka, Zambia site in June 2009.

Findings and Outcomes:

- Findings and recommendations from the Bondo, Kenya site have been incorporated into materials for the FEM-PrEP clinical trial. For the clinical training in Bondo July 2008, SBC Preparedness results were incorporated into the presentations for informed consent, adherence (3 presentations, counseling manual, job aids, and visit checklists), retention and recruitment. For the site initiation training held in April 2009, the SBC results were incorporated into the presentations for contraceptive counseling, risk reduction counseling, community engagement and acceptability. All SBC clinical trial materials and input were completed in April 2009. This includes the 1) adherence counseling manual, job aids, and counseling checklists for screening, enrollment, and follow-up, 2) the informed consent job aids for screening and enrollment, which include additional information to provide verbally to participants during the informed consent process to enhance understanding of the consent form based on areas of misunderstanding found in the SBC data, 3) GPS-mapped recruitment areas, and 4) input into the following clinical trial SOPs: recruitment, retention, adherence, screening visit, enrollment visit, and follow-up visits, risk reduction counseling, and contraception counseling.
- Similarly, the findings and recommendations have been incorporated into the materials for the clinical trial training presentations for the Pretoria, South Africa site held in June 2009.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- The Tanzania site will complete preparedness activities July 2009 with data analysis to immediately follow for recommendations to be incorporated into the clinical trial training.
- The SBC recommendations will be incorporated into the final clinical trial materials for the Pretoria, South Africa site initiation training scheduled for July 2009.

- The Mazabuka, Zambia site will initiate activities in late 2009. Data collection and community activities will be conducted over 5 months. Two months after data collection is completed, data analysis will be completed and findings incorporated into training materials for the clinical trial materials.
- If it is determined that the Malawi sites will not conduct the clinical trial, within the year a new site will be identified and data collection and community activities will begin.
- Once the clinical trial activities begin for each site, reporting of continuing SBC activities will transition to the SBC on-going phase.

Funding Source(s):	Gates Foundation, Bill and Melinda/Foundation; Gates Foundation, Bill and Melinda/Private; USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:	136105 Aug 2007 136106 Aug 2007 136108 Jul 2007 136112 Sep 2007 136111 Sep 2007 12331 Jul 2007 12332 Jul 2007 12333 Dec 2007 12334 Jul 2007 12335 Jul 2007 12336 Oct 2007
Total Approved Budget:	136105 \$ 163,483	Projected End Date:	Jun 2010
	136106 \$ 199,614		
	136108 \$ 1,084,248		
	136112 \$ 206,004		
	136111 \$ 196,352		
	12331 \$ 111,031		
	12332 \$ 637,422		
	12333 \$ 333,203		
	12334 \$ 818,305		
	12335 N/A		
	12336 N/A		
	\$ 3,749,662		

Africa Regional: Truvada - FEMPrEP Study: Social, Behavioral & Community Activities (FCO 12354/12355/136109/136117/136121/136122)

Technical Monitor: ACorneli

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.I.: Innovative strategies to increase retention and reduce product interruptions in trials developed and tested.
Microbicides I.H.: Social and behavioral components and/or ancillary studies within microbicide clinical trials conducted to provide information on: sexual relationships and practices, the social and cultural context for microbicides, potential for covert use, and community support and policies.

Objective(s): Three distinct objectives are included in the socio-behavioral and community (SBC) on-going activities of the FEM-PrEP clinical trial. They are:

- 1) To conduct SBC research integration and monitoring of the behavioral-related components of the clinical trial to inform recruitment, retention, adherence, informed consent process, contraceptive counseling, and HIV/STI risk reduction counseling;
- 2) To implement a community engagement program to coordinate ongoing partnering, education, and outreach efforts with community and civil society stakeholders; and
- 3) To implement a separate qualitative protocol on intervention planning to inform site-specific intervention design plans for using PrEP if found to be safe and effective.

Description: The Socio-Behavioral and Community (SBC) on-going phase incorporates three protocols with components to be carried out by the SBC team throughout the FEM-PrEP clinical trial. This includes: 1) organizing non-research community engagement activities begun during the preparedness phase; 2) integrating SBC preparedness phase research and monitoring the behavioral-related components of the clinical trial; and 3) implementing a protocol to inform site-specific pilot prevention interventions for using PrEP if found to be safe and effective.

The first protocol was implemented under FCO 136108 to prepare for the implementation of the clinical trial. Community mapping activities for recruitment as well as community stakeholder interviews begun during the SBC preparedness phase will continue in this on-going phase.

Within the clinical trial protocol, SBC research activities include research integration and monitoring of the behavioral-related components of the clinical trial and a non-research community engagement program. The SBC research activities will include qualitative interviews with trial participants to explore issues related to trial participation. Data collected during community mapping activities and interviews with participants and civil society/community stakeholders will be rapidly analyzed throughout the course of the clinical trial in order to inform trial procedures, as appropriate, and other community activities. The community engagement activities have evolved from the preparedness phase and involve building partnerships with existing or newly-established community advisory boards and other key stakeholders. Activities include community education forums; establishing access to care; and provision of ongoing training to build research literacy and ethics capacity.

In the third protocol, data will be collected from participants to inform the design and implementation of a future, site-specific pilot prevention program using Truvada.

Subgrantee(s): IMPACT - RDO; Synexus Clinical Research; University of Cape Town; University of Malawi; University of North Carolina

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Activities, Accomplishments, Problems through December 31, 2008

- The FEM-PrEP clinical trial protocol, with SBC on-going activities, received approval in February 2008 with modifications.
- The Bondo, Kenya site data was analyzed and incorporated into materials for clinical training held July 2008.
- The PrEP Rollout protocol, "Sociobehavioral Research and Community Planning to Develop Site-Specific Pilot Intervention Plans for PrEP Rollout" (PI-Natasha Mack), received PHSC IRB approval in December 2008.
- The clinical trial was not approved in Malawi in July 2008. Two appeals have been made. We are awaiting a reply to the second appeal.
- The Arusha, TZ site was expanded to include the neighboring town of Moshi in late 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The clinical trial refresher training was conducted with the clinical team in April 2009 to provide refresher training on the SBC on-going protocol as well as clinical trial activities on adherence, recruitment, retention, informed consent, and behavioral CRFs. Community

activities, including working with the Community Advisory Board, were ongoing throughout the period.

- PrEP Rollout training was held in Bondo, KE in May 2009.
- The Pretoria, SA site preparedness phase data was analyzed and incorporated into materials for clinical training held June 2009. Community Advisory Board activities were ongoing throughout the period.
- Mazabuka, Zambia has been identified as a new site (replaces Kibera, KE which was discontinued in February 2008 due to civil unrest).

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- The Bondo, KE site will be continuing the SBC research and community activities throughout this period.
- Core clinical trial training, incorporating SBC on-going training, is expected in September 2009 for Arusha/Moshi, TZ site. The training is scheduled for late February 2010 in Mazabuka, ZA.
- Site initiation refresher training for the Pretoria, SA site is expected in July 2009. In the Arusha/Moshi and Mazabuka sites, it is expected to be conducted approximately 6 weeks after core training. The refresher training will be followed by initiating and continuing SBC research and community activities.
- PrEP Rollout training followed by implementation of research activities for Pretoria, SA is expected in July 2009. In Arusha/Moshi, TZ training is expected in November 2009. In Mazabuka, ZA the training will happen in early to mid-2010.
- PrEP Rollout activities will be ongoing throughout the period in Bondo, KE.
- Subagreements will be in place approximately 3 months prior to core clinical trial training.
- A new site or sites will be identified to replace the Malawi sites if the local IRB rejects the appeal.

Funding Source(s):	Gates Foundation, Bill and Melinda/Private; USAID - US Agency for International Development/USAID: Microbicides	FCO Approved: 136109 136117 12354 12355 136121 136122	Sep 2007 Apr 2008 Apr 2008 Apr 2008 Mar 2009 Mar 2009
Total Approved Budget:	136109 \$ 3,147,623	Projected End Date:	Apr 2010
	136117 \$ 989,136		
	12354 \$ 659,460		
	12355 \$ 1,124,085		
	136121 \$ 1,362,390		
	136122 \$ 1,273,615		
	<u>\$ 8,556,309</u>		

South Africa: RCT of Tenofovir Gel with CAPRISA (FCO 132108/132119/132120)

Technical Monitor: ATroxler

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.A.: Five pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate.

Objective(s): To assess the safety and effectiveness of candidate vaginal microbicide 1% tenofovir gel, relative to a placebo gel in preventing sexually transmitted HIV infection. The primary outcome is seroconversion. Secondary objectives include: incidence rate of deep epithelial disruption, assessing the impact of either product on viral load for women who become infected during the trial, assessing tenofovir resistance among HIV seroconverters, and ascertaining the impact, if any, of tenofovir gel on pregnancy rates and outcomes.

Description: The study is being conducted in South Africa by the Centre for the AIDS Programme of Research in South Africa (CAPRISA) with Dr. Quarraisha Abdool Karim and Dr. Salim Abdool Karim as Co-Principal Investigators. Participants were recruited from two areas: the Vulindlela clinic in the KwaZulu-Natal midlands, and the eThekweni Clinic in Durban among a population attending the Prince Cyril Zulu Communicable Disease Centre. Vulindlela has a very high prevalence of HIV, with almost 43% of women in antenatal surveys HIV positive while the prevalence of HIV among those attending the Prince Cyril Zulu CDC is over 50%. This study is a Phase IIb, two-armed, double-blinded, randomized, controlled trial comparing 1% tenofovir gel with the universal HEC placebo gel. Nine hundred (900) HIV negative, sexually active women (18-40 years) at high risk were recruited. The study duration is planned for approximately 30 months in total (accrual lasting 14 months and follow-up lasting 16 months). A DSMB will review the study at strategically chosen time points to determine whether the study should continue, be modified, or be discontinued. FHI will provide collaborative oversight and coordination to the trial, data management and analysis consulting services, monitoring, and quality assurance audits. FHI is also collaborating with CAPRISA on behavioral research and community activities. CONRAD is providing tenofovir gel product and placebo for the trial.

Subgrantee(s): CAPRISA; CAPRISA- Centre for the AIDS Programme of Research in S Africa; Columbia University

Collaborating Agency(s): CONRAD

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Activities, Accomplishments, Problems through December 31, 2008

- The study protocol was approved by FHI's PHSC and the local IRB in Oct. 2006.
- The South African Medicines Control Council (MCC) granted study approval in Dec. 2006.
- For a complete list of activities that took place prior to July 2008, see the July 2007-June 2008 Annual Report.
- Semi-annual progress reports were submitted to the MCC in Oct. 2007, Apr. 2008 and Oct. 2008.

- Monitoring visits were conducted in July, Oct., and Nov. 2007, as well as Jan., April, July and Oct. 2008.
- An additional recruitment team at CAPRISA was implemented to increase study enrollment in Nov. 2007.
- Local IRB annual renewal was granted in Jan. 2008 and again in Jan. 2009.
- An ad-hoc DSMB meeting was called in May 2008 to discuss enrollment of ineligible participants.
- PHSC granted renewal for 6 months at the May 2008 meeting and an additional 7 months at the Nov. 2008 meeting.
- New clinicians joined the study and MCC granted approval of the new clinicians in August-Sept. 2008.
- Revised Informed Consents and Educational Materials were submitted to the IRBs in August 2008. PHSC granted approval in September and the Biomedical Research Ethics Committee (BREC) granted approval in Nov. 2008.
- In November 2008, the PHSC requested revisions to the social harm section in the Informed Consents; the revisions were submitted to PHSC in Dec. 2008.
- All 185 ineligible participants were terminated from the study in Nov. 2008.
- A DSMB meeting was held in Nov. 2008 as one third of the anticipated study endpoints were reached in Aug. 2008. The DSMB recommended that the study continue. The co-PIs asked the DSMB to consider an amendment to the protocol, increasing the power of the study. The DSMB agreed with this recommendation. The DSMB also requested that the protocol be modified so that no new Hepatitis B surface antigen positive participants be enrolled.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Protocol Safety Review Team meetings have continued to occur every 2-3 months since the beginning of the study.
- Enrollment was closed in January 2009 with a total of 900 participants (excluding the 185 co-enrolled participants).
- Monitoring visits occurred in February and June 2009.
- The semi-annual MCC progress report was submitted in April 2009.
- Approval for the protocol amendment that increases study power was received by PHSC in January 2009, the MCC in April 2009 and the local IRB May 2009.
- Continuing review approval for 7 months was received from PHSC in May 2009.
- The revised protocol (v1.2), increasing the study power, and informed consents were implemented onsite in May 2009. The study manual and SOPs were revised as well in order to incorporate the protocol revisions.
- The next interim DSMB planning has been underway.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Quarterly monitoring visits will continue.
- Protocol Safety Review Team meetings will continue every 2-3 months.
- Due to the protocol amendment being approved, it is estimated that follow-up of participants will continue until December 2009. This will likely require an amendment to the subagreement and an extension in the overall timeline.
- The DSMB will meet in July 2009.
- An RAQA audit visit will occur in September 2009.
- The study will likely continue in 2010 under new funding.
- Data cleaning and analysis will begin in early 2010.
- A close-out monitoring visit will occur in the spring of 2010.
- Results should be available in mid to late 2010.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved: 132108 Feb 2006 132120 Dec 2006 132119 Dec 2006
Total Approved Budget: 132108 \$	2,225,445	Projected End Date: Apr 2010
132120 \$	632,195	
132119 \$	9,912,901	
	\$ 12,770,541	

Nigeria: Randomized Controlled Trial of Cellulose Sulfate, CS Gel, and HIV in Nigeria (FCO 2266/132100/132122/132123/132124/132125/132143)

Technical Monitor: VHalpern

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.A.: Five pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate.

Objective(s): 1) To determine the effectiveness of CS gel in preventing male-to-female vaginal transmission of HIV infection among women at high risk; and 2) to determine the effectiveness of CS gel in preventing male-to-female transmission of gonorrhea and chlamydial infection among women at high risk.

NOTE: A second objective was added in 2003 in order to more accurately reflect the protocol objectives.

Description: Given the continuing HIV epidemic, the search for an effective vaginal microbicide remains urgent. This is especially true in sub-Saharan Africa which bears a disproportionate burden of HIV/AIDS cases. Cellulose sulfate (CS) gel is a promising microbicide candidate. CONRAD (maker of CS gel) is the sponsor of this study and has supplied the study product for this Phase III study.

This randomized controlled trial was to enroll 2,160 women, aged 18-35 at high risk for HIV, who would be followed for one year of study participation. Half the women were assigned CS gel and half were assigned placebo gel. A combined incidence rate of HIV-1 and HIV-2 infection would be compared between the two groups to evaluate the effectiveness of CS gel. Also, incidence rates of gonorrhea and chlamydial infection would be similarly compared.

Due to the January 2007 findings of the CONRAD DMC on a parallel study, this subproject was brought to an early close with a total of 1,644 women enrolled. The HIV results were presented at the IAS conference held in Sydney, Australia in July 2007. The main manuscript was published in November of 2008. CS use had no effect on the risk of HIV transmission. The rates of infection were similar between the CS and placebo groups (HR = 0.8, 95% CI 0.3-1.8; p=0.56). Rates of gonorrhea and chlamydial infection were higher in the placebo group but the difference was not statistically significant (HR=0.8, 95% CI 0.5 -1.1; p=0.19 for the combined STI outcome).

Subgrantee(s): Health Matters Inc, Lagos Nigeria; Institute for Tropical Medicine-Prince Leopold; Institute of Tropical Medicine, Antwerp, Belgium; Lagos University Teaching Hospital, College of Medicine, Lagos, Nigeria; STOPAIDS Organization, Port Harcourt, Nigeria; StopAIDS; University of Lagos, College of Medicine; University of Port Harcourt Teaching Hospital; University of Port Harcourt Teaching Hospital, Port Harcourt, Nigeria

Collaborating Agency(s): CONRAD

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Activities, Accomplishments, Problems through December 31, 2008

- USAID granted preliminary approval for this subproject in September 2001; the protocol was approved by the PHSC in August 2003; the National Agency for Food and Drug Control (NAFDAC) of Nigeria approved the protocol in December 2003.
- Please refer to the 2007-2008 Annual Report for all other activities that took place prior to July 2007.
- The final data freeze was done on August 7, 2007. A pregnancy outcome dataset was frozen for analysis on January 16, 2008. A statistical report was completed in October 2007.
- We concluded all 5 subagreements for cost and reimbursement purposes.
- Both PIs Drs. Obunge and Ogunsola visited FHI in August 2007 and worked with FHI staff on a publication regarding recruitment strategies in the CS trial in Nigeria.
- Three members of the CS FHI team and six members of the CS Nigeria teams attended the M2008 conference in New Delhi. Four abstracts were accepted, two as oral presentations and two as posters (see the Findings and Outcomes section).
- In May 2008, the PI from Lagos presented the poster 'Recruitment Strategies...' at AIDS 2008 and the poster 'Prevalence of... Nigeria' at the ICASA 2008 (see the Findings and Outcomes section).
- The PI from Lagos submitted in June 2008 and presented the poster "Sexually Transmitted Infections among High-risk Women in Lagos, Nigeria" at the ICASA 2008. (see Findings and Outcomes section).
- The final report to the FDA was submitted in October 2008.
- A 15% variance letter was submitted to USAID in November 2008 to cover additional costs through the end of the project associated with additional data analyses and paper writing.
- The main manuscript was published in November 2008 in PLoS ONE (See Findings and Outcomes section).

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The manuscript "Interim data monitoring to enroll higher-risk participants in HIV prevention trial" was accepted for publication in BioMed Central Medical Research Methodology in June 2009.
- The abstract "Predictors of Pregnancy in Microbicide Trials" was submitted to "International Conference on Family Planning: Research and Best Practices" to be held in Kampala, Uganda.
- The manuscript "Predictors of Pregnancy in Microbicide Trials" was submitted for publication in the American Journal of Obstetrics and Gynecology.
- Both sites conducted a series of dissemination sessions with study participants and local stakeholders in the field of HIV prevention research in Nigeria. The final report was received from the Lagos site and the final report from the Port Harcourt site is pending.

Findings and Outcomes:

- The study was prematurely stopped on Jan. 31, 2007 due to the unexpected negative effect on HIV acquisition observed in an interim analysis of data from a parallel trial of CS conducted by CONRAD. There was no apparent increased risk of HIV in the CS groups in the FHI study at the interim analysis but the DMC recommended stopping the trial due to safety concerns raised in the CONRAD trial.

- The main manuscript was published in Nov. 2008 (FHI Pub 2008-128). We observed fewer infections in the active arm (10) than on placebo (13), a difference that was not statistically significant. Likewise, rates of gonorrhea and chlamydial infection were higher in the placebo group but not statistically significant. Rates of adverse events were similar across study arms. No serious adverse events related to CS use were reported.
- Despite the scientific failure, the implementation of the study had a long-term positive impact on the community: McNeil L, et al. Microbicide Research in Nigeria - Other Than Scientific Successes. Microbicides 2008 (Abstract D020-513).
- Abstract "Recruitment Strategies in the Phase III Randomized Controlled Trial of CS Gel and HIV in Nigeria" (Abstract MOPE0441) was presented at AIDS 2008.
- Abstract "Prevalence of STIs among High-risk Women in Lagos, Nigeria" was presented at ICASA 2008.
- Abstract "Predictors of Pregnancy in Microbide Trials" (submitted for presentation at the Gates conference and for publication in the American Journal of Obstetrics and Gynecology. These data suggest that current use or acceptance of intrauterine contraception, implants, sterilization or injectables is the most effective approach to reduce pregnancy rates in trials and might be a useful eligibility criterion in future HIV prevention trials.
- The abstract of the manuscript "Interim data monitoring to enroll higher-risk participants in HIV prevention trial" was accepted for publication in BioMed Central Medical Research Methodology in June 2009. It stated that given the difficulties in estimating HIV incidence, a close monitoring of HIV prevalence and incidence rates during a trial is warranted. The on-going modification of recruitment strategies based on the regular analysis of HIV rates appeared to be an efficient method for targeting populations at greatest risk of HIV infection and increasing study power in the Nigeria trial.
- The following study-related abstracts have also been published: FHI Pub2006-48; 2006-60; 2006-61; 2006-62; 2007-43.

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Planned Activities for July 1, 2009 – April 28, 2010

- The subproject completion date will occur in April 2010, the subproject and the final FCO (132100) will be closed.

Funding Source(s):	USAID - US Agency for International Development/USAID:	FCO Approved:	2266	Sep 2001
	Core; USAID - US Agency for International Development/USAID:		132100	Jul 2005
	Microbicides		132143	Oct 2006
			132122	Oct 2006
			132123	Oct 2006
			132124	Oct 2006
			132125	Oct 2006
Total Approved Budget:	2266	\$	4,452,495	Projected End Date: Apr 2010
	132100	\$	10,102,737	
	132143	\$	1,783,896	
	132122	\$	1,799,546	
	132123	\$	48,250	
	132124	\$	136,622	
	132125	\$	102,200	
		\$	<u>18,425,746</u>	

USA: New Delivery Device for Vaginal Microbicides (FCO 1844/2290/12164/132103/132178)

Technical Monitor: CJoanis

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.F.: Two new delivery systems/methods of administration for topical microbicides evaluated. Results will be submitted to the FDA, other regulatory bodies, and other interested parties as appropriate.

Objective(s): 1) To develop hand-made prototypes of a new vaginal delivery device for microbicides or other vaginal preparations; 2) to assess acceptability of the device via focus group discussions or in-depth interviews; and 3) to assess acceptability through vaginal insertion and removal of the device saturated with a marketed vaginal lubricant.

Note: The third objective was added as the research progressed, partially supported by funding from the International Partnership for Microbicides (IPM).

Description: Current vaginal applicators are designed to deliver a prescribed amount of drug or lubricant. Though inexpensive, these applicators do not always deliver effective drug doses. Efficacious drug delivery is dependent on three factors: (1) delivery of the drug into the vagina; (2) spread of that drug throughout the vaginal vault; and (3) retention of the drug in the vagina. Consequently, efficacy and user satisfaction may be compromised by human error that results in leakage and/or inadequate coverage/spread of the drug. The proposed device is intended to employ an applicator technology that has not previously been used for vaginal microbicides, and placement, retention and leakage are intended to be minimized through the use of a non-woven material. It is believed that this device will release the microbicide evenly, retain drug within the vagina for longer periods of time, and possibly allow for multiple sexual acts without re-dosing. Its unique design would possibly provide a degree of physical barrier protection as well. Under this subproject, a new vaginal delivery device for microbicides or other vaginal preparations was prepared. Focus group discussions or in-depth interviews regarding prototype acceptability were conducted. A review of relevant patents was conducted, and a patent application for the new device was prepared. This activity is supported by USAID funds designated for microbicide research and private funds.

Subgrantee(s): RHRU

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Activities, Accomplishments, Problems through December 31, 2008

- This subproject was approved in July 2004.
- In February 2005, prototypes were provided for CONRAD's Phase I trial of citric acid and FHI conducted a sub-study to gather data from study participants.
- Funds were requested from IPM and were awarded in May 2006. Work began on the design of 3 prototypes: doughnut-shaped, round and teardrop. Device materials were selected in June 2006.
- A patent application was submitted in July 2006.
- Focus groups were held with FHI female employees in October 2006 and a report was written in November 2006.

- Second generation materials were chosen in December 2006 and tests were conducted on the release of fluids from these materials.
- Focus groups and interviews with Latina and African women were held and the data was analyzed from January -June 2007. Results led to design changes (DVD2).
- An international patent was submitted in June 2007.
- A protocol was written for an acceptability study of DVD2 in South Africa and was approved by the PHSC in November 2007.
- In August 2007, an active agent to use with DVD2 for a future safety study was chosen.
- Toxicity and safety tests on DVD2 were completed in October 2007.
- A poster was presented at the Microbicides Conference in New Delhi in February 2008.
- The DVD2 acceptability protocol was modified and sent to the South African IRB in January 2008. It was approved in March 2008. (IPM funds will be used to conduct this study.)
- Additional toxicity and shelf-life studies were conducted during March and April 2008.
- The team continued to seek additional funding (Gillings and Nine-Sigma) to support needed research into materials, active agent selection and human testing. An additional \$60K was requested from USAID to complete the acceptability study in South Africa. The study in South Africa was delayed due to the loss of the project coordinator (nurse). Third generation materials were identified (second generation material require more expensive manufacturing procedures to fuse component parts).
- Research to identify active agents for the treatment of yeast and bacterial vaginosis infections began.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- USAID funding was provided through the end of Year 4, June 30, 2009.
- A letter with a revised life-of-subproject budget was obtained from USAID/Washington and approved in late March 2009.
- Due to the lengthy signoff period, the study product expired.
- A manuscript on the results of the lime juice study was submitted to AIDS and Behavior in April 2009. (Reference: Acceptability of a non-woven device for vaginal drug delivery of microbicides or other active agents).
- An NIH Challenge grant was submitted in April 2009 to obtain funding for future research.
- New study products were manufactured and tested in May and June 2009.
- Study initiation was conducted by teleconference on June 23 and 25, 2009.
- The study will be completed using IPM funding.
- FCO 132103 was closed on June 30, 2009.

Findings and Outcomes:

- A unique non-woven vaginal drug delivery prototype was developed. It is believed that the device will deliver microbicides more efficiently than currently available methods. The device uses inexpensive materials and if mass produced, the estimated cost would be about \$0.05 per unit (excluding drug).
- Results of the focus group discussions support continued research efforts and the prototype was modified to reflect new insights.
- An international patent application was submitted, including a male version of the device.
- Results of the acceptability study in South Africa are expected in December 2009.
- Abstract of the manuscript submitted to AIDS and Behavior is as follows: Introduction: Vaginal microbicides could reduce new cases of HIV. However, the current method of delivering gel formulations (standard applicator) results in vaginal leakage and acceptability problems. Objectives: To determine the acceptability of using a non-woven device for vaginal drug delivery. Methods: This sub-study was conducted within a 6-day, Phase I safety trial of lime juice used intra-vaginally. Forty-eight women were enrolled in this crossover, randomized controlled trial. Participants were randomized to one of four groups: bottled water, 25%, 50%, and 100% lime juice concentrations. The women were instructed to use their assigned solution as a douche and with a saturated, modified tampon. Of the 48 women

enrolled, 16 women were interviewed about their experiences for this sub-study. Results: There was a dose-response relationship between lime juice concentration and adverse medical events. Fifty-six percent (n=9) of the women had no difficulty inserting the wetted device and 14 women had no difficulty in removing it. Leakage from the device was minimal. Ten women said they would consider using a non-woven drug delivery device for HIV prevention, and 12 women said they would consider use for treatment of vaginal yeast infections. Conclusions: Women found the vaginal drug delivery device to be acceptable for use in delivery of medications for yeast and bacterial infections. Research should focus on smaller devices and incorporating drug formulations with less irritation potential.

- Future work (reports, manuscripts, testing, etc.) will be conducted under FCO 1844 or other accounts from different funding sources.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Using IPM funding (FCO#1844), the study to evaluate the acceptability of the DVD2 device will begin enrollment on July 20, 2009.
- The study will be monitored using scanned DCFs on a weekly basis.
- If funding becomes available, we will physically monitor the study in Durban in October 2009.
- We conduct the analysis of the data beginning in October 2009.
- The study will be completed and a report generated by December 2009.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: Microbicides; International Partnership for Microbicides (IPM)/Private	FCO Approved: 2290 Jun 2004 132103 Aug 2005 1844 May 2006 12164 Nov 2008 132178 Feb 2009
Total Approved Budget:	2290 \$ 220,917	Projected End Date: Dec 2009
	132103 \$ 555,368	
	1844 \$ 200,000	
	12164 \$ 67,236	
	132178 \$ 23,891	
	\$ 1,067,412	

Madagascar: Diaphragm Plus Microbicide Expansion Study of STDs (FCO 132150/132151)

Technical Monitor: GPittman

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.B.: Through Phase I trials in collaboration with CONRAD, the initial safety of three new microbicide candidates determined.

Results will be submitted to the FDA, other regulatory bodies, and other interested parties as appropriate.

Objective(s): To provide funding to CONRAD to determine if the diaphragm and a microbicide used separately or together are effective at preventing *Neisseria gonorrhoea* and *Chlamydia trachomatis* re-infections in women. The candidate microbicide selected is BufferGel based on results from the preliminary safety study comparing Acidform and BufferGel conducted at the University of Pennsylvania, University of Pittsburgh and Eastern Virginia Medical School, as well as favorable interactions with the company which owns the product. The intended population to be studied are HIV-negative, non-pregnant women aged 15-55 years at high risk for STI with laboratory-confirmed GC/CT infection at screening who are willing to use hormonal contraception or who are sterilized.

Description: This multi-site, randomized clinical trial (RCT) will assess the effects of the diaphragm and BufferGel use on the acquisition of *Neisseria gonorrhoea* and *Chlamydia trachomatis* among women in five cities in Madagascar (Antananarivo, Antsiranana, Mahajanga, Toliara and Toamasina). There will be four arms in this partially-masked, effectiveness and extended safety trial: 1) diaphragm used continuously with BufferGel applied once daily in the dome of the diaphragm and intravaginally before every coital act (main intervention; "diaphragm + BufferGel"); 2) diaphragm used continuously with HEC applied once daily in the dome of the diaphragm and intravaginally before every coital act ("diaphragm + HEC"); 3) BufferGel applied intravaginally before every coital act ("BufferGel only"); and 4) HEC applied intravaginally before every coital act ("HEC-only" control arm). The asymmetrical design will be used to concentrate 90% of the study population into the main intervention and control arms while maintaining masking of gel assignment. All groups will receive male condoms. A total of 1,540 women who are at high risk of acquiring STIs will be recruited. These women will be evaluated consistently during the six months of follow-up.

This activity was co-funded by CDC and NIH (under the STI-CTG, FCO 12094). FHI had no study-related tasks assigned under this activity; it served as a funding mechanism for USAID support of the activity. This funding was transferred back to CONRAD at the end of September.

Subgrantee(s): CONRAD

Collaborating Agency(s): CONRAD; Centers for Disease Control and Prevention (CDC)

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Activities, Accomplishments, Problems through December 31, 2008

- The FCO was set up in July 2007.
- Upon receipt of the final invoice, FHI completed the transfer of funds to CONRAD in October 2008.
- The subagreement ended and the FCO was closed in November 2008

Findings and Outcomes:

- The project will continue under CONRAD, and any future reporting of this activity to USAID will be done by CONRAD.

Funding Source(s):

USAID - US Agency for International Development/USAID: Microbicides	FCO Approved: 132150 Jul 2007 132151 Jul 2007
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Total Approved Budget: 132150

132151 \$

N/A

1,169,925

Projected End Date: Nov 2008

India: Sustained Acceptability of Vaginal Microbicides: Male and Female Perspectives (FCO 9386/136100/136102)

Technical Monitor: BTolley

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.I.: Innovative strategies to increase retention and reduce product interruptions in trials developed and tested.
Microbicides I.H.: Social and behavioral components and/or ancillary studies within microbicide clinical trials conducted to provide information on: sexual relationships and practices, the social and cultural context for microbicides, potential for covert use, and community support and policies.

Objective(s): 1) To identify and describe factors that enable individuals and couples to use microbicides consistently and long-term; and 2) to account for the effects of clinical trial and acceptability research participation on microbicide use including: motivations for joining the trial; the importance of counseling and support provided by clinical trial staff in maintaining product use; and the importance of interactions with acceptability research staff in maintaining product use.

Description: The Sustained Acceptability study integrates qualitative and quantitative methods in a longitudinal study of microbicide acceptability in Pune, India. It does so by building on to Phase I (FCO 433) and Phase II microbicide clinical trials research funded by NIAID and implemented under the auspices of the HIV Prevention Trials Network (HPTN). A pilot study, conducted during the Phase I clinical trial, included repeated in-depth interviews with high and low-risk individuals and couples on key concepts believed to influence risk-reduction behaviors including: HIV risk perception, self efficacy, couple harmony, and sexual communication. Based on the qualitative data, approximately 130 items were drafted to represent key concepts. The items were then administered to 300 women and 150 male partners and factor analyzed to produce draft psychometric scales which will be used in a longitudinal assessment of acceptability.

A total of 100 women will be enrolled in the HPTN Phase II parent study and followed for 6 months. These women and their primary partners will be recruited into the parallel acceptability study. Participants will provide two sets of data: core acceptability data developed for the clinical trial and enhanced acceptability data. The enhanced questionnaires will measure individual and couple scores on key psychosocial factors believed to mediate microbicide or condom use, as well as motivations for clinical trial participation. A second cohort of 100 women who were screened but found ineligible to participate in the HPTN parent study, along with their primary partners, will also be recruited, but administered the enhanced questionnaire only. In addition, clinical trial providers and a small sample of women and willing partners will also be interviewed in-depth, using a more flexible and open format.

Note: This study has two PHSC numbers: 9781 and 9481.

Subgrantee(s): National AIDS Research Institute (NARI)

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Activities, Accomplishments, Problems through December 31, 2008

- Pilot qualitative data collection was conducted between Oct. 2003 and Feb. 04.
- The TM conducted a data analysis workshop in Feb. 04 for approximately 25 NARI staff. In June 04, 10 field staff were trained in administering the scale survey.
- Feb.-March 05, a questionnaire was developed and administered to a total of 456 individuals (305 women and 151 husbands). In April the quantitative data were analyzed.
- NARI withdrew from the HPTN 035 Phase IIb study but FHI received USAID's approval to shift the prospective acceptability research onto HPTN 059.
- The prospective protocol was revised and approved in Dec. 04. NARI's pilot study subagreement was extended to include behavioral and social science research. The PHSC approved these changes in July 05. In Sept. and Nov. they approved the pilot and prospective study protocols for continuation.
- In March 06, the TM and analyst participated in the HPTN 059 site initiation training and trained 5 staff in procedures for the prospective study.
- Findings from the pilot were presented at the 06 Microbicide Conference, S. Africa.
- In Sept. 06 the prospective acceptability study was initiated. Tolley traveled to Pune to review data management in Sept. 06 and March and July 07.
- In March Tolley presented the study's approach to identifying predictors of sustained microbicide use at the Microbicide Trial Network's annual meeting.
- Prospective study enrollment was completed in June 07.
- The provider interview guide and consent form were approved by FHI's PHSC in Aug.
- Rewa Kohi visited FHI in Oct. to assist with data analysis and report-writing; 2 abstracts were submitted to the Microbicides 08 conference.
- PHSC approved continuing review in Nov. 08.
- In Dec. 07 Tolley presented mixed model analyses of condom and gel adherence at a meeting on Adherence and Its Measurement in DC.
- Follow up interviews were completed in Dec. 2008.
- Data from HPTN 059 clinical trial was obtained from SCHARP in July 2008 and quantitative analyses were conducted between October and December 2008.
- NARI subagreement was closed in December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Tolley and Tsui participated in an adherence workshop in March 2009. This workshop provided information to support adherence-related analyses from the Pune study.
- Tolley and Tsui traveled to Delhi and Pune, India in March 2009 to participate in dissemination activities.
- A six-hour policy-level dissemination workshop was conducted in New Delhi on 3/25/09 and attended by 30 representatives from governmental and non-governmental organizations.
- A community dissemination workshop was conducted on 3/28/09 in Pune, India and attended by 90 representatives from research and service delivery organizations, as well as former study participants.
- In May 2009 Tolley presented findings at two meetings: 1) "Predicting Adherence Within and Beyond the Clinical Trial Setting" presented on 5/10/09 to approximately 50 scientists involved in HIV Vaccine trial research; and 2) "Married Women and Microbicides: Implications for Product Introduction" presented at the Global Health Coalition meeting on 5/26/09, attended by 75-100 participants.
- Tolley provided revisions to a paper on Male Acceptability drafted by NARI counterparts for submission to a peer reviewed journal.
- An FHI Fellow completed analysis of qualitative couple data in May 2009 and wrote a paper entitled "Exploring Married Couples' Sexual Communication within the Context of a Microbicide Clinical Trial and Acceptability Study in Pune, India". The paper will be submitted to a peer-reviewed journal by July 2009. A second paper is underway and will be completed as part of the FHI Fellowship agreement.

- Tolley and Tsui have drafted a paper entitled "Predicting Product Adherence in a Topical Microbicide Trial". The paper will be submitted by July 2009.
- Additional papers are underway at NARI on acceptability of daily versus coital use of microbicides and FHI on risk perception. These papers will be completed under other FCOs or budget arrangements.
- The final FCO for this study (FCO 136100) was closed on 6/30/09.

Findings and Outcomes:

- The qualitative phase found that women will not likely consider microbicide use unless they perceive themselves to be at risk of HIV. HIV risk was most associated with a partner's infidelity, easily detected by a lack of marital harmony. Despite this, high-risk women denied perceiving HIV risk until confronted with specific evidence like a husband's positive HIV test or diagnosis of an STD.
- Women's perceptions of control and sexual power influenced attitudes towards microbicide consistency.
- Factor analysis produced five scales, measuring Couple Harmony, Perception of Partner Infidelity, AIDS Fatalism, Pervasiveness of HIV Risk, and Protection Efficacy.
- Findings were published in the July/August 2006 edition of "Culture, Health & Sexuality in an article entitled "Examining the context of microbicide acceptability among married women and men in India." (FHI Pub 2006-51)
- Analyses of couple qualitative data found that participation in the prospective acceptability study improved couple communication. No negative impacts from study participation were reported.
- Prospective study findings included the following: while trial participants were similar to non-trial participants in terms of most socio-demographic and relationship characteristics, they reported significantly higher baseline condom use and increased use over time compared to non-trial participants.
- Within trial, higher condom consistency was predicted by: higher levels of Couple Harmony; higher assessment of Protection Efficacy; more positive attitudes towards condoms; and lower perceived HIV risk from personal, partner or other sources.
- In the clinical study, gel adherence was not associated with perceptions of couple harmony, risk perception or efficacy.
- Microbicide products may be more acceptable than condoms for HIV prevention.
- Widespread uptake may depend on introduction strategies that avoid associations with infidelity.
- Findings suggest that microbicide introduction should emphasize positive product attributes and the potential to enhance couple harmony.
- Additionally, more research is needed to understand how clinical trial requirements influence participant characteristics, their HIV risk profiles and ability to adhere to product use and the trial protocol.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: Microbicides	FCO Approved: 9386 Oct 2001 136100 Dec 2005 136102 Dec 2005
Total Approved Budget:	9386 \$ 822,278	Projected End Date: Jun 2009
	136100 \$ 613,000	
	136102 \$ 131,017	
	<hr/> \$ 1,566,295	

USA: Assessment of Soluble and Cellular Markers of Inflammation after Vaginal Product Use (FCO 132109)

Technical Monitor: GPittman

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.B.: Through Phase I trials in collaboration with CONRAD, the initial safety of three new microbicide candidates determined. Results will be submitted to the FDA, other regulatory bodies, and other interested parties as appropriate.

Objective(s): To provide data management and analysis support to a CONRAD-led study designed to assess proinflammatory cytokines and related factors in female participants who use a vaginal product (cellulose sulfate, HEC-based "universal" placebo or 4% nonoxynol-9).

Description: FHI will provide data management and analysis support to this CONRAD-led multicenter, comparative, blinded, randomized study in 60 healthy, sexually abstinent women. Twenty women were randomized to each of three groups to apply either cellulose sulfate, a HEC-based "universal" placebo or 4% nonoxynol-9 to the vagina twice daily for 13.5 days. Cervicovaginal lavages (CVLs) for soluble and cellular markers of inflammation, vaginal smears for Nugent scores, semiquantitative vaginal cultures, vaginal pH, and colposcopy were carried out at baseline, after the 13th dose, after the last (27th) dose, the day after the last dose, and three days after the last dose. Biopsies and cytobrush specimens were obtained before product use and one day after the last use. The biopsies and cytobrush specimens were carried out at the same point in each of two subsequent cycles. Results from this study will be used to refine the preclinical rabbit vaginal irritation (RVI) protocol in order to triage candidate microbicide products for further study in early clinical trials, eliminating those which have an inflammatory profile similar to N-9. In addition, this study will correlate results from CVLs with colposcopy, biopsy, Nugent scores, and clinical diagnoses of infection. It will also add to the literature on normative values for cytokines and inflammatory cell types in the genital tract.

Collaborating Agency(s): CONRAD

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Activities, Accomplishments, Problems through December 31, 2008

- The Investigators' Meeting was held in July 2006.
- The FHI study team reviewed drafts of case report forms starting in August and the FHI study team worked with CONRAD to review and finalize the protocol in October 2006.
- The protocol was amended and approved in March 2007.
- The case report forms were revised and approved in June 2007.
- A CONRAD monitor initiated the study sites in June 2007.
- The protocol was amended and approved as v4.0 in October 2007.
- The Data Management Plan was finalized and enrollment began in November 2007.
- Error specifications were finalized upon review/comments from CONRAD and the DM system set-up was completed and ready to receive data in April 2008.
- Recruitment ended in June 2008 with the target number of 60 women enrolled.
- Closeout visits were conducted at the study sites by the CONRAD monitor in July 2008.

- The analysis plan was finalized and approved in September 2008.
- Data entry was done, with all data being received in-house at FHI late November 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- All remaining queries were resolved, all data coding completed, and the final data freeze was done in March 2009.
- The statistical report (descriptive component) was completed and sent to CONRAD in April 2009 for the Europrise Conference.
- With active collaboration with the CONRAD PI, FHI began follow up analysis in preparation for data modeling.
- FHI provided review of CONRAD's presentation materials for NIH and the Europrise conference in Stockholm, April 2009.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- FHI statisticians will complete verification of statistical analyses being conducted by EVMS central laboratory on data collected outside of clinical database.
- FHI will continue follow up analysis as requested by CONRAD PI.
- FHI will provide review of CONRAD's presentation material as requested for the NIH meeting to be held in December 2009 and Microbicides 2010.
- FHI will provide review of the manuscript as requested by CONRAD.
- The subproject will end, study documents will be archived, and the FCO will be closed EOY April 2010.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:	Jun 2006
Total Approved Budget:	\$ 264,437	Projected End Date:	Apr 2010

Worldwide: Independent Monitoring of CONRAD Collaborative Studies (FCO 2285/132101)

Technical Monitor: GPittman

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.A.: Five pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate.

Microbicides I.B.: Through Phase I trials in collaboration with CONRAD, the initial safety of three new microbicide candidates determined. Results will be submitted to the FDA, other regulatory bodies, and other interested parties as appropriate.

Objective(s): To provide clinical monitoring services to CONRAD specifically for USAID funded studies.

Description: This subproject is funded by USAID designated microbicide funds and is intended to cover monitoring of USAID-supported CONRAD microbicide research. When monitoring services are provided in addition to statistical and/or data management support services, then monitoring costs are charged directly to the study-specific FCO.

Collaborating Agency(s): CONRAD

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Activities, Accomplishments, Problems through December 31, 2008

- The original FCO for this subproject was established in October 2003.
- A closeout monitoring visit was completed in October 2003 for the study, "A Randomized Controlled Trial of the Diaphragm to Prevent Sexually Transmitted Infections," that was conducted in Nairobi, Kenya.
- An interim monitoring visit was completed in January 2004 for the formative portion (Phase I) of the study, "Diaphragm Acceptability among Sex Workers, Their Clients, and Their Partners." This study was conducted in Nairobi, Kenya.
- An initiation visit was completed in May 2004 for the study, "A Phase I Safety Trial of the Diaphragm Used with Sodium Cellulose Sulfate and KY Jelly." This study was conducted in Zimbabwe.
- An initiation visit was completed in Kenya in September 2004, for the safety portion (Phase II) of the study "Diaphragm Acceptability among Sex Workers, Their Clients, and Their Partners."
- An interim monitoring visit was conducted in January 2005 in Zimbabwe for the study, "A Phase I Safety Trial of the Diaphragm Used with Sodium Cellulose Sulfate (CS) and KY Jelly." Another interim visit was conducted in August 2005 in Zimbabwe. During this visit, the monitor worked with the site to resolve findings from an audit in May 2005 conducted by JRobinson (FHI) and JSchafer (CONRAD), as assigned by CONRAD.
- In May 2005, an interim monitoring visit was conducted in Nairobi, Kenya for the study, "Diaphragm Acceptability among Sex Workers, Their Clients, and Their Partners." In August 2005, a closeout visit was carried out.
- A new FCO (132101) was opened with microbicide funding under the CRTU in July 2005, and the CTR-related FCO (2285) was closed in October.
- A closeout visit was conducted in November 2005 in Zimbabwe for the study, "A Phase I Safety Trial of the Diaphragm Used with Sodium Cellulose Sulfate and KY Jelly."
- No monitoring activity occurred under this FCO during January 2006 - December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- There was no monitoring activity under this subproject during the January - June 2009 time period.

Findings and Outcomes:

- As part of the ongoing FHI-CONRAD collaboration, FHI completed clinical monitoring services as agreed to by FHI and CONRAD.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- The subproject will end and the FCO will be closed.

Funding Source(s): USAID - US Agency for International Development/USAID: Microbicides; USAID - US Agency for International Development/USAID: Core
FCO Approved: 2285 Oct 2003
132101 Jul 2005
Total Approved Budget: 2285 \$ 164,234
132101 Annually Approved
Projected End Date: Apr 2010

**Worldwide: Site Identification, Assessment & Development
(FCO 1041/132113/132118/132145/132152/132153/132154/132155/
132156/132160/132161/132162/132163/132164/132165/132166/
132167/132171/132172/132173/132174/132175/136114/136116/
136118)**

Technical Monitor: SHorn

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.C.: Five new sites for pivotal microbicide trials established, qualified, and functioning, with appropriate stakeholder involvement.

Objective(s): To identify, prepare, and establish five new sites for future Phase I to Phase III microbicide studies with appropriate stakeholder involvement. Secondary objective: To develop and fully implement a new multistage, interdisciplinary paradigm based on lessons learned from Phase I, II and III microbicide trials.

Description: The spread of HIV and disproportionately high rates of transmission in women reflect the need for expanded prevention options, particularly those that women can control. Prevalence rates in sub-Saharan Africa and Asia create an immediacy to place well-designed trials for new products in new locations. We will develop and apply a multidisciplinary, systematic approach to identify, assess and prepare microbicide trial sites. This approach will draw upon our expertise in clinical research, epidemiology, behavioral and social sciences, training, field services, regulatory affairs, health services, research ethics, communication, biostatistics and data management.

This subproject is an essential component for future clinical studies. The first stage, site identification, gathers and/or makes use of existing epidemiologic, social and behavioral data, as well as information about the material and human resources available locally, in order to identify and assess potential sites for future microbicide clinical trials. A Site Identification Database (FCO 132118) has been established as a central resource to facilitate activities for site identification, assessment, and development. The second stage, site assessment, narrows to approximately 10 most promising sites and assesses them in greater depth. The third stage, site

development, further evaluates and prepares five of the 10 sites for study suitability and preparedness using a multistage, interdisciplinary approach.

Successful implementation of future microbicide research requires additional international clinical research sites that: 1) can identify, access, recruit and follow study populations at high risk of HIV acquisition; 2) are trained to adhere to GCP and other international ethical and biomedical standards; and 3) are part of communities that support the research goal(s).

Prior to December 2006, this subproject was funded with G&A funds from FCO 1041.

Subgrantee(s): Armauer Hansen Research Institute (AHRI); Aurum Institute; Aurum Institute for Health Research; Catholic University of Mozambique; Catholic University of Mozambique (UCM); INS Chokwe Development; Ifkara Health Institute; JOSHA Research; JOSHA Research Bioemfontein; National Institute of Health (Mozambique); National Institute of Medical Research; Nyabisase Construction Company; Provincial AIDS Committee (PAC); Provincial AIDS Committee (Vietnam); University of Illinois; University of Illinois

Collaborating Agency(s): Centers for Disease Control and Prevention (CDC); European/Developing Country Clinical Trial Programme (EDCTP); International AIDS Vaccine Initiative (IAVI); UNAIDS

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Activities, Accomplishments, Problems through December 31, 2008

- Please refer to Annual Report (2006-2007) for accomplishments that took place prior to July 2006, and Annual Report (2007-2008) for accomplishments that took place prior to July 2008.
- The core and study-specific training courses were given at the SA and VN sites (June-Dec 2008).
- CDC agreed to fund laboratory work in the VN and SA incidence studies for calibration of the BED and other assays.
- Renovations for research facilities in VN and SA were done.
- Charges for clinic renovation in Arusha, Tanzania to FCO 132156 were transferred to the Fem PrEP subproject from July 2008 forward.
- The Partnering for Care monograph was printed and 382 copies were disseminated since September 2008 to AIDS conf. in Mexico City, MTN (Microbicides Trials Network) regional meeting in Cape Town, S.A., CRS site leaders, investigators, study coordinators, community working group members, community educators, PRIM&R (Public Responsibility in Medicine & Research) board of directors, UNAIDS, researchers and university faculty and staff.
- The South Africa, Vietnam, Mozambique, Tanzania, Ethiopia subagreements were fully executed.
- The protocol to enumerate women at higher risk of HIV in two cities in Tanzania was approved by the PHSC and the national IRB, and commenced in Dec. 2008. The core and study-specific training courses were given at the Tanzania site in Oct. 2008.
- The Arusha and Bondo renovations were completed in Dec. 2008.
- A protocol for a qualitative study of multiple and concurrent partnerships (MCP) with co-funding from UNAIDS in Lesotho was approved; it began in Mar. 2008 and was completed in Aug. 2008. Analysis has been completed and the final report has been drafted.
- Discussions were held with UNAIDS to conduct similar MCP studies in Zambia and Mozambique, with co-funding from UNAIDS.
- The core training course was revised after its initial delivery in South Africa.
- The second phase of the Site Information Database was implemented with changes that enhance user-friendliness and permit addition of ethics review and regulatory information.
- Enrollment began in the Vietnam and Rustenburg, SA HIV incidence studies. Enrollment began in the Vietnam sexual network study.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The core and study-specific training courses were given at the Ethiopia and Beira, Mozambique sites (April-June 2009)

- The community mapping phase of the Tanzania Site Population Estimation and Community Activities (SPECA) study was completed in April 2009.
- The Combined Cross-Sectional and Prospective Study for Measurement of HIV Incidence in Beira, Mozambique was approved by the PHSC in April 2009.
- The planned HIV incidence study for the Zambia site was canceled in April 2009.
- A training course on research literacy for community members was begun.
- Renovations for research facilities in Mozambique were done.
- Following study-specific training, the MCP behavioral study commenced at the Zambia site in June 2009.
- The Zambia MCP study commenced.
- Enrollment began in the Bloemfontein HIV incidence study.

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Planned Activities for July 1, 2009 – April 28, 2010

- Statistical analysis plans will be written for each HIV incidence study.
- Core training and study-specific training will be held at the Chokwe, Mozambique site.
- MCP studies will be done at the Mozambique sites, with co-funding from UNAIDS.
- The incidence protocols will commence at the Mozambique and Ethiopia sites. Incidence research at one Mozambique site will be co-funded by the EDCTP.
- Analysis will be done for the initial incidence studies, the Tanzania study of women at higher risk, and the MCP studies.
- The Vietnam and Bloemfontein HIV incidence studies will be completed.
- Short-courses on epidemiologic study design, scientific paper-writing, and qualitative research methods are planned.
- Monitoring and evaluation of the SIDI project will be undertaken, as will compilation of the toolkit to guide future site development efforts.
- FHI staff will disseminate information about the development of and successes at the study sites at international and regional HIV conferences.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides; USAID - US Agency for International Development/USAID: Core	FCO Approved:	1041	Nov 2005
			132113	Jun 2006
			132118	Dec 2006
			132145	May 2007
			136114	Sep 2007
			136116	Nov 2007
			132152	Apr 2008
			132153	Apr 2008
			132154	Apr 2008
			132155	Apr 2008
			132156	Dec 2007
			132166	Apr 2008
			132165	Apr 2008
			132164	Apr 2008
			132163	Apr 2008
			132162	Apr 2008
			132161	Apr 2008
		132160	Apr 2008	
		132167	Apr 2008	
		136118	Jul 2008	
		132171	Jun 2008	
		132173	Aug 2008	
		132174	Aug 2008	
		132172	Aug 2008	
		132175	Aug 2008	

Total Approved Budget:	1041	\$	128,038	Projected End Date:	Apr 2010
	132113	\$	7,233,252		
	132118	\$	183,788		
	132145	\$	168,583		
	136114	\$	80,189		
	136116	\$	86,635		
	132152	\$	342,876		
	132153	\$	316,284		
	132154	\$	523,879		
	132155	\$	1,275,353		
	132156	\$	287,814		
	132166	\$	180,772		
	132165	\$	492,233		
	132164	\$	139,159		
	132163	\$	1,436,574		
	132162	\$	613,882		
	132161	\$	618,135		
	132160	\$	704,447		
	132167	\$	247,899		
	136118	\$	734,040		
	132171	\$	174,637		
	132173	\$	161,460		
	132174	\$	139,958		
	132172	\$	750,000		
	132175	\$	134,234		
		\$	17,154,121		

Worldwide: Use of DHS Data for Site ID Recruitment (FCO 136103)

Technical Monitor: BTolley

Strategy Outcomes(s) to be addressed: Microbicides I.C.: Five new sites for pivotal microbicide trials established, qualified, and functioning, with appropriate stakeholder involvement.

Microbicides I.I.: Innovative strategies to increase retention and reduce product interruptions in trials developed and tested.

Microbicides I.H.: Social and behavioral components and/or ancillary studies within microbicide clinical trials conducted to provide information on: sexual relationships and practices, the social and cultural context for microbicides, potential for covert use, and community support and policies.

Objective(s): 1) To identify and characterize subsets of women at a country, region or sub-regional level country who are at high risk of HIV, based on their responses to demographic and psychosocial questions currently collected by DHS; and 2) to develop a rapid and inexpensive tool for identifying population segments in specified countries at high risk of HIV.

Description: This study involves the secondary analysis of DHS data for one or more countries that are targeted for FHI's Site Identification and Development Initiative (SID). Findings from this subproject will be used to inform the Microbicide Strategy and SID.

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Activities, Accomplishments, Problems through December 31, 2008

- No activity took place on this subproject before June 2008.
- A part-time staff member was hired in July 2008 to conduct analysis.
- Tanzania DHS datasets were downloaded, merged and cleaned. Variables were identified for analysis.
- As of December 2008, a conceptual framework was developed and the analysis strategy further defined.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Documents were submitted in February 2009 to PHSC and exempt status was obtained for this secondary data analysis.
- Latent model analysis was completed using Tanzania 2003 data in March 2009.
- All data analysis steps were described in a document for replication using a new DHS country dataset.
- Data analysis with Cote d'Ivoire 2005 DHS was completed by June 30, 2009.

Findings and Outcomes:

- We tested our model on data from the Tanzania 2003 HIV/AIDS Indicator Survey (AIS). Our final sample included 4,568 sexually active women for whom an HIV test result existed and were either negative or did not know the result of their positive, anonymous test.
- Four sets of psychosocial variables were used to construct the latent classes, including: 1) 15-item HIV Knowledge Score; 2) 5-item HIV Norms Scale; 3) 3 Self-Efficacy questions; and 4) one HIV Risk Perception question.
- Four classes emerged from the latent class modeling based on women's responses to the six psychosocial variables. All six variables showed significant differences between groups.
- Socio-demographic and other variables, often used as screening questions, also varied by class. Examination of the latent class and predictor variables helped us develop labels for the four classes.
- Latent classes significantly varied by HIV status.
- Logistic regression models indicated socio-demographic, regional and risk behavior variables that differed by class.
- Given that most site ID activities currently rely on personal networks and/or intensive – but limited primary data collection efforts, this project has the potential of providing a more systematic, inexpensive, and relatively rapid approach to identifying countries, regions and sub-districts for HIV prevention trials. By comparing the models developed from different country or regional-level DHS data, it may also provide some new insights into the role that culture plays in shaping HIV risk –leading to better tailoring of recruitment strategies to the local contexts in which a trial is situated.

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Planned Activities for July 1, 2009 – April 28, 2010

- Under a separate FCO, a Tanzania-specific report will be provided for the Site Identification and Development Initiative. The report will include: a list of geographic locations with high HIV prevalence; recommendations for targeting population segments by socio-demographic and/or psychosocial indicators; and draft specific eligibility criteria or screening questions that could help in recruitment efforts. A set of procedures for using DHS data for additional country analyses will be drafted.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:	May 2007
Total Approved Budget:	\$ 50,000	Projected End Date:	Jun 2009

Worldwide: Assuring Stakeholder Involvement at New Microbicide Research Sites (FCO 136115)

Technical Monitor: KMacQueen

Strategy Outcomes(s) to be addressed: Microbicides I.C.: Five new sites for pivotal microbicide trials established, qualified, and functioning, with appropriate stakeholder involvement.

Microbicides I.E.: A new multistage, interdisciplinary paradigm based on lessons learned from Phase I, II and III microbicide trials developed. Results will be shared with other research organizations, funding agencies, and other interested parties.

Objective(s): To support microbicide site development efforts with a systematic approach to ensure stakeholder involvement throughout preparation and conduct of HIV prevention trials.

Description: Building on FHI community preparedness research, research communications strategies, and community involvement models we will develop a toolkit for:

- a) Systematically identifying stakeholders in each of the five Prevention Science Research Committee (PSRC) categories;
- b) Convening stakeholder meetings during the site development process;
- c) Developing communications strategies and materials for different stakeholder audiences;
- d) Establishing a community advisory board and/or other stakeholder engagement mechanisms in preparation for a microbicide trial; and
- e) Developing SOPs and staffing guidelines to support stakeholder engagement during trial implementation.

The toolkit will be piloted with microbicide stakeholders, who will be asked to assess its effectiveness for meeting the stated objectives. The toolkit components will then be revised as appropriate and integrated into comprehensive site development activities at a new microbicide site. Since the toolkit will build on significant existing experience and a pilot phase, the potential for replication at other sites will be high.

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Activities, Accomplishments, Problems through December 31, 2008

- The subproject began in September 2007, and the approval to implement letter was approved by USAID in October 2007.
- A consultant was identified to provide technical leadership for the project.
- Meetings and conference calls with microbicide and HIV prevention research stakeholders were held to get initial input on content of the toolkit.
- Materials for inclusion in the toolkit were identified and a database was created for referencing them.
- Potential sites were identified for prototype development and piloting of the toolkit from among sites participating in the Site Identification and Development Initiative (SIDI).

- The consultant, along with FHI project staff persons, continued to identify materials for inclusion in the toolkit.
- The consultant interviewed microbicide and HIV prevention research stakeholders to continue to gather input on the content of the toolkit.
- The consultant completed field visits at SIDI sites in Ethiopia in August; Tanzania in October; and South Africa, Tanzania and Ethiopia in November 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- In consultation with colleagues at FHI and at research sites in Africa, the consultant designed a recommended process for stakeholder engagement in HIV prevention studies in January 2009.
- In March 2009, the consultant completed the literature review and selected relevant resources for inclusion in the Toolkit, incorporated selected quotes into the Toolkit from the interviews that he conducted in Ethiopia, South Africa and Tanzania and the USA in 2008, and completed a preliminary draft that included “prototypes” of the Worksheets for each Toolbox.
- Preparations were made to upload the Toolkit onto a Wiki site where successive drafts of the Toolkit can be made available for review and comment in April 2009.

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Planned Activities for July 1, 2009 – April 28, 2010

- The Toolkit “Glossary” will be completed and links will be inserted into the Wiki pages.
- Guidance for those participating in the pre-piloting of the Toolkit will be prepared.
- The first draft of the Toolkit will be completed and will be pre-piloted at research sites in Ethiopia, South Africa and Tanzania.
- Successive drafts of the Toolkit will be made available on the Wiki site for review and comment.
- The Toolkit will be revised/refined based on (a) the results of pre-piloting and (b) the comments and suggestions of reviewers.
- Depending on the availability of funds, a decision will be made as to whether a formal evaluation of the Toolkit can be undertaken.
- The final report will be completed in April 2010.
- The Toolkit will be disseminated at the Microbicide 2010 Conference that will be held in May 2010 in Pittsburgh.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:	Sep 2007
Total Approved Budget:	\$ 353,636	Projected End Date:	Apr 2010

Worldwide: Global: Good Microbicide Communication Practice (FCO 133101)

Technical Monitor: BRobinson

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.E.: A new multistage, interdisciplinary paradigm based on lessons learned from Phase I, II and III microbicide trials developed. Results will be shared with other research organizations, funding agencies, and other interested parties.

Objective(s): 1) To integrate communications planning and ongoing assistance into microbicide research in order to both avert and manage potentially controversial issues related to microbicides research; and 2) to enhance the community engagement, policy, and advocacy aspects of microbicides research by strengthening key relationships and information-sharing between researchers and microbicide advocates at the international and country levels, complementing but not duplicating efforts led by the Global Campaign for Microbicides (GCM).

Description: This subproject is designed to complement the Site Identification, Assessment and Development (SIDI) effort managed by BBR. (See the report associated with FCO 132113). This subproject will implement a number of coordinated activities, in collaboration with the MOU and other partners. These include:

A communications network analysis to identify and survey the communications networks used by HIV prevention and microbicide activists, with a focus on trial countries.

Ongoing coordination with FHI research teams to test approaches, share information, monitor local research team needs and concerns, and integrate communications.

Regular coordination with FHI microbicide site development and research tool development groups, including sharing of developments with all research teams via electronic updates.

A systematic and ongoing effort to develop relationships with key activists, to participate actively in discussions over electronic venues which cover HIV prevention trials, and to develop supportive materials for activists lacking the technical background to inform their constituencies accurately.

Co-sponsorship with the Global Campaign for Microbicides (GCM) and an African NGO of sessions at international AIDS conferences on advocacy, HIV prevention science, and the role of community.

Presentation to the Global Fund board on issues in communication and advocacy on microbicides research.

Quick responses to any negative publicity that occurs. To anticipate and counter misinformation that can generate disruptive political responses, we will proactively identify trial stakeholders, develop reference materials, prepare in-country and FHI spokespersons to address controversies, work with prevention advocacy organizations, and send FHI staff to the field in a timely manner when a trial is in jeopardy.

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Activities, Accomplishments, Problems through December 31, 2008

- Approval to implement the subproject was received from USAID on Oct. 26, 2007.
- Staff wrote backgrounders on microbicides for print, email and web dissemination.
- Staff developed a Powerpoint and also supported one-day community dissemination events on Savvy and CS trials in Lagos and Port Harcourt, Nigeria (Oct 08).
- Staff participated actively in the Microbicides Media Communications Initiative (MMCI) convened by GCM, providing advice on communications strategies for trials discussed by group. B. Robinson, the technical monitor (TM) was named to MMCI's steering committee and worked with MMCI members to plan responses to emerging media issues. She attended annual MMCI meetings in Washington, DC.
- At the Microbicides 2008 in Delhi, India, staff co-facilitated a media training; presented on a panel, "Media: Microbicide Friend or Foe?"; developed/distributed 125 CD-ROMs; and organized a communications support booth, providing TA to 20 advocates and researchers and videotaping 10 mock interviews.

- Staff outlined the “Communications Handbook for Clinical Trials,” an activity awarded expanded funding for this subproject; worked with the SIDI team to plan a research literacy training and video to complement the book.
- Initiated an informal network of PrEP-trial communications staff (MTN, NIH, UW, UCSF, CDC) to support coordination for management issues; developed a password-protected portal for its use.
- An audio slideshow of a Malawi microbicide site was developed (cost-shared with FCO 0065).
- Staff monitored news coverage of microbicides and related HIV prevention research.
- TA was provided to researchers and communications staff at various agencies on issues management. Staff responded to requests for information from civil society groups and news media on various trials and served as technical reviewers of materials by advocacy and other groups on microbicides research, e.g., helped Nigeria's HIV Vaccine and Microbicides Advocacy Group with research dissemination and counteracting inflammatory news articles in Nigeria.
- Materials on PrEP research were provided to Act Up/Paris for their use to educate members on HIV prevention research at their annual meeting.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The TM continued to serve on the steering committee of MMCI, presenting at the annual meeting in DC, providing advice to members on communications strategies for HPTN 035 and MDP 301 trials, contributing to design of MMCI website (launched Jan 09), and working on the Communications Handbook for Clinical Trials.
- Drafts of 7 chapters and the graphic design for the Communications Handbook were developed; vignettes were solicited from multiple partner agencies.
- With CAPRISA and GMC, staff organized and conducted a meeting on 31 Mar 09 in Durban, S Africa, with 45 African site-level researchers to solicit input on the handbook and collect video footage to be used in the handbook DVD.
- Staff shared FHI's CRTU impact indicators for research utilization and information dissemination with GCM/MMCI to support their proposal for re-funding of the MMCI.
- Staff monitored news coverage of microbicides and related HIV prevention research on a daily basis, and disseminated updates to FHI offices and partner agencies to keep them informed.
- TA continued to be provided to researchers and communications staff at various agencies on issues management related to HIV prevention trials, e.g., supported cellulose sulfate research team in Port Harcourt, Nigeria for a visit by a microbicide advocacy group.
- Staff responded to requests for information from civil society groups and news media on various trials and served as technical reviewers of materials by advocacy and other advocacy groups on microbicides research.
- Staff responded quickly to concern expressed by various rectal microbicide advocates in US for more inclusive messaging in CRTU materials on microbicides (Apr 09)
- The TM served on the PrEP communications working group (PCWG), providing input and sharing information; staff participated in and presented updates at two PCWG meetings organized by AVAC.
- Staff updated various backgrounders on microbicides for print, email and web dissemination.

Findings and Outcomes:

- TA provided at the M2008 communications booth proved an innovative approach to providing communications assistance, as it allowed advocates and research staff from around the world to be paired with an experienced professional for individualized support. Self-evaluations by participants revealed reported changes in skills, confidence, and motivation to continue collaborating with partner organizations on microbicide communications.
- Efforts to coordinate messaging on microbicide trials and to engage advocates in balanced communication on microbicide and other HIV prevention trials have largely been successful. Approaches developed during CRTU trials to communicating about research are now being

standardized and adopted by many sister organizations, leading to greater harmonization of messaging and collaboration across agencies.

- Proactive outreach by two advocacy groups (NHVMAG and Act Up/Paris) to FHI for technical support on materials indicates a new level of trust and helps ensure accuracy of the information they distribute to their respective memberships.
- The frequency of contact and level of trust between FHI, as a microbicide research organization, and advocates and activists, has markedly improved. Instead of misunderstandings or concerns escalating, they are typically solved directly and satisfactorily. For example, regarding FHI's response to concerns by an outreach coordinator for an MTN AIDS Clinical Trials group on a CRTU article on microbicides, he wrote: "Thank you for your thoughtful response to our concerns. It is very appreciated. I am continually impressed by FHI's good works in the microbicide development effort." Another advocate for rectal microbicides wrote: "Thank you very much for taking our concerns and comments seriously." Trust and common understanding are indicators of collaboration and teamwork.
- Many organizations involved in HIV prevention have agreed to contribute to or review the Communications Handbook: DFID accepted to contribute a short article; HPTN groups will serve as reviewers and possible contributors; IPM, CONRAD, the Population Council, MTN and various African groups are also providing signed pieces.

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Planned Activities for July 1, 2009 – April 28, 2010

- Additional funds will be requested to produce and disseminate the Communications Handbook – both the printed book and the accompanying DVD. (NB: In February 2009 budget increase was approved.)
- Staff will continue to monitor and analyze news media coverage of microbicides and related HIV prevention research. Analysis will be shared with key stakeholders, and FHI will respond quickly to any misinformation or negative publicity about trials that FHI is involved in and support other research organizations as needed.
- Technical assistance will be provided in strategic communication to investigators within FHI and at collaborating sites in the field to make their research more successful, and to anticipate and avoid controversy.
- Staff will actively participate in MMCI meetings and follow-up activities.
- Proactive efforts will be undertaken to prevent negative publicity on microbicide trials, including initiating and maintaining contact with advocates and journalists internationally and in countries where trials are most controversial, such as South Africa.
- FHI will coordinate with communications staff at other research institutions conducting microbicide trials.
- To stay in touch with the emerging needs of advocates on microbicide communications, staff will attend various microbicide and related conferences.
- Limited support will be provided to local dissemination efforts that link advocates and investigators in countries where FHI microbicide studies are ongoing or recently completed.
- The "Communications Toolkit for Clinical Trials," developed in collaboration with GCM and other organizations, will be finalized and published, along with the accompanying DVD.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:	Jul 2007
Total Approved Budget:	\$ 398,001	Projected End Date:	Jun 2010

Africa Regional: Evaluating Informed Consent Comprehension (FCO 136101/136113)

Technical Monitor: KSimpson

Strategy Outcomes(s) to be addressed: Microbicides I.E.: A new multistage, interdisciplinary paradigm based on lessons learned from Phase I, II and III microbicide trials developed. Results will be shared with other research organizations, funding agencies, and other interested parties.

Objective(s): 1) To use behavior-coding to investigate the effectiveness of two different comprehension instruments.

2) To develop a pilot tool for eliciting local terminology and explanations for sexual behavior, sexual and affective relationships, reproductive health terms, and concepts relevant to participation in clinical trials.

(Note: In 2009 the original objectives were modified to encompass the objectives of 136113 and also the objectives originally associated with 136101)

Description: This effort was originally two subprojects (136113, 136101), and, in June 2009, USAID gave approval to combine the two subprojects into one. As a result, activities initially associated with both subprojects will now be reported as one activity.

This research study aims to develop a process for eliciting verbal lexicons and non-verbal communication patterns that could improve the informed consent process in clinical trials related to sexual and reproductive health. Two dimensions of the communication process during informed consent for clinical research will be examined.

(1) The verbal dimension will be assessed through the use of qualitative methods to develop an elicitation tool that can be used to create culturally and linguistically valid verbal lexicons of key research-related terms and concepts. The research-related terms and concepts addressed in this study will be common terminology used in clinical trials, based on existing data sets at FHI and the Population Council, that our collaborating overseas colleagues find most problematic.

(2) The non-verbal dimension will be assessed through use of quantitative and qualitative methods to develop culturally valid non-verbal communication patterns of high and low comprehension. Informed Consent (IC) counselors for microbicide trial preparedness research will be trained to administer (1) a comprehension checklist (IC-C) and (2) an open-ended comprehension tool (IC-O). Both the checklist and the tool will be administered to all participants, but the order will be varied randomly. The administration of the checklist and tool will be videotaped, and the interactions will be behavior-coded.

Collaborating Agency(s): Population Council

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Activities, Accomplishments, Problems through December 31, 2008

- In May 2007, Friedland, from the Population Council, traveled to FHI-NC to work with Mack and to meet with clinical and behavioral researchers at FHI regarding the most critical points for the elicitation tool to address.
- In September 2007, an initial planning meeting was held with an outside expert in behavioral coding (Dr. Norman Markel, professor emeritus in psycholinguistics from UF-Gainesville) to outline potential approaches to the research design.

- Mack met with Kate MacQueen to discuss how to coordinate this project with MacQueen's complimentary project on non-verbal cues for informed consent comprehension. It was decided that one joint coordinator would provide the most effective management and implementation of the projects.
- A Project Leader/Technical Monitor was identified for the subproject in November 2008.
- The general study design and a draft protocol was developed.
- The site selection process was completed in December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- An approved budget was developed in January 2009.
- A study site and partner organization were identified to perform specialized data analysis in February 2009.
- A draft protocol was completed in March 2009.
- In March 2009:
- FHI analysts were identified for the study team.
- The development of sub-agreements with partner organizations in Tanzania (study site) and England (data analysis group) was initiated.
- The development of sub-award to FHI from our partner on the verbal lexicon component (Population Council) was initiated.
- FHI began drafting the study instruments and the protocol was revised.
- Final USAID approval was received to combine FCOs 136113 and 136101 into one subproject.
- In June 2009:
- The first draft of the data analysis plan was completed for both the verbal and nonverbal components.
- The project leader attended Harvard University's Ethics in Global Health Research Workshop.
- The team's statistical support member, Mario Chen, met with our partners at Manchester Metropolitan University to gain a critical understanding of the nuances in the Silent Talker software.

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Planned Activities for July 1, 2009 – April 28, 2010

- The draft budget will be revised and approved
- Site negotiations will be completed with our collaborating partners.
- The study protocol will be finalized.
- Necessary ethics approvals will be obtained.
- Data collection will be conducted.
- Data analysis will be executed.
- Final reports and publications will be completed.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:136101 Jul 2006 136113 Sep 2007
Total Approved Budget:136101	\$ 67,000	Projected End Date: Apr 2010
136113	\$ 330,178	
	\$ <u>397,178</u>	

USA: Statistical Support - Microbicides (FCO 139101)

Technical Monitor: DTaylor

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Microbicides I.D.: Two new approaches for evaluating the safety or effectiveness of topical microbicides developed and validated. Results will be shared with other research organizations, funding agencies, and other interested parties.

Objective(s): 1) To review statistical methods needed to answer questions concerning the effectiveness of microbicides in preventing HIV/STI transmission; 2) to conduct research on such methods; and 3) to develop recommendations for study design and analysis.

Description: Randomized trials designed to evaluate the effectiveness of microbicides in preventing HIV/STI transmission pose a number of statistical challenges. These challenges include, but are not limited to: choice of an appropriate control, heterogeneity of randomized participants, interval censoring of outcomes, and competing risks due to co-infections. We also need more efficient study designs for evaluating effectiveness against HIV, other STIs and pregnancy.

Collaborating Agency(s): Population Council

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Activities, Accomplishments, Problems through December 31, 2008

- P. Chen improved statistical methods for estimating HIV incidence from age-specific prevalence data by adding confidence intervals and accounting for mortality rates, with results applied to SIDI, The Site Identification and Development Initiative (2007).
- D. Taylor and M. Weaver attended and/or gave presentations related to microbicide trial design and analysis at USAID, NIH, WHO, and other sponsor agency meetings, including: Microbicides for Prevention: Current and Future Perspectives (Sydney, Australia, Nov 2005); Microbicide Safety Consensus Meeting (March 2006); Regional Workshop on Regulatory Issues for Microbicides in Asia (Oct 2007); Microbicides 2008; Furthering the PrEP Scientific Agenda" (Atlanta, GA, May 2008); QWG meetings (2006-2008).
- BIOS staff performed secondary analyses of microbicide trial data for papers, meetings, and scientific advancement (2006-2008).
- K. Tweedy completed secondary analysis of a Population Council Phase II study of Carraguard (2006-2007).
- Taylor explored the utility of adaptive design methods for improving the efficiency of the CAPRISA 004 trial. Results of simulation studies presented at CAPRISA-sponsored microbicide safety meeting in South Africa (Spring 2007).
- Taylor and Weaver explored alternative survival analysis methods for microbicide trials based on staggered entry of participants (Fall 2007).
- Weaver assisted FHI researchers in developing statistical tools for describing adherence data in microbicide trials (Fall 2007).
- Weaver and Taylor provided support to nested case-cohort study design in CAPRISA 004 (2007).

- Taylor reviewed manuscripts and clinical reports for collaborating agencies, including Population Council (Carraguard Phase 3 trial) and CONRAD (Biomarkers of Adherence); 2007-2008.
- Taylor participated as a member of the task group on Adherence and its Measures in Microbicide Clinical Trials, and attended related meeting in Arlington (2008).

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Taylor co-authored a manuscript on Measuring Adherence in Phase 2b/3 Microbicide Trials (journal TBD).
- Taylor completed a manuscript on the impact of rectal intercourse on vaginal microbicide effectiveness trials (Ian McGowan, co-author), submitted to STD, June 2009.
- Taylor participated in monthly Tenofovir Gel Development Team meetings.
- Secondary analysis of pooled data from the CS and SAVVY trials was completed for three manuscripts by Lie, Weaver, and Taylor (manuscripts currently under internal review or submitted) and for a manuscript on HIV testing algorithms in the CS-CONRAD trial (co-authored with the Institute of Tropical Medicine).
- Taylor provided consult for a Letter to the Editor re: CS-CONRAD trial (Journal of AIDS).
- Secondary analysis of pooled microbicide trial data began for two additional manuscripts (impact of pregnancy on risk behaviors; analysis of adherence data in microbicide trials).
- Taylor presented at QWG meeting in New York City, NY (February 2009).
- Taylor presented at Global Campaign for Microbicides (GCM) Standards of Prevention in HIV Prevention Trials (Uganda, 2009 - travel paid by GCM).
- Taylor presented at GCM-sponsored Consultancy on FP and HIV Prevention (Washington, DC, 2009 - travel paid by GCM).
- Taylor participated in End of Phase 2 planning meeting for Tenofovir Gel (organized by CONRAD), June 2009.
- Weaver presented at NIH-sponsored meeting on pregnancy in microbicide trials (Maryland, March 2009).

Findings and Outcomes:

- High pregnancy rates (requiring product withdrawal), low HIV incidence, prevalent rectal intercourse, participant retention, and product adherence remain serious challenges to finding an effective microbicide.
- Alternative trials designs (e.g. using flexible recruitment strategies, more efficient fertility analyses, and other data-driven trial decisions) need to be considered as the field moves forward.
- Site identification processes need to be expanded and improved to find appropriate study populations with high retention and adherence rates.

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Planned Activities for July 1, 2009 – April 28, 2010

- Taylor will participate in QWG and Tenofovir Gel Development meetings.
- BIOS Department will complete secondary analysis for at least three additional manuscripts based on pooled microbicide trial data.
- BIOS Department will provide statistical consultation to USAID-funded organizations (e.g., the Population Council, CONRAD, PATH) and collaborators working on microbicide development, including design and analysis issues in microbicide research.
- BIOS staff will provide review of microbicide papers submitted for publication and/or presentation.
- As the microbicide portfolio expands and statistical methods research shifts to active-control study designs, community-based interventions, and other public health applications, we anticipate an expansion in workscope under this FCO.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:	Jun 2005
Total Approved Budget:	Annually Approved	Projected End Date:	Apr 2010

USA: Biomarkers of Semen Exposure Study with CONRAD (FCO 132149)

Technical Monitor: GPittman

USAID Intermediate Objective to be addressed: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Barriers I.E.: Innovative research methodologies that lower the cost and speed the pace of bringing new products to market developed and validated. Microbicides I.D.: Two new approaches for evaluating the safety or effectiveness of topical microbicides developed and validated. Results will be shared with other research organizations, funding agencies, and other interested parties.

Objective(s): To provide data management and analysis support to a CONRAD-led study designed to characterize the vaginal residence time (decay time) of the following semen biomarkers in two groups of women who are exposed to semen via either inoculation or unprotected intercourse: the sex-determining region of the Y chromosome DNA (Yc DNA) using two different primers; protamine-2; and prostate specific antigen (PSA). Note: With amendment #3, CONRAD deleted biomarker "Semenogelin as measured by the Rapid Stain assay" from the protocol.

Description: FHI will provide data management and analysis support to this CONRAD-led single-blinded, comparative, randomized, parallel study in 32 healthy couples. Women will be randomized to one of two groups. One group will undergo inoculation of the vagina with their partner's semen. Women in the second group will engage in a single act of unprotected intercourse. Eight randomly selected women in each group will return for vaginal swabbing at each of 7 time points after inoculation or intercourse. The remaining women will return for vaginal swabbing only at 6 hours, 24 hours and 7 and 15 days. In addition, up to two women in each subgroup will be invited to participate in a substudy. These women will be asked to go through the study visits a second time using the alternative sampling technique (choosing to do some sampling at home) to confirm that samples collected by participants yield results similar to samples collected in the clinic by clinicians. "Decay curves" will be created for the biomarkers and compared. Development of new biomarkers with enhanced sensitivity and specificity will provide a more reliable way of verifying protocol compliance in contraceptive and HIV/STD-prevention trials as well as enhancing the determination of barrier efficacy

Collaborating Agency(s): CONRAD

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- In December 2007, a draft study design was received from CONRAD.

- The protocol was finalized and approved in April 2008, however in June 2008, the site staff and IRB requested changes regarding sample size (from 30 to 32 couples) and randomization. CONRAD drafted the protocol amendment.
- Case Report Forms (CRFs) were developed, approved, and printed in May 2008. The forms were shipped to the study site in June 2008.
- FHI began drafting the analysis and data management plans.
- Research Informatics worked with CONRAD to develop a lab data transfer plan.
- Error spec development began in June 2008.
- CONRAD amended the protocol, and v2.0 was finalized in July 2008.
- FHI provided the revised randomization envelopes (for new protocol with slightly different sample size and randomization allocation) in July 2008.
- FHI sent draft error specs to CONRAD for review in July 2008.
- The data management plan was completed and approved in November 2008.
- CONRAD sent authorization to Johns Hopkins to begin screening/enrolling in December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Recruitment began in February 2009.
- Data cleaning specs were programmed into ClinTrial and the DM system complete and ready to accept data in February 2009.
- CONRAD amended the protocol, and v3.0 was finalized in May 2009. In addition to administrative changes, amendment #2 included a substudy to compare levels of markers obtained by sampling in the clinic vs. at home for the same participant.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- The analysis plan will be finalized and approved.
- CONRAD will amend the protocol and finalize v4.0 in July 2009. Primarily, this amendment will allow for a second study site (EVMS), and will delete biomarker "Semenogelin as measured by the Rapid Stain assay" from those being tested.
- Recruitment will end.
- All data cleaning and querying will be completed for CRFs and lab data.
- Funding will continue under a new FCO to allow for completion of study activities.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:	Jul 2007
Total Approved Budget:	\$ 159,294	Projected End Date:	Apr 2010

Africa Regional: Africa: Improving Measurement of Pregnancy Intentions (FCO 134000/134001)

Technical Monitor: DMcCarragher

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Microbicides I.I.: Innovative strategies to increase retention and reduce product interruptions in trials developed and tested.
Microbicides I.H.: Social and behavioral components and/or ancillary studies within microbicide clinical trials conducted to provide information on: sexual relationships and practices, the social and cultural context for microbicides, potential for covert use, and community support and policies.

Objective(s): To develop an accurate measure of pregnancy intentions with acceptable reliability and demonstrated validity. To achieve this goal the study has the following specific objectives: 1. To identify potential content domains and individual items for a scale that will predict pregnancy through analysis of existing qualitative data and a review of peer-reviewed literature; 2) To develop a psychometric scale to reliably measure pregnancy intentions using factor analytic methods based on cross-sectional surveys with women in one or two countries; 3) To partially validate the scale using additional correlational and “known-groups” analysis of cross-sectional survey data.

Description: Several microbicide effectiveness trials have reported high pregnancy rates among trial participants. Pregnancies are problematic because there are concerns about the safety of product use by pregnant women and because they have implications for interpreting the trial study results. Two mechanisms to limit pregnancy among trial participants are to either screen out women likely to become pregnant or to require participants to use effective forms of contraception. This study focuses on the development of a measurement tool that can be used to identify women who are likely to become pregnant.

This study has three main phases that are described below in detail.

Phase I: Content domains and individual items for the new pregnancy intentions scale will be developed through a review of the literature and analysis of formative data being collected by the FEM-PrEP socio-behavioral and community (SBC) study team. Through the SBC work, focus groups and in-depth interviews about women’s fertility intentions and factors that influence them are being conducted with women in the FEM-PrEP study sites.

Phase II: The reliability of the content domains and individual items will be tested through use of thinkaloud interviews and cross-sectional surveys that will be conducted with women in two countries. The data from the surveys will be factor analyzed to produce the final measurement scale.

Phase III: The final measurement scale will be validated in two separate ways. First, the scale will be administered to various populations to obtain different scores on the scale. For example, we would expect women seeking a family planning method would score lower on a pregnancy intention scale than women who are seeking infertility services. Validity of the scale to actually predict pregnancies will be assessed via the use of the scale in a clinical trial setting where pregnancy outcomes are being assessed.

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- In October 2007, the concept paper was finalized and the FCO was opened. The data collections forms that are being used in the Truvada trial were also finalized.
- A literature search was completed.
- This project was delayed due to competing demands of other projects on the technical monitor.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The study protocol was completed and was circulated for review.
- The protocol was reviewed and approved (pending changes) by the University of Witswatersrand ethics committee in June 2009.
- Progressus, a contract research organization firm, was identified to lead the data collection efforts in South Africa.
- An FCO request for the subagreement was submitted in June 2009.

- The subcontract for Progressus was under development.
- A codebook was developed and finalized for the FEM-PrEP SBC data in May 2009.
- The coding of the FEM-PrEP SBC was nearly completed.
- The development of relevant content domains was initiated through the FEM-PrEP SBC data analysis and a previous literature review.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- The FEM-PrEP SBC data review and analysis will be finalized in July 2009. The development of relevant content domains and drafting of scale items is anticipated to be finalized in July 2009.
- A manuscript that summarizes the results of the analysis of the FEM-Prep data will be prepared and submitted for review by November 2009
- Once the comments from the University of Witswatersrand have been received, the protocol will be revised and submitted to PHSC for approval. The subagreement with Progressus will be finalized by August 2009.
- An expert review of the proposed domains and pregnancy intentions scale is anticipated to be completed by August 2009.
- McCarraher and Headley will travel to Pretoria to conduct the interviewer training and initiate data collection activities by September 2009. Phase II of the study includes think aloud interviews and cross-sectional surveys.
- A local research agency and study coordinator will be identified in Malawi by September 2009. If a suitable agency or coordinator cannot be found, an alternative country will be considered. Phase II data collection activities will be implemented in Malawi (or an alternative country by) December 2009.
- The pregnancy intentions scale will be validated using a known groups approach (anticipated by February 2010 in both South Africa and Malawi).
- Dissemination activities including a manuscript summarizing the study results will be prepared and submitted for publication by June 2010.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: Microbicides	FCO Approved: 134000 134001	Oct 2007 Jul 2009
Total Approved Budget: 134000 \$ 134001	300,000 N/A	Projected End Date:	Apr 2010

Worldwide: Microbicide Strategy Group (FCO 139102)

Technical Monitor: PFeldblum

Objective(s): To further refine the CRTU microbicide strategy and to shape the research portfolio meeting the strategy objectives.

Description: As a management account, this subproject will not be routinely reported.

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- The strategy group met during August-October 2006 to critique concept proposals submitted by FHI researchers for funding with microbicide monies.
- The strategy group prioritized projects and made recommendations to the FHI leadership group in October 2006.
- Several new projects were forwarded to USAID for funding as part of the CRTU workplan for Year 2.
- The strategy group did not meet during the July 2008 through December 2008 period.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The strategy group did not meet during the January 2009 through June 2009 period.
- The FCO was closed on June 30, 2009.

Findings and Outcomes:

- The strategy group was active during the first few years of the CRTU and provided a forum for sharing subproject updates and, initially input on priority setting. As the microbicide activities became more robust, individual team meetings largely took over the role of the strategy group.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:	Oct 2005
Total Approved Budget:	Annually Approved	Projected End Date:	Jun 2009

Africa Regional: Sociobehavioral Research and Community Planning to Develop Site-Specific Pilot Intervention Plans for PrEP Rollout (FCO 136123)

Technical Monitor: NMack

Objective(s): 1) To conduct qualitative research at the FEM-PrEP clinical trial sites to inform site-specific planning for PrEP rollout pilot interventions that may be implemented if PrEP is demonstrated to prevent HIV infection; 2) to facilitate community planning of site-specific pilot interventions; and 3) to create site-specific pilot intervention plans with recommendations based on the qualitative research and community planning results

Description: The purpose of this study is to develop anticipatory, site-specific recommendations for rollout of pre-exposure prophylaxis (PrEP) at the FEM-PrEP clinical trial sites. Pilot intervention plans are intended to be implemented by public health stakeholders at each site if Truvada is demonstrated to be safe and to prevent HIV infection when taken daily. The study design combines the following qualitative research and non-research activities:

1) Qualitative research: In-depth interviews and focus groups; 2) Non-research community planning activities: Community planning workshops, fact-finding of background information, HIV prevention services inventory, and Identification and coordination of potential partners; 3) Development of site-specific pilot intervention plans for PrEP rollout as study output. Up to 105 in-depth interviews will be conducted at each of the FEM-PrEP clinical trial sites. Up to 4 focus groups will be conducted at each site. At the Arusha/Moshi Tanzania site, up to 135 in-depth interviews and up to 6 focus groups will be conducted.

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Activities, Accomplishments, Problems through December 31, 2008

- The protocol, "Sociobehavioral Research and Community Planning to Develop Site-Specific Pilot Intervention Plans for PrEP Rollout" received PHSC IRB approval in December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- A study training was held in Bondo, Kenya in May 2009.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Data collection will be initiated in Bondo, Kenya and Pretoria, South Africa.
- Study training will be conducted in Pretoria, South Africa in July 2009 and in Arusha, Tanzania in December 2009.
- PrEP Rollout activities in Bondo, KE, Pretoria, SA, and Arusha, TZ will be ongoing throughout the year.
- In Mazabuka, ZA the training will happen in early to mid-2010.

Funding Source(s):	USAID - US Agency for International Development/USAID: Microbicides	FCO Approved:	Apr 2009
Total Approved Budget:	\$ 1,088,480	Projected End Date:	Apr 2010

YOUTH

GOALS	OUTCOMES
I. To expand the evidence base of youth RH/HIV prevention programs.	<ul style="list-style-type: none"> A. Up to two youth RH and HIV prevention tools evaluated, such as the CFLE/MFLE manuals or a peer education tool. B. Up to two integrated services models for youth evaluated, including one using the YouthNet counseling/testing manual.
II. To increase the use of evidence-based knowledge, practices, and tools for youth RH/HIV prevention.	<ul style="list-style-type: none"> A. At least two knowledge management tools implemented globally. B. At least three papers on youth RH health and HIV prevention research submitted for publication to peer-reviewed journals. C. A synthesis of existing evidence and intervention models completed and disseminated. D. Utilization of at least two youth tools developed by FHI or its partners increased. E. Interagency Youth Working Group established and developed.
III. To meet country level needs for improving youth RH through the scale up of innovative programs.	<ul style="list-style-type: none"> A. A. Up to two youth tools utilized in a scaled up country program.

FHI/NC subprojects fully or partially funded by USAID's CRTU Agreement:

- Worldwide: Global Knowledge Management: Youth RH/HIV Prevention (FCO 125001/125005)
- Worldwide: Knowledge Management: Youth Report (FCO 125002/125003)
- Worldwide: Knowledge Management: Youth II (FCO 113144/183000)
- Worldwide: Research Utilization: Youth (FCO 113143/183001)
- Kenya: Evaluation of "What's New & Cool for Youth" Booklet (FCO 143101/143118)
- South Africa: ABC Approach Youth South African University Campuses, 2008 (FCO 153131/153132/153135)
- *Worldwide: Improving Dual Protection Counseling for Youth (FCO 114120)
- South Africa: Care and Prevention Among Positive Youth (FCO 153146/153147)

* Subproject reported under "Barrier Methods"

Worldwide: Global Knowledge Management: Youth RH/HIV Prevention (FCO 125001/125005)

Technical Monitor: BFinger

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded
IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: Barriers II.C.: Evidence-based counseling approaches for male and female condom promotion incorporated into family planning service guidelines, including those used by HIV/AIDS programs in up to three countries.

Youth II.A.: At least two knowledge management tools implemented globally.

Youth II.D.: Utilization of at least two youth tools developed by FHI or its partners increased.

Youth II.E.: Interagency Youth Working Group established and developed.

Youth III.A.: Up to two youth tools utilized in a scaled up country program.

Objective(s): 1) To expand the worldwide knowledge base on youth RH/HIV prevention through synthesis, production, and dissemination of the latest information, new evidence, and best practices; and 2) to increase utilization of key program resources through UN, CA, Ministry, and other systems, focusing on major program resources completed in the last 18 months of YouthNet, so that the USAID investment in these resources is fully realized.

Description: The attention to youth RH/HIV prevention has grown enormously since International Conference on Population and Development (ICPD) in 1994, leading to a vast increase in reports, interventions, research studies, and youth involvement. Synthesizing the key information from this growing volume of activity and findings has become a challenge, as well as disseminating the most helpful lessons learned for use and implementation. This process of gathering information and facilitating the use of the critical parts can be referred to as knowledge management.

In September 2006, the USAID 10-year global program focusing on adolescent health ended; FHI coordinated the last five years of this program through its YouthNet project. USAID then developed a new focus for youth activities through the Youth Global Leadership Priority (GLP) effort to provide continuity to youth technical leadership activities. FHI/CRTU plays a lead role in knowledge management for the Youth GLP by continuing many of the same knowledge activities from YouthNet, as well as taking the leadership role in coordinating the Interagency Youth Working Group (IYWG), a new interagency effort by USAID on youth RH and HIV prevention issues. This subproject continues to develop and maintain a knowledge base of youth information, publications, and guidance on a broad range of program areas. Youth information and best practices are systematically shared and discussed among CAs, USAID, and a larger audience of youth-serving institutions through multiple mechanisms: a Website, monthly email digests (Youth InfoNet), new publications, IYWG Partners' meetings, workshops, large technical consultations, and by linking with other agencies.

In addition to the process of synthesizing, writing, coordinating, and dissemination, some tools developed during recent years by the USAID-funded program require focused effort to ensure utilization in the field. This subproject works to ensure that such utilization occurs.

Collaborating Agency(s): Johns Hopkins University; Johns Hopkins/CCP

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- From Jan.-Dec. 07, a total of 18,185 YouthNet and IYWG publications were disseminated.
- FHI launched the new IYWG with USAID and FHI serves as secretariat.
- The IYWG developed, launched, and promoted a new Web site, working with the INFO Project at Johns Hopkins University. FHI is responsible for the content.
- FHI coordinated meetings among CAs receiving Youth GLP funds, called IYWG Partners, in Nov. 06, Feb. 07, and July 07 to share information and consult on IYWG efforts.
- With USAID, FHI coordinated two open IYWG meetings. 1) May 6-7: About 100 people attended the first day of presentations and discussions on new research and program information. The second day was a workshop on utilizing key youth tools (40 people). 2) Dec. 6-7: About 100 people attended the first day on parents and integrated services for youth. The second day IYWG sponsored a half-day workshop on M&E (50 people) led by other CAs.
- The YouthNet End of Program Report and CD ROM of YouthNet publications were completed and disseminated.
- Seven new YouthLens pubs (No. 19-25) were produced.
- Twelve new Youth InfoNet publications from Nov. 06 through Dec. 07 (Nos. 28-40) were produced covering a total of 165 program resources and 173 research summaries. Each issue is disseminated electronically to 7,000 people and to listservs reaching up to 100,000 per issue.
- The Muslim Family Life Education (FLE) manual was completed and disseminated.
- Utilization efforts are underway for Christian and Muslim FLE Manuals for Adults and the HIV Counseling and Testing Manual for Providers. FLE plans were informed by a questionnaire completed by five organizations.
- An IYWG Partners meeting was held in Mar. 08 to review IYWG activities; H. Burke presented on the YouthNet PE study in Zambia.
- IYWG/FHI conducted knowledge sharing activities at the international conference, Youth Deliver the Future, in Abuja from Apr. 27-May 1, 2008. Partners on these activities were FHI/HQ, FHI/Kenya, NOPE, FHI/Tanzania, FHI/Namibia, World Council of Churches, and East Africa Regional Office.
- A half-day IYWG meeting, co-sponsored by Gates, was held in DC on June 23 to discuss advocacy and technical tips from the conference.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The HIV Counseling and Testing Manual was reprinted with small revisions. The training guide for the HIV CT Manual was field tested in St. Lucia in July 2008.
- YouthLens Nos. 19-22, 24, and 25 were translated into French and Spanish.
- YouthLens on injecting drug use (No. 26) and young adolescents (No. 27) were drafted and ready for production.
- Youth InfoNet issues 41-46 were published (included 67 program summaries and 80 research articles, plus summaries of presentations at the Asia/Pacific meeting in Oct. 2007).
- A TOT of the HIV Counseling and Testing Training Guide was completed in Zambia with FHI/Zambia and PSI/Zambia. Support was also provided to FHI/Uganda in training to scale up HIV CT manual.
- A plan was created to utilize FHI youth tools in Nigeria with FHI-Nigeria staff.
- Assistance was provided to FHI/Tanzania's youth program with publications, including six briefs.
- Future PE activities were assessed using key informant interviews, field visits in Tanzania, and an informal technical consultation.
- Revision of the PE standards document for a new printing began.
- Assistance was given for dissemination and use of CFLE tools and HIV CT manual.

- Subproject was closed in November 08.

Findings and Outcomes:

- As of November 2008:
- Eighteen new Youth InfoNet publications were distributed electronically, sharing 232 program resources and 263 research summaries to more than 7,000 people directly, plus listservs reaching up to 100,000.
- Seven new Youth Lens publications were developed.
- The new IYWG Web site was launched. Feedback from users has been very positive.
- Three large, public IYWG meetings in DC (March and Dec. 2007, and June 2006) were organized and implemented with strong attendance at each (about 100, 94, and 50 people, respectively). Note attendance was less at the June meeting since it provided technical updates for those unable to attend a conference in Abuja. Evaluation results from the Dec. 6 meeting were very positive. The last meeting's results are not yet available.
- Knowledge sharing activities were conducted at the international conference, Youth Deliver the Future, in Abuja from April 27 to May 1, including: a panel of three presentations on working with faith-based organizations; a panel of three presentations on youth PE; one presentation on curricula-based sex education standards; a workshop on using faith-based tools (60 people); and a workshop to improve PE program management (50 people). An evaluation of the PE workshop was very positive.
- Four meetings of the IYWG partners were conducted.
- Utilization of tools was enabled through multiple contacts, initiating the use of tools and responding to requests.
- A total of 23,721 publications were distributed based on requests, plus mailings of YouthLens, the YouthNet End of Program Report, and other documents.

Funding Source(s):	USAID - US Agency for International Development/USAID: GLP	FCO Approved: 125001	Oct 2006
		125005	Oct 2006
Total Approved Budget:	125001 \$	300,000	Projected End Date:
	125005 \$	400,000	Jul 2008
	\$	700,000	

**Worldwide: Knowledge Management: Youth Report
(FCO 125002/125003)**

Technical Monitor: BFinger

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Youth II.B.: At least three papers on youth RH health and HIV prevention research submitted for publication to peer-reviewed journals.
Youth II.C.: A synthesis of existing evidence and intervention models completed and disseminated.

Objective(s): To expand the worldwide knowledge base on youth RH/HIV prevention through further publication of research results from the YouthNet project.

Note: Originally an objective for a synthesis report on youth intervention projects was included. The decision was made to not pursue this objective.

Description: In September 2006, the USAID 10-year global program focusing on adolescent health ended; FHI coordinated the last five years of this program through its YouthNet project. USAID developed a new focus for youth activities through the Youth Global Leadership Priority (GLP) effort. In 2001, the FOCUS End of Project report included a meta-analysis of intervention projects and made recommendations as to which types of projects have the most potential. As originally conceived, this subproject would update that study. However, with USAID, we decided to modify the focus in the first fiscal year to support the completion and dissemination of findings and reports completed after the YouthNet program ended. At the same time, a needs assessment was conducted to determine whether the field needed a new synthesis report. It was determined not to do such a report and to use these funds to support FHI's participation in other large youth reports instead.

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- Staff held discussions of options for a synthesis report, given the fact that several major synthesis reports were completed in 2006. These include a WHO report guiding policymakers on interventions for youth, a World Bank report on youth, and the YouthNet End of Program Report focusing on program results.
- At the suggestion of USAID, a decision was reached to modify the direction of this funding to focus on other writing projects and best practices promotion, including completing reports on YouthNet research subprojects.
- Reports on YouthNet research subprojects on Voluntary HIV Counseling and Testing in Tanzania and Haiti were completed, printed, and disseminated: Youth Research Working Papers (WP) No. 5 (Tanzania, which had been completed under YouthNet but not printed) and No. 6 (Haiti).
- A report on the YouthNet research on post-abortion care (PAC) was completed and printed. (WP No. 7).
- Other reports on YouthNet research subprojects were drafted: Early Sexual Debut (Jamaica and Uganda), Youth Peer Education Program Effectiveness (Zambia and DR), and "Be Faithful" Messages (Tanzania).
- Presentation of the "Be Faithful" study was made at the IYWG meeting in Washington (May 2007); presentation on the Early Sexual Debut report was made at the July 2007 meeting in Washington at the next GLP Partners meeting, with USAID staff invited.
- Youth Issues Paper No. 7 on peer education was printed and disseminated.
- A concept paper was developed on whether we should proceed with a synthesis report. The paper was based on a needs assessment with about 15 key stakeholders globally, prepared by a consultant (S. Adamchak). In a meeting in July 2007 with USAID, we decided not to proceed with a synthesis report.
- A commitment was made to WHO to collaborate with them on a study/book-length report on preventing maternal mortality among youth, with FHI focusing on a chapter/review on unintended pregnancy.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Due to space limits; this is a continuation of the cumulative accomplishment section:
- Reports on YouthNet research on peer education and sexual violence/early sexual debut were drafted and prepared for printing. Printing and completion of these papers occurred under new subprojects FCO 113144 and FCO 18300.
- Writers were determined for FHI's participation in the WHO study on preventing maternal mortality among youth.

- The subproject was closed at the end of Nov. 2008. Further youth knowledge management activities will continue under subproject “Worldwide: Knowledge Management: Youth RH/HIV II” (FCO #113144) and “Worldwide: Knowledge Management: Youth HIV Prevention” (FCO #183000).

Findings and Outcomes:

- Findings from an assessment study indicated wide consensus that a overall synthesis report for the field is not currently needed. With USAID, we decided not to pursue the synthesis report.
- Funds were reprogrammed to complete YouthNet research reports and publish them in the FHI Youth Research Report series.
- YouthNet research reports number 5-9 were completed: Impact of Youth Peer Education Programs: Final Results from an FHI/YouthNet Study in Zambia (#9), Early Sexual Debut, Sexual Violence, and Sexual Risk-taking among Pregnant Adolescents and Their Peers in Jamaica and Uganda (#8), Operations Research Study to Improve Postabortion Care (PAC) Services among Adolescents in the Dominican Republic (#7), Voluntary HIV Counseling and Testing Services for Youth and Linkages with Other Reproductive Health Services in Haiti (#6), Voluntary HIV Counseling and Testing Services for Youth and Linkages with Other Reproductive Health Services in Tanzania (#5).

Funding Source(s):	USAID - US Agency for International Development/USAID: GLP	FCO Approved: 125002 Oct 2006 125003 Oct 2006
Total Approved Budget: 125002	\$ 300,000	Projected End Date: Nov 2008
125003	\$ 400,000	
	<hr/> \$ 700,000	

Worldwide: Knowledge Management: Youth II (FCO 113144/183000)

Technical Monitor: JCunningham

Objective(s): To help USAID maintain and expand a global knowledge base of information on youth RH/HIV issues, share useful information in strategic ways, and help plan and administer the Interagency Youth Working Group (IYWG) activities.

Description: Since the International Conference on Population and Development (ICPD) in 1994, synthesizing the tremendous amount of information youth RH/HIV prevention has become a challenge, as well as disseminating the most helpful lessons learned for use and implementation. This process of gathering information and facilitating the use of the critical parts can be referred to as knowledge management.

Phase 1 of this subproject (FCOs 125001/125005) played a lead role in knowledge management for the Youth GLP by coordinating the Interagency Youth Working Group (IYWG), a new interagency effort by USAID on youth reproductive health (RH) and HIV prevention issues. Phase 1 continued many of the same knowledge management activities from the YouthNet project (2001-2006) including promoting YouthNet publications and other research utilization activities. Now in Phase 2, this subproject focuses on knowledge management and information dissemination of youth RH/HIV information, while a separate subproject (FCOs 183001/113143)

focuses on promoting promising practices through research utilization and technical assistance activities.

The aim of this subproject is to gather, synthesize, and disseminate information through publications, discussion forums, a website dedicated to youth RH/HIV, and other approaches to sharing youth information and best practices. These key activities include: functioning as the IYWG secretariat by organizing and hosting large biannual meetings (Youth Strategy outcome IIE); producing 6 to 8 YouthLens research briefs annually (Youth Strategy outcome IIA); producing Youth Infonet, a monthly electronic summary of new youth resources (Youth Strategy outcome IIA); and creating content and supporting utilization of the IYWG Website (Youth Strategy outcome IIA). These activities are feasible and are helping to support the potential for scaling up through country ministries and large bi-lateral projects.

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- An IYWG Partners meeting was held in March 2008 to review IYWG activities.
- IYWG/FHI conducted knowledge sharing activities at the international conference, Youth Deliver the Future, in Abuja from April 27 to May 1.
- A half-day IYWG meeting, co-sponsored by the Gates Institute, was held in DC on June 23 to discuss technical and advocacy topics presented at the conference (more than 50 people).
- YouthLens Nos. 19-22, 24, and 25 were translated into French and Spanish.
- YouthLens Nos 26-30 were produced and disseminated.
- Youth InfoNet issues 41-52 were published and distributed to over 7,000 people directly.
- A TOT of the HIV Counseling and Testing Training Guide was completed in Zambia on March 2008 with FHI/Zambia and PSI/Zambia for 18 providers. Support was also provided to FHI/Uganda in training to scale up of HIV CT manual.
- A work plan was created to utilize FHI youth tools in Nigeria.
- Assistance on publications was provided to FHI-Tanzania's youth program.
- Future PE activities were accessed using key informant interviews, field visits in Tanzania, and an informal technical consultation.
- Dissemination of the CFLE/MFLE and HIV CT manual continued.
- An evaluation for the IYWG website and activities was completed.
- The development of a White paper on Most at Risk Youth populations was initiated in Nov. 2008: this includes assessing the literature, tools, activities by various UN and other agencies, and recommendations for the field.
- FHI represented IYWG interests at the UN Inter-Agency Task Team (IATT) for Youth and HIV at the June 2009 meeting to spur potential collaborations, share dissemination strategies, and network with major global organizations working on common interests.
- Revision of the Peer Education Standards began.
- The Youth Participation Guide was reprinted through UNFPA. Staff made small editorial changes, did layout, and coordinated printing. UNFPA paid for the staff time and printing.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- InfoNet issues 53-58 were published and distributed to over 7,000 people directly.
- YouthLens 28-30 were produced, printed and disseminated.
- The Peer Education Guidelines was drafted. Focus group discussions were held in Nairobi, Kenya and Washington DC to gain feedback. Revisions to incorporate feedback are in process.
- A researcher/writer was identified for a paper on Multiple Concurrent Partnerships, and research was initiated.
- A TOT was conducted for 20 trainers in Nairobi, Kenya, with representatives from all provinces, utilizing the "HIV Counseling and Testing for Youth" Training Guide and Manual.
- Research and writing continued for the Youth Most at Risk for HIV/AIDs issues paper.
- Revisions to the IYWG website were made, including updating the homepage.

- The IYWG meeting on “Young People Most at Risk for HIV/AIDs” was held in Washington DC on June 25th, 2008 with approximately 100 participants.

Findings and Outcomes:

- Selected findings for Phase 1 and Phase 2 of this subproject (see results of Phase 1 under FCOs 125001/125005):
- Twenty-nine new Youth InfoNet publications were distributed electronically, to more than 7,000 people directly, plus listservs reaching up to 100,000 (2006-2009).
- Twelve new YouthLens publications were developed (2006-2009).
- The IYWG Web site has been updated and feedback from users is very positive.
- Two large, public IYWG meetings in DC (June 2008, and June 2009) were organized and implemented with strong attendance at each. These followed on similar meetings held in March and Dec. 2007 under FCOs 125005/125001.
- Knowledge sharing activities were conducted at the international conference, Youth Deliver the Future, in Abuja from April 27 to May 1, 2008 including: a panel of three presentations on working with faith-based organizations; a panel of three presentations on youth PE; one presentation on curricula-based sex education standards; a workshop on using faith-based tools (60 people); and a workshop to improve PE program management (50 people). An evaluation of the PE workshop was very positive.
- The HIV Counseling and Testing for Youth Training Guide and Manual was utilized for a TOT in Nairobi, Kenya for 20 participants representing all provinces.
- Four meetings of the IYWG partners have been conducted.
- A total of 21,992 publications were distributed based on requests, plus mailings of YouthLens, the YouthNet End of Program Report, and other documents.
- WHO provided \$25,000 in October 2009 towards the paper on reducing maternal mortality.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Conduct individual interviews with 10-15 electronic IYWG survey respondents to glean information on future planning for IYWG and FHI youth technical areas.
- Maintain IYWG Website by expanding key areas, updating program area pages, refreshing home page quarterly, promoting and tracking use.
- Produce 2 YouthLens in English and French versions.
- Disseminate Youth InfoNet monthly to approximately 100,000 thru listservs and feeding information into the IYWG Website database.
- Collaborate on working and scientific papers including: Most at Risk Adolescents, Preventing Early Pregnancy and Negative Reproductive Outcomes among Adolescents, and peer education assessment tool.
- Collaborate with the UN IATT on Youth and HIV as needed.
- Participate in selected global meetings to represent FHI on global youth issues and the IYWG.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: GLP/Youth	FCO Approved:183000 Jul 2008 113144 Jul 2008
Total Approved Budget:183000	\$ 400,000	Projected End Date: Apr 2010
	113144 \$ 300,000	
	<hr style="width: 100%; border: 0.5px solid black;"/>	
	\$ 700,000	

Worldwide: Research Utilization: Youth (FCO 113143/183001)

Technical Monitor: KFazekas

Strategy Outcomes(s) to be addressed: Youth II.A.: At least two knowledge management tools implemented globally.

Objective(s): To help USAID and other NGOs implement promising practices in youth RH/HIV through research utilization activities such as promoting and developing evidence-based tools and guidance, provision of technical assistance, and establishing collaborations or linkages with other technical leaders.

Description: The attention to youth RH/HIV prevention has grown enormously since International Conference on Population and Development (ICPD) in 1994, leading to many programs and research activities worldwide. Synthesized research studies and lessons learned now serve as an evidence base of promising practices, yet much work is still needed to ensure promising practices improve the effectiveness and capacity of youth RH/HIV efforts. In September 2006, the USAID 10-year global program focusing on adolescent health ended; FHI coordinated the last five years of this program through its YouthNet project. FHI/CRTU now plays a lead role in knowledge management and research utilization coordinating the Interagency Youth Working Group (IYWG), a new interagency effort by USAID on youth RH/HIV prevention issues. This subproject aims to improve the use of promising practices and tools in youth RH/HIV in several strategic areas including: HIV counseling and testing, working with faith-based organizations, school and community based education, and peer education. Research utilization activities focus on promoting and developing evidence-based tools and guidance, providing technical assistance, and establishing collaborations or linkages with other technical leaders. This subproject complements the work of subprojects 183000/113144 on youth RH/HIV knowledge management and uses already established IYWG communication mechanisms (IYWG Web site, Youth InfoNet monthly digests, new publications, large technical meetings, etc.). To see research utilization work conducted through the IYWG prior to July 2008, see subproject 125001/125005.

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Activities, Accomplishments, Problems through December 31, 2008

- Approval to implement was received from USAID in Aug 2008.
- HIV Counseling and Testing (HIV CT): "Training Guide for HIV Counseling and Testing for Youth: A Manual for Providers" was developed and printed in collaboration with IPPF/Western Hemisphere and PSI to help train providers on information and skills in HIV CT manual. An article entitled "Improving HIV Counseling and Testing for Youth" was published in the journal MERA (Nov. 2008) and an FHI Research Utilization case study.
- School and Community Education: A report based on 11 key informant interviews about the degree of utilization of the document Standards for Curriculum-based RH and HIV Education Programs was developed. A short-term TA activity with USAID/South Africa to map out priority components for a longer-term TA plan to strengthen the school-based response to HIV was developed.
- Peer Education (PE): 1) Evidence-based Guidelines for Youth Peer Education in HIV and RH was drafted. This publication is now in the editing stage. 2) An abstract on the impact of youth PE was submitted, but not accepted at the GHC 2009 Conference.
- Faith-Based Activities: 1) A short print-run of the Christian Family Life Education (CFLE) Handbook for Adults was drafted and completed and is available online. 2) Co-sponsored a five-day training of trainers (TOT) workshop in Kenya Aug. 18-22 through APHIA II on

implementing CFLE for youth. 25 participants and four trainers, representing 16 group/organizations, were trained. 3) A participant from the April 30, 2008 FHI/IYWG FLE conducted a presentation on the FLE resources to the Interfaith Coalition of Nigeria.

- Multiple and Concurrent Partnerships (MCPs): Staff participated in a two-day consultation on MCPs hosted by AIDSTAR-One on Oct. 29-30 in DC.
- Advocacy and Expanded Impact: Supplied all FHI/Nigeria zonal offices with FLEs and the HIV CT manual.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- HIV Counseling and Testing (HIV CT): A three day training in Nairobi, Kenya was held in May utilizing the HIV CT for Youth Training Guide. Twenty health care providers attended. Action plans for implementation and scale up were also developed.
- Curricula-based Education: 1) Original plans for a short-term TA activity with USAID/South Africa and the Department of Education (DoE) were reshaped to focus specifically on youth peer education (see bullet below #3). 2) youth sex education curricula compendium was in development. 3) A final SOW and outline of an evidence-based tool to integrate multiple and concurrent partnership and be faithfulness messages into curricula-based sex education programs was developed.
- Peer Education (PE): 1) A technical review meeting with peer education implementers was conducted to get feedback on the draft of the Guidelines for Youth Peer Education in HIV and RH. The publication is now being edited based on this review. 2) An interactive two and a half hour session on best practices in peer education for the centrally funded ABY Partners was conducted on Friday, May 8 in DC. Between twenty to twenty-five implementers were in attendance. 3) A consultant was hired who provided management and technical assistance to develop South Africa national guidelines for peer education for the DoE. The guidelines are now being finalized. 4) An abstract on YouthNet's peer education research in Zambia was accepted for the 2009 APHA meeting.
- Staff attended the FHI Global Strategic Behavioral Communication (SBC) Forum in Bangkok, Thailand from March 30th to April 3, 2009 in order to promote best practices and research utilization for youth RH and HIV and present on the topic of alcohol use and youth in the context of HIV.

Findings and Outcomes:

- The Training Guide for HIV Counseling and Testing for Youth: A Manual for Providers was developed and printed in collaboration with IPPF/Western Hemisphere Region and Population Services International. Prior to printing, 17 providers in Zambia were trained as well as 24 providers from four organizations in Uganda. After printing, 20 providers/trainers were trained in Nairobi, Kenya as part of a TOT. Each trainer then developed scale-up plans to conduct trainings in their own region.
- A short print-run of the Christian Family Life Education (CFLE) Handbook for Adults was drafted and completed and is now available on the IYWG Web site.
- In Kenya, a five-day training of trainers (TOT) workshop took place August 18-22 through APHIA II on implementing CFLE for youth. Twenty-five participants and four trainers took part in a training of trainer's workshop to learn to use two Christian resources from the FLE series produced by the YouthNet Project.
- Conducted a presentation on alcohol use and youth in the context of HIV for the FHI Global Strategic Behavioral Communication (SBC) Forum in Bangkok on March 30, 2009.
- Conducted a mini workshop on applying best practices in peer education May 7, 2009 attended by twenty to twenty-five peer education implementers funded through the Abstinence/Be Faithful for Youth program that is funded by PEPFAR.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- HIV CT: New funds are being received to expand this work through the USAID HIV Counseling and Testing Working Group. A new work plan for these funds will be developed and transitioned to the new PTA.
- Curricula-based Education: 1) Finish developing an annotated online list of adult- and peer-led RH/HIV educational curricula; 2) Develop and pilot a new evidence-based tool to help integrate MCP and be faithfulness messages in curricula-based programs, working closely with ETR Associates; 3) Collaborate with UNESCO on launching global guidance for school-based RH/HIV education (activities TBD).
- Peer Education: 1) Adapt, update, and expand YouthNet's Standards for Peer Education Programmes for a new publication, titled, Guidelines for Youth Peer Education in HIV and Reproductive Health; 2) Develop a journal article on utilizing the evidence-based Assessing the Quality of Youth Peer Education Programmes using the YouthNet Zambia research; 3) Conduct one to two presentations on best practices in peer education; 4) Finish providing technical assistance to South Africa DoE and USAID/South Africa to develop guidelines for peer education in schools. Write a short report detailing this TA.
- Advocacy and Expanded Impact: 1) Work with USAID missions to use IYWG resources and respond to youth information needs, potentially focusing on one or two missions; and 2) Promote youth resources with FHI country offices and related FHI global tools as requested.
- Ensure smooth transition of many of these work plan deliverables to the new PTA.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 183001 Jul 2008 113143 Jul 2008
Total Approved Budget:	183001 \$ 400,000	Projected End Date: Apr 2010
	113143 \$ 300,000	
	\$ 700,000	

Kenya: Evaluation of "What's New & Cool for Youth" Booklet (FCO 143101/143118)

Technical Monitor: AOlawo

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Youth I.A.: Up to two youth RH and HIV prevention tools evaluated, such as the CFLE/MFLE manuals or a peer education tool.

Objective(s): To inform the National Coordinating Agency for Population Development (NCAPD) on how to maximize exposure to the "What's New and Cool for Youth" booklet among Kenyan youth, thereby equipping them with knowledge, skills and attitudes to make informed decisions about their reproductive health needs and rights. More specifically, this proposed subproject aims to:

- 1) create consensus among key stakeholders (including NCAPD and the Kenya Institute of Education) on the best strategy to reach in- and out-of-school youth with the booklet;
- 2) pilot-test the distribution and utilization of the booklet and related orientation tools;

- 3) assess whether the booklet can help improve awareness of RH issues among youth; and
- 4) identify lessons learned that may inform NCAPD's efforts to scale-up the booklet distribution to other districts in Kenya.

Description: To address the need to provide Kenyan youth with adequate reproductive health and HIV/AIDS information, the National Coordinating Agency for Population and Development (NCAPD), with technical assistance from Family Health International (FHI) and financial support from USAID/Kenya produced a booklet entitled "What's New and Cool for Youth." The booklet aims to reach both in- and out-of-school youth aged 10-24 years with information on various issues such as the relationship between population and development, rights and responsibilities, family planning, HIV/AIDS, and setting short- and long-term goals for various aspects of life including schooling, friendships, and other personal interests. The booklet was launched in August 2005, under the CTR (FCO 3446) with over 100 stakeholders, including the MOH, Ministry of Education, African Youth Parliament, Kenya Scouts Association, Kenya Girl Guides Association, Marie Stopes/Kenya, and the Policy Project. Also under FCO 3446, 5,000 copies of the booklet entitled "What's New and Cool for Youth" and 10,000 copies of a summary brochure were produced.

Building on the activities and accomplishments achieved under FCO 3446, this subproject will continue FHI's collaboration with NCAPD to inform NCAPD's scale up of booklet distribution to in- and out-of-school youth in Kenya. NCAPD is responsible for formulating and overseeing population policies, strategies and programs in Kenya, and in 2003, they spearheaded the development of the Kenya Adolescent Reproductive Health and Development (ARH&D) Policy and Action Plan. NCAPD considers the "What's New and Cool for Youth" booklet to be one of the key first steps towards implementing the ARH&D policy. Through this subproject, FHI will generate evidence and provide technical assistance to NCAPD and its partners in support of Kenya's ARH&D Policy and Action Plan.

Collaborating Agency(s): National Coordinating Agency for Population and Development (NCAPD)

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Activities, Accomplishments, Problems through December 31, 2008

- Field support funds and approval to implement were received from USAID in January 2006.
- In January 2007, additional field support funds were received from USAID/Kenya to explore strategies for reaching out-of-school youth with the booklet and to support continuing policy dialogue regarding access to the booklet for both in- and out-of-school youth in Kenya.
- A variance letter reflecting the additional funding from USAID/Kenya and reprogramming of funds from FCO 143103 was submitted to USAID/Washington. Approval was received in February 2007.
- The booklet facilitator's guide was revised based on feedback from the November 2006 orientation workshop and distributed to teachers in all 40 intervention schools.
- Monitoring visits were conducted at the intervention schools in Siaya district to document and support teachers use of the "What's New and Cool for Youth" booklet and associated facilitators guide. These visits were conducted by staff from FHI/Nairobi, NCAPD and the Ministry of Education on February 19 – 23, March 5 – 8, March 13 – 19, 2007.
- A contract graphic designer was hired to lay out the Kiswahili booklet for printing. A draft of the first section of the booklet was sent to FHI/Kenya staff for review.
- FHI and NCAPD agreed to develop an advocacy brief to support continuing policy dialogue with the Kenya Institute of Education.
- End line data was collected in July 2007. Two data interpretation workshops were convened in April 2008. About 60 staff from the study schools as well as MOE officials from study districts Nyanza province attended the workshops.
- A complete page layout for the Kiswahili booklet was done and feedback was obtained from NCAPD, FHI and other key stakeholders. Illustrations for the booklet were also incorporated. The draft Kiswahili booklet was field tested in Nairobi, Machakos, Kisumu, Mombasa, Kwale

and Garissa districts through a total of 19 focus group discussions with mostly out-of-school youth.

- In collaboration with NCAPD, FHI developed a strategy for further dissemination of both the English and Kiswahili booklets.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Finalized and printed the evaluation report in February 2009.
- Revised the English booklet in line with comments from the field test of the Kiswahili booklets in June 2009.
- Identified a consultant to adapt the facilitator guide into one that is more focused on out-of-school youth in June 2009.
- A new page lay out and set of illustrations was developed for both booklets in June 2009.

Findings and Outcomes:

- With support from UNFPA, NCAPD has printed 3,500 additional copies of the "What's New and Cool for Youth" Booklet.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

FHI will:

- Finalize and print the Kiswahili booklet.
- Finalize evaluation report.
- Convene a national dissemination workshop to share the evaluation results and report, as well as launch the Kiswahili booklet.
- Explore opportunities within APHIA II to reach out-of-school youth with the booklet.
- In collaboration with NCAPD, policy dialogue will continue with the MOE and Kenya Institute of Education regarding the importance of reproductive health information and education among secondary schools in Kenya.
- Provide technical assistance to NCAPD to finalize the strategy for further dissemination of both the English and Kiswahili booklets.

Funding Source(s):	USAID - US Agency for International Development/USAID: Field Support	FCO Approved: 143101 Dec 2005 143118 May 2009
Total Approved Budget:	143101 \$ 390,000	Projected End Date: Apr 2010
	143118 \$ 95,000	
	\$ 485,000	

South Africa: ABC Approach Youth South African University Campuses, 2008-10 (FCO 153131/153132/153135)

Technical Monitor: SPilusa

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Youth I.I.D.: Utilization of at least two youth tools developed by FHI or its partners increased.

Objective(s): 1) To establish a peer education system that will provide capacity and support to youth of tertiary institutions (MEDUNSA, Western Cape/Cape Peninsula University of Technology (CPUT) and Qwa-Qwa); 2) to train peer educators (PEs) on life skills that will enhance responsible sexual and reproductive health practices; and 3) to have trained PEs reach other youth with ABC messages aimed at reduction of STI/HIV and unwanted pregnancies. This subproject is a continuation of "ABC Approach for Youth on University Campuses in South Africa" (FCO 153101).

Description: Most efforts addressing sexuality and reproductive health needs for young people are focused on out-of-school youth and those in secondary school in SA. Young adults at institutions of higher learning represent a special group at risk as they are often left unsupervised by both parents and teachers, who believe they are mature enough to protect their sexual and reproductive health. Available evidence suggests that these young men and women have high rates of STI and unintended pregnancy, an indication that they are not yet equipped with the knowledge and skills required to protect themselves from these adverse outcomes. The subproject is implemented using USAID PEPFAR funding and will contribute to the prevention of new STI/HIV infections through training of the youth of four universities (Qwa-Qwa, MEDUNSA Western Cape and Cape Peninsula University of Technology) and communities around these universities. Youth will be provided with life skills enhancing responsible sexual and reproduction health that will ultimately lead to delay in sexual debut, reduction in sex acts, fewer partners or reduction in unprotected sex and prevention of unwanted pregnancy. The subproject aims at reaching as many students within and outside campus boundaries in addition to youth out of school and adjacent tertiary institutions through campaigns and other community outreach programs.

The expected outcomes of the project are to increase the number of students who have specific information on ABC strategies; increase human capacity development through ongoing training of ABC/life skills; increase the number of students seeking and completing CT; increase student demand for family planning (FP); and foster university commitment to sustain active support of the peer education program.

Subgrantee(s): Bokamoso Barona and Association of Catholic Tertiary Students (ACTS)

Collaborating Agency(s): South Africa Department of Education; South African University Vice Chancellor Association (SAUVCA)

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- In August 2007, FHI visited 3 campuses to discuss FY09 project activities. FHI also introduced the implementing agencies (IAs), Bokamoso Barona and ACTS, whose subagreements were approved from January and closed in December 2008.
- In November 2007, FHI expanded the curriculum to include a section on gender, particularly transactional and cross-generational sex, and involve men as change agents.
- FHI/SA worked with the campuses on workplans, outlining key activities and determining roles and responsibilities for FHI/SA, the IAs and universities.
- IAs worked on the "Graduate Alive" project, which motivates students to get skills and knowledge to prevent STI/HIV and unwanted pregnancies.
- FHI and IAs reviewed and added educational graphics to the previously RUTANANG developed training manual in 2005.
- PEs supported other outreach programs conducted during STI/HIV prevention awareness campaign, which reached approximately 500 individuals including students, academic staff, student leadership organizations, CBOs and communities surrounding the campuses.

- Communities were reached with STI/HIV prevention messages during project launch events at the MEDUNSA and Qwa-Qwa campuses during May and August 2008.
- Communities continued to be reached using Audio CDs containing life-skills messages.
- During FY07: 114 PEs were recruited from campuses – 67 PEs were trained through FHI funding and 37 were trained by other PEPFAR partners working on these campuses.
- Training and workshops conducted by IAs from May-September 2008 ensured that trained PEs reach students with ABC messages.
- Workshops reached a total of 1100 students – 100 students from ACTS in Mpumalanga, 200 students from the Anglican Students Federation in the Free State, and 800 students from the South African Students Congress Organization in the Eastern Cape.
- The program has been targeted to reach youth via media coverage on the South African Broadcasting Corporation in the international health and environmental affairs program, the regular appearance of PEs on local radio slots and articles in community newspapers on campuses.
- Subagreements with new IAs were developed for 2009 – HOPE Africa and SACBC.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- In January 2009, FHI SA and HOPE Africa began the process of reviewing the current training curriculum, RUTANANG, developed by FHI SA and representatives of 4 campuses, adding FP content as part of the life skills component. The current curriculum involves ABC, secondary abstinence, values clarification, self-esteem, communication, decision making and negotiation, and utilizes participatory learning techniques. Other key components of the ABC and life skills training are gender equity and basic information about prevention of HIV and AIDS and unwanted pregnancies. The content provides the PEs strategies for adopting and strengthening AB and life skills in their personal lives. The PEs are able to support each other in the behavior change process, including seeking counseling and testing (CT) and FP services.
- A total of 120 PEs have been recruited from the 4 campuses with the inclusion of CPUT campus.
- A period supervisor/coordinators workshop was conducted in May. This provided the supervisors with skills to support PEs; ensure the implementation of project activities; and ensure quality data collection, reporting, and M&E systems. Each campus was represented, totaling 18 participants.
- Training conducted for Qwa-Qwa and Medunsa in May and June respectively reached 54 participants.
- FHI SA continued to provide capacity building and technical support. A workshop was conducted in May for IAs - HOPE Africa and SACBC/ACTS. The purpose of the workshop was to guide IAs on developing and revising workplans, budgets, and M&E tools.
- IAs are provided with support as they implement project activities; conduct quarterly project report reviews; and provide mentoring and guidance towards implementation of project activities which include achieving the project goals.
- Sub agreements for HOPE Africa and SACBC have been finalized and approved.

Findings and Outcomes:

- From March - September 2008, these activities reached a total figure 3071 individuals which exceeds the target figure of 1080 and indicates a 284% positive performance on this particular indicator.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

FHI SA will:

- Develop workplans, a monitoring and evaluation plan, sub agreements, and ensure that these are approved by HQ.
- Consult the IAs and advocate for activities with the universities, support the process of peer educator identification.

- Provide TA during implementation of the activities including 1) incorporating of ABC/life skills peer education program within the university plans in a cost effective manner; 2) conducting ABC/life skills training for all PEs in the program; 3) conducting refresher trainings to strengthen basic peer education/facilitation skills; 4) conducting supervision skills training for and providing TA to supervisors to help support PEs and the BCC group process; 5) building and strengthening relationships between PEs and student health services, and formalizing referral links to health services; 6) monitoring ABC/life skills and the BCC group process. These activities will be achieved through the support of IAs as stated in the sub agreements.
- Progress is in place to continue with training the two campuses, UWC and CPUT, in July.
- In September 2009, an annual seminar for all peers coming from the 4 campuses will be held in order for PEs to share their experiences and best practices.
- FHI SA will review the budget, subproject progress and compile reports; semi and annual reports, communicate lesson learned and share best practices with SA communities.

Funding Source(s):	USAID - US Agency for International Development/USAID: IAA;	FCO Approved: 153132	Jan 2008
	USAID - US Agency for International Development/PEPFAR	153131	Jan 2008
		153135	Feb 2009
Total Approved Budget:	153132	\$ 145,671	Projected End Date: Dec 2009
	153131	\$ 97,889	
	153135	\$ 150,441	
		\$ <u>394,001</u>	

South Africa: S Africa: Care and Prevention Among Positive Youth (FCO 153146/153147)

Technical Monitor: SPilusa

Objective(s): 1) To establish a peer education system that will provide capacity and support to youth of tertiary institutions (MEDUNSA, Western Cape/Cape Peninsula University of Technology (CPUT) and QwaQwa); 2) train peer educators on life skills that will enhance responsible sexual and reproductive health practices; and 3) trained Peer Educators reach other youth with ABC messages aimed at reduction of STI/HIV and unwanted pregnancies.

Description: Most efforts addressing sexuality and reproductive health needs for young people are focused on out-of-school youth and those in secondary school in SA. Young adults at institutions of higher learning represent a special group at risk as they are often left unsupervised by both parents and teachers, who believe they are mature enough to protect their sexual and reproductive health. Available evidence suggests that these young men and women have high rates of STI and unintended pregnancy, an indication that they are not yet equipped with the knowledge and skills required to protect themselves from these adverse outcomes. The subproject is implemented using USAID PEPFAR funding and will contribute to the prevention of new STI/HIV infections through training of the youth of four universities (Qwa-Qwa, MEDUNSA Western Cape and Cape Peninsula University of Technology) and communities around these universities. Youth will be provided with life skills enhancing responsible sexual and reproduction health that will ultimately lead to delay in sexual debut, reduction in sex acts, fewer

partners or reduction in unprotected sex and prevention of unwanted pregnancy. The subproject aims at reaching as many students within and outside campus boundaries in addition to youth out of school and adjacent tertiary institutions through campaigns and other community outreach programs.

The expected outcomes of the project are to increase the number of students who have specific information on ABC strategies; increase human capacity development through ongoing training of ABC/life skills; increase the number of students seeking and completing CT; increase student demand for FP; and foster university commitment to sustain active support of the peer education program.

Subgrantee(s): South African Catholic Bishops Conference (SACBC)

Collaborating Agency(s): South Africa Department of Education; South African University Vice Chancellor Association (SAUVCA)

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- To support sub partner develop project work plans; monitoring and evaluation plan; develop sub agreements for sub partners and ensure that are approved by HQ.
- Support sub partners through the process of consulting and advocate for the project with the universities, support the process of peer educator identification.
- FHI SA provides technical assistance to the IA's as they implement project activities; conduct quarterly project report reviews, provide mentoring, guidance towards implementation of project activities.
- Provide guidance and support towards achievement of project goals and objectives.
- Provide TA during implementation of the activities; 1) Incorporation of ABC/life skills peer education program within the university plans in a cost effective manner; 2) conduct ABC/life skills training for all PEs participants in the program; 3) conduct refresher trainings to strengthen basic peer education/facilitation skills; 4) conduct supervision skills training for and provide TA to supervisors to help support PEs and the BCC group process; 5) build and strengthen relationships between PEs and student health services, and formalize referral links to health services; 6) monitor ABC/life skills and BCC group process, this will be achieved through implementing partners support as stated in the sub agreements.
- FHI SA will review the budget, project progress and compile reports; semi and annual reports, communicate lesson learnt and share best practices with SA communities.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR; USAID - US Agency for International Development/USAID: IAA	FCO Approved: 153146 May 2009 153147 Jun 2009
Total Approved Budget: 153146 \$	65,300	Projected End Date: Dec 2009
153147 \$	9,780	
\$	<u>75,080</u>	

CROSS-CUTTING ACTIVITIES

As a cross-cutting activity, these subprojects facilitate the translation of research results into practice by working across strategic areas of work.

FHI/NC subprojects fully or partially funded by USAID's CRTU Agreement:

Worldwide:	BBR Technical Leadership (FCO 116103)
Worldwide:	BIOS Technical Leadership (FCO 119100)
Worldwide:	HSR Technical Leadership (FCO 114106)
USA:	Regulatory Affairs and Quality Assurance for the CRTU (FCO 119200)
Worldwide:	Technical Assistance to Develop a Standardized Family Planning Curriculum (FCO 113128)
Africa Regional:	CRTU Network of Champions (FCO 113113)
Africa Regional:	Technical Assistance to Improve Family Planning Uptake (FCO 113133)
Africa Regional:	Advancing the Application of FP/RH Evidence-based Practices in WHO SPP Countries. (FCO 113134/113140)
Worldwide:	Technical Leadership: Collaboration with Multi/Bi-Lateral Procurement Agencies (FCO 118101)
Worldwide:	Technical Assistance to Field Programs (FCO 118102)
Worldwide:	Technical Oversight Committee (FCO 118103)
Worldwide:	Inter-Laboratory Trials (FCO 118104)
Worldwide:	Production Surveillance, Domestic and Off-Shore, for Hormonal and Long-acting and Permanent Methods (FCO 148101)
Worldwide:	Enhanced Country Program Implementation (FCO 113117)
Kenya:	Enhanced Country Program Implementation (FCO 113122)
India:	Enhanced Country Program (ECP) (FCO 113132)
Madagascar:	Enhanced Country Program (FCO 113129)
South Africa:	Enhanced Country Program Implementation (FCO 113123/133100)
Tanzania:	Enhanced Country Program (FCO 113148)
Uganda:	Enhanced Country Program (FCO 113125)
USA:	Development of Guidelines for Contraceptive Users (FCO 2706/112110/172003)
Worldwide:	Cochrane Fertility Regulation Review Group, 2005-2010 (FCO 112112/172002/890047/890048)
Worldwide:	Research to Practice Leadership (FCO 113114/113154)
Worldwide:	USAID Best Practices Package: Development and M & E (FCO 113115/123101)
Worldwide:	USAID Best Practices - MAQ Funds (FCO 123103)

Worldwide: Implementing Best Practices Consortium (FCO 113116)
Worldwide: CRTU Knowledge Management (FCO 113118)
Worldwide: CRTU Monitoring and Evaluation (FCO 119501/119507)
USA: Coordination and Statistical Support of CONRAD Activities (FCO 112100/132176)

Kenya: Division of Reproductive Health Capacity Development: Follow-on Activity (FCO 143103/143117)

Kenya: Building Strategic Information Capacity within NASCOP (FCO 153102/153133)

Kenya: Male Involvement in FP through MC Services (FCO 114147)

Worldwide: Research Ethics Training Curriculum for Community Representatives (RETC-CR) (FCO 1398/1600/1601/2710/172000)

Worldwide: Tool for Local Lexicon to Explain Difficult Informed Consent Terms (FCO 136101)

Worldwide: Research Capacity Assessment (FCO 113137/993501)

Switzerland: WHO Technical Assistance – Sarah Johnson (FCO 119505)

USA: Cost-Effectiveness Analysis of Assisted Reproductive Technology (FCO 174001)

Kyrgyzstan: Dissemination Meeting (FCO 119506)

Madagascar: Use of Dynamics of Cycle Beads and Other Methods in CBD (FCO 114142)

Uganda: Traditional Male Circumcisers in HIV Prevention (FCO 154103)

Uganda: Needs Assessment for Male Circumcision (FCO 156101/156102)

Uganda: Support to MoH to Increase Access to FP (FCO 143110)

USA: FHI Support for CONRAD NIH-IAAS (FCO TBD)

Madagascar: Regional Mini - U for Evidence-Based Program (FCO 143116)

Kenya: Multiple Enrollment & Flow of Patient Information for ART (FCO 153137)

Worldwide: CRTU Project Achievements Dissemination (FCO 113153)

Worldwide: BBR Technical Leadership (FCO 116103)

Technical Monitor: CGeary

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To provide staff time for completing papers begun under the CTR Program, developing concept proposals for workplans, working on research synthesis, and external consultations.

Description: This subproject was originally created to facilitate completion of papers begun under the CTR. It continues on largely to finance the development of new research concepts under CRTU strategy areas.

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Activities, Accomplishments, Problems through December 31, 2008

- Corneli, Guest, and Steiner developed a concept proposal, "Improving Self-report Measures using Biomarkers and In-depth interviews."
- The final report (M2005-24), "Consistent Condom Use among Ugandan Couples in Primary Relationships," prepared by five co-authors, it is the reference document for future presentations and papers. Those papers are: "Breaking the Ice: Introducing Condoms into Stable Relationships in Uganda" and "Learning to Accept the Condom."
- Tolley participated in a Clinical Trials Working Group meeting held in London, England (Oct 2005). The objective was to draft a microbicide development strategy, later presented to funders in Seattle, WA (Nov 2006).
- A qualitative study of condom use among married couples in Kampala, Uganda. Williamson NE, Liku J, McLoughlin K, Nyamongo IK, Nakayima F. *Reprod Health Matters* 2006 Dec. 14 (28):89-98 (FHI Pub 2006-86).
- Work continued on the 1) development of research on pregnancy in microbicide trials, 2) a review paper on vasectomy acceptability, 3) a paper on recruitment of microbicide trial participants, and 4) "Male attitudes toward vaginal microbicides in India."
- Community perspectives on care options for HIV prevention trial participants. MacQueen KM, Namey E, Chilongozi DA, et al. *The HPTN 035 Standard of Care Assessment Team. AIDS Care* 2007 Apr. 19 (4):554-60 (FHI Pub 2007-14; FCOs 735, 9396).
- Practice brief: adolescents and HIV clinical trials: ethics, culture, and context. MacQueen KM, Abdool Karim Q. *J Assoc Nurses AIDS Care* 2007 Mar-Apr. 18 (2):78-82 (FHI Pub 2007-24).
- Tolley began development for an expert meeting on adherence and its measurement.
- Work was completed on a policy paper from The Partnership for Care Project.
- Tolley conducted a presentation at the Alliance for Microbicides meeting (May 2007).
- This FCO was originally set up specifically for BASS; with the merger of Clinical Research and BASS, it became the FCO for the new BBR Department in July 2007.
- Tolley co-chaired the Track C subcommittee of the Microbicides 2008 conference.

- A paper on biological specimens based on data presented at HPTN meetings was completed and submitted for publication.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Hubacher submitted the following paper to Contraception: Hubacher D, Lopez L, Steiner MJ, Dorflinger L. Menstrual pattern changes from LNG implants and DMPA: systematic review and evidence-based comparisons.
- Hubacher presented the following paper at the Association of Reproductive Health Professionals Annual Meeting in September 2008. Hubacher D, Chen PL, Park S, Reyes V, Lillo S. Do side effects from the copper IUD dissipate over time? PUB2008/024
- Hubacker made a poster presentation on the following paper at the same meeting: Hubacher D, Lopez L, Steiner MJ, Dorflinger L. Menstrual pattern changes from LNG implants and DMPA: systematic review and evidence-based summary measures to help clinicians and clients manage choice and expectations. Contraception 2008;78(2):172.
- Nanda worked on the following papers: 1. RCT Quickstart vs. Advance Provision of COCs to be submitted to Contraception and 2. COCs and myocardial infarction.
- Morrison worked on the following paper for Best Practice and Research in Clinical Obstetrics and Gynecology. Highly-Effective Contraception and Acquisition of HIV and other Sexually Transmitted Infections. The paper is currently 'in press'.
- McCarraher attended a one-day meeting held by Pathfinder in Washington, DC entitled "Saving Young Lives: Youth-Friendly PAC" on Oct 31, 2008. She presented a paper, "Operations Research to Improve Postabortion Care among Young Women".
- Burke worked on a paper on youth peer education for submission to a peer reviewed journal.
- Geary worked on a paper on qualitative data on sexual behavior of young people in Jamaica for peer reviewed journal.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Research concepts will be developed throughout the year, as appropriate.
- Papers will be written on RH related topics.
- Tolley will continue her co-chair activities for the Microbicide 2008 meeting.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2005
Total Approved Budget:	Annually Approved	Projected End Date:	Apr 2010

Worldwide: BIOS Technical Leadership (FCO 119100)

Technical Monitor: DTaylor

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
 IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.
 IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To develop biostatistical research subprojects to be funded under the CRTU; and 2) to prepare papers that report on findings of BIOS research funded under the CRTU.

Description: This subproject funds the time that various members of BIOS spend in preparing concept papers in these areas. Once approval has been received to proceed with a concept paper, an FCO will be assigned. The subproject also funds the preparation of papers for which the research was funded under the CTR.

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Activities, Accomplishments, Problems through December 31, 2008

- This activity has been ongoing since the beginning of the CRTU. For activities that occurred before July 2007, see the annual report for July 2006 - June 2007.
- BIOS staff attended meetings or trainings on data analysis methods (details in July 2007-June 2008 Annual Report).
- BIOS staff investigated the availability of data from FHI and CONRAD pregnancy studies for secondary analysis pertaining to WHO guidelines on the pregnancy checklist (2007).
- P. Chen attended the WHO Steering Group Consultation for Hormonal Contraception and HIV Progression (Oct., 2007).
- Weiner and Lai attended an RTP-CDISC meeting on analysis data set standards for FDA and related Webinar (Feb.-April 2008).
- M. Chen and Weaver compiled and updated materials and programs for clustered data analysis methods used in support of HSR and other projects (2008).
- Weaver developed a dynamic macro for simulating clustered data from a broad array of study designs, allowing objective evaluation of designs and analysis methods prior to implementation of studies (2008).
- Weaver and M. Chen developed and implemented a seminar series for ARD and BBR staff related to mixed model analysis, survey sampling, structural equation models, and other statistical methods and tools (2008).
- A letter to the editor was published: Chen PL, Weaver M, Kwok C, Morrison CS. Effect of pregnancy on HIV disease progression during the era of highly active antiretroviral therapy (letter) *J Infect Dis* 2008; 197: 1075-6. (FHI Pub 2008-34).
- Weaver consulted on and attended a CONRAD-sponsored female condom meeting in July 2008.
- Taylor attended the ISO TC 157 meeting in Switzerland in Oct. 2008 as a member of the expert working group on barrier contraceptive studies.
- Taylor assisted in drafting an ISO guidance document for performance of male condom functionality trials in Nov. 2008.
- M. Chen and Weaver developed SAS macros for designing and evaluating studies with clustered binary outcome data (one macro for simulating data and one for modeling the simulated data) in Dec. 2008.
- Weaver developed a SAS macro for creating table shells in Nov. 2008 as part of an ongoing effort to improve the efficiency of the BIOS group.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Staff provided consultation on various BBR staff projects.
- Staff continued to train on statistical methodologies and analysis methods in support of USAID-funded research projects.
- Taylor's manuscript on challenges surrounding the design and analysis of condom functionality trials was accepted for publication in *Contraception* (to appear 2009).
- Weiner attended CDISC training on analysis data set standards re: FDA submissions (Raleigh NC, January 2009).

- Taylor and Tweedy co-authored a manuscript (with CONRAD staff) on ACIDFORM with Diaphragm in March 2009 (manuscript under review at Contraception).
- P. Chen attended International Biometrics Society Meeting (San Antonio, TX) and took training course on use of MSM analysis methods (March 2009).
- C. Kwok and Y. Ma trained on using Marginal Structural Models (MSM) for causal analysis in non-randomized studies.
- Weaver prepared and conducted seven 1-hour training sessions on advanced SAS programming techniques for HSR and BASS analysts (February – April, 2009).
- BIOS staff attended Webinar on the use of statistical graphics techniques in SAS v9.2 (May 2009).
- D. Weiner attended PharmaSug conference and related workshops on validating SAS programs in FDA-regulated environment using SAS (June 2009).
- KTweedy closed out 15 CRTU studies or projects (e.g. archiving data and programs) whose FCOs were no longer active (May - June 2009).
- M.Chen assisted HSR staff on revision of manuscript “Bridging EC users to regular contraceptives” (April-June 2009).
- S. Park trained (under supervision of M. Chen) to serve as an independent statistician for CAPRISA004 and FEM-PrEP DSMBs (May 2009; co-funded with CAPRISA004 and FEM-PrEP projects).
- J.Lai performed an expanded analysis of CONRAD cytokine study data (June 2009).
- P.Chen trained on multivariate survival analysis methods (June 2009) for secondary analysis of hormonal contraception use and HIV.

Findings and Outcomes:

- Since 2008, numerous publications have resulted from work funded by this subproject, including:
- Chen PL. Assessing learning effects and nonrandom dropout in a contraceptive device trial. *J Biopharm Stat* 2008. 18 (2): 382-92. (FHI Pub 2008-32).
- Chen PL, Weaver M, Kwok C, Morrison CS. Effect of pregnancy on HIV disease progression during the era of highly active antiretroviral therapy (letter). *J Infect Dis* 2008 Apr 1. 197 (7): 1075-6. (FHI Pub 2008-34).
- Taylor DJ, Kupper LL, Johnson BA, Kim S, Rappaport SM. Statistical models for exposure-biomarker relationships with measurement error and censoring. *J Agric Biol Environ Stat* 2008 Dec. 13 (4): 367-87. (FHI Pub 2008-137).
- Taylor D (2009). Issues In the Design, Analysis, and Interpretation of Condom Functionality Trials. (to appear in *Contraception*).
- Taylor D, Weaver M, Cheung-Hall N (2009). A Proportional Odds Beta-Binomial Model for Evaluating the Effect of Treatment in Cross-over Studies with Baseline Covariates: An Application to Condom Failure Data (to appear in *Communications in Statistics*).
- Additional publications were partially funded by this subproject; consulting was provided on further publications but not directly attributed.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Biostatistics staff will provide continued statistical consult to CRTU investigators and will assist investigators in performing secondary analyses of CRTU project data and in preparing manuscripts.
- Training on new statistical methods will be provided to BIOS and other FHI staff.
- Statistical methods, consult, secondary analysis, paper writing, and training work will be completed as needed.
- Biostatistics staff will provide limited consultation to CRTU partners on USAID-funded projects of mutual interest.
- Biostatistics staff will evaluate new and existing methods for analyzing social, behavioral and health services research data (e.g., recent developments in factor analysis, item response

theory and scale development) and make recommendations for analysis of ongoing and future studies.

- Statistical research needed to address selected analytical challenges posed by CRTU studies will be carried out and resulting recommendations will be reported. For example, Biostatistics staff will collaborate on secondary analysis papers that address CRTU research questions that can be addressed by existing datasets.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2005
Total Approved Budget:	Annually Approved	Projected End Date:	Apr 2010

Worldwide: HSR Technical Leadership (FCO 114106)

Technical Monitor: BJanowitz

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded
IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To develop health services research subprojects to be funded under the CRTU and; 2) to support paper writing on general HSR/CRTU topics as well as for subprojects that have been closed.

Description: FHI strategies under the new CRTU emphasize increasing the acceptance and continued use of existing methods of contraception and of integrating FP into HIV services. HSR's research aims to find ways of increasing access, quality and efficiency of service provision to accomplish these goals. As a result, our research should lead to greater acceptance and higher continuation rates of methods and thus to important public health outcomes. This subproject funds the time that various members of HSR spend in preparing concept papers in these areas. Once approval has been received to proceed with a concept paper, an FCO will be assigned. This technical leadership subproject also funded the writing of papers from studies conducted under the CTR and CRTU, and the dissemination of results.

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Activities, Accomplishments, Problems through December 31, 2008

- Health Services Research concept proposals for new CRTU subprojects were routinely developed under this subproject.
- See previous annual reports for papers published by year.
- Baumgartner cancelled a provider-focused paper from the late DMPA clients with Morroni at the University of Cape Town.[M2005-23]

- McCarraher "Improving post-abortion care (PAC) counseling and contraceptive uptake among adolescents seeking public services in the Dominican Republic: an operations research study" was rejected by Maternal and Child Health Journal.
- Wesson "Infrequent condom use with personal partners and risk of sexually transmitted infections among female sex workers in Madagascar" was rejected by Sexually Transmitted Diseases. [Pub 2007-035]
- Wesson "Association between self reported condom use and incident of sexually transmitted infections over time in cohort of female sex workers in Madagascar" was submitted to Jour of STD and AIDS in Dec 2008 [Pub 2007-034].
- Stanback "Menstruation requirements and the effectiveness of a job aid to rule out pregnancy in Egypt" and Stanback "Excluding Pregnancy Prior to Contraceptive Initiation: Time to Lower Our Standards" were cancelled.
- Hatzell prepared a paper, "Serving the contraceptive needs of PMTCT clients: the challenges and opportunities" and it was submitted to special issue of Bulletin of the World Health Organization focused on HIV-reproductive health integration [PP 2008-080].
- The Columbia-led manuscript on the female condom to be written by Hatzell was cancelled.
- Reynolds "Cluster randomized trial of the uptake of a take-home infant dose of nevirapine-Kenya" was rejected by AIDS Care [Pub 2007-032].
- Reynolds "Risk for unintended pregnancy and HIV among youth seeking voluntary counseling and testing (VCT) services in Haiti and Tanzania" was asked to be revised by Vulnerable Children and Youth Studies [Pub 2006-018].

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Evens attended the Strategic Behavior Change (SCB) Global Meeting in Thailand in March/April 09.
- Hatzell, Janowitz participated in the RESPOND-sponsored Community of Practice meeting focused on LAPM, held in Washington DC, June 09.
- McCarraher "Improving post-abortion care counseling and contraceptive uptake among adolescents seeking public services in the Dominican Republic: an operations research study" will be reported under the BBR technical leadership subproject.
- Baumgartner resubmitted the paper "Being faithful in a sexual relationship: perceptions of Tanzanian adolescents in the context of HIV and pregnancy prevention" to AIDS Care in June 09. [PP 2006/055].
- Hatzell prepared a manuscript documenting the CBD of DMPA experience in Madagascar, for submission to Health Policy and Planning. A working draft of the paper was reviewed at the June 09 WHO consultative meeting.[PP2008/077]
- Hatzell submitted "Serving the contraceptive needs of PMTCT clients: confronting the challenges and opportunities" to the Bulletin of the World Health Organization, but it was declined [PP 2008/080]. Hatzell began revisions for resubmission as a "Brief Report" to AIDS and Behavior.
- Eichleay attended the Contraceptive Technology meeting in April 09.
- Janowitz, Otterness "Estimating the size of the unsubsidized private sector in Indonesia" was reviewed in-house. [PP2009/011]
- Wesson "Association between self reported condom use and incident of sexually transmitted infections over time in cohort of female sex workers in Madagascar" was rejected and may be resubmitted later. [PP 2007/034]
- Bratt "Predicting impact of price increases on demand for reproductive health services: can it be done?" was completed and reviewed in-house.[PP2008/041]

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Planned Activities for July 1, 2009 – April 28, 2010

- Sutherland will attend the International Aids Society meeting and a pre-conference meeting on Health Systems Strengthening in July 2009.

- Dulli will finalize two reports: "Assessing the Management of Late DMPA Clients in Madagascar" and "Improving Access to Postpartum Family Planning in Madagascar" by the end of August 09.
- Janowitz and Otterness "Estimating the size of the unsubsidized private sector in Indonesia" will be submitted to Int Fam Plann Perspect by the end of August 09.[PP2009/011]
- Bratt "Predicting impact of price increases on demand for reproductive health services: can it be done?" will be submitted to Health Policy and Planning in August 2009.[PP2008/041]
- Brunie will write a paper on the piloting of CBD of DMPA in Madagascar (findings from CBD of DMPA study) in French to be completed by the end of October 09.
- Chin-quee "Look both ways before you cross: why bridging from emergency contraception to ongoing contraception would not work for everyone" will be submitted to Contraception in October 09.[PP2008/079]
- Hatzell will submit a "Brief Report: Serving the contraceptive needs of PMTCT clients: confronting the challenges and opportunities" to AIDS and Behavior.[PP2008/080]
- Sutherland will complete the paper "Unmet contraceptive needs among female sex workers in Kenya" and submit to Perspectives in December 09.[PP2009/023]
- Sutherland will complete the paper "An assessment of the contraceptive needs among pregnant and postpartum HIV+ women attending MCH services in Coast Province, Kenya" and submit to STIs in December 09.
- Bratt will complete the paper "Using break-even analysis to improve decision-making: three examples from health programs in the developing world" and will submit to the International Journal of Health Planning and Management in January 2010.[PP2008/051]
- Jackson will write a paper on findings from the Uganda TPMC study between February-April 2010.
- Evens will write and submit two papers for publication titled "Provider Initiated HIV Testing and Postabortion Care" and "Developing a Multidimensional Measure of Pregnancy Intentions" in March 2010.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2005
Total Approved Budget:	Annually Approved	Projected End Date:	Apr 2010

USA: Regulatory Affairs and Quality Assurance for the CRTU (FCO 119200)

Technical Monitor: MCommins

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To provide Regulatory Affairs and Quality Assurance (RAQA) support to CRTU subprojects.

Description: This subproject covers costs associated with FHI's regulatory support for the Contraceptive and Reproductive Health Technologies Research and Utilization Program. A number of RA/QA activities are funded and reported as part of the specific studies; this subproject supports more general and short-term CRTU-related efforts, including RA/QA representation on a

number of CRTU project teams to provide regulatory and quality assurance guidance. It also supports a portion of the RA/QA work related to the continued enhancement of the serious adverse event reporting, tracking of institutional review board approval, and study files systems used to support the CRTU as well as other Programs.

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Activities, Accomplishments, Problems through December 31, 2008

- Routine regulatory and quality assurance support was provided to CRTU studies.
- Staff began development of RA/QA tools to increase efficiency across CRTU studies globally.
- Templates were developed to facilitate the preparation of regulatory submissions in June 2007.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Technical assistance was provided to the CRTU Programs, in particular advice on the regulatory and quality assurance strategy for new CRTU-funded subprojects.
- Assistance was provided for study regulatory files and management of clinical supplies for CRTU research projects.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

RAQA will:

- Develop refined processes for the registration of protocols that meet the WHO definition of “clinical research” used by the ICMJE.
- Alternative regulatory strategies will be developed for approval, by sophisticated and internationally accepted regulatory agencies, of investigational products tested as part of CRTU programs.
- Model regulatory submission templates will be developed as requirements change to facilitate and expedite preparation and maintenance of submissions needed for CRTU programs.
- Development and review of tracking systems to assure efficiency and quality for CRTU studies will take place.
- Staff will continue to provide technical assistance to the CRTU Programs, in particular advising on the regulatory and quality assurance strategy for new CRTU-funded subprojects.
- Beyond April 2010 we anticipate continued support under a Microbicides award. This is appropriate given the trend to greater involvement in microbicide clinical trials and a declining number of contraceptive-related clinical trials.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Oct 2005
Total Approved Budget:	Annually Approved	Projected End Date:	Apr 2010

Worldwide: Technical Assistance to Develop a Standardized Family Planning Curriculum (FCO 113128)

Technical Monitor: IYacobson

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.E.: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Barriers II.B.: Training and supervision approaches and job aids that heighten family planning or HIV service providers' capacity to promote barrier methods (most immediately, male and female condoms) developed, tested and implemented in at least three countries.

As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To collaborate with Capacity Project and other CAs to conceptualize and develop the Standardized Family Planning Resource Package.

Description: FHI staff will: 1) collaborate with Capacity Project and other CAs to conceptualize and develop the Standardized Family Planning Resource Package based on WHO's Family Planning: A Global Handbook for Providers guide; 2) facilitate cooperating agencies' integration of up-to-date family planning training resources into pre-service and in-service training efforts; and 3) provide an additional resource for the ongoing Toolkit to Increase Access to Appropriate and Effective Contraception for Clients with HIV.

Collaborating Agency(s): Capacity Project; Extending Service Delivery Project (ESD); Jhpiego; World Health Organization (WHO)

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Activities, Accomplishments, Problems through December 31, 2008

- Approval to implement the subproject was sought from USAID in December 2006.
- Approval was received from USAID to provide technical assistance to the Capacity Project to develop a standardized family planning curriculum.
- Discussions with the Capacity Project team and USAID were initiated to define FHI's role as well as the involvement of other CAs.
- A November 16, 2007 meeting between USAID, Capacity Project and FHI outlined the broad content and structure of the Resource Package. Initial consensus was achieved around the purpose, intended users, content, and design of the package.
- A follow-up meeting was held in January 2008 with the Capacity Project to discuss the process, timeline and roles and responsibilities. As a result of these two meetings, FHI's role grew from providing technical assistance to the Capacity Project to taking a larger role in developing key technical components of the package, such as training materials for contraceptive methods, starting with non-clinic based contraceptives.
- A meeting was held with Sarah Johnson to discuss the WHO contribution to the development process.
- FHI, Capacity, ESD and JHPIEGO staff conceptualized the format and content of the FP Resource Package.
- FHI and Capacity staff developed and circulated a questionnaire to other CAs and organizations to solicit additional materials related to FP providers training.
- FHI hired an intern (June 2008) to help with reviewing submitted materials and creating a database of materials that can be adapted for the FP Resource Package.
- FHI collected and reviewed materials that may contribute to FP Resource Package.
- Several meetings were held with CAs to refine the FP Resource Package concept, discuss selection criteria for including/adapting existing materials and decide on what materials need to be newly developed.
- FHI, Capacity, ESD and JHPIEGO staff developed an outline for the COC section.
- FHI and other CAs identified experts and formed a working group to develop a section on provider behavior change (November 2008).

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- A working group identified materials to be included in the section on behavior change and held a meeting to discuss format and structure of the section (February 2009).
- FHI developed the first draft of the COC section for higher level providers and circulated it to other CAs for review (Q1, 2009). The materials were circulated to USAID in March 2009.
- FHI and other CAs held a series of meetings with Capacity to discuss the background paper which Capacity is contributing to the project.
- FHI developed the objectives and the first draft of materials related to the DMPA section for the community health worker cadre.
- A draft of the behavior change introduction and matrix materials was submitted to the other CAs for review (June 2009).
- FHI opened discussions with representatives of K4Health regarding inclusion of the FPTRP materials on the website.
- FHI identified additional resources to assist in materials creation and online interface design.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Seek additional funding to cover the expanded role FHI is carrying out on this subproject. (NB: In February 2009 the budget was increased as reflected in the report.)
- Finalize the DMPA for community health workers section.
- Develop sections on other contraceptive methods, including injectables (for clinical health workers), emergency contraception, implants, IUD, sterilization, barrier methods and fertility based methods.
- Develop sections for training CHWs and other paraprofessionals on contraceptive methods, including COCs, injectables, barrier methods and fertility based methods.
- Develop sections on informed choice counseling for both higher and lower level providers.
- Finalize behavior change section.
- Identify materials for inclusion in section on basic training skills.
- Develop instructions on how to use Training Resource Package, including examples of training schedules, which will vary depending on trainees' needs and training objectives, and suggestions on how to apply the Resource Package in the private sector.
- Field-test the components of the package in at least two countries with providers of different levels.
- Revise the materials based on field-testing results and circulate for final review.
- Produce 10,000 CD-ROMs.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Nov 2006
Total Approved Budget:	\$ 560,000	Projected End Date:	Apr 2010

Africa Regional: CRTU Network of Champions (FCO 113113)

Technical Monitor: TPetrunev

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: HIV/FP II.C.: Research evidence provided to at least four countries to inform policy reviews and strengthen policies focused on increasing contraceptive use in HIV programs to avert HIV-positive births.

HIV/FP II.D.: International recommendations for contraceptive use by people at risk of HIV and HIV-infected, including women on ART changed or strengthened; and international recommendations used in country guidelines and program documents.

HIV/FP II.E.: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs.

Objective(s): 1) To implement and evaluate a network approach to enhance RtoP; 2) to support "change agents" efforts to introduce or facilitate evidence-based change at the programmatic or policy level in-country; 3) to increase partnerships in the field, primarily through memorandums of understanding (MOU) with the champions' home agencies; and 4) to improve local input into FHI's research agenda, strengthening the important link between practice and research.

Note: Objectives were updated in July 2006 in an effort to make them more specific to the proposed activities and projected outcomes of the subproject.

Description: The process of research utilization aims to bridge the gap between research and practice by ensuring that policy-makers, health practitioners, or other decision-makers are able to access, understand, and implement recommendations stemming from new research findings in a timely and efficient manner. Applying the principles of Everett Rogers' Diffusion of Innovations Theory, research utilization literature asserts that access to, understanding, translation, and uptake of research findings can be facilitated by influential local opinion leaders who assume the role of advocates or "change agents." In line with the change agent model, the proposed subproject will build on lessons learned from FHI's experience with the innovative pilot Network of Champions subproject implemented under the CTR agreement (FCO 3305).

Collaborating Agency(s): Ministry of Health, Uganda; Private Nurse Midwives Association of Tanzania (PRINTMAT); Sustainable Health Initiative (SHI) Nigeria; Zambia HIV Prevention Care and Treatment Partnership (ZPCT)

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Activities, Accomplishments, Problems through December 31, 2008

- Approval to implement was given in Jan 06.
- The theme of FP/HIV integration for next iteration was named to be implemented in Tz, Zambia, Ug, and Nig.
- Champions attended an FP/HIV conference in Addis in Oct.
- An extension into Aug 09 was approved June 08.
- Tz: A needs assessment for integrated FP/HIV services was conducted in 20 sites; results were disseminated at a stakeholders meeting with 45 participants (Oct. 07) and to government officials, UNICEF, WHO, Canadian Embassy, and ICAP from Sep 07-Feb 08. A 3-day meeting was held (Mar 08) to review progress, challenges, lessons learned, technical information, and workplans for 08-09; 2 HQ staff and 3 Champions attended; and a ½ day field visit was made to a PRINMAT clinic. The M&E methodology was developed May 2008. A PMTCT training for 12 midwives was held in June; A PITC training was conducted for providers from 25 PRINMAT clinics, July 08.
- Zambia: A 3-day FP/PMTCT training workshop for 19 service providers from 7 facilities in (ZPCT) was conducted, Oct 07. A core health team was formed and a stakeholders meeting was held for the District Health Management teams (10 people), Oct 08.
- Uganda: Key integration issues were identified during ongoing advocacy meetings, community sensitization, and training of health workers. Reviews of existing IEC materials and job aids on FP and its use among PHAs was conducted. A joint session of the PMTCT

- and FP/HIV Working Groups was facilitated, April 2008. The Champion's 08-09 activity was approved and included in a minimum package for integration being developed by the MOH.
- Nigeria: Between Sep-Nov 07, advocacy meetings were held for 17 participants, a 4-day service provider training was conducted for 15 participants, and activities for 08-09 were planned by adding one additional State in 08. Between June-Dec 08 two-day trainings on FP methods for HIV+ were held in Plateau and Benue States for 28 service providers. Support was provided to an FMOH staff member to attend FHI's Technical Meeting on Integration in Ethiopia.
 - An Interim Progress Report for July 08 activities was shared with Champions, key FHI staff, and USAID (Feb 08).

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- In Nigeria the champion: held meetings with policy makers in 4 states, trained 32 HIV providers in FP, met with the new Nat'l HIV/AIDS Coordinator; conducted a post-training survey for trained providers.
- Tanzania: Follow up visits were conducted for trained providers in each of the 25 clinics; a proposal to continue expanding PMTCT training to all PRINMAT clinics was approved by MOH to receive funds from UNICEF. Integrated services have begun in at least 17 of the 25 clinics. A report on project activities was drafted in collaboration with the FP Coordinator of the MOH and will be shared with USAID and other partners.
- Uganda: The champion disseminated IEC materials (posters and leaflets) developed in year one of the project; 500 of each were disseminated with the help of several Village Health Teams. Service delivery protocols for Maternity and Postnatal Care clinics were developed (in conjunction with field staff), field tested and finalized; 50 copies of each were disseminated in the district. The protocols developed have been approved for inclusion in MOH Minimum Package for PMTCT. Clinical Mentorship for health facility staff were held twice a month.
- Zambia: The champion conducted a post intervention survey to determine the levels of FP integration into HIV/AIDS services at facilities with health workers trained in the first year. A meeting was held for 19 stakeholders to disseminate results of survey. A 3-day training was conducted for 31 health care providers from 12 ZPCT facilities. Staff oriented 155 community volunteers from 16 facilities and communities to issues of FP/HIV integration and mobilized them to become advocates for PLWHA to address their RH needs.
- (Official champion activities closed in 06/09, the remainder of subproject will focus on applying lessons learned). A 3-day End-of-Project Meeting was held in S Africa, with a 1-day learning exchange with the S Africa Network of Champions initiative; 18 participants attended, 3 from FHI HQ.

Findings and Outcomes:

- Some key recommendations from the evaluation of the 04-05 Network of Champions subproject under the CTR were considered in the development of the follow-on 2006-2007 subproject under the CRTU.
- A unifying theme of FP and HIV was chosen, to encourage sharing of experiences and approaches between the champions.
- It has been difficult to cultivate a "network" between individuals. Communication via e-mail was limited in 07-08, and efforts were made to improve network discussion for 08-09.
- In Uganda, an assessment of the status of FP and HIV/AIDS services in Gombe Hospital provided information for the Champion on key areas to address through advocacy meetings, community sensitization, and training of health workers. The Champions presented a poster on the findings at the 2nd Annual National Pediatric Conference in Uganda 08/08.
- In Tanzania, the needs assessment for the integration of FP and HIV services found that current challenges for access to HIV testing include stigma, limited or no access to VCT services, gender issues, and missed opportunities for referrals. The assessment results led to the follow-on counseling and training activities planned for 08-09.

- The Nigeria Champion had a direct impact on policy/strategy development at the federal government level in Nigeria. He was hired by the government (Nov-Dec 07) as a thematic consultant on Treatment Care and Support (TCS). This was for a Joint Mid-Term Review (JMTR) of the Nigeria Strategic Framework for HIV/AIDS (2005-2009), the primary national HIV policy, and recommendations he made based on his NoC experience were included in the JMTR TCS thematic report, which informs the National Strategic Framework activities for 08-09, and also for development of the next National Strategic Framework for 2010-2015.
- The Lagos State MOH hired SHI (Champion's organization) for their Training of Trainers for Family Planning Services, and appointed the Champion as Chief Trainer. He used this opportunity to include a section on FP/HIV integration in the family planning training for 47 providers, and to provide the Lagos MOH training team with training guides, notes, and presentations based on the NOC project.

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Planned Activities for July 1, 2009 – April 28, 2010

- A publication on the research utilization approach of engaging champions will be submitted.
- The Champions will be encouraged to submit presentations to regional and international conferences to share lessons learned, and supported for attendance if accepted.
- Each champion has been given the opportunity recruit, engage, and train peers and colleagues by conducting a TOT-style champions workshop in each of their countries, with nominal financial support and technical assistance from FHI staff.
- A comprehensive evaluation will examine the general efficacy of the approach and also of individual champion efforts at the close of the project. After champion workplan activities ended in June 2009 Dr. Adetunji from Nigeria plans to adapt and promote the forthcoming WHO/USAID document "Strategic Considerations for Strengthening Linkages between Family Planning and HIV/AIDS Policies, Programs, and Services" for dissemination and implementation in Nigeria (cost share 113147).

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2005
Total Approved Budget:	\$ 471,779	Projected End Date:	Apr 2010

Africa Regional: Technical Assistance to Improve Family Planning Uptake (FCO 113133)

Technical Monitor: TZan

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Hormonal I.I.E.: Policies and service delivery guidelines will be changed in at least one country to reflect new research findings. As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To provide technical assistance to: 1) the Ministries of Health in Kenya, Uganda, and Madagascar to reduce medical barriers to OC provision; 2) the Ministries of Health

in Kenya and Uganda to develop and implement CBD of DMPA programs; and 3) the Ministry of Health and other APHIA II partners in Kenya to introduce the Standard Days Method using CycleBeads.

Description: Through the CRTU Enhanced Country Program (ECP), FHI is working with local partners in Kenya, Uganda and Madagascar to advance evidence-based programming in order to increase access to and quality of family planning services. Specifically, FHI staff in focus countries are providing broad technical assistance to partners to advocate for evidence-based programming, particularly within existing bilateral programs, to familiarize partners with FHI's menu of evidence-based practices and to discuss potential strategies and collaborative opportunities for introducing specific evidence-based approaches. These ongoing ECP activities have generated requests for targeted technical assistance from FHI to advance three key evidence-based approaches for increasing uptake of family planning: 1) reducing barriers to oral contraceptive (OC) use; 2) expanding provision of DMPA through community-based distribution (CBD); and 3) introducing the Standard Days Method. This subproject responds to country level opportunities identified under the CRTU for reducing medical barriers and increasing access to contraception. This proposal will allow FHI to provide targeted technical support to enable programs to implement the most up-to-date and evidence-based practices related to the provision of pills, injectables, and the Standard Days Method (SDM).

Collaborating Agency(s): Institute for Reproductive Health; Jhpiego

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Oral Contraceptives:

- Kenya: In 07, the DRH approved integrating OC strategies into national FP guidelines. In Sep 08 they approved a revised version of the COC Strategy Guide and an addendum to the guidelines. In Dec the Kenya COC job aid was finalized and 5,000 copies were sent to Nairobi.
- Uganda: In 07 MoH approved revising the training curriculum. FHI assisted the MoH to develop the revised text. In 08 5,000 copies of the COC job aid, co-branded by the MoH, were sent to Uganda. 1660 copies were distributed at workshops, trainings, and to other CAs between July and Dec 08

CBD of DMPA:

- Uganda: Busia was assessed for scale up readiness (Aug); MoUs were signed by FHI, and Bugiri and Busia districts; a stakeholders' meeting was held in Bugiri to plan for scale up (Nov); in Bugiri 28 CBDs were trained to provide DMPA (Dec); in Busia 20 CBDs were trained (Feb 08); TA was provided to strengthen the M&E and supervision system (March, 113108); District Review meetings to gather implementation results and review the M&E and supervision strategy were held in Busia and Bugiri (Apr).
- Kenya: An Advisory Committee (AC) was formed to guide activities including an assessment of potential sites (Sep 07); the AC recommended Tharaka as a potential site; a meeting was held with Tharaka District Health Management Team in Feb and Eastern Province's MoH and RH Coordinator in May to garner support for the pilot project.

SDM in Kenya:

- In 07 Kenya's DRH approved SDM introduction, an MOU between the CRTU and IRH was signed, Kenya assigned an MOH point person for SDM activities, FHI estimated demand in Kenya to be 80,000 cycle beads over 5 years, and an assessment began to evaluate the policy environment and training needs. The assessment was completed and a report and executive summary were presented to stakeholders in June 08. In preparation for a piloted introduction in the Northeastern Province, a TOT was held Aug 14 with 19 professional trainers from the DRH, JHPEIGO and APHIA II. In Sep internal and external IRB approval was obtained in order to collect data using a brief "new user" questionnaire. Five service providers from four facilities were trained in SDM in Dec.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- All oral contraceptive activities were completed by June 09.
- The CBD of DMPA components have been completed.
- Standard Days Method in Kenya:
 - 1.) The introduction pilot of the SDM in the NEP began in Jan 09 and data was collected on new users from Jan-June. 2.) In Feb 09, FHI and IRH staff conducted site visits to two facilities in the Ijara district to meet with district ministry officials, APHIA 2 staff, religious leaders, providers, and clients to hear their first hand accounts of the SDM introduction. Special attention was given to identifying areas of difficulty in SDM provision and suggesting solutions to address identified challenges. Challenges identified include gaps in provider knowledge of SDM provision, occasional errors in data collection and potential for commodity stock-outs. 3.) In March, additional district facility providers were trained on SDM provision through on-the-job training. 4.) Gaps in provider knowledge were addressed and service providers were interviewed at a review meeting in April.

Findings and Outcomes:

Oral Contraception:

- In Kenya, Department of Reproductive Health (DRH) staff objected to the inclusion of Quick Start in the COC strategies for two reasons: 1) women were motivated to take their pills without direct observation and 2) the instructions may be confusing to some providers and/or clients. Although FHI staff presented evidence that quick start improves continuation and has not been found to be confusing, the DRH declined to include this strategy in the package of COC strategies.

CBD DMPA:

- See FCO 143110 for findings of work in Uganda.
- The Kenya CBD DMPA site assessment revealed that all but one district medical health team expressed their interest and willingness to support implementation of a pilot project. The interest in collaborating with JHPIEGO led to choosing Tharaka district in Eastern province, where JHPIEGO is the lead on APHIA II and where CBD agents are already well incorporated into the MOH system and are recognized by health agents.

Standard Days Method in Kenya:

- 125 interviews were conducted for the SDM country assessment. Results indicate that nearly all respondents believe the SDM could reach women wanting an effective yet natural method.
- Preliminary data from collection of new user questionnaires in Jan – March indicates:
 - The majority of clients choosing to use the SDM are new FP users.
 - Of the 11 percent who switched from another method, the primary reason for switching reported was undesirable side effects.
 - Most clients learned about the SDM from their health care provider.
- Provider interviews conducted at the April review meeting revealed:
 - Both providers and clients had positive attitudes and opinions towards the SDM.
 - The method is appropriate for communities in the Ijara district because it does not conflict with cultural and religious beliefs and practices.
- There were some gaps in knowledge among trained service providers and concern regarding adequate commodity supply.

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Standard Days Method in Kenya:

- Data will be analyzed in July and a summary report will be presented at a dissemination meeting in August during which time scale-up strategies will be reviewed, year 5 plans presented, and adequate commodity procurement will be discussed using IRH's SDM commodity forecasting tool.
- FHI will provide TA for several FP updates with an emphasis on effective provision of the SDM. In addition, FHI will facilitate provision of IEC materials on the SDM as needed.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Jun 2007
Total Approved Budget:	\$ 326,621	Projected End Date:	Sep 2009

Africa Regional: Advancing the Application of FP/RH Evidence-based Practices in WHO SPP Countries. (FCO 113134/113140)

Technical Monitor: CLasway

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To promote introduction and application of WHO-endorsed FP/RH practical, evidence-based practices, approaches and tools aimed at improving access to and quality of family planning and reproductive health services in WHO/Strategic Partnership Programme participating countries.

Description: The application of evidence-based policies and guidelines maximizes the quality, efficiency and effectiveness of FP/RH services. WHO, in partnership with UNPFA, initiated the Strategic Partnership Programme (SPP) to support the introduction and implementation of selected evidence-based guidance and practices in 25 countries in Asia & Africa. However, even in these countries where there has been progress to change national policies and guidelines according to the Medical Eligibility Criteria and Selected Practice Recommendations WHO 2004, guidelines have not yet been translated and/or adopted into service delivery practice. A multitude of barriers exists, including the need for local introduction and adaptation of evidence-based approaches to facilitate implementation, as well as the lack of job aids and training to make guidelines more practical for service providers. To address these barriers, WHO approached FHI, a founding member of WHO's Implementing Best Practices (IBP) partnership, to be a partner to the SPP program and assist in introduction, adaptation, and implementation of these evidence-based practices.

Under this subproject, FHI will collaborate with in-country WHO SPP, MOH, and other NGO partners to promote introduction and facilitate the utilization of evidence-based practices, approaches, and tools in two SPP participating countries: Nigeria & Tanzania. FHI will apply a combination of approaches from the Guide for Fostering Change to Scale Up Effective Health Services (developed by the IBP Consortium) and those implemented under the USAID Best Practices Package project in Madagascar (113115) to achieve its objectives. Key approaches will include: a) facilitating local acceptance, ownership and adaptation; b) identifying and encouraging in-country cooperating agencies (CAs) and NGOs to adopt these practices in their FP/RH programs; and c) strengthening in-country partners' capacity to introduce and integrate practices and tools into their programs.

Collaborating Agency(s): EngenderHealth; Ministries of Health of Nigeria and Tanzania; Society for Family Health of Nigeria; WHO/UNFPA SPP

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Activities, Accomplishments, Problems through December 31, 2008

- Approval to implement the subproject was received (July 07) from USAID. A budget increase was approved in Feb 2009.

Nigeria (113134):

- Consultations with Nigeria Federal MOH (FMoH) staff about scope of project were conducted. FMoH agreed to approve implementation (Aug 07).
- An interagency JobAid/IEC task force was convened to update the national standardized package of job aids and IEC materials (Dec 07). Partner agencies committed to adapting their materials based on the task force's recommendations. FHI provided technical review of FMoH and suggested adaptations to FHI materials (Jan 08).
- FHI distributed 2,000 contraceptive effectiveness charts to FHI/GHAIN offices.
- Resources were leveraged through FHI/GHAIN to integrate the screening checklists, MEC charts, and effectiveness charts into their integrated PMTCT/RH, and RH-HIV Integration trainings (204 providers trained between Jan. and June 2008).
- A task force meeting to review and revise IEC/BCC materials and job aids for FP/RH/STIs was held, during which plans for pre-testing of the materials and for future printing and dissemination were made (July 08). Field tests of these materials were conducted in Anambra, Oyo and Sokoto States by FMoH and FHI-GHAIN staff (Aug 08).
- FHI staff participated in the regional WHO-SPP meeting held in Abuja, Nigeria and made a presentation on FP/HIV integration efforts in FHI-GHAIN programming (Oct 08).

Tanzania (113140):

- FHI provided technical assistance to adapt the WHO Decision Making Tool (DMT) to the Tanzania setting (Nov 07). In May 2009, WHO approached FHI to support field-testing of the DMT.
- FHI facilitated the technical review of the FP content of the integrated FP and HIV package for service providers developed by AMREF and the Clinical Management of HIV/AIDS developed by the NACP.
- In November 2008, the Terms of Reference for revising the FP Procedure Manual and Curriculum were discussed and approved by the MOHSW.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The task force finalized pre-print alterations of the job aids and secured FMoH approval of pre-print materials in June 2009.

Tanzania (FCO 113140):

- In February 2009, FHI led the establishment of a FP Guideline/Curriculum taskforce and was nominated - with Pathfinder - as secretariats. An operational workplan was developed.
- In March 2009, a consultant was hired to assist in content revisions of the manual. Also experts from FHI, EngenderHealth, and Pathfinder conducted an indepth review and provided technical recommendations to the manual and curriculum.
- In April 2009, FHI hosted a five-day workshop resulting into draft one of the Manual. I. Yacobson from FHI attended the workshop to provide technical assistance on incorporating new evidence-based practices in the manual. The MOHSW and stakeholders fully adopted the recommendations in the FP handbook.
- In June 2009, FHI and Pathfinder led the incorporation of comments from technical review resulting in a 3rd draft.
- In June 2009, FHI completed the revisions of the short-acting module of the FP curriculum, including the development of trainer's Powerpoint slides as a new addition to the curriculum package.
- In Nigeria: The finalized materials (pregnancy checklist; quickstart COC checklist; DMPA, IUD and COC checklists; missed pill guide; and Quick Reference Chart on medical eligibility) were shared with FMoH and their feedback was received (Jun 09). FHI-N received in-country approval to print materials and arrange for final stakeholder meeting which will be held in July 2009.

Findings and Outcomes:

- Lack of permanent staff during most of 2008 to manage this activity in Tanzania has caused significant delays. However, staff have now been recruited and expected to officially start January 2009. Inability to secure technical support for the instructional design component from IntraHealth is an inhibiting factor since this is a key priority for the MOHSW. Efforts to solicit support from alternative partners, including JHPIEGO, WHO, and TRG is underway.

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Planned Activities for July 1, 2009 – April 28, 2010

- A TOT on the adapted job aids and IEC materials for FP providers in three states (Anambra, Oyo and Sokoto) will take place in July and August 2009. Nigeria staff will also coordinate the integration of materials into local trainings, including the scale up of PMTCT and RH-HIV integration trainings; and mobilize and support in-country CAs and NGOs to promote and adopt these practices in their programs.
- In Tanzania, staff will:
- Together with EngenderHealth and Pathfinder, host a five-day workshop to review the newly developed FP curriculum and PowerPoint slides.
- Finalize the technical content of the Procedure Manual and curriculum.
- Disseminate the FP Procedure Manual.
- By September 2009, leverage funding from WHO to finalize adaptation of the Decision-Making Toolkit for Tanzania.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:113134	Jul 2007
		113140	Jul 2007
Total Approved Budget:113134	\$ 206,506	Projected End Date:	Apr 2010
113140	\$ 212,891		
	\$ 349,838		

Worldwide: Technical Leadership: Collaboration with Multi/Bi-Lateral Procurement Agencies (FCO 118101)

Technical Monitor: ECarter

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To improve donor procurement practices and develop appropriate product specifications for field programs.

Description: USAID fully supports collaborations among donor agencies. PQC routinely provides technical assistance in establishing procurement specifications, pre-qualification of potential suppliers, and handling field complaints. These and other activities will continue as appropriate under the CRTU. They are a continuation of activities conducted under the CTR (FCO 8010).

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Activities, Accomplishments, Problems through December 31, 2008

- September 2006: Eli Carter, Director of FHI's Product Quality and Compliance Division, participated in IUD Technical Meetings at the WHO, Geneva, Switzerland.
- November 2006: E. Carter participated in a WHO/UNFPA Technical meeting in Geneva, Switzerland to develop prequalification criteria and inspection schemes for IUDs and condom suppliers.
- July 2007: E. Carter met at the WHO, Geneva, Switzerland, with technical experts to finalize pre-qualification schemes for IUDs and condom suppliers.
- October 2007: E. Carter conducted a technical assessment of the Female Health Company, FC2 factory in Kuala Lumpur, Malaysia. A confidential report was issued to WHO and UNFPA.
- January/February 2008: Carter assisted with the preparation and facilitation of WHO Workshops held in Beijing, China, Bangkok, Thailand, and New Delhi, India.
- March 2008: Carter completed a second technical assessment of the Female Health Company FC2 factory in Kuala Lumpur, Malaysia. A confidential report was issued to WHO and UNFPA.
- March 2008: Carter and Steve Hamel participated in an inter-agency meeting to develop technical criteria for USAID/JSI 2008 condom procurement.
- July 2008: PQC hosted a WHO-funded meeting of technical experts to revise the WHO Male Condom Specification & Procurement Guidelines.
- October 2008: Carter, along with other WHO experts, met with condom producers to present the revised WHO Male Condom Specification and Procurement Guidelines.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- February 2009 Carter traveled to Botswana and South Africa to conduct WHO Condom Supplier Pre-Qualification Workshops.
- March 2009 Carter traveled to Vietnam and Indonesia to conduct WHO Condom Supplier Pre-Qualification Workshops.

Findings and Outcomes:

- The prequalification criteria and inspection schemes for IUDs and condoms were developed and made available on the UNFPA website for all parties interested in manufacturing or procuring IUDs and condoms for WHO and UNFPA sponsored projects. The prequalification criteria and inspection schemes were then introduced and explained to interested parties in Botswana, South Africa, Vietnam and Indonesia in February and March 2009.

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Planned Activities for July 1, 2009 – April 28, 2010

- Support WHO contraceptive program initiatives through participation on expert technical committees, and in collaboration with other CAs develop product procurement specifications, train field staffs, and evaluate manufacturing facilities worldwide.

Funding Source(s):	USAID - US Agency for International Development/USAID: CSL-Core	FCO Approved:	Jul 2005
Total Approved Budget:	Annually Approved	Projected End Date:	Apr 2010

Worldwide: Technical Assistance to Field Programs (FCO 118102)

Technical Monitor: ECarter

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: Barriers III.B.: In-country product testing capacity developed and or enhanced in up to ten sites in support of family planning and HIV/AIDS prevention programs; documented compliance with local government regulations. As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To provide technical assistance to USAID field-funded programs and support field services initiatives through training and mentorship.

Description: Existing and potential contraceptive users must be assured that the products they receive are of good quality and will function as expected. Frequent use failure may discourage their acceptance and can jeopardize the sustainability of field programs. This subproject helps to ensure that the integrity of USAID-provided contraceptives and other commodities are adequately maintained during shipment and in-country storage. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCO 8011).

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Activities, Accomplishments, Problems through December 31, 2008

- The following field complaints were received, investigated and resolved: 1) DMPA, Mali, September 2005; 2) DMPA, Ghana, October 2005; 3) Condom, Myanmar, June 2006; 4) Condom, Rwanda, July 2006; 5) Condom, Myanmar, January 2007; and 6) Condom, Ghana, August 2007.

Technical assistance was provided to the following country programs:

- Uganda: In house training was provided to laboratory technicians from MOH test laboratory in December 2005. Follow up technical assistance was provided to MOH test laboratory in April 2006.
- Zimbabwe: A technical assessment of the MCAZ test laboratory in Harare was conducted in January 2006, to determine level of competence and test capacity. In-house training was provided in March 2006 to technicians from the MCAZ laboratory.
- Ghana: A technical assessment of contraceptive testing facility in Accra was conducted in August 2007 to determine level of competence and testing capacity.
- Ethiopia: A technical assessment of the government's contraceptive testing facility in Addis Ababa was conducted in November 2007 to determine level of competence and testing capacity.
- Zambia: A DMPA complaint was investigated and resolved (January-April 2008). A confidential Report was issued to USAID/CSL.
- Honduras: Technical assistance and training was provided to the MOH and the IHSS in establishing a quality management system for in-country contraceptive procurement in July and September 2008,
- Ethiopia: A condom field complaint was investigated and resolved (November-December, 2008). A confidential report was issued to USAID/CSL.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Training video entitled "ISO 4074 Condom Testing Methods" completed.
- Training manual that will accompany the training video was started. It is expected to be completed by September/October 2009.

Findings and Outcomes:

- Nine major field complaints investigated and resolved.
- Technical assistance was provided to Ghana, Ethiopia, Uganda, and Honduras to enhance quality management systems and laboratory testing capabilities.
- Two in-house trainings were conducted for developing country laboratory technicians, a total of 8 technicians were trained.

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Planned Activities for July 1, 2009 – April 28, 2010

- Provide technical assistance to field programs and local governments as requested by USAID. Activities may include the following:
 1. Investigation and resolution of product complaints.
 2. Strengthening local procurement programs
 3. Enhancing laboratory testing capabilities
 4. Workshops and ad hoc training
- Complete "ISO 4074 Condom Testing Methods" training manual.

Funding Source(s):	USAID - US Agency for International Development/USAID: CSL-Core	FCO Approved:	Jul 2005
Total Approved Budget:	Annually Approved	Projected End Date:	Apr 2010

Worldwide: Technical Oversight Committee (FCO 118103)

Technical Monitor: ECarter

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To facilitate annual Technical Oversight Committee meetings to review PQC's program activities and strategies for the CRTU.

Description: The Technical Oversight Committee (TOC), established in 1995, is comprised of technical experts that monitor and advise PQC's program of work. Meetings are held annually, or as needed, to ensure compliance with CRTU requirements. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCO 8015).

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The following TOC meetings were held:

- April, 2005: Dothan, Alabama
- March 2006: FHI Headquarters, RTP, North Carolina
- November 2006: FHI/Arlington, Virginia
- May 2007: FHI/Arlington, Virginia
- November 2007: FHI Headquarters, RTP, North Carolina
- May 2008: FHI/Arlington, Virginia
- December 2008: FHI Headquarters, RTP, North Carolina.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- A meeting scheduled for June 2009 in Arlington, VA was cancelled by USAID for various reasons.

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Planned Activities for July 1, 2009 – April 28, 2010

- Meetings will be scheduled semi-annually or as necessary to oversee the implementation of program objectives, and to develop strategies for addressing product quality and procurement issues. A TOC meeting will be held on September 15, 2009 at FHI/Arlington.
- A meeting in June 2010 at FHI Headquarters, RTP, North Carolina will be held presuming FHI receives a new award. In this case FCO 118103 will be closed and a new FCO will be opened under a new award.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Jul 2005
Total Approved Budget:	Annually Approved	Projected End Date:	Apr 2010

Worldwide: Inter-Laboratory Trials (FCO 118104)

Technical Monitor: ECarter

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To conduct annual proficiency trials among accredited independent laboratories and condom manufacturers. This exercise helps ensure PQC's testing competence, and compliance with international laboratory performance standards.

Description: Inter-laboratory trials are key to establishing consistency and comparability among laboratories. Most, if not all, international procurement agencies depend on third-party laboratory testing to determine the acceptance of condoms prior to shipment. USAID and other procurement agencies use the results of these inter-laboratory trials to identify qualified

laboratories. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCO 8015).

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Activities, Accomplishments, Problems through December 31, 2008

- August 2006: PQC participated in Enersol Inter-laboratory Proficiency Trials. The laboratory was determined to be operating at or above standard.
- October 2005: PQC's Inter-Laboratory Proficiency Study was initiated with 24 international laboratories, and the PQC laboratories (NC and Thailand) were found to be operating at or above standard. Confidential reports were issued to all participating laboratories.
- November 2006: PQC's Inter-Laboratory Proficiency Study was initiated with 26 international laboratories, and the PQC laboratories (NC and Thailand) were found to be operating at or above standard. Confidential reports were issued to all participating laboratories.
- October 2007: PQC's Inter-Laboratory Proficiency Study initiated with 35 international laboratories, and the PQC laboratories (NC and Thailand) were found to be operating at or above standard. Confidential reports were issued to all participating laboratories.
- October 2008: PQC's Inter-Laboratory Proficiency Study was initiated with 36 international laboratories, and the PQC laboratories (NC and Thailand) were found to be operating at or above standard. Confidential reports were issued to all participating laboratories.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- June 2009: PQC's Inter-Laboratory Proficiency Study was initiated.

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Planned Activities for July 1, 2009 – April 28, 2010

- PQC will initiate close out this FCO. The subproject is anticipated to continue under a new award, in which case PQC will initiate an Inter-Laboratory Proficiency Study in June 2010.

Funding Source(s):	USAID - US Agency for International Development/USAID: CSL-Core	FCO Approved:	Jul 2005
Total Approved Budget:	Annually Approved	Projected End Date:	Apr 2010

Worldwide: Production Surveillance, Domestic and Off-Shore, for Hormonal and Long-acting and Permanent Methods (FCO 148101)

Technical Monitor: ECarter

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To ensure pre-distribution quality of hormonal methods and long-acting and permanent methods, procured domestically or offshore, for developing country programs.

Description: This program provides close scrutiny of both domestic and offshore production and ensures that a variety of hormonal and long-acting and permanent contraceptive methods produced by contracted factories meet USAID procurement specifications prior to distribution to field programs. Periodic audits of the products and manufacturers are conducted to ensure compliance with GMP and USAID contracts. The activities conducted under this subproject are a continuation of domestic surveillance activities conducted under the CTR (FCO 8017); off-shore surveillance began only under the CRTU.

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Activities, Accomplishments, Problems through December 31, 2008

- 2005: Audits or production planning visits for USAID contraceptives were made for Wyeth-Puerto Rico (Duofem and Lofemenal oral contraceptives) in March, Pfizer (Depo-Provera) in July, Wyeth-Canada (manufacturer of Duofem and Ovrette oral contraceptive) in November, and Oss, Netherlands (Megestron injectable contraceptive) and Organon in December.
- 2006: Audits or production planning visits for USAID contraceptives were made for Wyeth-Puerto Rico (Duofem and Lofemenal oral contraceptives) in April, Pfizer in July, Schering Oy-Finland (Jadelle) in October, Wyeth-Canada in November, and Oss, Netherlands and Organon in December. In July staff visited the Organon production facility in OSS, Netherlands to review the Megestron six month stability study data; staff visited the Schering Oy Pharmaceutical manufacturing facility in Turku, Finland to perform a post award assessment and to discuss contract requirements. In October staff visited Wyeth production facilities in Montreal, Canada to conduct a production surveillance audit and to participate in a production planning meeting with USAID representatives.
- In November 2006 staff attended a meeting of the USAID/DELIVER Management Team at the John Snow, Inc. (JSI) office in Arlington, VA. The purpose of this meeting was to establish a long term strategy for the Project and a short term workplan for the first global procurement of oral contraceptives.
- 2007: March: A method transfer was conducted for the testing of Jadelle; May: An audit and production planning visit was made at Wyeth-Puerto Rico and a follow-up visit of the audit and production planning visit of USAID contraceptives was made at Wyeth-Puerto Rico.
- 2008: June: A quality visit was made to Bayer Schering Pharma, Lys-Ley-Lynnoy, France to assess the quality of Microgynon; October: Hamel traveled to Germany, Belgium, and France for production surveillance at Bayer, and to Denmark to conduct assessments of Mission Pharma and UNICEF.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Between January 1- June 30, 2009 the following was accomplished: 3 lots of IUDs, 3 lots of Depo-Provera and 2 lots of Jadelle were tested.
- May 2009: Carter, Hamel and Jenkins traveled to Arlington, VA to participate in an Injectable Procurement Strategy Meeting.

Findings and Outcomes:

- In January 2008, concerns were raised in Zambia that vials of Depo-Provera, supplied by USAID, were infected with HIV antibodies. The Zambian government subsequently withdrew the drug from all public health facilities. FHI's Product Quality and Compliance Division investigation concluded that the Depo-Provera was safe for use and showed no evidence for contamination with HIV, human blood products, or HIV antibodies. By April of 2008, the Ministry reinstated the use of Depo-Provera nationwide, thus allowing the continued use of the product. In July 2008, a lot of Depo-Provera was rejected by PQC (assay, specific gravity, pH, volume of injection), because this lot was understood to have been on a delayed shipment to Zambia, presumably as a result of the Zambia issue discussed above.

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Planned Activities for July 1, 2009 – April 28, 2010

- Each supplier will be audited annually to insure compliance with GMPs and USAID contract requirements
- Random production lots will be evaluated for acceptability.
- Shelf-life studies (accelerated and real-time) will be initiated for all products from new suppliers. Real-time studies already underway will continue.
- Production stocks stored in domestic and international warehouses will be monitored.
- Product failure investigations will be conducted to determine cause and effect. Corrective actions will be recommended/initiated when necessary.
- Field complaints will be investigated, monitored and analyzed. Recommendations will be submitted to USAID when warranted
- Supplier report cards will be maintained for all suppliers.

Funding Source(s):	USAID - US Agency for International Development/USAID: Field Support	FCO Approved:	Jul 2005
Total Approved Budget:	Annually Approved	Projected End Date:	Apr 2010

Worldwide: Enhanced Country Program Implementation (FCO 113117)

Technical Monitor: SClapp

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To identify and prioritize local reproductive health research and program needs in up to five enhanced countries; and 2) to facilitate efficient, effective implementation and utilization of reproductive health research and programs in the enhanced countries.

Description: The enhanced country program (ECP) was implemented in 4 priority countries, Kenya, South Africa, Uganda and Madagascar now defined as the tier one countries. Activities in the tier one countries are to facilitate the PHI impact of the CRTU by leading the prioritization, implementation and utilization of research to inform local policies and programs. More specifically, the subproject serves to identify and prioritize local research and program needs, develop and implement work plans that address those needs, foster collaborative partnerships, and facilitate the translation of research into practice.

The program is grounded in the following activities: development and support of field presence through two existing offices (Kenya and South Africa; local costs for the South Africa office will be funded by another FCO) and the placement of local staff in existing IHA or partner offices in Uganda, Madagascar, Nigeria, Tanzania and India; engagement of local stakeholders to guide research-to-practice efforts; needs assessment and prioritization to the development of a

research and program agenda that meets needs at the country level; promotion/utilization of Best Practices; program and research project planning and management; monitoring and evaluation of work plans; management of the overall approach; and mobilization/diversification of resources to sustain and expand implementation.

A subset of the activities listed above will be conducted in a second tier of countries, including Nigeria, Tanzania and India. Visits were conducted to identify local stakeholders and RH experts. A steering committee comprised of multidisciplinary FHI senior staff, will provide technical oversight to all ECP approaches and activities. Within each country, activities will be implemented in collaboration with the MOH, local universities, the USAID Mission, MOU partners, other CAs as well as local NGOs, research firms, and community/advocacy groups.

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Activities, Accomplishments, Problems through December 31, 2008

- For prior accomplishments, see the CRTU Annual Report (2006-2008).
- An ECP conceptual framework, and other supporting materials were produced.
- Subcommittees were formed to select focus countries and to develop an M&E methodology.
- In Feb. 2008, NC staff traveled to India to assist the CRTU Project Director in prioritizing local RH needs, revise the Results and Logic matrix, train staff on RU M&E, develop new concepts for possible local funding and finalize the work plan for FCO 113136. Multiple meetings were held with the MOH, MOU partners and local stakeholders.
- In April 2008, Project Directors from Madagascar, Kenya, South Africa and Uganda met in NC for an ECP retreat.
- Country office systems for supporting the CRTU were reviewed and improved.
- Africa Regional office staff visited NC to work with staff to refine CRTU management systems.
- The FCP contributed to the printing of youth materials for the MOH in Tanzania (Adolescent Reproductive Health Services standards, facilitators guide and participant handout).
- NC staff participated in the USAID CRTU management review in April.
- NC staff conducted two quarterly portfolio reviews with all four tier one countries to ensure activities are on track and within budget.
- Senior CRTU management traveled to Nigeria in May 2008 to ensure staffing for and management of CRTU activities.
- Country advocacy plans for LAPMs in Kenya were developed and implementation is scheduled to start in July 2008.
- A quarterly “network” group call was facilitated for 3 Champions from Uganda, Tanzania, and Nigeria; 2nd quarterly funds were disbursed to all three.
- Technical Assistance for the Research Portfolio in Tanzania, Madagascar, Kenya, and India was conducted.
- FCP staff attended the National Family Planning Stakeholder Meeting in Tanzania (July 2008).
- In August 2008 staff assisted in developing the Ensuring Utilization work plan and new staff orientation in Tanzania.
- In Madagascar, staff assisted in the development of an advocacy panel for CBD of DMPA.
- Field support for the development of a proposal to outline several research utilization activities was provided.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- A Portfolio Tracking Tool was developed to closely monitor the FCP activities to ensure all objectives of subprojects are met.
- Technical Assistance for the Research Portfolio in Uganda, Kenya, and India was conducted.
- FCP staff conducted a Champions workshop in South Africa in May 2009.
- FHI and several other organizations assisted in the reviewing of the national South African contraception guidelines.

- Monthly conference calls were held with each FC to discuss implemented and proposed activities, identify obstacles, and develop solutions in order to meet each subproject's goals.
- Madagascar FCP activities transferred to PROGRESS; however, due to the political situation, all activities are on hold.

Findings and Outcomes:

- RH priorities were identified through stakeholder meetings/assessments in Kenya, Uganda and South Africa during Nov 2005, Dec 2005 and March 2006, respectively. Also, the Best Practices Assessment team met with several key stakeholders to identify RH priorities in Madagascar during the March-April 2005 assessment visit. Full reports of meeting proceedings and findings are available for each country: (Uganda M2005-85)
- Common themes and RH needs/challenges identified across countries include:
- HIV & FP: to refine models of integration and evaluate impact of innovative integration models; and improved dissemination of evidence and knowledge on FP and HIV integration to inform policymakers and program managers.
- LAPMs: to increase demand by addressing misinformation and improving attitudes of both clients and providers; to strengthen providers' skills and confidence; and to investigate and support efforts to improve access by expanding the types of providers delivering LAPM services.
- Hormonal Methods: to expand access by increasing service delivery points (i.e. pharmacies, CBD of DMPA); and improve providers' attitudes, skills and confidence to provide hormonal methods.
- All Methods/Cross-Cutting: to update, harmonize and improve dissemination of RH policies and guidelines; to increase providers' efficiency and improve counseling skills on sexuality and the full range of contraceptive methods; to expand male and youth involvement in RH and strengthen RH services for these populations; to support advocacy efforts to reach opinion leaders and policymakers to mobilize resources and commodities for FP programs and to enhance IEC to increase demand for and to augment the capacity of providers to offer quality FP/RH services.
- For the Year 3 work plan, 27 concept proposals were developed in collaboration with local partners in Kenya, Uganda and Madagascar. Of those, 11 were selected for submission to USAID, representing a significant proportion of the total new subprojects submitted for USAID's consideration.
- See the April 2008 Management Review and FHI's Self-Assessment of the CRTU Research Utilization component for more details on ECP accomplishments.

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Planned Activities for July 1, 2009 – April 28, 2010

Staff will:

- Work with tier one country staff to draft country RU accomplishment summaries, update the CRTU Results and Logic Matrices and prepare other documentation in preparation for the mid-term assessment.
- Work with Country Office staff to facilitate visits by the assessment team.
- Travel to Uganda, Tanzania, South Africa, Kenya, Madagascar and India to provide technical assistance to Project Directors to implement the focus country program, promote new evidence based practices, seek research topics that respond to local needs and develop new project ideas.
- Convene country meetings in NC to share country-specific experiences and research findings, to provide country specific updates on RH priorities and partner interests, and to identify possible synergies and collaborations between projects.
- Advocate for and facilitate the development of new project ideas for Year 5 in the enhanced countries.
- Follow-up with ECP staff to monitor the implementation of the M&E system at the country level.

- Continue to ensure that research results and best practices generated in other countries are shared with enhanced countries and integrated into their work plans when appropriate.
- Provide updates to USAID on the ECP.
- Work closely with each of the focus countries to ensure that all CRTU deliverables are obtained on time and within budget.
- Travel to India to provide TA to new CRTU Project Director and to Madagascar to provide TA to acting CD and assist with recruitment of new permanent CD.
- Bimonthly phone calls to track progress will be conducted to identify obstacles and to determine solutions to obstacles.
- Country Directors will convene in Nairobi in the spring to review progress made toward research utilization outcomes in their countries. Plans will be developed to facilitate the utilization of results.
- The Nairobi-based Director of Research at the Africa Regional Office will travel to NC to report on new RH priorities in the region and to develop new projects with NC staff.
- Office operations and systems for supporting the research and research utilization portfolio will be reviewed and improved.
- Short term TDY to Kenya to assist with regional FCP will be provided.
- Short term TDY to Tanzania to assist with regional FCP will be provided.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2005
Total Approved Budget:	\$ 2,809,915	Projected End Date:	Apr 2010

Kenya: Enhanced Country Program Implementation in Kenya (FCO 113122)

Technical Monitor: MKuyoh

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To identify and prioritize local reproductive health research and program needs; and 2) to facilitate efficient, effective implementation and utilization of reproductive health research and programs.

Description: The enhanced country program (ECP), which will be implemented in four priority countries including Kenya, will facilitate the public health impact of the CRTU by leading to the prioritization, implementation and utilization of research to inform local policies and programs. More specifically, the ECP will serve to identify and prioritize local research and program needs, develop and implement country workplans that address those needs, foster collaborative partnerships with local groups, and facilitate the translation of research into practice. The program will be grounded in the following core activities: 1) Creating and supporting a CRTU Stakeholder Committee composed of CRTU memorandum of understanding (MOU) partners,

RH/HIV/AIDS NGOs, USAID cooperating agencies, local universities and professional organizations, the MOH, and USAID Mission staff to identify and prioritize country RH needs; 2) Convening partners to assist in developing research and program agendas that meet country level needs, identify opportunities for collaboration and joint work planning, identify approaches to improve policies and programs and scale-up programs improved by FHI research; 3) Promoting and utilizing existing RH research results and USAID Best Practices; 4) Providing assistance with program and research planning and development, and subproject oversight; 5) Developing and monitoring country workplans; 6) Supporting local staff salaries and costs associated with office infrastructure; and 7) Mobilizing and diversifying resources to sustain and expand country level activities.

A steering committee comprised of multidisciplinary FHI senior staff will provide technical oversight to all approaches and activities. Within each focus country, activities will be implemented in collaboration with the Ministry of Health, local universities, the USAID Mission, MOU partners, other cooperating agencies as well as local NGOs, research firms, and community/advocacy groups.

Collaborating Agency(s): Adventist Development Relief Association (ADRA); Division of Reproductive Health; EngenderHealth; Jhpiego; Johns Hopkins/CCP; National AIDS and STI Coordinating Program (NAS COP); National Coordinating Agency for Population and Development (NCAPD); PATH; Population Council

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Activities, Accomplishments, Problems through December 31, 2008

- For prior accomplishments, see the CRTU Annual Report (2007-2008).

FHI staff:

- Prompted mission to organize a session with APHIA partners to disseminate research results, and evidence based practices and tools. Disseminated relevant research results and products to APHIA partners and US government CAs during PMTCT technical working group (approx. 40 participants) and FP technical team (32 participants) in Feb 08 and presented evidence-based products and tools to APHIA directors in July 08.
- Produced and disseminated 32 CRTU country newsletters "Family Health Research" on Integration, CBD of DMPA and Long-acting and permanent methods and Microbicides.
- Hosted a CRTU stakeholders meeting in June 08 with 49 stakeholders from the MOH, collaborating agencies (CAs) and NGOs.
- Prepared CRTU country profile and drafted 9 RU success stories in preparation for mid-term evaluation. Hosted the CRTU mid-term evaluation team in Sept 08.
- Hosted 9th and 10th Partner Council Meeting in May 08 and Nov 08. Shared the results of the stakeholder assessment on facilitators and barriers to research utilization, gave a briefing on the mid-term evaluation and progress on CRTU's response to the identified priority research ideas.
- Presented to APHIA II in Nairobi (12 participants) Rift Valley (11 participants) and Coast Province (20 participants) in May, Aug. and June 2008 respectively. In Nairobi, the meeting comprised mainly the directors and technical officers. In the Rift Valley and Coast there were mainly technical officers supporting programs from the facility, community and home-based care levels.
- Hosted a meeting in Nov 08 to help the DRH include questions on use of evidence based tools and job aids including the provider checklists in the RH supervision tool.
- Developed concept paper and discussed with MOH/DRH how to conduct update sessions on evidence-based FP practices with pre-service medical training institutions (eg University of Nairobi, Kenya Medical Training Colleges, Nairobi Hospital, Aga Khan Teaching University and Moi Referral Teaching University).
- Recruited Research Associate in Nov 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

FHI:

- Prepared and began implementation of final 18 month work plan for the country program.
- Developed work plan and obtained approval from USAID/Kenya for allocation of FY 08 field support funds.
- Initiated discussions on transition from CRTU to PROGRESS and/or CRTU follow-on during staff retreat on 23rd -24th Feb 2009.
- Supported dissemination of 230 newly produced HIV toolkit and other service delivery tools during scientific conferences namely during the University of Nairobi STD/AIDS collaborative meeting, Jan 2009; Kenya Obs/Gyn Society (KOGS) 32nd Annual Scientific Conference, Feb 2009; Kenya Clinical Officers' Association conference, March 2009; and the Contraceptive commodity strategy Launch (MoPHS - DRH), April 2009. Made presentations on FP needs of women traditionally targeted for HIV/STI services, FP needs of HIV positive women and the Standard Days Method.
- Hosted and facilitated field visits for C Mauney, USAID/Washington 19-21 March.
- Documented success story of the House girls subproject (FCO 154100) in the IRIN Africa English reports, May 26, 2009.
- Held USAID/K quarterly meeting and shared subproject updates and prompted them to organize a session with APHIA partners to disseminate research results and evidence based practices and tools in June 09.
- Facilitated the national launch of the long-acting and permanent methods strategy, and two regional dissemination meetings in June 09 (FCO 113109). Submitted 11 abstracts for the International Conference on Family Planning: Research and Best Practices scheduled to take place in Kampala in Nov 09.
- Submitted 4 abstracts and facilitated review of abstracts as part of the technical committee for the 8th International Conference on Urban Health in Nairobi in Oct 09.
- Facilitated 1st CME with 33 tutors and lecturers from pre-service medical training institutions on evidence-based FP practices with DRH, UON and KMTC in June 09.

Findings and Outcomes:

- See prior reports for the RH priorities identified by stakeholders.
- The ECP contributed to the following RU successes:
- In annual Obstetrics and Gynecology Society (KOGS) meeting (Feb 07), presentations were made on CBD of DMPA, contraception for HIV+ women and repositioning FP for PMTCT. In Feb 08 presentations on successful LAPMs approaches (113111) were made.
 - Staff participated in the 36th Kenya Medical Association Annual Scientific conference.
 - Use of the pregnancy, COC, DMPA and IUD checklists were scaled up under FCO 113122. The MOH incorporated the checklists into in-service training and supervision and into their Community Mid-wifery Orientation package.
 - As a result of FHI's IUD advocacy and repositioning activities, 4087 additional APHIA II facilities in Coast and Rift Valley provinces are providing IUDs in their programs.
 - "What's New and Cool for Youth" booklet is being used by the Centre for Studies in Adolescence to orient students in their programs to RH issues.
 - The CRTU has continued to mobilize utilization of products and has provided TA to non-FHI APHIA II provinces to scale up implementation of FP/VCT integration. Cumulatively 168 VCT providers from 70 sites were trained in FP service delivery and two partner organizations (EngenderHealth and PATH) are using the products and tools developed (113126/123102).
 - The CRTU Model was applied to increase reach of an existing program. As a result ICL-Africa uses FHI-initiated ABC Model to expand operations and increase funding base (153110/153111). Over the last year, ICL has initiated an 'ABC model' activity at five colleges around the country. These new sites have been initiated in collaboration with and funding from USAID through APHIA II projects. In all the sites, ICL will replicate the model as implemented at the University of Nairobi, using the same structure and materials. In 2009, ICL has been able to raise funds to support the ABC activities at the local universities from AIDS Care and Treatment Services (ACTS).

- The FCP shared study results on FP needs of women traditionally targeted for HIV/STI among 215 stakeholders in different forums, conducted 60 training of trainers and facilitated orientation of 141 providers on the new FP/ART package and provided TA in the development of the National Strategy for Integration of RH services (156100).
- The House girls study (154100/154102/154104/154105) was scaled up to 5 sites.
- To date, ECP has leveraged \$6,289,568 from donors.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

Staff will:

- Implement and monitor country level research application/utilization activities included in the ECP Ensuring Utilization Work Plan.
- Prepare quarterly programmatic and financial reports for USAID/Kenya.
- Monitor, coordinate and support the implementation of the CRTU portfolio.
- Generate and capitalize on opportunities to disseminate FHI's menu of evidence based practices and support research utilization within the RH program.
- Contribute to development of new research ideas and identify appropriate partners and sites.
- Identify and document success stories; and explore possible RU and dissemination through thematic meetings with members of the partner council to share knowledge and experiences.
- Prepare for close out of subproject through the following activities:
- Hold final stakeholders' meeting.
- Complete all study reports.
- Disseminate 4th FHI Research newsletter on evidence-based interventions for youth.
- Update the CRTU results and logic matrix progress report.
- Conduct 2 additional seminar sessions with MOH/DRH on evidence-based FP practices with pre-service medical training institutions and facilitate follow-on seminar sessions with students at the respective institutions.
- Support presentation of successful papers during the 8th International Conference on Urban Health scheduled to take place in Nairobi in Oct 09 and the International Conference on Family Planning: Research and Best Practices in Kampala in Nov 09.
- Continue discussions on the transition from CRTU to PROGRESS.
- Promote the use of research results, tools and products within MOH, APHIA II and other implementing partners.
- Keep stakeholders updated on CRTU research results and products in response to identified priorities.
- Generate and capitalize on opportunities to disseminate evidence based practices and support research utilization within the RH program.
- Share program updates and progress with Information Programs for inclusion in the quarterly Family Health Research newsletter and produce and disseminate the newsletter.
- Meet regularly with Partner Council members, including MOU partners, the Ministry of Health (MOH) and the National Coordinating Agency for Population and Development (NCAPD), in order to update them on the close out of CRTU.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Oct 2005
Total Approved Budget:	\$ 5,041,726	Projected End Date:	Apr 2010

India: Enhanced Country Program (ECP) in India (FCO 113132)

Technical Monitor: AWidge

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To identify and prioritize local reproductive health (RH) research and program needs in India; and 2) to facilitate efficient, effective implementation and utilization of reproductive health research and best practices in India.

Description: ECP, will be implemented in four priority countries and two secondary countries. India, one of the secondary countries, will facilitate the public health impact of the CRTU by prioritizing, the implementation and utilization of research to inform local policies and programs. The program in India will be grounded in the following core activities: 1) Regularly convening CRTU stakeholders composed of CRTU memorandum of understanding (MOU) partners, RH/HIV/AIDS non-governmental organizations (NGOs), USAID cooperating agencies, local universities and professional organizations, the Ministry of Health (MOH), and USAID Mission staff to identify and prioritize country RH needs; 2) Working with partners to assist in developing research and program activities that meet country level needs, identify opportunities for collaboration and joint work planning, identify approaches to improve policies and programs and scale-up programs improved by FHI research; 3) Promoting and utilizing existing RH research results and USAID best practices; 4) Providing assistance with program and research planning and development, and subproject oversight; 5) Developing and monitoring the country workplan. 6) Supporting local staff salaries and costs associated with office infrastructure; 7) Mobilizing and diversifying resources to sustain and expand country level activities.

A steering committee comprised of multidisciplinary FHI senior staff will provide technical oversight to all approaches and activities. Within each focus country, activities will be implemented in collaboration with the MOH, local universities, the USAID Mission, MOU partners, other cooperating agencies as well as local NGOs, research firms, and community/advocacy groups.

Collaborating Agency(s): Indian Council of Medical Research, New Delhi; Ministry of Health and Family Welfare, India

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Activities, Accomplishments, Problems through December 31, 2008

- Meetings were held with the State Innovations for Family Planning Services Agency (SIFPSA) to encourage them to incorporate the checklists for all 33 districts of Uttar Pradesh (UP).
- FHI made a presentation on the utility of the provider checklists at the Federation of Obstetric and Gynecological Societies of India continuing medical education workshop.
- FHI shared the handbook on CBD of injectables with the Government of India (GOI) to advocate with the government to expand FP choices and introduce injectables into the national program.
- FHI participated in an expert committee to explore the possibility of introducing an additional intrauterine device (IUD), in addition to the existing TCu 380A, into the national program.

Evidence reviews were undertaken and based on multiple factors, it was decided that the Multiload 375 will be included into the national program.

- FHI participated in an expert committee established to plan the national advocacy workshop on repositioning family planning to achieve maternal and child health goals. (113132 and 143111).
- FHI, SIFPSA, and the UP Government met to share findings of the qualitative study 'Vasectomy acceptability among clients and providers in UP, India'. Study results were disseminated in September 2008 to the key stakeholders. (FCO 116100).
- The study, 'Survey of women and private providers to determine perspectives on using the private sector for family planning', received local and PHSC approval Dec 2008. (FCO 114138). ORG-MARG will be the research partner on this study. (FCO 114138).
- USAID funding for the FHI-ICMR RCT of Three Vasectomy Techniques (FCO 112128) is being discontinued due to budget limitations. However, as an Indo-US Grant-funded project, ICMR has funds from the Government of India to implement the study. ICMR has taken the lead on the study.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- In March 2009, FHI conducted a training on 'Good Clinical Practice and Research Ethics' for ICMR and FHI India staff.
- CRTU activities have leveraged additional field support for FHI's family planning program in India. In May 2009, USAID/India Mission approved \$400,000 under PROGRESS in India.
- In June 2009 an FHI strategy paper on injectable contraceptives was submitted to USAID/India Mission for review. The paper is result of an extensive desk review of literature and key informant interviews. The document provides a synthesis of the historical and current context; issues and opportunities related to injectable contraceptives; and strategies to overcome barriers to use and non-use in the Indian context including its introduction through the public sector.
- In June 2009, a case study of the FHI Aastha Project in Maharashtra on integrating HIV prevention and family planning (FP) services was finalized and translated in two local languages (Hindi and Marathi). A total of 100 copies were printed for further dissemination and utilization. The case study was disseminated during the one-day national workshop on HIV/ Sexual Reproductive Health convergence organized by PATH, in March 2009.
- In June 2009, four FHI/USAID tools and resources including training and reference guides to initiate COCs; IUD; DMPA; and to identify women who are not pregnant were translated in local language (Hindi) for use by HLPPT and for FHI to train services providers in UP. A total of 500 have been printed.
- In June 2009, the USAID/Population Council toolkit 'Enhancing Quality for Clients: Balanced Counseling Strategy' was translated in Hindi and a total of 5,000 copies were printed. The toolkit will be shared with Abt Associates to train its network of 5,000 private providers under the Saathiya network in UP.

Findings and Outcomes:

- In 2008, a total of \$200,000 in field support funds was leveraged in support of CRTU activities. In May 2009 \$400,000 was approved under PROGRESS.
- In February 2008, FHI was invited by USAID/India to participate in the expert technical review of Hindustan Latex Family Planning Promotion Trust (HLPPT)'s training protocols for different cadres of staff at the Merrygold, and Merry Silver Training clinics in UP. As a result of this participation, HLPPT decided to adapt FHI-developed provider checklists on screening clients for IUD, depot medroxyprogesterone acetate (DMPA), combined oral contraceptives (COC) usage and pregnancy. HLPPT committed to reprint and share the pregnancy checklists with approximately 120,000 Accredited Social Health Activist (ASHA) in UP.
- The national strategy on 'Repositioning IUD in Family Welfare Program: Strategy, Operational Plan and Achievements, MOHFW, GOI 2008' was finalized and 5000 copies were printed. (FCO 113136). 4700 copies of the national strategy were distributed to 23 State

Health and Family Welfare departments, and more than 15 international and national agencies and funders.

- 4200 copies of 'Operational guidelines on fixed day static approach in sterilization services under the National Family Welfare Program' were printed and distributed to 36 State Health and Family Welfare departments, 18 State Health and Family Welfare Training centers and to the National Institute for Health and Family Welfare on the request of the GOI.
- Other accomplishments pertaining to the India ECP program can be found in the individual subproject reports.

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Planned Activities for July 1, 2009 – April 28, 2010

- Staff will continue to foster relationships with local CRTU MOU partners, RH/HIV/AIDS NGOs, USAID cooperating agencies, local universities and professional organizations, the MOH and USAID/India to identify and prioritize country RH needs, identify opportunities for collaboration and joint work planning, and identify approaches to improving policies and programs.
- In collaboration with the Gates Foundation. The CRTU will continue to integrate family planning into FHI/India programs. This will include documenting integration processes and best practices and disseminating with key stakeholders for further utilization.
- Staff will follow-up with Abt Associates and HLFPT to review how tools and resource materials have been adapted and utilized for enhancing skills of service providers in UP.
- The NSV acceptability study report will be finalized and published in the CRTU newsletter and Family Health Research journal. These materials will be distributed to at least 1000 stakeholders.
- A briefing kit on injectable contraceptives for policy makers and pressure groups in India will be developed.
- Staff will leverage support from the Gates supported URHI project to scale-up injectable contraceptives through the private sector; build on both URHI and PROGRESS to conduct operations research; pull together the science on the safety and effectiveness of hormonal contraception; engage advocacy groups to change the national perception of the method; and test the impact of a mass media campaign on public perceptions.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Apr 2007
Total Approved Budget:	\$ 624,948	Projected End Date:	Apr 2010

Madagascar: Enhanced Country Program in Madagascar (FCO 113129)

Technical Monitor: MMalkin/TZan

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To identify and prioritize local reproductive health research and program needs in Madagascar; and 2) to facilitate efficient, effective implementation and utilization of reproductive health research and programs in Madagascar.

Description: The enhanced country program, which was implemented in four priority countries including Madagascar, is to facilitate the public health impact of the CRTU by leading to the prioritization, implementation and utilization of research to inform local policies and programs. The program serves to identify and prioritize local research and program needs, develop and implement country workplans that address those needs, foster collaborative partnerships with local groups, and facilitate the translation of research into practice.

The program in Madagascar is grounded in the following core activities: 1) Creating and supporting a CRTU Stakeholder Committee composed of CRTU memorandum of understanding (MOU) partners, RH/HIV/AIDS NGOs, USAID cooperating agencies, local universities and professional organizations, the MOH, and USAID Mission staff to identify and prioritize country RH needs; 2) Convening partners to assist in developing research and program agendas that meet country level needs, identify opportunities for collaboration and joint work planning, identify approaches to improve policies and programs and scale-up programs improved by FHI research; 3) Promoting and utilizing existing RH research results and USAID Best Practices; 4) Providing assistance with program and research planning and development, and project oversight. 5) Developing and monitoring country workplans; 6) Supporting local staff salaries and costs associated with office infrastructure; 7) Mobilizing and diversifying resources to sustain and expand country level activities.

A steering committee comprised of multidisciplinary FHI senior staff, will provide technical oversight to all program approaches and activities. Within each focus country, activities will be implemented in collaboration with the Ministry of Health, local universities, the USAID Mission, MOU partners, other cooperative agencies as well as local NGOs, research firms, and community/advocacy groups.

Collaborating Agency(s): Action Santé Organisation Secours (ASOS); Adventist Development Relief Association (ADRA); Institut National de Sante Publique et Communautaire (INSPC); Medical Care Development International (MCDI); Mercy Ministries; Ministry of Health and Family Planning, Madagascar; National Leadership Institute of Madagascar; PENSER; Population Services International (PSI); SAFJKM; Santénet

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Activities, Accomplishments, Problems through December 31, 2008

- Approval to implement the subproject was obtained in Dec 06.
- The Project Director (PD), Dr. Serge Raharison, was hired and negotiated with stakeholders the start-up of 114116, 114113, and 123103.
- FY07 field support funds were received for 143107, 143108 and 143109.
- The following staff were hired in 2008: 1) Senior Technical Officer—Dr. N. Ranaivoson (resigned in Aug 2008), 2) Senior Research Associate—Dr. Ny Lova Rabenja, 3) M&E Officer—H Rasoloharimahefa, 4) Administration and Finance Manager—P. Rakotondratovo, 5) Senior Technical Officer—H. Andrianaivo, 6) Driver—M Bearivony, 7) Administration and Logistics Assistant—E. Ralairitinasoa, 8) Administrative and Financial Assistant—N. Razakamandimby.
- N Rahajason hired as an intern in Oct 07, was switched to consultant in Dec 08 to lead the CBD of DMPA scale-up activities and assist with communication management.
- N Razafindrasata was hired as a consultant to assist in administrative tasks.
- The PD attended the Enhanced Country Program (ECP) Retreat in NC.
- FHI staff participated in preparing for 8 inter-regional workshops for MOH staff at which FHI's adolescent RH tools (FCO 143108) were presented and discussed. An FHI team attended 2 of the 8 workshops to negotiate scale-up plans for CBD of DMPA.
- FHI staff served as group facilitators at the National RH Coordination Meeting for MOH staff.

- The Madagascar office participated in the CRTU mid-term assessment in Sept 08 during which 31 individuals were interviewed. A final report was produced.
- FY08 field support was obtained to continue with FY07 activities as well as to conduct regional Mini-U's on best practices.
- A. Brunie (FHI/NC) traveled in Aug 08 to meet with staff, INSPC, and CBD workers in preparation for FCO 114134 and FCO 114142.
- L. Dulli (FHI/NC) traveled in Oct 08 to work with staff and INSPC on FCO 114116 and FCO 114113.
- The Global Operations Senior Director (AFRO) traveled in Nov 08 to meet with staff, USAID, and other potential partners.
- Darsi Lotay (of PharmAccess) traveled in Nov 08 to introduce sino-implant into the national FP program.
- S. Raharison, resigned in Dec 08.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- A Country Director, Dr. Solomon Razafindratandra, was hired in March 2009.
- In March 2009, Andry Rajoelina, mayor of Antananarivo, took power from President Marc Ravalomanana and put a new government into place. In response, the U.S.—via the State Department and USAID—announced that all non-humanitarian assistance would cease. CRTU activities were suspended, though the staff and office are being maintained.
- Discussions with USAID/W and Mission led FHI to transfer remaining funds from CRTU to PROGRESS effective July 1 2009. This CRTU FCO (113129) was closed as of June 30, 2009 and a new FCO under PROGRESS will be opened.

Findings and Outcomes:

- Securing MOH commitment and USAID financial support to scale-up CBD of DMPA and the use of the pregnancy checklist and systematic screening in MOH sites under the subproject USAID Best Practices Package: Development and M & E (FCOs 113115, 123101).
- Based on initial, positive experiences with 1) CBD of DMPA, 2) the pregnancy, COC, and DMPA checklists, and 3) systematic screening, the MOH, USAID/Madagascar, and other local stakeholders committed to expanding and funding services to approximately 8 new districts with new partners. Evaluation data are being used to guide scale-up decisions.
- To date, the enhanced country program has leveraged \$1,550,000 from population field support and bilateral agreements.
- In collaboration with WHO and SanteNet, FHI helped the MOHFP assess key issues and made sure that national guidelines complied with international technical recommendations.

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Planned Activities for July 1, 2009 – April 28, 2010

- All activities are currently on hold pending further guidance from State Department and USAID. This FCO was closed as of June 30, 2009.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Nov 2006
Total Approved Budget:	\$ 1,263,132	Projected End Date:	Jun 2009

South Africa: Enhanced Country Program Implementation in South Africa (FCO 113123/133100)

Technical Monitor: SPilusa

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To identify and prioritize local reproductive health research and program needs in South Africa as one of the four tier one focus countries under the CRTU; and 2) to facilitate efficient, effective implementation and utilization of reproductive health research and programs in South Africa (SA).

Description: The program will facilitate the public health impact of the CRTU by leading the prioritization, implementation and utilization of research to inform local policies and programs. More specifically, the program will develop and implement country workplans that address those needs, foster collaborative partnerships with local groups, and translate research into practice. The program in SA will be grounded in the following core activities: support of field presence in the existing SA field office; engagement of local stakeholders to oversee Research to Practice efforts; country needs assessment and prioritization to inform the development of a research and program agenda that meets needs at the country level; promotion and utilization of USAID Best Practices; program and research project planning and management oversight; monitoring and evaluation of country workplans; management of the overall program approach; and mobilization and diversification of resources to sustain and expand program implementation. A steering committee composed of FHI staff will provide technical oversight to the program approach and activities. Activities will be implemented in collaboration with the MOH, local universities, the USAID Mission, Memorandum of Understanding partners, other cooperative agencies as well as local NGOs, research firms, and community and advocacy groups. The stakeholders will meet annually, or as the need arises, to discuss new RH needs, additional collaboration opportunities, and the potential application of new evidence to their programs. Moreover, in this subproject, the SA Project Director (PD) and FHI/NC staff will monitor the office operating budget; review financial reports; develop ideas for annual PEPFAR Country Operational Plans; provide TA on new study development in SA by helping identify collaborating partners and geographic project and study focus; and coordinate activities with FHI's Public Health Programs Group.

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Activities, Accomplishments, Problems through December 31, 2008

- The Champions project (FCO 153130) supported the NDoH to build capacity of 283 health personnel in HIV / FP integration including comprehensive Sexual Reproductive Health (SRH). All trained personnel received the FP hand book.
- FCO 153104 supported strengthening partnerships and implementation of PMTCT/FP integration study findings with the DoH. FHISA collaborated with the districts and provinces to disseminate DMPA and NET-EN study findings and share progress of the project.
- Using FCO 153139, FHISA supported DoH to support HIV affected and infected populations though working with five sites in 3 provinces through implementation of comprehensive palliative care.

- In March 2006, FHI held a CRTU stakeholders meeting with DOH, CRTU MOU CAs, and other key RH organizations to launch the SA CRTU, identify and prioritize challenges and needs related to FP/HIV integration and develop strategies to address them.
- A total of 338 health services providers, lay counselors, traditional and religious leaders have been trained since June–December 2008 on integrated FP/HIV services and programs using the FHI tool "Contraception for Women and Couples with HIV" and the FHI Integrated Palliative Care manual which focuses on integrating FP into PC.
- In July 2008, FHI SA staff attended the FP/HIV Integration meeting in Ethiopia and presented on FP/HIV integration activities in SA.
- A comprehensive matrix summarizing CRTU activities in SA including results/products, partners and outcomes/indicators was presented to USAID/W in June 2006. FHI continued to update this matrix regularly to include current research utilization (RU) targets and progress in achieving them. FHI also developed a life-of-subproject workplan to ensure application of research results and use of evidence-based products.
- The CRTU PEPFAR Portfolio has expanded significantly and two trainers, an SPO, PO, and two M&E Officers joined the CRTU team.
- FHI/SA established an FP/HIV integration forum to ensure that FP/HIV integration issues are addressed within all ongoing FHI projects and new proposals in SA.
- FHI/SA staff supported development and dissemination of quarterly "Family Health Research" newsletters.

Findings and Outcomes:

- In December 2005, the USAID Mission agreed to the inclusion of SA as a CRTU-enhanced country.
- Participants in the stakeholders' meeting in March 2006 identified priorities in the area of FP/HIV integration in SA. These priorities were documented in the baseline assessment.
- FHI pursued the idea from the stakeholders' meeting to support "integration champions" in the NDOH and in SA's nine provinces to help establish evidence-based policies, training curricula, and programs related to FP/HIV integration. Core funding was secured and FHI hired an FP/HIV integration advisor to help establish a broader network of champions within South Africa. In November 2007, FHI/SA secured PEPFAR funds to support the Champions Project previously supported by core funding through FCO113127.
- FP/HIV integration has been identified as a priority area for all FHI projects in SA, including those funded through the CRTU mechanism as well as other projects and funding sources.
- FHI made contributions to strengthen the FP component of PMTCT programs by developing training curricula and other tools for PMTCT providers, conducting trainings, providing TA, and revising national PMTCT guidelines.
- FHI supported the Integrated Community Palliative Care Services at both the primary health care and hospital level, and continues to work to strengthen the connection between PC, CT, ARV, and FP services. In this effort FHI revised a national PC training manual, which was accredited by the NDOH, and the protocol for step-down facilities for PC. FP is now institutionalized into the PC package of care, as approved by the National PC steering committee.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Continue to have meetings, consultations, and give support to NDOH and provincial DOHs in the implementation of DMPA and PMTCT/FP study results.
- Intensify activities in the 18 priority health districts and focus on strengthening SRH/ FP activities in those districts.
- Continue to provide support to the CRTU portfolio in SA.
- Lead Resource Development activities to support FP/HIV integration.
- Provide guidance and support on FP/HIV Integration for other FHI/SA projects as per the SA Operational Plan.

- Collaborate closely with FHI colleagues regionally and globally to ensure that CRTU strategy areas and the needs identified at the local stakeholder meeting are being addressed.
- Continue to update and regularly review the SA CRTU Results and Logic Matrix and Ensuring Utilization work plan to determine which FHI results will be taken up by partners and what outcomes will be expected by the end of the CRTU.
- Contribute to implementation of the FHI/SA business plan to continue to expand and support FHI's FP/HIV integration activities in SA.
- Compile and update (as needed) a document with all relevant, available tools/products for promotion in SA.
- Share the newly updated Menu of Best Practices with other FHI projects and staff in SA as well as with DOH, MOU partners and other stakeholders.
- Implement newly funded CRTU subprojects and promote the application of relevant research results and evidence-based tools/products.
- Facilitate the placement of new core-funded research in country.
- Maintain core support for key staff and Enhanced Country Program management and backstopping.
- Prepare quarterly reports for USAID/SA.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: Microbicides	FCO Approved: 113123 Oct 2005 133100 Jul 2006
Total Approved Budget: 113123 \$ 133100	72,446 Annually Approved	Projected End Date: Apr 2010

Tanzania: Enhanced Country Program in Tanzania (FCO 113148)

Technical Monitor: CLasway

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To identify and prioritize local reproductive health research and program needs; and 2) to facilitate efficient, effective implementation and utilization of reproductive health research and programs.

Description: The enhanced country program (ECP), which has been implemented in six priority countries including Tanzania, is intended to facilitate the public health impact of the CRTU by leading to the prioritization, implementation and utilization of research to inform local policies and programs. More specifically, the ECP will serve to identify and prioritize local research and

program needs, develop and implement country work plans that address those needs, foster collaborative partnerships with local groups, and facilitate the translation of research into practice. The program in Tanzania will be grounded in the following core activities: 1) regularly convening CRTU stakeholders composed of CRTU memorandum of understanding (MOU) partners, RH/HIV/AIDS non-governmental organizations (NGOs), USAID cooperating agencies, local universities and professional organizations, the Ministry of Health (MOH), and USAID Mission staff to identify and prioritize country RH needs; 2) working with partners to assist in developing research and program activities that meet country level needs, identify opportunities for collaboration and joint work planning, identify approaches to improve policies and programs and scale-up programs improved by FHI research; 3) promoting and utilizing existing RH research results and USAID best practices 4) providing assistance with program and research planning and development, and subproject oversight; 5) developing and monitoring country workplan; 6) supporting local staff salaries and costs associated with office infrastructure; and 7) mobilizing and diversifying resources to sustain and expand country level activities.

Collaborating Agency(s): AED/T-MARC; Engender Health/ ACQUIRE; Management Sciences for Health (MSH); Ministry of Health Reproductive Health Division

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Activities, Accomplishments, Problems through December 31, 2008

- As of November 2007, a decision was made to establish Tanzania as a tier 2 ECP country and hire full-time research personnel to ensure effective oversight of the CRTU projects.
- In August 2008, Christine Lasway was selected as the new CRTU focus country representative for Tanzania, replacing Eric Ramirez-Ferrero.
- In September 2008, FHI, in collaboration with other partners, supported the establishment of a National Family Planning Working Group (NFPWG) to serve a coordinating and advisory body to the MOHSW on issues related to the National Family Planning program.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- As of January 2009, S. Mujaya was recruited as a Program Officer for CRTU in Tanzania.
- C. Lasway presented on CBD of DMPA at the Measure Evaluation symposium - From Data to Impact: Using health data for results held in Arusha, Tanzania on January 28-29, 2009. [Cost share with FCO 113118]
- In March 2009, S. Mujaya attended an EngenderHealth workshop to provide technical assistance to develop an orientation package for Repositioning FP champions .
- In May 2009, FHI leveraged funding from WHO to provide technical assistance towards a Rapid Assessment of the extent of integration in Tanzania. The results will inform the development of the National Framework for FP/HIV integration.
- As of June 2009, the development of a database of thirteen local research organizations in Tanzania was finalized.
- In June 2009, two abstracts were submitted to the International Conference on Family Planning: Research and Best Practices.
- In June 2009, S. Mujaya attended the MOHSW/Reproductive and Child Health Section Annual Meeting with the objective to assess and evaluate the national implementation of RCH services Based on reports from different zones, new concepts for research have been developed for submission in YR 3 of PROGRESS
- C. Lasway continued to represent CRTU in quarterly USAID partners meetings and monthly NFPWG meetings.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

Staff will:

- Continue to represent CRTU in quarterly USAID partners meetings and the NFPWG meetings.

- Support the dissemination of an Advocacy Package for Repositioning Family Planning Champions in Tanzania [Cost-share with FCO 113109].
- Cost-share printing of updated versions of the National Family Planning Procedure Manual. [Cost share with FCO 113140]
- From January 2010, support dissemination of the National Framework for FP/HIV integration, currently in development under FCO 113131.
- Cost-share dissemination of results and planning meeting from assessment of accredited drug dispensing outlets for provision of expanded family planning services funded under FCO 113135.
- Finalize an information brief on ethics review procedures of key institutions in Tanzania.
- By September 2009, leverage funding from WHO to finalize adaptation of the Decision-Making Toolkit for Tanzania.
- Attend and present at the Technical Meeting on Family Planning/HIV Integration, in Ethiopia on November 2009.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2008
Total Approved Budget:	\$ 243,182	Projected End Date:	Apr 2010

Uganda: Enhanced Country Program in Uganda (FCO 113125)

Technical Monitor: AAkol

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To identify and prioritize local reproductive health research and program needs in Uganda; and 2) to facilitate efficient, effective implementation and utilization of reproductive health research and programs in Uganda.

Description: The enhanced country program (ECP) was originally implemented in four priority countries including Uganda to facilitate the public health impact of the CRTU by leading to the prioritization, implementation and utilization of research to inform local policies and programs. More specifically, the ECP serves to identify and prioritize local research and program needs, develop and implement country work plans that address those needs, foster collaborative partnerships with local groups, and facilitate the translation of research into practice.

The program in Uganda is grounded in the following core activities:

- 1) Creating and supporting a CRTU Stakeholder Committee composed of CRTU memorandum of understanding (MOU) partners, RH/HIV/AIDS NGOs, USAID cooperating agencies, local universities and professional organizations, the MOH, and USAID Mission staff to identify and prioritize country RH needs.
- 2) Convening partners to assist in developing research and program agendas that meet country level needs, identify opportunities for collaboration and joint work planning, identify approaches to improve policies and programs and scale-up programs improved by FHI research.

- 3) Promoting and utilizing existing RH research results and USAID Best Practices.
- 4) Providing assistance with program and research planning and development, and subproject oversight.
- 5) Developing and monitoring country work plans.
- 6) Supporting local staff salaries and costs associated with office infrastructure.
- 7) Mobilizing and diversifying resources to sustain and expand country level activities.

A steering committee comprised of multidisciplinary FHI senior staff provides technical oversight to all approaches and activities. Within each focus country, activities are implemented in collaboration with the Ministry of Health, local universities, the USAID Mission, MOU partners, other cooperating agencies as well as local NGOs, research firms, and community/advocacy groups.

Collaborating Agency(s): AFFORD (JHUCCP); Engender Health/ ACQUIRE; Health Communication Partnership/Uganda (JHU); Management Sciences for Health (MSH); Ministry of Health Reproductive Health Division; Minnesota International Health Volunteers (MIHV); Save the Children

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Activities, Accomplishments, Problems through December 31, 2008

- Please refer to the previous FHI annual report for past details.
- FHI staff utilized local RH events as avenues for advocacy and dissemination activities for CBD of DMPA (e.g. the launch of RH Uganda, the quarterly MoH Reproductive Health Commodity Security meeting, the quarterly FPRWG meeting, World Population and National Safe motherhood Days of 2007 and 2008).
- In January and April 2008 staff supported Bugiri and Busia districts to improve supervision and monitoring systems for CBD/DMPA, and to assess service statistics (FCO 113133). In January 2008 FHI-U supplied FP counseling flip charts and CBD/DMPA storage bags to these districts.
- In June – December 2008 FHI-U disseminated 4,797 FP checklists, 35 Quick Reference Charts, 2,299 COC job aides, 135 Contraceptive Efficacy Charts and 20 CBD/DMPA Implementation Handbooks.
- FHI staff continued to hold quarterly CBD/DMPA Coordination Meetings with the MOH and implementing districts (see also 113108 and 143110). In addition, staff led review meetings in Busia and Bugiri districts in September and December 2008.
- In March 2008 FHI-U provided technical assistance to the MoH to update the national FP basic skills and ToT curricula with evidence based strategies for improving uptake of oral contraceptives (see also 113133).
- FHI-U participated in FHI organized training events. In March 2008 the Program Officer attended a ToT for FHI's youth HCT manual in Zambia with a staff member of the Mulago Pediatric Infectious Disease Clinic. In July 2008 the Project Director participated in training on FP/HIV integration in Ethiopia with an MoH staff.
- In April 2008 the Project Director attended the FCP Retreat in North Carolina.
- FHI-U staff developed concept proposals for Field Support.
- Staff successfully coordinated the CRTU research utilization assessment in September 2008.
- Umbrellas and t shirts were distributed to 148 CBDs in 5 districts to ease CBD/DMPA service delivery
- In November and December 2008 FHI-U led the national dissemination of two studies, i.e. an assessment of FP/HIV integration; and an assessment of male circumcision.
- Project staff were hired in 2007 and 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- In January 2009 the project conducted family planning advocacy and sensitization workshops for 1,050 women and youth in FHI implementing districts.
- The project continued to disseminate family planning materials and job aids. 340 FP screening checklists and 340 COC job aids were distributed in January.

- The Infectious Diseases Institute was provided TA in February to train 30 HIV service providers to provide FP services.
- During February – June 2009 the project supported the MOH AIDS Control Program to train and follow up with 168 HIV service providers in concepts of family planning for couples living with HIV/AIDS.
- Related to the above, the project developed a partnership with the MOH and WHO to promote FP/HIV integration activities in Uganda.
- During April - June 2009, the project provided support to SATELOCO, an indigenous Faith Based Organization to conduct 9 Youth-Adult communication workshops, based on FHI's FLE Manual "Teaching Adults to Communicate with Youth from a Muslim / Christian Perspective". The workshops involved 238 adults and 211 youth.
- In March the Project Director participated in FHI's 2009 Global Leadership Meeting and participated in Focus Country Program (FCP) Work planning meetings at FHI HQ.
- In June 2009 FHI staff nationally disseminated Family Health Research Newsletter on youth.
- An intern from JHUCCP's GOLD program was engaged to support the Uganda Country Office to implement planned activities.
- A Finance and Administration Officer was recruited.

Findings and Outcomes:

- In November 2005, the USAID Mission agreed to the inclusion of Uganda as a CRTU enhanced country.
- The registration of FHI as an international NGO operating in Uganda was finalized in November 2007.
- FHI/NC's M&E Unit developed the Uganda Baseline report (Feb-June 2006) in collaboration with FHI/Uganda staff.
- In 2006, the Mission requested that FHI continue to support and facilitate the national Family Planning Working Group (FPWG). The FPWG is now an institutionalized structure of the Ugandan Health Sector, providing the framework for coordination of the national FP program.
- In May 2007 and June 2008, USAID-Uganda awarded FHI-Uganda field support and PEPFAR funds.
- USAID / FHI menu of best practices for oral contraceptive uptake was institutionalized in Uganda, with inclusion of five strategies for the uptake of hormonal contraceptives in the national FP training curriculum. These strategies are: The FP provider checklists; Quick start; Advance Provision; updated instructions on missed pills; and the pregnancy checklist.
- As of 2008 Uganda expanded CBD of DMPA into 7 districts. FHI's contribution to this includes TA, advocacy, and development of training curricula, M&E strategies, and implementation guidelines.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

Staff will:

- Continue to implement activities on the Ensuring Utilization work plan.
- Continue to meet with MOU partners annually and with other FP partners routinely to solicit ideas for collaboration and coordination.
- Participate in Global Leadership Meetings and FCP meetings at FHI HQ.
- Participate in national, regional and global technical meetings to disseminate FHI / CRTU results and best practices.
- Continue to support CBD of DMPA coordination, supervision and monitoring.
- Participate in the international conference on family planning in November 2009.
- Attend FHI's meeting on FP/HIV integration in Addis Ababa.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Apr 2006
Total Approved Budget:	\$ 1,303,628	Projected End Date:	Apr 2010

Worldwide: Development of Guidelines for Contraceptive Users (FCO 2706/112110/172003)

Technical Monitor: KNanda

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To develop and implement a system to ensure that the "Medical Eligibility Criteria" and the "Selected Practice Recommendations" remain current and based on the best available science. The system provides for ongoing monitoring and critical appraisal of available evidence and assures that this information is available for updating guidance.

Description: The World Health Organization (WHO) provides evidence-based family planning guidance for use worldwide. WHO currently has two such guidelines, Medical Eligibility Criteria (MEC) for Contraceptive Use and Selected Practice Recommendations (SPR) for Contraceptive Use, which are used globally and often incorporated into national family planning standards and guidelines. These documents are the first evidence-based, global consensus guidelines that address 'who' can safely and effectively use contraceptive methods (the "Medical Eligibility Criteria") and 'how' to safely and effectively use contraceptive methods (the "Selected Practice Recommendations"). A third guideline, the Handbook for Providers, is currently in development. To ensure that these guidelines remain up-to-date, WHO, in collaboration with CDC and the INFO Project at JHU, developed the Continuous Identification of Research Evidence (CIRE) system to identify, synthesize, and evaluate new scientific evidence as it becomes available. The second component of the system, conducted by CDC and WHO, and assisted by FHI, consists of: 1) determining which new research reports are relevant; 2) critically appraising new, relevant reports; 3) preparing or updating systematic reviews; 4) obtaining peer review of systematic reviews and revising as appropriate; and 5) providing final systematic reviews to WHO Secretariat.

FHI staff are involved in writing systematic reviews, serve as peer-reviewers on an ongoing basis for reviews generated from the CIRE system, and provide technical leadership by participating in WHO Expert Working Group meetings and providing other assistance to WHO secretariat. This leadership role also involves identifying research gaps identified by the systematic reviews and Expert meetings, and working with WHO to fill these research needs.

This subproject has been supported by the CTR and CRTU population core funds as well as by an Interagency Agreement from NIH (#8141/0082).

Collaborating Agency(s): Centers for Disease Control and Prevention (CDC); National Institutes of Health (NIH); World Health Organization (WHO)

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Activities, Accomplishments, Problems through December 31, 2008

- Detailed activities that took place prior to July 2005 can be found in the Year 1 CRTU Annual Report .
- FHI updated, translated, and printed several thousand copies of the MEC in various languages and distributed them to Ethiopia, Kenya, Madagascar, Nigeria, South Africa, Swaziland, Tanzania, Uganda, Dominican Republic, Zambia, Rwanda, Thailand, Haiti, and the US, July 2006 - June 2007.
- A technical brief was prepared in April 2007 for countries applying for Round 7 Global Fund grant cycle on how to strengthen linkages between FP and HIV.
- The WHO MEC chart was incorporated as a training tool in guides for screening checklists.
- WHO, CDC, and FHI staff updated several systematic reviews
- WHO convened 4 meetings in Geneva, attended by FHI-one technical consultation, 2 Guidelines Steering Group meetings, and one Expert Working Group meeting - to revise the 3rd edition of MEC and the 2nd edition of the SPR guidelines. FHI staff prepared systematic reviews for two of the meetings and made presentations.
- In preparation for the MEC/SPR meeting, 46 systematic reviews were developed or updated.
- Following the outcomes of these meetings, WHO and colleagues at the CDC and FHI began revising the two guidelines, and developing products to globally disseminate the changes in guidance.
- Recommended changes to the MEC were incorporated into the second printing of WHO's Family Planning: A global handbook for providers.
- In April 2008, the expert Working Group developed new recommendations for 5 selected practice recommendations within the 2nd edition of the SPR. An insert summarizing these changes was published on the WHO website and is available in English, French, and Spanish. Printed copies were distributed at regional and scientific meetings, and to WHO regional and country offices, professional organizations, NGOs, MOHs, and SRH partners.
- 19 systematic reviews were submitted for publication by WHO and CDC.
- WHO convened a special technical consultation on HC Use during Lactation and the Effects on the Neonate in Fall 2008. FHI contributed to a systematic review on progestin only contraception in lactation and attended the consultation held by WHO on 22 Oct. 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- FHI staff were peer-reviewers for systematic reviews for the US MEC, to be developed by CDC.
- FHI staff attended the US MEC meeting at CDC in February 2009.
- In April 2009, the English version of the MEC Wheel was updated to reflect the recommendations that will appear in the 4th edition of the MEC

Findings and Outcomes:

- Twelve systematic reviews were published in Contraception.
- Findings from several systematic reviews led to changes in eligibility criteria for several contraceptive methods. A key change was a lowering of the MEC category for DMPA and antiretrovirals, based on research conducted by FHI. One medical condition (SLE) was added to this edition.
- The EWG developed new recommendations for five selected practice recommendations. A key change was FHI research on extending the reinjection window for DMPA, which was critical in reducing barriers by leading to a recommendation for a 4-week window for late reinjection.
- FHI staff presented updated data on the safety of progestin-only methods during breastfeeding; however, the group was unable to achieve consensus on recommendations related to this data. Specifically, the group was divided as to whether the recommendations for women who are breastfeeding and less than 6 weeks postpartum should 1) remain a '3' for the use of POPs, DMPA/NET-EN, or implants, or 2) be changed to a '1' for these

methods. Similarly, questions arose regarding a recommendation for women < 48 weeks postpartum and the use of the LNG-IUD. To overcome the impasse, the WHO Secretariat convened a technical consultation on progestin-only methods and breastfeeding and decided to keep the "3" for progestin only methods in the first 6 weeks postpartum. A summary of this consultation will be posted on the WHO website.

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Planned Activities for July 1, 2009 – April 28, 2010

- FHI and CDC staff will submit a manuscript on contraception for women with HIV to AIDs.
- WHO anticipates submitting the completed guideline for WHO approval during the summer of 2009.
- Other WHO guidelines such as the Decision-making tool will be updated based upon the new MEC and SPR recommendations.
- Plans to disseminate the updated recommendations beyond the published guidelines (provider briefs, user-friendly tools, journal articles) will be further developed.
- FHI will adapt its provider and country tools to reflect the new guidance.
- Efforts to maintain a 'finger on the pulse' through the evidence identified by the CIRE system will continue.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: IAA	FCO Approved: 2706 Aug 2003 112110 Jul 2005 172003 Dec 2005
Total Approved Budget:	2706 \$ 500,000 112110 \$ 213,047 172003 \$ 750,000 \$ 1,463,047	Projected End Date: Apr 2010

Worldwide: Cochrane Fertility Regulation Review Group, 2005-2010 (FCO 112112/172002/890047/890048)

Technical Monitor: DGrimes/LLopez

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded
IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work. Hormonal V.B.: Results of these evaluations disseminated via professional literature, outreach, technical assistance, client materials, or other means to service delivery partners, normative bodies, USAID, clients, and other interested parties for incorporation into practice and procurement decisions.

Objective(s): To perform systematic reviews and meta-analyses of randomized controlled trials on methods of family planning, with an early emphasis on IUDs and barrier methods.

Description: The Cochrane Collaboration is an international network of scientists and physicians conducting systematic reviews of medical evidence. A dangerous lag of over a decade exists between publication of life-saving research and its introduction into medical practice. Much of this utilization gap relates to the challenges in finding and absorbing the best available evidence about clinical practice. The Fertility Regulation Review Group, based in Leiden, the Netherlands, is coordinating a world-wide effort to identify, analyze, and disseminate in easily understood fashion the scientific evidence on family planning. The Cochrane systematic review process has several discrete steps that occur sequentially. The first is to register a title with the central office in Leiden. The next is to submit a protocol, which is a formal description of the methods to be used in searching and synthesizing the literature. This protocol is submitted to peer review and, after revision, is approved. The next step is to perform the actual review and write the report using Cochrane software (RevMan). The submitted review then undergoes external peer review and revision before its final acceptance. Once this is done, the review is published on the Cochrane Library (CLIB) CD-ROM. Cochrane reviews are also published in peer-reviewed journals.

This subproject represents Cochrane research and review activities starting in October 2005. Funded by both USAID core funds and through an Interagency Agreement from NIH (NIH#8141), the budget for this activity is negotiated annually. Previous activities were reported under the Cochrane Fertility Regulation Review Group, 1998-2005 subproject report.

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- Refer to the 2007-2008 Annual Report for results prior to July 2008.

Reviews published:

- 1) Lopez et al. Oral contraceptives containing drospirenone for premenstrual syndrome, 2008 Issue 1 (FHI Pub 2008-22).
- 2) Lopez et al. Skin patch and vaginal ring versus combined oral contraceptives for contraception, 2008 Issue 1 (FHI Pub 2008-23).
- 3) Lopez et al. Immediate start of hormonal contraceptives for contraception, 2008 Issue 2 (FHI Pub 2008-50).
- 4) Lopez et al. Strategies to communicate contraceptive effectiveness, 2008 Issue 2 (FHI Pub 2008-63).

Articles or letters published:

- 1) Grimes et al. Do clinical experts rely on the Cochrane Library? *Obstet & Gynecol* 2008; 111:420-2 (FHI Pub 2008-12).
- 2) Grimes DA, Lopez LM. "Oligozoospermia" and other semen terminology: the need for better science. *Fertility and Sterility* 2007; 88:1941-4 (FHI Pub 2007-101).
- 3) Lopez L, Grimes D. When to start hormonal contraceptives. *Journal of Evidence-Based Medicine* 2009; 2:62-63.
- 4) Helmerhorst et al. Letter to the Editor re: "Premenstrual syndrome." *Lancet* 2008; 372: 446 (FHI Pub 2008-107).

Reviews updated and published with new trials:

- 1) 20 µg versus >20 µg estrogen combined oral contraceptives for contraception (FHI Pub 2008-150).
- 2) Combination injectable contraceptives for contraception (FHI Pub 2008-148).
- 3) Combination contraceptives: effects on weight (FHI Pub 2008-149).

Posters presented, APHA 2008:

- 1) Immediate start of hormonal contraceptives for contraception
- 2) Strategies to communicate contraceptive effectiveness

Handsearch – Updated the search of the journal *Contraception* (Jan 2007 – Dec 2008) for trials to be included in the Cochrane Central Register of Controlled Trials.

Reviews updated (no new trials):

- 1) Biphasic versus monophasic oral contraceptives for contraception; 2008 Dec (FHI Pub 2001-18).
- 2) Biphasic versus triphasic oral contraceptives for contraception; 2008 Dec (FHI Pub 2001-59).
- 3) Triphasic versus monophasic oral contraceptives for contraception; 2008 Dec (FHI Pub 2006-49).

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- New Cochrane review published: Lopez et al. Theory-based interventions for contraception. Updated Cochrane reviews were published (new trials):

- 1) Lopez et al. Steroidal contraceptives: effect on bone fractures in women (FHI Pub 2006-72).
- 2) Grimes et al. Oral contraceptives for functional ovarian cysts (FHI Pub 2006-72).

Protocol published and review drafted:

- 1) Grimes et al. Progestin-only pills for contraception
- 2) Halpern et al. Repeated use of pre- and postcoital hormonal contraception for prevention of pregnancy

Review drafted: Allen et al. Interventions for pain with intrauterine device insertion

Article published: Lopez et al. Theory-based interventions for contraception: a systematic review. *Contraception* 2009; 79:411-7 (FHI Pub 2009-29).

Reviews updated with new trials:

- 1) Lopez et al. Steroidal contraceptives: effect on carbohydrate metabolism in women without diabetes (FHI Pub 2007-19)
- 2) Arowojolu et al. Combined oral contraceptive pills for treatment of acne (FHI Pub 2007-13)
- 3) Grimes et al. Steroid hormones for contraception in men (FHI Pub 2007-65)

Reviews updated (no new trials):

- 1) Diaphragm versus diaphragm with spermicides for contraception (FHI Pub 2001-17)
 - 2) Nonsteroidal anti-inflammatory drugs for heavy bleeding associated with intrauterine device use (FHI Pub 2006-71)
 - 3) Scalpel versus no-scalpel incision for vasectomy (FHI Pub 2006-93).
 - 4) Vasectomy occlusion techniques for male sterilization (FHI Pub 2007-44)
- Handsearch – Updated the search of the journal *Contraception* (Jan 2009–Mar 2009) for trials to be included in the Cochrane Central Register of Controlled Trials.

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Planned Activities for July 1, 2009 – April 28, 2010

Reviews will be completed:

- 1) Grimes et al. Progestin-only pills for contraception
- 2) Allen et al. Interventions for pain with intrauterine device insertion
- 3) Halpern et al. Repeated use of pre- and postcoital hormonal contraception for prevention of pregnancy
- 4) Hiller et al. Education for contraceptive use by women after childbirth (revised and updated by new authors)

Reviews will be updated:

- 1) Manchikanti, et al. Steroid hormones for contraception in women with sickle cell disease
- 2) Gallo et al. Cervical cap versus diaphragm for contraception
- 3) Grimes et al. Antibiotic prophylaxis for intrauterine contraceptive device insertion
- 4) Grimes et al. Fertility awareness-based methods for contraception
- 5) Lopez et al. Skin patch and vaginal ring versus combined oral contraceptives for contraception

Handsearch – Update the search of the journal *Contraception* (Apr - Mar 2009) for trials to be included in the Cochrane Central Register of Controlled Trials.

Additional Cochrane reviews will be updated with new searches according to Cochrane policy.

Pertinent topics for review will continue to be identified and at least two new topics will be

registered.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: IAA	FCO Approved: 112112 Aug 2005 172002 Sep 2005 890047 Jul 2009 890048 Jul 2009
Total Approved Budget:	112112 \$ 750,000 172002 \$ 750,000 890047 \$ 495,000 890048 \$ 450,000 \$ 2,445,000	Projected End Date: Apr 2010

Worldwide: Research to Practice Leadership (FCO 113114/113154)

Technical Monitor: TZan

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To provide internal technical assistance (TA) and strengthen capacity building for research utilization (RU); 2) to identify Research to Practice (RtoP) priority topics and strategies; and 3) to develop, maintain and implement memorandums of understanding (MoU) with key partners.

Description: Public health research is not an end in itself; rather, it is intended to improve service delivery, policies, and practices. Yet, the gap between existing evidence and clinical and programmatic practice is substantial, with policy and practice changes often lagging well behind the evidence, despite substantial investments in research. Under the CTR, FHI undertook the RtoP initiative, FCO 3003, as a concerted effort to reduce this gap by establishing more effective links between researchers and service delivery organizations to both promote new and under-used research findings, and identify research questions that would address current issues in service delivery. Under the CRTU Project, this RtoP Leadership subproject will support the strengthening of capacity to promote research utilization and serve as the principal vehicle for developing, maintaining and implementing a network of Global MoU partnerships. MoU partnerships will help inform FHI's research priority-setting process to ensure that future research addresses current service delivery needs. In addition, strong partnerships will facilitate adoption of research findings and thereby enhance impact on policies and programs.

Subgrantee(s): ExpandNet

Collaborating Agency(s): CONRAD; EngenderHealth; Management Sciences for Health (MSH); PATH; Population Council; Save the Children; World Health Organization (WHO)

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For prior accomplishments, see the CRTU Annual Report (2006-2008).

- The RU Orientation package was finalized.
- Feedback on the new RU Manual was solicited and received from 2 FHI staff external to the RtoP team and from 3 staff members recently oriented; revisions were made and the new manual was finalized.
- A. Abbott traveled to Uganda, Kenya and Nigeria for several different subprojects; and presented to the Kenya and Nigeria staff on 'What's New in RU' and on the CRTU (in the case of the Nigeria office).
- J. Smith presented at APHA on scaling up FP programs as well as FP and the global development agenda.
- Two new STO's have accepted positions: T. Zan joined RtoP Dec 8, 2008; E. Canoutas joined RtoP on Jan 16th, 2009.
- A. Gupta was hired as TO, FHI India and started Nov 2008. His responsibilities are to manage the IUD activities in Lucknow.
- N. Gupta (FHI India) and S. Raharison (FHI, Madagascar) tendered their resignations effective Dec 2008.
- The FCP and RtoP teams were merged and S. Clapp was appointed Associate Director, of the new RtoP team.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- L Ghiron, R Simmons and P Fajans of ExpandNet/WHO met to discuss using the ExpandNet scaling-up framework to guide advocacy for and scale-up of CBA of injectables in Uganda.
- FHI's abstract to APHA on scaling-up was accepted as part of a panel entitled, "Lessons from scaling up experience and research in developing countries." Other panelists include ExpandNet, IRH, and MSH.
- FHI submitted a pre-formed panel on scaling-up to the Gates Institute International FP Conference in Kampala entitled, "Scaling up innovations: size really does matter!" Other panellists include URC, ExpandNet and IRH.
- Three abstracts were submitted to the same conference in Kampala: "Removing barriers to DMPA continuation: Field-testing a provider job aid in Senegal", "The use of FP checklists in Kenya" and "Costing for Scale Up: A Skills-Building Workshop."
- The updated Quick Reference Guide to FP Research was disseminated to all of FHI NC.
- A review of 120 collaboration indicators in the RU database took place in June 2009, with updates where needed.
- The FHI Kenya team is working with the government to bring the FP guidelines and the checklists up to WHO standards. Funding for the revisions, printing and distribution will be covered by FCO 113109/113114.
- Staff initiated development of an orientation program, in Feb 2009, to train existing FHI technical staff on RU concepts and tools.
- A case entitled, "Costing Pilot Projects and Scale Up Exercise," created by K Rademacher and J Bratt was finalized. UNC-CH requested permission to reproduce the case for its new, online financial literacy program.
- J Smith conducted a RU Brown Bag for FHI South Africa staff in the Pretoria office in May, for 16 SA staff.
- S Clapp participated in a meeting to discuss the issues surrounding the possibility of scaling up Pro 2000 Microbicide gel if results of MDP trial (due out the end of 2009) support/surpass the HPTN 035 study results.

Findings and Outcomes:

- Please refer to the 06-07 annual report for findings and outcomes prior to July 07.
- We have renewed our MoU with IBP and developed a subproject-specific MOU with Georgetown. As of Dec. 2007, we have 53 ongoing or completed collaboration activities.
- ESD has disseminated the Contraceptive Effectiveness Chart, the CBD of DMPA Handbook, and the LAPM advocacy briefs to their country offices.
- Hubacher D, Mavranezouli I, McGinn E. Unintended pregnancy in sub-Saharan Africa: magnitude of the problem and potential role of contraceptive implants to alleviate it *Contraception* 2008 Jul. 78 (1) : 73-8 (FHI Pub 2008-78, FCO 112122).
- In May 2008, K Tumlinson presented on Barriers to Postpartum Family Planning in Peru at Global Health Conference (GHC) and the 2008 International Conference on RH Management in Bali (delivered by I Anartati).
- A peer-reviewed journal article looking at the outcome of training workshops on job aid utilization was submitted to Guttmacher's *International Family Planning Perspectives*.

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- Further institutionalization of "Research to Practice" and "Practice to Research" approaches to FHI's work, will be achieved through:
 - 1) further roll-out of the RU Planning tool;
 - 2) development and implementation of a strategy to institutionalize Scaling Up approaches within ARD/FHI; and
 - 3) continued assistance with documenting/tracking RU indicators.
- Message development and promotion strategies will be achieved through updating the Under Used Research Findings, and including two new sections: Healthy Timing and Spacing of Pregnancy and postpartum family planning. The UURF will also be updated in French.
- The RU case studies and Menu of Practices briefs will be printed and posted to www.fhi.org; new ones will be developed as needed.
- FHI checklists and the new Training and Reference Guides will continue to be disseminated.
- Three or more RU-related presentations will be made at global/regional conferences (e.g., MAQ mini-U, Global Health Conference).
- Assistance with the dissemination of 1,000 OC job aids will be provided.
- A JSI Russian translation of FHI Checklists will be reviewed and formatted, and posted to www.fhi.org.
- TA will be provided to FHI staff to incorporate 1) RtoP in concept proposals, protocols, and utilization strategies and 2) Scaling Up concepts and activities into FHI's work including working with HSR to develop and promote a package of information and TA on costing for scale-up.
- TA will be provided to the Enhanced Country Program and other country partners on evidence-based practices (e.g., technical review of policies, stakeholder meetings) where funding permits.
- Maintenance and implementation of MoUs with key partners will be achieved via:
 - 1) one Relationship Manager meeting to review MOU partner progress; and an update to the MoU Collaborations Poster;
 - 2) development of implementation strategies for 2008-09 for each MoU partnership; and
 - 3) finalizing the evaluation of the MoU partnerships and feeding it into CRTU mid-term evaluation and decisions regarding new MoU partnerships/CRTU follow-on.
- The revision of the RtoP fhi.org web pages will be completed.
- Monthly RU Orientation for all new staff will continue.
- Individual departmental RU orientations will be planned and implemented for all current staff.
- RU orientation with the Asia and Africa regional offices will be initiated.
- The revised institutionalized scale up strategy will be implemented.
- Collaboration indicators in RU database will be updated.
- Under Utilized Research Findings will continue to be updated and then disseminated 2008 results

- RU case studies will continue to be developed, new additions will be finalized, and a dissemination plan will be implemented.
- DMPA job aid will be revised and disseminated and its field testing will be facilitated.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 113114 Sep 2005 113154 Jul 2009
Total Approved Budget: 113114	\$ 2,735,123	Projected End Date: Apr 2010
113154	\$ 41,652	
	\$ 2,776,775	

Worldwide: USAID Best Practices Package: Development and M & E (FCO 113115/123101)

Technical Monitor: MMalkin

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To develop strategies and tools to enhance timely and convenient delivery of contraceptive methods; 2) to change policies and guidelines to reflect new research findings; 3) to facilitate increased acceptance, support for, and uptake of contraceptive methods; 4) to facilitate USAID Health, Population and Nutrition (HPN) officers oversight of the design and evaluation of country-level family planning programs; 5) to identify and market in collaboration with USAID, an improved coordination among cooperating agencies (CAs) to promote a basic package of best practices for FP/RH programs; and 6) to facilitate increased funding for and implementation of RH best practices at the country level.

Description: Reproductive health research over the past decade has yielded a number of practices, which, if widely incorporated into practice, have the potential to greatly improve the reproductive health and family planning options of individuals worldwide. Practices such as advance provision and Quick Start of oral contraceptives (OCs), for example, can help reduce the medical barriers new clients may face when seeking to begin OC use. Similarly, specially designed screening tools such as the "Pregnancy Checklist" can expand access to high quality family planning services by strengthening the capacity of community-based workers.

Although such practices have been acknowledged as applicable to many family planning and reproductive health programs, most have not been widely implemented. There is a significant need among FP/RH programs to identify locally-relevant practices which can strengthen both quality and accessibility of services.

FHI proposes to participate in a collaborative effort to develop and field test a package approach to promoting RH best practices. This process will be carried out in collaboration with USAID Missions, the Office of Population and Reproductive Health, and other key partners such as EngenderHealth, the Population Council, and The Adventist Relief Agency. The first identified

activity under this subproject will take place in Madagascar. The specific objective of this activity is to work with local partners to implement and evaluate the introduction of a package of best practices that includes Systematic Screening and the Pregnancy Checklist. The evaluation will also consider the community based distribution (CBD) of DMPA as part of the package of best practices (the implementation of these activities is funded under FCO 114100). The process evaluation will investigate patterns of use, correctness of use, and barriers and facilitators to adoption of the Best Practices Package (BPP).

Collaborating Agency(s): EngenderHealth; Population Council; Population Services International (PSI); Santénet

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- USAID, FHI, and ADRA conducted a best practices assessment in Madagascar in April 2006. The Mission selected three practices for implementation: systematic screening, CBD of DMPA, and implementation of the CBD and pregnancy provider checklists.
- A “USAID Best Practices Package” concept proposal was developed and approved by USAID in May 2006.
- FHI and USAID held a session at Global Health Mini-University in Oct 2006 on Key Best Practices for FP Programs.
- NC staff traveled to Madagascar in Oct 2006 to work with stakeholders to develop a workplan and M&E plan for BPP.
- A training manual for introducing the BPP was developed and translated into French, Dec 2006.
- Introducing the BPP in Cambodia was investigated but not deemed appropriate.
- Five sites were selected in each of the 3 demonstration districts, Moramanga, Ambositra and Antananarivo Atsimondrano, for the implementation of the BPP.
- BPP training of providers and program managers took place in March-April 2007. A total of 57 staff were trained in implementing BPP. For each demonstration district 7-10 people were trained including: program managers and supervisors, and 2 care providers per site.
- Action plans for each health facility were prepared to assist in the implementation.
- BPP supervision was integrated into the usual supervision by District and regional staff.
- NC staff traveled to Madagascar to conduct an informal supervision of project activities in Moramanga and Antananarivo Atsimondrano. A list of recommendations was drafted.
- The NC staff and the Project Director/Madagascar traveled to DC to meet with USAID RU staff to report on the progress and experiences to date from the BPP project in Madagascar.
- NC staff traveled to Madagascar in Nov 2007 to begin data collection and supervise the first 2 weeks of field worker interviews for the evaluation of the BPP.
- Field workers were trained and questionnaires pre-tested in Nov 2007.
- Field work was completed in Dec 2007.
- Data analysis was completed and presented to stakeholders at the MOH. FHI provided assistance to the MOH to interpret the process evaluation findings.
- A summary was prepared for Mini-U in June 2008.

Findings and Outcomes:

- Over 1,300 clients and 50 providers and supervisors were interviewed as part of the evaluation.
- Providers completed systematic screening forms for about one-quarter of the clients, although some of these clients could have been outside the target group (women aged 15-49). The proportion of screened clients increased following a supervision visit. Providers' reactions to systematic screening were positive and 73% said they thought they were providing more services after its introduction.
- 85% of clients said they were very satisfied with the service and attention they received at the facility and 49% said the services were better than they had been in the past. Although

providers worried about keeping clients waiting with the systematic screening approach, "more clients said that the wait time was shorter (36%) than longer (23%) or that the wait time was the same (18%), as compared to a few months ago."

- Graphing the utilization of services over an 18-month period revealed that, while there was a general increase in utilization of services, the implementation of the intervention did not appear to spur an increase of utilization beyond the trend that had already been observed.
- Providers were less positive about the pregnancy checklist. Although they received information to the contrary in the training, 64% of providers still said that the National Reproductive Health Norm and Standards require that a woman is menstruating when she initiates a family planning method. 49% of providers said they use the pregnancy checklist very often but 14% said that they never use the checklist. 25% of providers said if the checklist rules out pregnancy they still order the client to have a pregnancy test or be menstruating before initiating a method of family planning.
- One-quarter of providers agreed that introducing more than one practice at a time was difficult. The main challenge (15/44) was changing the organization of their services so that all services were available on any given day, which constituted a major change in the way that many facilities worked. However, providers also saw advantages in introducing more than one practice at a time.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: GLP	FCO Approved:113115 Sep 2005 123101 Feb 2006
Total Approved Budget:	113115 \$ 179,282	Projected End Date: Oct 2008
	123101 \$ 135,600	
	\$ 314,882	

Worldwide: USAID Best Practices - MAQ Funds (FCO 123103)

Technical Monitor: MMalkin

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To identify, develop and market a package of USAID's select Reproductive Health Best Practices.

Description: This activity will assist USAID, CAs and in-country partners to identify, develop, and market packages of RH best practices. This process will provide in-country partners with the resources necessary to begin incorporating models, tools, and strategies into local programs. The packages will be directed towards: 1) USAID Mission Health, Population and Nutrition (HPN) Officers: Packages will increase HPN Officers knowledge of effective FP programs in their countries. HPN officers will be encouraged to implement those practices which have the greatest potential for public health impact in their respective countries; 2) USAID CAs: Best practice

packages will also be promoted to USAID CAs in order to increase the uptake of a standard set of best RH practices among all USAID partners.

Based on the number of best practices being implemented in Madagascar (see FCOs 113115, 123101 and 144100), USAID made the decision for this subproject to support the documentation and dissemination of Madagascar's experience with implementing their package of best practices. Specific activities under this subproject include: (a) Implementing a national-level dissemination meeting in Madagascar in the spring of 2008, to discuss research results around the implementation of best practices in Madagascar and how to scale-up of the results. The meeting will bring together national stakeholders to highlight lessons learned from the pilot activities, transfer knowledge to providers and program managers from different regions within Madagascar and foster future scale-up efforts by engaging a broader audience than those already involved in pilot activities; (b) Documenting the Madagascar experience through a case study which will describe the results of the pilot and the implementation process. The case study will be disseminated globally; and (c) More broadly, disseminating the Madagascar best practices experience with presentations at one to two international conferences.

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- The approval to implement letter was signed in April 2007.
- A presentation and technical briefing tools on CBD of DMPA in Madagascar were prepared for the WHO sponsored international workshop on community health in Bamako, Mali in June.
- FHI funded the trip of 2 MOHFP staff to the workshop as part of a Malagasy delegation. They gave a presentation on implementing CBD of DMPA.
- A concept paper for disseminating the results of the BPP and other FHI research results generated in Madagascar was developed. A Mini-U dissemination event was planned to bring together key stakeholders to create national support for evidence based programming, update them on current best practices in Madagascar and internationally, and identify next steps for scale-up priority activities.
- Key stakeholders met to discuss next steps for the Mini-U and decided to postpone the Mini-U from May to June 2008 due to full schedules. Based on their input the approach and scope was revised. A new concept paper was drafted and shared with key stakeholders from Madagascar and USAID/W.
- In April 2008 a call for abstracts was shared with key partners.
- A selection committee selected topics to be included in the Mini-U: 1) Cervical cancer prevention using the visual inspection with acetic acid method; 2) BPP; 3) Scale up of the SDM; 4) The rapid result initiative; 5) Champion commune and samia mitondra telo approaches; 6) WHO's contraceptive eligibility criteria; 7) Obstetric fistula; 8) Post partum FP; 9) Sexual violence and the red card initiative; 10) The social franchise; and 11) CBD of DMPA.
- The Mini-U was convened at the National Leadership Institute of Madagascar (NLIM) on June 12-13. Approximately 180 participants attended, including key MOH FP decision-makers at national and regional levels; other key ministries such as education, sports and culture, communication and finance; technical and financial development partners, local NGOs, medical associations; and universities and Schools of Medicine.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- A CD of the session presentations and the commitments made by key stakeholders was prepared and sent to participants after the Mini University.
- The NLIM was unable to lead the development of a more articulated action plan or track the progress of action plans due to the political instability which arose in January 2009. The activities of the NLIM have been halted indefinitely.
- In October 2008 the FCO and subproject were closed.

Findings and Outcomes:

- The Mini-University succeeded in convening national stakeholders to highlight lessons learned from the pilot activities, transferring knowledge to providers and program managers from different regions within Madagascar and fostering commitment to future scale-up efforts.
- A report, entitled “Madagascar’s Commitment to Evidence-Based Programming in Reproductive Health” was written to document the Madagascar experience with the Best Practices Package and community-based distribution of DMPA. The report will be disseminated in Madagascar in 2009.

Funding Source(s):	USAID - US Agency for International Development/USAID: GLP	FCO Approved:	Feb 2007
Total Approved Budget:	\$ 75,000	Projected End Date:	Oct 2008

Worldwide: Implementing Best Practices Consortium (FCO 113116)

Technical Monitor: ECanoutas

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To identify how FHI’s institutional goals can dovetail with those of the IBP; 2) to incorporate partnerships with the IBP into existing workplans and strategies; and 3) to increase utilization of the IBP’s Electronic Communication System (ECS) among FHI staff and in-country partners.

Description: FHI is a founding member of the Implementing Best Practices (IBP) Initiative, which was established in 1999 by the World Health Organization’s Reproductive Health and Research Unit (WHO/RHR). A formal consortium, which is now comprised of over 20 partner agencies, including the USAID, was established in 2001. The primary goal of the IBP is to improve access to and quality of reproductive healthcare through a systematic approach focused on developing and supporting strategies that introduce, adapt, and apply evidence-based practices in reproductive health. Initiatives such as the IBP have the potential to improve reproductive health outcomes by expanding the quality and reach of reproductive health services worldwide.

Under this subproject, FHI will contribute staff time and resources to sustain active membership in the Consortium and to support activities in the IBP program of work. The subproject will primarily contribute to fulfillment of FHI’s mandate to ensure that relevant research findings are broadly disseminated and utilized.

By nature, participation in the IBP Consortium will involve coordination and collaboration with other member agencies, including USAID, WHO/RHR, and several CA’s and international partners.

Collaborating Agency(s): Academy for Educational Development; CARE; EngenderHealth; Extending Service Delivery Project (ESD); Institute for Reproductive Health; International Planned Parenthood Federation (IPPF); Jhpiego; Management Sciences for Health (MSH); Pathfinder International; Population Council; UNFPA; US Agency for International Development; University Research Corporation; World Health Organization (WHO)

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Activities, Accomplishments, Problems through December 31, 2008

- Global: FHI participated in the IBP Consortium meetings, steering committee and knowledge sharing task teams, and assisted in revising its MOU (2006, 2007, Jun 08). An indefinite renewal of the MOU with IBP was signed (Aug 07).
- FHI co-sponsored two electronic fora on the IBP Knowledge Gateway, one on contraceptive implants which had 225 participants from 46 countries (Jan 08), and the second on male and female sterilization with 130 participants from 41 countries (Mar 08).
- FHI joined the IBP Post-Partum FP working group (Jun 08).
- FHI distributed IBP partner Population Council's "BCS (+)" to its WHO-SPP Nigeria team (FCO 113134) (Jun 08). FHI staff participated in UNFPA/WHO Working Group on Condom Quality Continuum for Male and Female Condom (CQC) (July 08).
- In 2008 FHI country staff participated in WHO-SPP regional meetings held in Zambia, Indonesia and Nigeria; presentations on FHI's FP and HIV integration work were presented in Indonesia and Nigeria.
- FHI participated in a 'Working with Champions' panel at the IBP annual meeting in DC (Nov 08).
- FHI provided technical review of YQA resource center on male condoms website for WHO (Aug 08). FHI-HQ participated in an RH Essential Medicine Resource Centre video conference with WHO/RHR, JHU/CCP, PATH, and JSI (Sept 08).
- Kenya: In collaboration with WHO FHI supported the development of a Kenya Best Practices in RH document. A Task Force was set up, Terms of Reference developed and an initial meeting held (Jun 07). WHO committed \$15,000, and FHI provided staff time (\$5,000 total from 113116). FHI presented a summary of the Kenya work to IBP consortium participants in Baltimore (Nov 07). FHI assisted the MOH with the data collection tool, and hiring a consultant to support the IBP compendium. Analysis and selection of submissions to the compendium began and a first draft of the compendium was produced (Dec 08). FHI distributed Population Council's BCS tools through APHIA II programs, used during their CT-FP integration trainings.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Global Activities: FHI staff attended the WHO-SPP regional meeting in Senegal (Jan 09). The addition of funds for Year 5 participation in the IBP was approved by USAID. FHI staff contributed to the IBP-hosted global e-forum on Task Shifting (May 09). FHI-HQ participated in the bi-annual IBP consortium and steering committee meetings (June 09), including group sessions on working with champions and community-based distribution of FP.
- Kenya: In April 2009 FHI supported a meeting of the DRH and IBP task force where the consultant presented the final IBP compendium document. Of 37 submissions, ten qualified as "best practices" and six were labeled as "promising practices." The document will be finalized and circulated to the task force members at the May task force meeting.
- FHI-K submitted an abstract entitled "Creating a Compendium of Best Practices: Contributions of the IBP Kenya Team in collaboration with DRH" to the Nov FP conference in Kampala hosted by the Gates Center (May 09).

Findings and Outcomes:

- Supported by this and other FCOs under the CTR and CRTU, Kenya's IBP effort was initiated in 2004. FHI's role in the Kenya IBP has included establishing the country team, developing the country action plan and working with subcommittees on implementation, supporting WHO's effort to document best practices, and through the Research to Practice initiative

(RtoP), compiling and disseminating a list of evidence-based practices that can easily be adopted by implementing organizations.

- At the Kenya IBP meeting held October 2006, the Kenya MOH reported the following achievements of its IBP efforts: 1) Advocacy: a) secured budget line item for Reproductive Health; and b) increased support for family planning at the national level. 2) Demand creation: a) increased awareness of FP at the community level; b) created demand for FP services; and c) improved perception of FP in the communities. 3) Training: a) enhanced FP and infection prevention (IP) knowledge and skills; and b) enhanced adherence to FP service provider standards and guidelines. 4) Logistics management: a) All districts reported no stock outs in at least 3 modern FP methods at any given time; b) created awareness of the value of timely data for decision making; and c) the district reporting rate went up from 38% to 71%
- Although facility reporting remained low, it moved from 16% to 20%. Perhaps most importantly, the IBP model has been taken up by the Kenya MOH/DRH as the way for increasing the uptake of family planning. The IBP model is being applied in the APHIA II projects, and at a CTU carried out May 2007 for service providers in Rift Valley, the IBP CTU manual was used. FHI/Kenya continues to work with WHO to support Kenya MOH/DRH in the development of a Best Practices document in Reproductive Health.
- For prior accomplishments/outcomes, see CRTU Annual Reports (2005-2006; 2006-2007).

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Planned Activities for July 1, 2009 – April 28, 2010

- Global:
 - FHI will continue to participate in all IBP consortium, and Knowledge Task Force meetings (held bi-annually).
 - FHI will continue to provide support to WHO/RHR Essential Medicine Resource Centre as needed.
- Kenya:
 - FHI-Kenya will contribute to the printing of the BP Compendium, and its national dissemination (July 09).
 - The team will also continue to sponsor the IBP-Kenya task force meetings (charges for both will come from FCO 143103/143117).

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2005
Total Approved Budget:	\$ 177,059	Projected End Date:	Apr 2010

Worldwide: CRTU Knowledge Management (FCO 113118)

Technical Monitor: BRobinson

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work. Hormonal V.B.: Results of these evaluations disseminated via professional literature, outreach, technical assistance, client materials, or other means to service delivery partners, normative bodies, USAID, clients, and other interested parties for incorporation into practice and procurement decisions.

Objective(s): 1) To develop communications and dissemination strategies for all relevant research; 2) to implement CRTU research dissemination priorities; 3) to provide technical assistance in dissemination; and 4) to maintain core infrastructures to support CRTU dissemination and issues management.

Description: This subproject maintains scientific synthesis writing capabilities, manages planning and implementation of routine/cross-cutting research dissemination/communications, ensures the transfer of CRTU results to MOU partners for dissemination, engages research stakeholders through communications outreach, and develops/implements communication strategies for potentially controversial CRTU research. In support of specific RtoP subprojects, it promotes access to relevant syntheses of research information among CRTU partners in a position to influence application in service delivery, provider training and news media, especially in enhanced countries. This subproject includes issues management, i.e., proactive planning to prevent problems from occurring, and quick response to mitigate damage once a problem related to USAID-supported contraceptive technology research has occurred. In enhanced countries where high-visibility research is conducted, it involves management of partnerships relevant to community outreach. It also supports CRTU M&E by documenting and disseminating evidence of RU activities specific to communication.

Collaborating Agency(s): Johns Hopkins University; PATH; Population Council

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- Received Approval to Implement from USAID in March 2006.
- For prior accomplishments, see the CRTU Annual Report (2006-2008).
- Developed communications plans for 12 studies; managed communications for closure of cellulose sulfate trial; handled media inquiries; provided media relations support to field projects/partners.
- Implemented dissemination plans for multiple publications and research results; provided TA in research dissemination to researchers and partners in the field.
- Published country-specific English and French editions of FH Research for distribution in CRTU focus countries.
- Wrote 9 articles/year for the MERA journal; 10 research briefs/year, distributed in Eng/Span; and co-authored various materials published by JHU and the Population Council.

- Wrote op-ed pieces for African newspapers; published regular FP-RH columns in The Nation (Nairobi); wrote FP/HIV integration articles, press releases and factsheets for S.African newspapers (Star; Business Day).
- Translated guidebook and briefs on CBD of DMPA as well as QRM field guide into French; published "Contraception for Women and Couples with HIV" CD-ROM in English and French; supported production of Partnering for Standard of Care manual, primarily funded by SIDI.
- Maintained over 3,000 RH publications on FHI.org.
- Distributed announcements on research reaching 140,000-200,000 recipients/year.
- Maintained mailing list, responded to requests, mailed tens of thousands of materials/year.
- In collaboration with MSH, EngenderHealth and JHU, managed various e-forums on contraception.
- Presented at key conferences, e.g., national dissemination meeting in Kenya on FP needs of women using HIV/STI services; one-day scientific paper writing workshop for FHI/India research staff, March 08; on LAPMs at Kenya Medical Association annual meeting and national nurses conference (Kenya) and Univ. of Nairobi Collaborative Meeting and Measure Evaluation Data Impact Workshop (Tanzania). Produced video on CBD of injectables, presented at GHC, May 08.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

FHI Staff:

- Published FH Research newsletter issue 3.1 on youth: Distributed 1,920 copies (English) and 5,242 copies (French).
- Wrote 14 English research briefs, distributed 21 globally in English, and 10 in Spanish.
- Reached 42,136 individuals via email and 123,206 via listserv distribution (total of 165,000+) with announcements on the Contraception for Clients with HIV Toolkit, the Family Health Research issue on microbicides for HIV Prevention, the new Clearinghouse on Male Circumcision for HIV Prevention, the Knowledge for Health (K4H) survey, quarterly research briefs, and Global Health Pearls.
- Co-chaired HIPNet meetings in DC.
- Implemented dissemination plans for: Implants training guides and checklist; Training Guide for HIV Counseling & Testing for Youth; Increasing Access to Contraception for Clients with HIV.
- Added 925 and updated 1630 mailing list records; responded to 1,761 information requests by email/phone; mailed 21,463 materials.
- Created over 100 "reach" indicators in the RU Database.
- Submitted an abstract on FP/HIV web analysis to APHA 2009 conference that was accepted.
- Provided support to FHI researchers and other CAs to respond to inquiries, on sensitive issues such as non-surgical sterilization, research ethics, the safety of DMPA (Uganda), HIV and hormonal contraception, and HIV prevention research. Monitored media coverage of CRTU research on daily basis and provided assistance in rapid response as needed.
- Reprinted copies of materials requested by CRTU staff and research sites: CRTU folders (1,000); factsheets (4,000); Handbook of Essential Concepts in Clinical Research (100); published, then reprinted Fr. CBD of DMPA Implementation Handbook (300).
- Submitted analysis of use of health publications by developing county professionals to BMJ.

Findings and Outcomes:

- Provided significant TA to Knowledge for Health Project, prior to signing of a formal subagreement between FHI and JHU.
- Originated agreement with Medpedia to develop series on FP/RH topics; wrote and submitted pieces on FP/HIV integration, contraceptive implants and PrEP.
- FHI backgrounders/Q&As on microbicide research were the basis for fact sheets distributed by CONRAD and the GCM; re-distributed to other stakeholders (IPM, MDP, Population Council, MRC/SA, WHO, AMD, NIH, HPTN, MTN) and donors (Gates, DFID, USAID). FHI daily media analyses were redistributed by MMCI to global stakeholders. These played an important role in managing media coverage of trial closures/promoting positive outcomes.

Implementation of the communications plan for the Ghana Savvy study resulted in positive responses and avoided potential controversy.

- PAHO's 2005 Spanish translation of FHI's field guide on qualitative research made modern research methodologies available to SRH researchers in Latin America.
- From Jan 06–Jun 09, news coverage of FHI and CRTU programs/research reached more than 500M people.
- CRTU and CTR materials on RH on www.fhi.org received 2.82 million visits (57% Eng.; 33% Sp.; 10% Fr.) from July 08-June 09.
- FHI's checklists were translated into Romanian by JSI for use throughout Romania, and also described in INFO's Global Health Technical Brief, "Five Simple Ways to Improve Oral Contraceptive Provision and Use," (Apr 06); FHI's pregnancy, COC, DMPA, and IUD checklists were the basis of an INFO Global Health Technical Brief, "Checklists Reduce Medical Barriers to Contraceptive Use" (Apr 06); the IUD checklist was printed in Population Reports and the DMPA checklist in the issue on injectables (06).
- Teaching Aides at Low Cost (TALC) reprinted dozens of CRTU materials on CD-ROMs distributed to 10,000 health professionals.
- Qualitative Research Methods: A Data Collector's Field Guide was used in site initiation trainings by 120 individuals at 8 study sites in Africa.
- Nurses and Midwives' associations in Uganda used the Family Health Research (FHR) newsletter in a May 07 training; the German development agency GTZ highlighted FHR in its electronic bulletin.
- PAHO redistributed CRTU research briefs in Spanish to 200 libraries in Latin America over the REPEBIS listserv each quarter.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

The following activities will be carried out between July 09 and April 2010:

- Conduct scans and country-specific communications diagnoses to identify opportunities/priorities.
- Write/distribute major syntheses of research for use in facilitating discussion among service delivery organizations on future research/interventions.
- Develop/implement two major topical communications strategies and related materials packets on planned topic areas, as well as specific communications plans for all relevant research or products (with co-funding).
- Coordinate with staff at CAs and CRTU partners to promote dissemination of findings and to provide technical assistance to USAID and researchers for small dissemination activities.
- Maintain dissemination databases on: key research stakeholder contacts; news media covering RH; project-specific photos; a calendar of emerging CRTU research; and impact indicators.
- Complete and post Medpedia articles on the following topics: male circumcision for HIV prevention, microbicides, injectable contraception (DMPA), and IUDs.
- Develop and implement 2-4 major communications strategies on key technical areas.
- Package and make accessible existing information and research on HIV/FP integration, contributing to development of training materials.
- Continue ongoing support to sensitive areas of research such as non-surgical sterilization, or standards of care. Coordinate communications approaches among CAs related to issues requiring special media management.
- Coordinate with dissemination staff at CAs and CRTU partners; participate in HIPNet and other communication groups; participate in inter-agency meetings to promote dissemination of research findings.
- Develop dissemination strategies and communications materials as needed and as budgets allow to support use of checklists, (FHI) Cochrane review results, awareness of the grace period for injectables, and other key issues.

- Repackage and disseminate research syntheses through various channels to reach colleagues in the developing world, including via packets (containing fact sheets, PowerPoint presentations, and case studies, as needed), the FHI website, 20+ listservs, e-Granary and the K4Health portals, and CD-ROMs.
- Document evidence of research utilization approaches and lessons learned (co-funded with other subprojects).
- Track progress of programs to identify newsworthy research or accomplishments, summarize these (about 60 summaries in FY09), distribute them to Missions and other key research stakeholders, and translate relevant summaries into French or other languages as needed.
- Develop supporting materials and provide TA to researchers on ad-hoc topics that come into media or stakeholder focus, produce 10-20 handouts on specific topics to support CRTU programs, conferences, workshops, or dissemination to stakeholders, collaborating with CRTU partners wherever possible.
- Monitor and proactively address issues related to CRTU research emerging in news media or among civil society groups.
- Provide TA to country partners or MoUs for 5-10 small dissemination activities that promote utilization of knowledge management products.
- Provide direct support to USAID such as writing at least 3 technical briefs.
- Plan communication with research stakeholders for key conferences such as the RHRU conference in South Africa, the AHILA annual meeting, AIDS 2010, APHA, and SAGO.
- Respond to about 6,000 information requests (emails, phone calls, faxes, and postal inquiries) and mail thousands of materials, as the freight budget permits.
- Update 15% of mailing list contacts per year; and add new contacts to support planned study dissemination.
- Support development and dissemination of CRTU end-of-project materials.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Sep 2005
Total Approved Budget:	\$ 2,959,885	Projected End Date:	Apr 2010

Worldwide: CRTU Monitoring and Evaluation (FCO 119501/119507)

Technical Monitor: SMcIntyre

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
 IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.
 IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To monitor performance in CRTU-related subproject efforts; 2) to share results promptly to guide subsequent efforts and decision-making; 3) to assess progress toward

the achievement of intermediate results; and 4) to evaluate the extent to which CRTU goals and objectives have been met and have had demonstrable impact.

Description: FHI will regularly assess the CRTU program and its subprojects' performance through routine monitoring. This will keep FHI and USAID management, as well as other stakeholders, informed of progress. Monitoring will also be used to alert management of the need to adjust plans. Each subproject will have an assigned manager charged with meeting subproject objectives and completing the subproject on time and within budget. The monitoring and evaluation (M&E) staff will focus on the measurement and tracking of outputs, outcomes, and the overall impact of the CRTU program. Country offices, and program officers for countries where there is no office, will play a role in gathering country-specific information needed to assess progress toward desired outcomes and impact. This information might include revisions to national guidelines, or trend data on the use of contraceptive or STI prevention technologies. FHI will also undertake an evaluation to assess the research-to-practice process. Baseline measurements will be sought for key indicators from priority or focus countries where FHI anticipates a substantial number of activities. These baseline measurements will include selected indicators already available through national family planning or reproductive health programs, DHS data, or other organizations' reports.

To keep FHI staff well informed, a CRTU intranet site is being maintained (shared responsibility with 119502, CRTU management) so that all U.S.-based staff have ready access to the Gap Analysis, M&E plans, concept proposal status, etc. International staff have access dependent on internet availability.

During the Assessment of the CRTU's research utilization activities in 2008, the FHI country offices in Kenya, Uganda, and Madagascar were heavily involved, arranging field visits and presentations for the Assessment team. As a result, FCO 119507 was established specifically to track their field costs.

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- See the Findings and Outcomes for additional specific products produced under this subproject.
- A "Gap Analysis" was completed of the first CRTU Workplan, whereby CRTU outcomes not currently addressed by any CRTU subproject were identified. This analysis continues to be routinely updated and used to monitor the CRTU's progress.
- The M&E Unit worked with research utilization (RU) staff to develop country matrices for the focus country programs, outlining outputs and research indicators to be addressed. Meetings were held with research staff to familiarize them with the M&E plan and to solicit their input in reporting CRTU-related RU examples.
- The CRTU's M&E plans, including a logic model, were presented at a Sept. 2006 management review.
- As of June 2007, all strategy groups had met over the course of a year with the CRTU Leadership group, reviewing their strategies and the Gap Analysis. M&E staff assisted each group with the process.
- In the fall of 2006 and 2007, and information on FHI's USAID-supported microbicide work was submitted to AIM's Microbicide database.
- FHI replied to CRTU Management Review questions in Nov. 2007. The M&E Unit (now renamed the Planning and Assessment Unit) oversaw this report. M&E activities were also presented during the Dec. 6-7, 2007 Management Review.
- Also in Dec. 2007, HRIT entries were completed for all 2005-06 CRTU research activities. In addition, 400+ entries from the CTR were updated and submitted for USAID's approval. CRTU entries were updated in 2008.
- A web-based RU database was completed and the data successfully migrated. In May 2008, McIntyre made a presentation about the database at the Global Health Council.
- In August 2008, Planning and Assessment with extensive input from the Research groups, completed a Self-Assessment Report on its research utilization efforts. P&A also facilitated

the external assessment of the CRTU's research utilization efforts, helping with logistics for the 4-country and FHI/NC visit , and coordinating all feedback on the external team's report which was finalized in November.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The latest CRTU Interim report (July 2008- December 2008) was completed.
- McIntyre traveled to Kenya and South Africa in early March 2009 to discuss the RU Assessment, EIS, and transitions as the CRTU closes. It was agreed that the country offices would work to produce an updated country brief, similar to that prepared for the RU Assessment, for the close of the CRTU. Kenya and Uganda will plan dissemination meetings while South Africa, which is expected to continue many of its activities post-CRTU, may chose to have more specific meetings at the close of certain subprojects.
- Between February and June 2009, the Planning and Assessment Unit added two new Associate Technical Officers to assist both with the new PROGRESS award (not tied to this subproject) and with the additional tasks involved in closing out the CRTU. Lucy Wilson is now chairing a new CRTU close-out committee which involves staff from Finance, Contracts and Grants, Accounting and the Research groups.
- Entries into the RU database increased as a result of having additional staff and as more activities were maturing or coming to a close.
- A new CRTU Project site was launched on FHI's intranet, bringing together many of the key documents pertaining to the Project. Progress was also made on assembling a common file with all CRTU Approval to Implement letters and variance requests.
- In June 2009, FCO 119507 was closed as field expenses for the RU Assessment had all been processed.

Findings and Outcomes:

- Between July 2006—June 2007, M&E staff worked closely with strategy group leaders to prepare for reviews with the CRTU Leadership group that included consideration of an up-to-date Gap Analysis and discussion of whether we were on track to meet each strategy's desired outcomes or whether modification was necessary. As of June 2007, all strategy groups had met with the Leadership Group once since the development of the 2007-08 Workplan. In planning for the Year 4 Workplan, newly proposed concepts that addressed identified "gaps", were encouraged and given some priority.
- Products generated by the Planning and Assessment Unit have included:
 - 1) Nine briefs outlining the impact of work done under the CTR Program were completed for the October 2005 meeting which marked the end of the CTR and launch of the CRTU. J. Smith and S. McIntyre presented on accomplishments and lessons learned under the CTR.
 - 2) Completing other work largely done under the CTR, 2-5 page reports on results in 20 countries were written.
 - 3) Baseline assessments of the four Tier 1 focus countries in the CRTU program were done with desk review and in-country input : Kenya (M2006-20); S. Africa (M2006-16); Uganda (M2006-17); and Madagascar (M2007-10).
 - 4) A listing of all CTR/CRTU final reports since September 2005, along with a compendium of abstracts from all publications supported by the CRTU (to-date through June 2008).
 - 5) Regular and comprehensive CRTU Annual Reports and Workplans as well as the Annual Key Results Report have been submitted.
 - 6) With significant input and assistance from the Research Departments, FHI's Self-Assessment of CRTU research utilization activities was completed in August 2008.
 - 7) A new and improved internet-based research utilization database was launched. This database makes it easier for multiple people to enter indicators of RU and for staff to search the database by country, partner, and/or indicator.
 - 8) A new CRTU Project site on FHI's intranet site (May 2009). The site contains many of the key Project documents, including all the original CRTU concept proposals.

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Planned Activities for July 1, 2009 – April 28, 2010

- In conjunction with CRTU management (FCO 119501), this subproject will continue to provide USAID with quality, on-time reporting of the CRTU Program. This will include completing a submission on all microbicide activities into the MARE database in July 2009 and a submission on all research to the HRIT database when requested. FHI's own internal projects database (the EIS) will also continue to be maintained.
- Progress towards meeting the desired outcomes of the CRTU will continue to be monitored and will be synthesized as the CRTU comes to a close.
- Six briefs, summarizing the key accomplishments in each of the main strategy areas will be prepared under this subproject for the March 2009 meeting in Washington, DC.
- Support will be provided to the March 2010 dissemination meeting by the M&E staff.
- In addition to the 2008-09 Annual Report and final year Workplan, an End-of-Project Report will be prepared.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved: 119501 Jul 2005 119507 Aug 2008
Total Approved Budget: 119501	Annually Approved 119507 \$ 40,194	Projected End Date: Apr 2010

USA: Coordination and Statistical Support of CONRAD Activities (FCO 112100/132176)

Technical Monitor: GPittman

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To provide general management and statistical support of CONRAD-sponsored activities that are supported by FHI staff.

Description: The number of studies on which FHI and CONRAD collaborate increased dramatically in 2004-2005 and now involve staff from several FHI divisions (Biostatistics, Research Informatics, Biomedical and Behavioral Research, and Regulatory Affairs and Quality Assurance). Oversight of these joint activities needs to be centralized to make their implementation more efficient. In addition, general statistical support by Biostatistics staff for CONRAD's USAID-supported work that does not have its own FCO will be provided via this subproject.

NOTE: FCO 112100 was closed Sept 30, 2008, and effective Oct 1, 2008, staff began charging microbicides-funded FCO (132176) which was opened to allow for continuation of these activities.

Collaborating Agency(s): CONRAD

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Activities, Accomplishments, Problems through December 31, 2008

- In Sept. 2004, FHI and CONRAD entered into a Memorandum of Understanding, principally but not exclusively for our work under the CRTU.
- A project site was created to facilitate communication between FHI and CONRAD for collaborative work.
- In 2006, two meetings were held at CONRAD and one at FHI for their staff and USAID.
- FHI provided general coordination and oversight for the specific subprojects in the collaboration.
- Guidelines on confidentiality were set up for managing subprojects & training was held.
- An FHI SOP was finalized & implemented Jun. 06 & training was held.
- Progress reports for the partnership were created.
- BIOS provided answers to follow-up questions from CONRAD on 2 closed studies: CS Cameroon (9766/FCO 2272); and SILCS PCT (9797/FCO 2281).
- Aug. 06 BIOS reviewed the manuscript for the closed Microbicide Placebo study (9820/FCO 2280).
- FHI's DM held DMNet training for CONRAD Oct. 06.
- Oct. 06 a representative from CONRAD, USAID and 2 from FHI met to discuss workplans for the next fiscal year.
- Nov. 06, BIOS reviewed the clinical report for PATH WC study (9857/FCO 112102), reviewed tables and reprinted the full stat report.
- Nov. 06, CONRAD asked for SAS data sets & documentation for 6 Ph I studies be prepared & sent to S. Ballagh, EVMS, for secondary analysis.
- D. Weiner attended a 2-day DAIDS class "Development of Standardized Microbicide Toxicity Tables for Clinical Trials" in DC, Nov 06.
- BIOS reviewed the manuscript for the Replens and KY Jelly Study Using 3 Vaginal Imaging Techniques (9754/FCO 9114) & conducted additional analyses.
- FHI helped revise the manuscript for the CS Cameroon study (9766/FCO 2272).
- FHI assisted with the completion of the clinical report for the PATH WC study (9857/FCO 112102).
- FHI provided consultative support for sample size calculations and statistical input for non-collaborative manuscript reviews during Jan.-Jun. 2008.
- Qly mtgs were held Aug.'08 at CONRAD, and Dec.'08 (videoconference) to discuss current and future activities.
- FCO 112100 was closed Sept. '08. Effective Oct. 1, '08, staff began charging microbicides-funded FCO 132176 which was opened to allow for continuation of these activities.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- FHI staff provided general coordination and oversight for the approximately 15 subprojects that are conducted via the FHI-CONRAD collaboration.
- The collaborative SharePoint site, accessed by both FHI and CONRAD, was maintained.
- A summary of technical reports of the collaborative activities was prepared and provided, as requested, to FHI senior management.
- Monthly summary financial reports of the FCOs under this collaboration were produced and posted on the collaborative SharePoint site.
- FHI responded to requests from CONRAD for statistical support of USAID-funded work that is not covered by established FCOs.
- FHI participated in discussions regarding study design, sample size, etc for new CONRAD activities.
- FHI and CONRAD staff consulted on the development of their respective workplans to be submitted to USAID.
- A quarterly meeting was held in April '09 (via videoconference) to discuss current activities & future ones.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- FHI staff will provide general coordination and oversight for the subprojects that are conducted via the FHI-CONRAD collaboration.
- FHI and CONRAD will conduct Quarterly Meetings to discuss the status of current collaborative activities and plan for new ones.
- The collaborative SharePoint site, accessed by both FHI and CONRAD, will be maintained.
- A summary of technical reports of the collaborative activities will be prepared and provided, as requested, to FHI senior management.
- Monthly summary financial reports of the FCOs under this collaboration will be produced and posted on the collaborative SharePoint site.
- FHI will respond to requests from CONRAD for statistical support of USAID-funded work that is not covered by established FCOs.
- Doug Taylor will participate in the planning for an end of Phase 2 meeting regarding tenofovir gel with FDA.
- FHI and CONRAD staff will consult on the development of their respective workplans to be submitted to USAID.
- New studies will be designed and protocols developed under study-specific FCOs.
- Funding for this activity will continue under a new FCO.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core; USAID - US Agency for International Development/USAID: Microbicides	FCO Approved: 112100 Jul 2005 132176 Oct 2008
Total Approved Budget: 112100 132176	Annually Approved Annually Approved	Projected End Date: Apr 2010

Kenya: Kenya Division of Reproductive Health Capacity Development: Follow-on Activity (FCO 143103/143117)

Technical Monitor: CMackenzie

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To enhance Kenya's Division of Reproductive Health (DRH) staff capacity at all levels in research management and data utilization for decision-making skills to ensure research utilization and evidence-based programming; 2) to provide a clear system and set of guidelines for conducting RH research in Kenya; 3) to provide efficient communications between the DRH (all levels) and partners as facilitated by establishing a DRH Website; 4) to provide a

platform for gathering strategic information and evaluating public health impact through the annotated bibliography on the Website and the existing resource center; and 5) to revise the current family planning guidelines which were last revised in 2005, so that they are in tandem with emerging evidence and practice.

Note: Objective 5 is new, and will be funded using the additional funding received (\$310, 000) FCO 143117.

Description: The MOH, DRH has clearly expressed growing concern over the current inability to identify, participate in, and coordinate RH research conducted in the country which has resulted in duplication, missed opportunities, and disregard for national RH priorities. As a consequence, a systematic pathway for identifying, prioritizing, and utilizing research findings and results in RH programs faces significant obstacles. FHI has been assisting the DRH to build its capacity in order to coordinate and make relevant data more readily available to policy makers, program managers, researchers, and individuals. This follow-on activity will build upon the accomplishments of the previous subproject (FCO 3444) by enhancing and scaling-up several ongoing components such as finalizing research management guidelines, roll-out and evaluation of research management and data-for-decision-making (D4D) trainings, and enhancements to the DRH Website. Additional funding received in 2009 will be used to revise the national family planning guidelines which were last revised in 2005. This activity will ensure that family planning practice is in tandem with emerging evidence. All of these activities enhance Kenya's ability to build and improve public health by refining national systems, upgrading skills sets, and building infrastructure at the national, provincial, and district levels. The previous subproject was implemented with collaboration from UNFPA, WHO, DFID, and MEASURE Evaluation. Since 2008, Management Sciences of Health has been a key collaborator during trainings for the Data for Decision Making.

Collaborating Agency(s): Management Sciences for Health (MSH); Measure Evaluation; Ministry of Health, Kenya; Population Council

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Activities, Accomplishments, Problems through December 31, 2008

- Staff finalized the data for decision making (D4D) training module and conducted three D4D training sessions in Coast (19), Western (15), and Nyanza Provinces (24).
- Staff trained 28 Provincial and District Health managers in D4D in six districts in June 2007 and in Sept. 2007, and 30 service providers in Rift Valley Province.
- Staff edited, designed, produced and disseminated 2,000 copies of the National RH Research Guidelines. These were included in the 2007 national RH policy. In August 2006, staff trained 22 program managers and Provincial and District Management teams in RH research management.
- The DRH resource centre was established, and one librarian trained on its management.
- In December 2007 and October 2008, the librarian and M&E officer were supported to attend the Annual African Health Information Librarian Association conference.
- In 2008, the web content and design of the DRH Website were revised.
- GTZ/MOH produced and disseminated 300 CDs of the DRH website for use at sites without internet access.
- One DRH IT staff was trained on maintenance and updating of the website. However, this officer has since left the DRH. Hence tracking website usage and feedback from users has not taken place. Once the DRH gets another IT officer, website usage will be tracked. In Q1 and Q2 of 2008, the Research Management training curriculum was reviewed and circulated to the MOH/DRH working group for final approval.
- TA was provided to DRH staff for initiating, maintaining, and evaluating the new administrative procedures for researchers seeking to collaborate with the DRH.
- 125 District Health Management teams were trained on D4D in Central (June 2008), Eastern (September and October 2008) and Rift Valley Provinces (October 2008).

- In August 2008, the DRH M&E Officer was supported to attend a three-week M&E training workshop.
- Consultants were hired to reset the RH research agenda and to develop a Geographic Reporting System (GRS) of RH indicators for the DRH.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Staff facilitated formatting of the updated annotated bibliography of abstracts and uploaded them onto the website.
- In March, the consultant working on the GRS presented the dummy system to the Research Working Group and the DRH for their review and input.
- On May 25th, the GRS consultant trained DRH staff on use of the new GRS.
- On March 9th, the consultant finalized the first draft of the revised RH research priority agenda and presented it to the research working group and the DRH for their review and input.
- On June 9th, staff facilitated a Research Working Group meeting where the 2nd draft priority research agenda was presented and reviewed by members.
- Staff hired a consultant to review the 2005 FP Guidelines. On June 29th, the consultant presented the revised draft of the FP guidelines to the Technical Working Group for their comments.
- Staff facilitated editing of the D4D manual.
- FHI supported two DRH officers to attend the International Council of Nurses Congress in Durban, South Africa. 26 June to 4 July, 2009.
- FHI bought 20 modems for DRH staff to facilitate communication and web access - June 2009.

Findings and Outcomes:

- Medical students and some collaborating agencies have been referred to use the DRH website to access new materials and information.
- The National Coordinating Agency for Population and Development has visited the DRH to seek technical advice on how to set up their own Website. The NCAPD Website has since been established and was officially launched in early 2007. The DRH Website has a link to the NCAPD website.
- In February 2006, the DRH has re-established a research working group to help them strengthen the management and utilization of RH data throughout the country. The working group is composed of 16 organizations including the MOH, government departments, training institutions, research agencies, and collaborating partners. Achievements include: 1) provided technical input to finalize the National RH Research Guidelines; 2) formulated the research guidelines dissemination strategy; 3) implemented the FP Guidelines dissemination strategy; and 4) a DRH Program Manager participated at a Conference on "Linking RH, FP and HIV/AIDS in Africa" held in Addis Ababa, Ethiopia (Oct. 2006) and made a presentation titled, "Integrating RH with HIV/AIDS services in Kenya: A MOH perspective". In 2009, the team has participated in revising the national RH research agenda.
- The Research Management manual was reviewed and finalized by the MOH/DRH working group. However, although the initial plan to print 300 copies of the manual and scale up the training at the provincial and district levels, this was not implemented due to budgetary constraints. It is anticipated that this activity will be take place in the third quarter of 2009 during the dissemination of the FP guidelines.
- Between Jan 27-30, staff made two round table presentations at a symposium in Arusha, Tanzania. Co-sponsored by Measure Evaluation, the symposium was titled "From Data to Impact: Using Health Data for Results". The presentation was titled "Strengthening research and data management through capacity building: the case of the Division of Reproductive Health, Kenya".

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

FHI staff will:

- Update the searchable data base on the website with the new information (2006 to 2008) from the annotated bibliography.
- Facilitate roll out training on D-4-D at the facility level in Lower Eastern Province (as an initial pilot province).
- Revise the research agenda activities including the following:
- Review the effectiveness and utilization of the current RH priority agenda.
- Develop a revised draft research priority agenda based on the results of the review, as well as interviews from key informants and a literature review.
- Present the revised draft agenda to the research working group members and in a stakeholders meeting for further input and amendments.
- Present the final revised research agenda to the research working group members.
- Hold a meeting with key institutions to disseminate the revised research agenda, as well as the Research Guidelines.
- Develop a RH Geographic Reporting System (GRS) including the following activities:
- As part of setting up of the GRS, review the existing data reported to the DRH and the range of RH data that the DRH receives.
- Build capacity of key DRH staff to use and maintain the system.
- Launch the system after an initial test period of 6 months.
- Revise the current FP guidelines which were last updated in 2005.
- Review and revise the current FP guidelines to be in tandem with current evidence and practice.
- Conduct a national launch of the revised guidelines.
- Print 10,000 copies of the revised guidelines and checklists.

Funding Source(s):	USAID - US Agency for International Development/USAID: Field Support	FCO Approved:143103 143117	Dec 2005 Feb 2009
Total Approved Budget:	143103 \$	500,000	Projected End Date: Apr 2010
	143117 \$	310,000	
	\$	810,000	

Kenya: Building Strategic Information Capacity within NASCOP (FCO 153102/153133)

Technical Monitor: RHoman

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To strengthen national systems for strategic information and operations research to improve reproductive health (including HIV/AIDS) programming, implementation, monitoring, and evaluation. FHI will work with Kenyatta University's School of Health Sciences and the National AIDS and STI Control Programme (NASCOP) to: 1) train four students (3 Master's and 1 PhD) in strategic information collation, analysis and interpretation; and 2) identify key RH/HIV program areas with gaps in strategic information and address these through the students' thesis reports.

Note: In FY 07, due to problems with training students in adequate time and of benefit to NASCOP, the focus shifted to the training of District Health Management Teams, data clerks at service provision sites, and Provincial AIDS/STD Control Officers in data for decision making. A total of 354 persons are to be trained through this approach.

Description: One key component of Kenya's annual PEPFAR Country Operational Plan (COP) is continued support for national surveillance and monitoring systems in order to document outcomes and evaluate the impact of PEPFAR-supported and national HIV/AIDS program activities. This subproject will build capacity in the areas of research design, monitoring and evaluation, and using data for decision-making at NASCOP and other institutions active in reproductive health and HIV/AIDS programming in Kenya. With technical support from FHI, the Division of Reproductive Health (DRH), NASCOP and Kenyatta University undertook four targeted evaluations designed to address key reproductive health and PEPFAR goals in Kenya. The topics for these evaluations were identified jointly by FHI, Kenyatta University, NASCOP, DRH, the USAID strategic information team in Kenya, and local PEPFAR program managers. In order to implement these evaluations, the Technical Monitor mentored four graduate students at Kenyatta University whose theses research contributed to the evaluation activities. The technical support and assistance provided by FHI responded not only to the needs of the selected students, but also NASCOP's monitoring and evaluation unit, and the Mission's strategic information priorities. From that experience it was decided to shift focus from students to persons actively engaged with SI data collection and interpretation. Therefore, KU with assistance from FHI will undertake the training of 354 persons in data for decision making (D4D) with an emphasis on the use of data used in NASCOP's M&E framework.

Subgrantee(s): Kenyatta University

Collaborating Agency(s): Kenyatta Univ. School of HS; National AIDS/STI Control Programme (NASCOP)

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Activities, Accomplishments, Problems through December 31, 2008

- Approval to implement was obtained from USAID on Feb. 2, 2006.
- The initial TM, P. Ngom, supported the four graduate students in the development of their proposals, and the students submitted their studies to the local IRB at the Ministry of Education, Sciences and Technology (MOEST) for clearance.
- A week-long research/monitoring and evaluation workshop was conducted for the four students by Kenyatta University in March 2006 with technical support from FHI/Nairobi.
- All four students initiated primary data collection to fill in gaps in information obtained from the secondary data by June 2006.
- In Sept.–Oct. 2006, the new TM, R. Homan and Z. Omungo, the program assistant, met with the students and Dr. Orinda of Kenyatta University to review progress to date and discuss potential obstacles to timely completion by Feb. 2007.
- In Oct., Homan, Omungo, and Dr. Orinda met with Mr. Baltazaar of NASCOP to discuss objectives for the continuation of this subproject in the next PEPFAR budget year.
- A draft training curricula was submitted by the local consultant in Oct. 2006.
- In March 2007, FHI hired a consultant to assist the students with data entry, cleaning and the implementation of their analysis plans.

- By Dec. 2007, three of the four students had their theses approved by committee members and sent for external review.
- An additional \$420,000 was approved by USAID/K for FY 2007.
- In Jan. 2008, a meeting was held with NASCOP to gain consensus for the refocusing of the project from students to those in data collection and interpretation.
- In March 2008, FHI presented an overview of this project to KARSCOM (the Kenya HIV and AIDS Research Coordinating Mechanism) as a courtesy since they supervise NASCOP's activities.
- In May 2008, a joint meeting with KU/NASCOP was held to review the D4D curricula and agree on modifications prior to implementation
- A subagreement with KU was prepared for approval during April–June 2008. This was then implemented in October 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Modified D4D training curricula was finalized in March 2009.
- Trainers from KU were trained in April 2009 and priority districts for training were identified.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Training of NASCOP HQ and Provincial staff will take place in July 2009.
- Trainings will be conducted in 2-3 provinces covering 40 districts and 354 persons will commence in August 2009.
- Project reports and briefing papers will be prepared and disseminated at the national level.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR	FCO Approved: 153102 153133	Aug 2005 May 2008
Total Approved Budget: 153102	\$ 670,143	Projected End Date:	Dec 2009
153133	\$ 263,857		
	<u>\$ 940,000</u>		

**Worldwide: Research Ethics Training Curriculum for
Community Representatives (RETC-CR) (FCO
1398/1600/1601/2710/172000)**

Technical Monitor: DBorasky

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To provide basic education to community representatives on the essential ethical questions that must be considered when research is being planned and conducted. The

Research Ethics Training Curriculum for Community Representatives (RETC-CR) will empower community representatives to have meaningful participation in the research process. In Year 2 of the CRTU, this subproject was expanded to include production of the 2nd Edition of the Research Ethics Training Curriculum (RETC).

Description: Increasing recognition and importance is being given to the participation of community representatives in the entire research process. This participation may be obtained by identifying specific community representatives or by the establishment of Community Advisory Boards (CABs). Community involvement optimizes the protection of research participants, enhances investigator's perception of the research goals, improves the way research is designed, and ensures that research is responsive to community needs and expectations. In the initial planning of this subproject, we were unable to find a similar educational tool. The new curriculum is based on FHI's experience in developing our previous Research Ethics Training Curriculum, which was designed for research staff. The curriculum has 4 main components: Content, Case Studies, Evaluation and References. The content section covers the material to be learned. It is composed of images and a narrative text. The case studies include actual research studies conducted by FHI. The evaluation section provides an evaluation form of the curriculum, and the reference section includes selected reading materials in the research ethics field. This curriculum has become a standard training tool for many national and international organizations. The RETC-CR development is the responsibility of FHI's Office of International Research Ethics, with the participation of Field, Information and Training Services, HIV Prevention Trials Network and the Behavioral and Social Sciences Research Group. The RETC-CR is designed to be used either as an interactive self-study program or a participatory group training experience. Completing the curriculum takes approximately 11 hours. It is anticipated that in settings where participants might have limited formal education, a group training conducted by a trained facilitator may be the best approach.

Collaborating Agency(s): Mellon Foundation; NIH

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Activities, Accomplishments, Problems through December 31, 2008

- In Feb 2004, the first draft was reviewed in-house by FHI staff with experience in research ethics and community participation.
- In Mar-Apr 2004, the second draft was reviewed by 13 international experts in the field, including experts from the anticipated sites of the future field tests.
- In May-June 2004, the third draft was field-tested in actual workshops organized for community representatives in Brazil, India, Malawi, USA, Zimbabwe and Zambia. A structured field test protocol was developed for this purpose.
- In Oct 2004, the final version of the English curriculum was completed and a total of 2,000 CD-ROMs and 2,000 brochures were printed. (M#2004-22)
- The Spanish and French translations of the curriculum were completed in Dec 2004.
- The English RETC-CR was showcased at the 2005 HPTN Annual meeting held Feb 14-18, 2005 in Washington, D.C.
- Copies of the curriculum have been distributed to the entire membership of the Forum for Ethical Review Committees in Asia and Western Pacific Region (FERCAP), The Latin American Forum of Ethics Committees for Health Research (FLACEIS) and The Pan-African Bioethics Initiative (PABIN). In addition, the curriculum has been distributed to selected individuals of major organizations including NIH Institutes, the Office for Human Research Protections (OHRP) and The World Health Organization (WHO).
- FHI staff from the IT department completed the development of the CD-ROM and Web versions of the English, French, Portuguese and Spanish curricula.
- The RETC-CR Instructor's Guide for Training-of-Trainers was completed in Oct 2005. This guide is similar to the guide produced for our Research Ethics Training Curriculum, and will enhance the impact of the RETC-CR by enabling trainees to train other community representatives.

- In Dec 2005, additional NIH funds (NIH#8142/0083) were granted to develop a 2nd Edition of the Research Ethics Training Curriculum (RETC). A detailed description of this curriculum can be found under the Research Ethics Training Curriculum subproject report.
- In Dec 2007, authors and external reviewers of the RETC 2nd Edition completed the review of the final draft of the curriculum.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- A request for additional funds was sent to the NICHD in order to support activities to complete the second edition of the RETC. Specifically, this funding would support: final editing of the second edition; translation of the curriculum into Spanish, French and Portuguese; preparation and posting of the web-based version of the curriculum in all languages; including enhanced capabilities for distributing certificates of completion; printing and dissemination of 1,000 CD-ROMs with all four languages included.

Findings and Outcomes:

- In March 2005, the RETC-CR received the 2004-2005 Distinguished Award of the Society for Technical Communication (STC), which is the highest award of this society. It also received the Merit Award at the STC International competition.
- In December 2005, the RETC-CR received the Best Practice Award for Excellence in Human Research Protection from the Health Improvement Institute. This annual award is given for demonstrated excellence in protecting and promoting the well-being of people who participate in research.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- The final draft of the RETC 2nd Edition was sent to the editor and graphic designer for final review. The final version is expected to be completed by the end of August 2009.
- FHI staff from the IT department will then work on the development of the CD-ROM and Web version of this 2nd Edition.

Funding Source(s):	Mellon Foundation; USAID	FCO Approved:	1600	Apr 1999
	- US Agency for		1398	Mar 2002
	International		1601	Feb 2002
	Development/USAID: IAA		2710	Jul 2004
			172000	Sep 2005
Total Approved Budget:	1600	N/A	Projected End Date:	Apr 2010
	1398	N/A		
	1601	\$		7,514
	2710	\$		50,000
	172000	\$		100,000
		\$		157,514

Worldwide: Research Capacity Assessment (FCO 113137/993501)

Technical Monitor: KBoos

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To assess FHI country office capacity to conduct research; 2) to assist the country office in establishing its research priorities and in developing a research agenda; 3) to determine whether existing datasets can address public health research needs; 4) to identify areas of need for research capacity building; and 5) to develop a plan to increase research capacity in these country offices.

Description: Selected FHI country offices were visited by a Research Capacity Assessment team. Working with country office staff, the teams addressed the research experience and skills of in-country staff, identified research questions and needs, and established priorities for research for Nigeria, Indonesia, Rwanda, Zambia, and Vietnam. Next steps include a more targeted approach to evaluating existing databases for potential research.

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Activities, Accomplishments, Problems through December 31, 2008

- During the July-December 2007 reporting period, a Steering Committee was formed to guide the overall project, and criteria were established to rank and prioritize countries for the planned assessments. An operational plan and assessment tool were developed.
- From November – December 2007, 2 teams of FHI staff visited Indonesia and Rwanda to conduct the first pilot of the country research capacity assessment.
- In January 2008, members of the Research Capacity Assessment team presented key findings from Indonesia and Rwanda at an FHI Brownbag in NC, with video link to Arlington. Both reports were posted to FHINow.
- From April-May 2008, FHI teams conducted Research Capacity Assessments in Zambia, Nigeria, and Vietnam.
- USAID contribution to this effort was expended and FCO 113137 was closed effective June 30, 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- In June 2009, final assessment reports were catalogued with the FHI library and a decision was made to close the FCO and to transfer remaining objectives to new teams created in FHI's recent reorganization.

Findings and Outcomes:

- Five separate reports were written, documenting the strengths, weaknesses, and opportunities for research in Indonesia (M2007-140), Rwanda (M2008-64), Vietnam (not found), Nigeria (M2008-63) and Zambia (M2008-65).
- Assessment findings have been used for organizational planning, particularly in Nigeria where a new research director is being hired.

- The assessments have contributed to the strengthening of research-field linkages, particularly in Rwanda and Zambia.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:113137	Aug 2007
		993501	Aug 2007
Total Approved Budget:113137	\$	60,715	Projected End Date: Jun 2009
	993501	231,758	
	\$	292,473	

USA: Cost-Effectiveness Analysis of Assisted Reproductive Technology (FCO 174001)

Technical Monitor: RHoman

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To model the costs and outcomes of assisted reproductive technologies as a function of the number of embryos transferred.

Description: As the success rate of assisted reproductive technology has improved, the risk and costs of poor birth outcomes associated with multiple birth pregnancies needs to be weighed with the lower success rate associated with fewer embryo transfers per transfer cycle. This subproject, funded through an Interagency Agreement with Centers for Disease Control and Prevention, used decision analytic techniques to make the cost and effectiveness outcomes explicit to serve as a guide to the development of assisted reproductive technology recommendations and policies.

Collaborating Agency(s): Centers for Disease Control and Prevention (CDC)

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Activities, Accomplishments, Problems through December 31, 2008

- CDC expressed their interest in applying FHI's cost effectiveness methodologies to an analysis of assisted reproductive health technologies. An Interagency Agreement was discussed as a potential funding mechanism to support this work.
- During the January-June 2006 time period, the interagency agreement was processed by CDC and USAID but there were no other activities.
- A kick-off teleconference was held with the CDC in September 2006.
- An Approval to Implement (ATI) letter was signed on September 11, 2006.
- In April 2007, a data request was submitted to the CDC for abstractions from their database of assisted reproductive technology interventions and a literature review on the costs of assisted reproductive technology and birth outcomes was completed.
- In October 2007, data were received from the CDC. The data was processed and cleaned by December 2007.

- Preliminary results were discussed via conference call in March and May 2008.
- Sensitivity analyses were conducted in June 2008 and an outline for a manuscript and writing assignments were agreed upon.
- A request for additional funds was sent to CDC in September 2008. While the CDC approved the use of funds already obligated to FHI for another study to be used on this subproject, after further review it was determined that there were not sufficient funds available.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- The FCO was closed in June 2009.
- The final report will be completed on the Technical Monitor's own time.

Findings and Outcomes:

- In almost all age/risk cohorts transferring of 2 embryos would be more cost-effective than more embryos. Current guidelines should be updated to consider not just the probability of success but also risk of multiple pregnancies.

Funding Source(s):	USAID - US Agency for International Development/USAID: IAA	FCO Approved:	Jun 2006
Total Approved Budget:	\$ 25,739	Projected End Date:	Jun 2009

Uganda: Needs Assessment for Male Circumcision (FCO 156101/156102)

Technical Monitor: AAkol

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To describe: 1) the degree of support for male circumcision (MC) amongst key political, ethnic, and religious leaders at national and local levels; 2) the acceptability of MC among men and women including in their roles as parents; 3) the themes and issues that should be taken into account in developing messages that will be most appropriate and acceptable for promoting MC as an HIV prevention strategy; 4) mechanisms for the integration of MC into other health programs; and 5) the availability of required human resources and infrastructure at hospitals and Health Center IVs for providing high quality MC services.

Description: The immediacy and urgency of a low-cost, safe and effective HIV prevention strategy is evident in an era in which it has been estimated that at least seven new infections occur for every one person on HIV treatment. Recent results on male circumcision (MC) have increased pressure from some HIV prevention experts and activists to aggressively promote MC as an HIV prevention strategy. However, caution is called for as there is no strategic information available in many developing countries to inform the design and implementation of quality and cost-effective large scale public sector circumcision interventions.

In order to address this knowledge gap, FHI has been asked by USAID/Uganda (PEPFAR) to conduct a situation analysis and gather strategic information at the policy, program design, service delivery, community, and client levels. The analysis will be conducted using the guidelines proposed in the WHO document "Male Circumcision Situation Analysis Toolkit." It will involve the following steps: 1. Key informant interviews with national-level leaders to gather opinions about MC in Uganda; 2. A national meeting to inform stakeholders of the current situation, encourage their participation in the process, elicit information, and increase their ownership in the decision of whether to proceed in Uganda with a MC program; 3. A survey (n=1,680) in each of four selected districts in order to explore the knowledge and personal preferences of men and women with regard to MC; 4. Focus groups to elicit viewpoints from men, women and key members at the community level to determine the socio-cultural/ethical barriers, including potential for stigma, that may inhibit or facilitate a MC intervention; 5. One-day workshops with local community leaders to gain a better understanding of the local situation and to gain buy-in; and 6. An assessment of service delivery infrastructure, staffing and commodity needs among hospitals and Health IVs in four districts.

Subgrantee(s): Makerere University School of Pub Health

Collaborating Agency(s): AFFORD (JHUCCP)

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Activities, Accomplishments, Problems through December 31, 2008

- In December 2007, the subproject was launched with a national stakeholder meeting held in Kampala with approximately 30 participants. The purpose of the meeting was to inform participants about the purpose of the study, to gather their input on the study, and to begin to gain buy-in for the study.
- Abstracts for the 2008 and 2009 PEPFAR Implementers' meeting were submitted in January 2008.
- Data collection was delayed due to long approval times at the local IRB. These delays caused data collection to occur during the rainy season, meaning that some re-sampling had to occur and some waiting occurred while attempting to reach villages surrounded by water.
- In February 2008, Thomsen traveled to Kampala to help train approximately 12 research assistants. Four district workshops, with approximately 25 individuals each, were held the same month.
- Between March and April 2008 a survey was conducted with 420 men and women in each of four districts of Uganda. During the same period, a survey was conducted with all providers and chief administrators in the hospitals and health center IVs of four districts and approximately 12 focus groups were conducted in each of 4 districts.
- Data were entered and analyzed by the sub grantee in April-May 2008.
- Preliminary data was presented at a regional WHO meeting on situation analyses of Male Circumcision in May 2008.
- FHI produced a final report of the assessment in November 2008.
- In collaboration with the MoH AIDS Control Program, USAID and the Makerere University School of Public Health, the findings of the formative assessment were disseminated at two events as follows: to 22 members of the USG team comprised of USAID, CDC, Peace Corps and PEPFAR on 18 November 2008; and to 57 stakeholders from Kampala at a national dissemination workshop and to UNICEF at a meeting in Kampala on 17 December 2008. Additional dissemination of qualitative results was done at a seminar for religious leaders on medical male circumcision hosted by Makerere University School of Public Health and the Health Communication Partnership in December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- In March 2009, staff submitted an abstract for the 2009 PEPFAR Implementers' Meeting; it was not accepted.

- In April 2009 FHI-Uganda participated in the inaugural meeting of the national Medical Male Circumcision Task Force and disseminated findings of the formative assessment.

Findings and Outcomes:

- Activities at the December 11, 2007 stakeholders meeting included an overview of male circumcision as an HIV preventive method plans to roll out MC in Uganda an overview of the National Needs Assessment; and a SWOT (strengths, weaknesses, opportunities, threats) analysis. Participants were also involved in a planning session for the next steps for needs assessment, selection of districts for the needs assessment, selection of key informants and district stakeholders. An analysis of a short questionnaire completed by each participant at the end of the meeting indicated that participants gave the study a priority of 7.5 out of 10.
- In February 2007 FHI trained 12 research assistants in research methods and research ethics.
- Collaboration with JHUCCP was developed to produce, pilot and disseminate information brochures on medical male circumcision in February–March 2008.
- The needs assessment produced results that showed a high level of acceptability for male circumcision (MMC) among women and men in Uganda; and uncovered issues that should be addressed in communicating MMC to the population.
- The findings of the national needs assessment were used in the development of the national MMC communication strategy.
- The national MMC task force chaired by the Ministry of Health accepted the findings of the national needs assessment and will use them in the development of a national MMC policy.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Manuscripts for publication will be finalized and submitted.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR	FCO Approved:156101	Jul 2007
		156102	Jul 2007
Total Approved Budget:	156101 \$	177,876	Projected End Date: Jun 2009
	156102 \$	122,124	
	\$	<u>300,000</u>	

Uganda: Uganda: Traditional Male Circumcisers in HIV Prevention (FCO 154103)

Technical Monitor: EJackson

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Objective(s): To conduct formative research on the practice of traditional male circumcision (TMC) in Uganda and traditional providers of male circumcision in order to better understand the context of TMC, to inform the rollout of medical male circumcision for HIV prevention in TMC areas and to explore opportunities to involve traditional providers of circumcision in HIV prevention.

Note: The research objective was changed in December of 2008 after meeting with in-country partners; the scope of the research was refined to better meet current MOH needs.
 Note: The research objective was changed again in May of 2009 after discussion with in-country partners; the scope of the research was refined to better meet current MOH needs.

Description: The government of Uganda intends to scale up medical male circumcision services for HIV prevention in communities throughout Uganda, including those where traditional male circumcision is practiced. This study will provide contextual information about the practice of traditional circumcision in the four cultures where traditional circumcision is practiced and will inform the development of policies and strategies for the promotion of medical male circumcision in these cultures in a culturally appropriate manner. The study will be cross-sectional and descriptive and will take place in districts where populations of the four major cultural groups who practice traditional male circumcision are concentrated. A total of approximately 140 subjects will participate in focus group discussions or interviews.

Note: The description was changed in May of 2009 after discussion with in-country partners; the scope of the research was refined to better meet current MOH needs.

Collaborating Agency(s): Traditional and Modern Health Practitioners Together Against AIDS (THETA)

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- Preliminary research objectives were established in November 2008.
- Development of a research protocol began in December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Information gathering activities to inform research sampling strategies were completed in March 2009.
- The research protocol describing formative research activities was submitted for technical review and received approval in June 2009.
- The protocol received ethical approval from PHSC in June 2009.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Data collection forms will be submitted for technical review and approval in July 2009.
- The protocol will be submitted for ethical approval in Uganda in July 2009.
- Research assistants will be recruited and trained in July 2009.
- Data collection will take place in October and November 2009.
- Data analysis will be completed by March 2010.
- An in-country dissemination meeting will be held to present findings to stakeholders in April 2010.
- A final paper presenting findings will be written and submitted to a journal in lieu of a final report by April 2010.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR	FCO Approved:	Jul 2008
Total Approved Budget:	\$ 300,000	Projected End Date:	Apr 2010

Uganda: Support to MoH to Increase Access to FP (FCO 143110)

Technical Monitor: AAkol

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To improve access to and use of FP services in Uganda by providing technical assistance (TA) to the MoH to: 1) strengthen national training for family planning; 2) enhance coordination and oversight of the FP program in Uganda; and 3) expand the CBD of DMPA innovation.

Description: Training of FP service providers in Uganda is insufficiently coordinated with no standardized training content. There is also considerable overlap and duplication of effort among partners. A comprehensive national training strategy will be essential for overcoming these challenges. Further, improved Family Planning Revitalization Working Group (FPRWG) coordination, cohesion, and accountability is critical for the MOH and its partners to improve access to and use of family planning services in Uganda.

The MOH has requested assistance from FHI not only to improve training and national-level coordination of FP activities, but also to expand existing efforts to promote DMPA provision by community based distributors (CBDs). Interest has been generated among both non-governmental organizations (NGOs) and local government entities for replication of the CBD of DMPA innovation. Minnesota International Health Volunteers (MIHV) and Conservation Through Public Health (CTPH) are NGOs who are being provided technical support through this subproject. The subproject is also providing technical assistance to develop a family planning training strategy and to strengthen coordination and oversight of family planning activities through the FPRWG.

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- Approval to implement was received from USAID in January 2008.
- The recruitment of a research associate for the field supported activities in Uganda was finalized in June 2008.
- With FHI assistance in May 2008 the MoH developed new Terms of Reference for the FPRWG for 2008 – 2011.
- In March 2008 CTPH with the support of FHI translated CBD of DMPA training materials into Rukiga in preparation for CBD / DMPA replication in Kanungu district.
- In April 2008 FHI staff conducted an exchange visit for MIHV and their district partners to learn from counterparts in Busia district in preparation for CBD DMPA scale up to Mubende district through MIHV.
- In May 2008, FHI staff worked with MIHV and CTPH staff to convene district stakeholder workshops in Mubende and Kanungu districts, respectively. Through these workshops, 49 district personnel approved CBD of DMPA replication in the district and provided input into the CBD of DMPA implementation process.
- In May 2008 FHI staff supported the training of 46 Community Family Planning Providers in Mubende and Kanungu districts to provide DMPA. Additional 30 CBDs were trained in

Mubende in November 2008. These trainings were accompanied by the provision of job aids and training materials to CTPH, MIHV and Bwindi Community Hospital (BCH) in June – November 2008.

- In July 2008 staff disseminated information briefs on CBD of DMPA to 75 districts to interest them in piloting the program.
- In September 2008 FHI-U finalized the development of a FP training strategy in collaboration with the Ministry of Health.
- Staff provided continued technical support to the Ministry of Health FPRWG for coordination of FP partners.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- In February 2009 FHI-U conducted district CBD of DMPA quarterly review meetings in Busia (24 participants) and Bugiri (28 participants).
- Support was provided to Busia district to train an additional 20 CBDs to provide DMPA in two new sub-counties, and to Bwindi Community Hospital in Kanungu district to train an additional 40 CBDs in seven new parishes.
- Compilation of data for a comparison report of CBD of DMPA implementation by public and private sector implementers was finalized and a draft report was produced.
- In collaboration with the MOH, staff convened a FP Revitalization Working Group Meeting in March, and a CBD of DMPA Core Team Meeting in March and June 2009.
- Staff continued to provide technical assistance to MIHV in the form of training and supervision tools in March 2009, for continued DMPA service provision in the community.
- FHI-U Provided financial support to seven CBD of DMPA implementing districts to support supervision of CRHWs in their communities.
- Staff provided M&E materials to Busia district for use in the two new sub counties where CBD of DMPA has been scaled up.

Findings and Outcomes:

- Terms of Reference for the FPRWG were developed with FHI technical assistance.
- In two districts the community family planning program was enhanced with the addition of DMPA to the method mix. Districts took ownership of the initiative by leading the stakeholder consultations and providing trainers.
- The Family Planning Training Strategy for Uganda was finalized in December 2008.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- A: Strengthen national training for FP.
- Convene consensus meeting on the developed FP training strategy.
- Produce, print and disseminate FP training strategy.
- B: Enhance Coordination and oversight of the FP program in Uganda
- hold quarterly meetings of the FPRWG.
- C: Expand CBD of DMPA innovation to new NGO partners, Conservation Through Public Health (CTPH) and Minnesota International Health Volunteers (MIHV)
- Hold quarterly review meetings with Mubende and Kanungu districts.
- Finalize CBD Of DMPA comparison report for private and public sector implementers.
- Hold annual CBD Of DMP a review meeting.

Funding Source(s):	USAID - US Agency for International Development/USAID: Field Support	FCO Approved:	Jan 2008
Total Approved Budget:	\$ 200,000	Projected End Date:	Apr 2010

Madagascar: Increased Contraceptive Choice and Contraceptive Use Dynamics in Madagascar's CBD Program (FCO 114142)

Technical Monitor: ABrunie

USAID Intermediate Objective to be addressed: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To report the number of new contraceptive users in CBD programs where CBD agents provide the Standard Days Method (SDM) and injectable contraceptives, either of these, or neither of these; 2) to characterize use dynamics and the reasons for observed contraceptive behavior (i.e., method continuation, switching, and discontinuation) among CBD clients initiating a new method; and 3) to investigate the factors influencing the choice of service delivery point among CBD clients initiating a new method.

Note: The title and objectives of this subproject were modified as the protocol was being developed in October 2008. Additional information regarding the supply of family planning methods in the CBD program together with logistical considerations made it impossible to pursue the original design.

Note: Following recent political development and the change of leadership in Madagascar, USAID suspended non-humanitarian aid. The funds supporting the study have been transferred to PROGRESS and the study was cancelled.

Description: Several countries have recently introduced DMPA and the Standard Day Method (SDM) to their community-based distribution programs in the hope of increasing contraceptive prevalence. There is, however, little data on how increased method availability affects contraceptive uptake and whether it translates into sustained contraceptive use. Madagascar's CBD program offers a unique opportunity to study uptake of SDM and/or DMPA as they are being added to typical CBD methods such as pills and condoms, as well as to explore patterns of contraceptive behavior among CBD clients. This research was to document and compare contraceptive uptake when the SDM and DMPA, either of these, or neither of these are added to CBD programs. It was also to characterize use dynamics and the reasons for method choice, switching, discontinuation, and investigate clients' motivations for choosing CBD services over clinic-based services.

The study proposed to use a descriptive factorial design of CBD of DMPA and the SDM and a retrospective cross-sectional survey of CBD clients in 18 communities. Women identified from CBD agents' records were to be interviewed 10.5 months after initiating a new method received from a CBD agent. CBD service statistics were to be collected.

This study was planned to produce useful information about the impact of the distribution of DMPA and the SDM through CBD agents, about obstacles to correct and continued contraceptive use, and about clients' motivations for choosing CBD services. Thus it was to provide insights to guide programmatic decision-making for the future development of CBD programs in Madagascar and other developing countries.

Following political events in Madagascar, research activities were suspended and the study was transferred to PROGRESS. A new FCO will be open as appropriate.

Collaborating Agency(s): Georgetown Institute for Reproductive Health; Ministry of Health and Family Planning, Madagascar

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2008

- A reconnaissance trip was made to Madagascar at the end of August / beginning of September 2008.
- Preliminary contact was made with a local research organization to manage data collection in September 2008.
- The protocol was developed and approved internally in November 2008.
- A data collection instrument was drafted in December 2008.

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Data collection forms were approved in March 2009.
- Informed consent forms were drafted in March 2009.
- The materials required for expedited review by PHSC were prepared in March 2009.
- The FCO was closed in June 2009 because USAID has suspended non-humanitarian aid in Madagascar due to recent political development and the change of leadership. The funds supporting the study have been transferred to PROGRESS.
- PROGRESS FCOs will be opened as appropriate.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Jul 2008
Total Approved Budget:	\$ 236,134	Projected End Date:	Jun 2009

Worldwide: FHI Support for CONRAD NIH-IAs (FCO 119508)

Technical Monitor: LWilson

USAID Intermediate Objective to be addressed: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To cover minimal FHI costs for administering the funds pertaining to two NIH-Interagency Agreements affiliated with CONRAD.

Description: This core-funded subproject will cover minimal FHI staff time, and related costs associated with NIH-IAA funds channeled through FHI to CONRAD. This will cover the time needed to routinely report and manage these funds. CONRAD will retain responsibility for achieving the objectives and managing the budget provided to them.

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- During January 2009 budget negotiations, USAID decided not to fund this subproject.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Dec 2008
Total Approved Budget:	\$ 20,000	Projected End Date:	Apr 2010

Madagascar: Madagascar: Regional Mini - U for Evidence-Based Program (FCO 143116)

Technical Monitor: MMalkin/TZan

Strategy Outcomes(s) to be addressed: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To conduct three regional Mini-University events targeted at regional representatives of the MOHFP and core group of regional partners.

Description: Following the June 2008 Mini-University (FCO 123103), the MOHFP, at both central and regional level, and their technical and financial partners agreed to a set of commitments to support and implement programs based on evidence presented at the meeting. Although the Mini-University succeeded in building a strong group of advocates for evidence-based programming, the participants did not adequately represent the program managers and implementers from the field. Subsequent to a follow-up meeting with decision makers to review the status of the commitments made during the Mini-University, FHI will conduct three regional Mini-University events.

Target attendees are regional representatives of the MOHFP and the core group of regional partners. By conducting regional events, the innovations can be shared with a larger audience and encourage engagement in the new programs from personnel at management and care provision levels. Ownership at the local level should ensure that these commitments are translated into action.

Suggested venues are:

Antsirabe, which is one of the three national "Pôle Intégré de Croissance" (PIC) and where several pilot development programs are taking place with strong support from NGOs and private stakeholders.

Mahajanga, where there is a strong potential of scientific expertise through the University, with a Medical School and a School of Public Health.

Toamasina, in the East Coast and Madagascar's second largest city, where there is a strong network of NGOs and where USAID is investing significant resources through Santénet (1 and 2).

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Approval to Implement was received on February 24, 2009.
- In March 2009, Andry Rajoelina, mayor of Antananarivo, took power from President Marc Ravalomanana and put a new government into place. In response, the U.S.—via the State Department and USAID—announced that all non-humanitarian assistance would cease. CRTU activities were suspended, though staff and office are being maintained.

- Discussions with USAID/W and Mission led FHI to transfer remaining funds from CRTU to PROGRESS effective July 1 2009. All office costs, including staff time, were charged to FCO 143116 for May and June 2009. The CRTU FCO (143116) was closed as of June 30, 2009.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- This activity is currently on hold pending further guidance from State Department and USAID.

Funding Source(s):	USAID - US Agency for International Development/USAID: Field Support	FCO Approved:	Jan 2009
Total Approved Budget:	\$ 115,000	Projected End Date:	Jun 2009

Kenya: Kenya: Multiple Enrollment & Flow of Patient Information for ART (FCO 153137)

Technical Monitor: GEmukule

Objective(s): To generate information and design an evidence based information flow system which will ultimately improve service delivery, limit duplication of efforts, minimize double registration and reporting and document the experiences for possible scale up. These funds were obligated by the USAID/Kenya for COP 08.

Description: In order to ensure quality care and treatment services for ART patients, there is need to ensure that patient's information and medical records are well maintained and readily accessed at the facility for clinical monitoring purposes. This study has the overall goal of designing a net-worked and web-based ART data Electronic Medical Records (EMR) system linking 5 ART facilities.

The subproject design will involve a baseline and follow up assessment by interviewing ART patients, services providers and reviewing patient records. Data from the baseline will be analyzed and used to develop and install a net-worked web-based system and followed up for a period of 9 months.

It is anticipated that this web-based system will improve service delivery to the ART patients; limit duplication of efforts and minimize possibilities of double registration and double reporting as records will be accessible from any of the five facilities. This will be beneficial to both the service providers and patients. Findings from the evaluation will be shared with the government of Kenya and other stakeholders.

2008—09 ANNUAL REPORT

Activities, Accomplishments, Problems between January 1, 2009—June 30, 2009

- Protocol and data collection instruments were developed and approved by the internal reviewers in June 2009. The study protocol was submitted to the PHSC and an approval is currently being awaited.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- The additional activities planned for the period January – April 2010 are:

- Pre-testing and installation of the web-based system (Jan-Feb).
- Routine monitoring and Support of the web-system (Jan - Apr).

Funding Source(s):	USAID - US Agency for International Development/PEPFAR	FCO Approved:	Mar 2009
Total Approved Budget:	\$ 150,000	Projected End Date:	Apr 2010

Worldwide: CRTU Project Achievements Dissemination (FCO 113153)

Technical Monitor: MMalkin

Objective(s): 1) To disseminate the findings and achievements of the CRTU to USAID, CRTU cooperating agencies, and others engaged in international family planning; and 2) to provide information on areas for future research to these groups.

Description: The CRTU Project Achievements Dissemination meeting will be held in Washington D.C. on March 30, 2010. The meeting will be a platform to share information on some of the CRTUs central aspects such as research utilization, community-based access (CBA) to injectable contraception, the integration of family planning and HIV services, and the Focus Country Program. Other key findings will also be shared. This FCO covers the planning of the dissemination meeting, travel for the meeting, the costs of the meeting, and dissemination in CRTU focus countries.

2009—2010 WORKPLAN

Planned Activities for July 1, 2009 – April 28, 2010

- Meeting logistics with the Ronald Reagan Building were finalized in July 2009. In July and August 2009 several planning meetings of NC FHI staff were held to discuss a meeting agenda, the list of attendees, and other meeting details. A meeting with USAID to discuss key themes of the meeting was held in August 2009. Save-the-Date invitations were sent out in August 2009.

Funding Source(s):	USAID - US Agency for International Development/USAID: Core	FCO Approved:	Jun 2009
Total Approved Budget:	\$ 42,942	Projected End Date:	Apr 2010



FINANCIAL INFORMATION

BUDGET & EXPENDITURE INFORMATION BY STRATEGY

**July 2008 – June 2009
Annual Report**

and

**July 2009 – April 2010
Workplan**

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CRTU Year 4 (July 2008 - June 2009) Expenditures & Year 5 (July 2009 - April 2010) Workplan

Fund Source	Obligated Funds FY08 and prior	Obligated Funds FY09	Total Obligated Funds	CRTU Expenditures Year 4	TOTAL Expenditures Years 1-4	Pipeline Funds for FY09	CRTU Budget Year 5
TOTAL (Core Funds)	37,305,179	7,936,849†	45,242,028	10,468,565	35,938,350	1,366,829	9,313,997
TOTAL (GLP Funds)	3,106,000	-	3,106,000	380,302	3,057,072	48,928	48,702
TOTAL (Venture Capital Funds)	113,000	-	113,000	21,186	131,555	(18,555)	(18,554)
TOTAL (Core-OHA)	600,000	-	600,000	277,709	277,709	322,291	323,510
TOTAL (FS Funds)	5,049,151	-	5,049,151	1,625,847	3,557,351	1,491,800	1,492,190
TOTAL (PEPFAR Funds)	12,083,130	2,272,719	14,355,849	4,157,866	9,401,205	2,681,925	4,953,258
TOTAL (NIH-IAA Funds)	2,024,300	-	2,024,300	289,310	1,368,558	655,742	660,711
TOTAL (CDC-IAA Funds)	584,935	-	584,935	60,745	260,629	324,306	326,931
TOTAL (CSL-Core Funds)	1,000,000	-	1,000,000	459,458	1,334,792	(334,792)	151,877
TOTAL (CSL-FS Funds)	9,000,000	300,000	9,300,000	1,978,808	8,287,103	712,897	494,753
TOTAL (Microbicides)	50,614,186	6,000,000	56,614,186	21,776,835	49,436,105	1,178,081	7,146,017
GRAND TOTAL	121,479,881	16,509,568	137,989,449	41,496,630	113,050,428	8,429,453	24,893,391

†\$7,406,000 in new Core-Pop funds plus \$530,849 in FS funds from Madagascar

CRTU Year 4 (July 2008 - June 2009) Expenditures & Year 5 (July 2009 - April 2010) Workplan

Group	FCO	Title	Fund Source	LOSP Budget	CRTU Expenditures Yrs. 1-3	CRTU Expenditures Year 4	CRTU Budget Year 5	Projected End Date
Barrier Methods								
BBR	116104	Formative Research to Recruit for True Efficacy Trials	Core	252,628	246,990	24,800	20,016	Dec. 2009
BBR	116107	Developing Strategies to Recruit for True Efficacy Trials		94,260	40,114	40,990	-	
BBR	116112	Sub: SA: Formative Research to Recruit for True Efficacy Trials		44,731	53,382	4,068	-	
		<i>Total</i>		<u>391,619</u>	<u>340,486</u>	<u>69,858</u>	<u>20,016</u>	
SF	112101	Pivotal Effectiveness Study of PATH SILCS Diaphragm	Core	1,313,190	468,454	332,138	-	Sept. 2008
BBR	112117	Structural Integrity of the FC2 Female Condom	Core	43,864	41,682	15,027	-	Sept. 2008
BBR	172004	ACASI vs FTF - A Randomized Comparison using PSA	CDC	10,903	21,711	(71)	-	Sept. 2009
BBR	172007	Sub UCSF: ACASI vs. FTF Interviewing-A Randomized comparison using PSA		88,097	88,855	-	-	
		<i>Total</i>		<u>99,000</u>	<u>110,566</u>	<u>(71)</u>		
HSR	114100	Evaluating the "Young Men as Equal Partners" Project	Core	404,835	384,977	(1,101)	-	Oct. 2008
HSR	114122	Kenya: Evaluation the "Young Men as Equal Partners" Project		119,791	-	-	-	
HSR	114123	Uganda: Evaluation the "Young Men as Equal Partners" Project		119,567	-	-	-	
		<i>Total</i>		<u>644,193</u>	<u>384,977</u>	<u>(1,101)</u>		
HSR	114120	Improving DP Counseling for Youth: Formative Research	Core	250,142	73,041	43,914	75,672	April 2010
HSR	114139	Sub: Tanzania: Youth Dual Protection: MUHAS		37,928	-	8,108	27,376	
HSR	114140	Sub: Tanzania: Youth Dual Protection (OPTIONS)		44,216	-	17,263	31,497	
		<i>Total</i>		<u>332,286</u>	<u>73,041</u>	<u>69,285</u>	<u>134,545</u>	
BBR	116113	Evaluation of the SPW Model of Peer Education - Zambia	Core	279,963	107,997	181,627	-	June 2009
ARD	113141	Worldwide: Document & Disseminate Condom Programming	Core	36,817	-	14,734	-	June 2009
BBR	172006	Immunological Markers of Chlamydial Infection (IMCI)	CDC	127,271	50,259	21,743	54,928	April 2010
BBR	172009	Rapid PSA Testing - Next Steps	CDC	11,341	8,893	15,416	23,973	April 2010
BBR	172008	Sub UNC: Rapid PSA Testing - Next Steps		38,659	6,539	19,296	83,899	
BBR	172011	Sub: ERTU: Jamaica - Rapid PSA Testing - Next Steps		-	-	-	164,131	
		<i>Total</i>		<u>50,000</u>	<u>15,432</u>	<u>34,712</u>	<u>272,003</u>	
PQC	118100	International Standards Development (ISO, ASTM, ANSI, etc.)	CSL-Core	Annual	183,387	91,362	16,949	April 2010
PQC	148100	Production Surveillance of Condoms, Domestic and Off-shore	CSL-FS	Annual	5,310,364	1,243,507	332,432	April 2010
PQC	148104	Production Surveillance of Condoms - Bangkok	CSL-FS	Annual	334,713	496,940	105,772	April 2010
HSR	144102	Improving FP Counseling of Clients	FS	500,000	130,994	93,091	185,916	April 2010
ARD	153110	Sub to ICL for ABC Approach for Youth in Institutions of Higher Learn	PEPFAR	379,230	217,996	163,668	-	Feb. 2010
ARD	153111	ABC Approach for Young Adults in Institutions of Higher Learning		260,770	119,884	63,233	80,011	
ARD	153145	ABC Approach for Youth Adults (FS)		480,183	-	-	480,182	
ARD	153144	ABC Approach for Infection Prevention (FS)		119,818	-	66,967	52,851	
		<i>Total</i>		<u>1,240,001</u>	<u>337,879</u>	<u>293,867</u>	<u>613,044</u>	

CRTU Year 4 (July 2008 - June 2009) Expenditures & Year 5 (July 2009 - April 2010) Workplan

Group	FCO	Title	Fund Source	LOSP Budget	CRTU Expenditures Yrs. 1-3	CRTU Expenditures Year 4	CRTU Budget Year 5	Projected End Date
Cross-cutting: Technical Leadership								
BBR	116103	BBR Technical Leadership	Core	Annual	735,236	572,338	360,869	April 2010
BIOS	119100	BIOS Technical Leadership	Core	Annual	350,934	175,546	131,949	April 2010
HSR	114106	HSR Technical Leadership	Core	Annual	1,036,931	379,966	368,801	April 2010
RAQA	119200	Regulatory Affairs and Quality Assurance	Core	Annual	593,182	155,336	150,000	April 2010
Cross-cutting: Enhanced Country Programs								
ARD	113117	Enhanced Country Program Implementation	Core	2,809,915	1,697,240	537,578	531,710	April 2010
ARD	113122	Kenya Enhanced Country Program Implementation	Core	5,041,726	1,767,011	173,151	112,288	April 2010
ARD	113125	Uganda Enhanced Country Program Implementation	Core	1,303,628	335,470	433,886	185,477	April 2010
ARD	113129	Madagascar Enhanced Country Program Implementation	Core	1,263,132	208,165	221,615	-	June 2009
ARD	113148	Tanzania Enhanced Country Program Implementation	Core	243,182	-	58,442	107,863	April 2010
ARD	113132	India Enhanced Country Program Implementation	Core	624,948	99,204	92,625	106,326	April 2010
Cross-cutting: Research Utilization								
BBR	112110	Development of Guidelines for Contraceptive Users	Core	Annual	137,298	72,806	39,038	Dec. 2009
BBR	172003	Development of Guidelines for Contraceptive Users	NIH	750,000	440,583	108,319	201,098	Dec. 2009
BBR	112112	Cochrane Fertility Review Group	Core	750,000	512,742	144,833	55,720	April 2010
BBR	172002	Cochrane Fertility Review Group	NIH	750,000	309,767	140,089	70,000	April 2010
ARD	113113	CRTU Network of Champions	Core	471,779	249,161	168,311	65,498	April 2010
ARD	113114	Research to Practice Leadership	Core	2,735,123	1,581,549	578,781	574,793	April 2010
ARD	113154	Sub: EXPANDNET: Building Capacity for Scale-up	Core	41,652	-	-	41,652	
		<i>Total</i>		<u>2,776,775</u>	<u>1,581,549</u>	<u>578,781</u>	<u>616,445</u>	
ARD	113115	USAID Best Practices Package: Development and M&E	Core	179,282	182,102	(2,324)	-	June 2008
ARD	123101	USAID Best Practices Package: Development and M&E	VC	135,600	110,369	21,186	(18,554)	Oct. 2008
ARD	113116	IBP Consortium	Core	177,059	104,315	28,538	31,921	April 2010
ARD	113118	CRTU Knowledge Management	Core	2,959,885	1,886,319	570,685	571,210	April 2010
ARD	113128	Technical Assistance to Develop a Standardized FP Curriculum	Core	560,000	47,935	162,280	303,728	April 2010
ARD	113134	Nigeria: Collaboration with WHO/SPP to Support the App of EBP	Core	206,506	47,400	53,835	138,891	April 2010
ARD	113140	Tanzania: Collaboration of WHO-SPP to Support the App of EBP		212,891	31,585	59,448	190,217	
		<i>Total</i>		<u>419,397</u>	<u>78,985</u>	<u>113,283</u>	<u>329,108</u>	
ARD	113133	Technical Assistance to Improve FP Uptake	Core	326,621	154,161	57,577	125,657	April 2010
HSR	114142	Madagascar: Use Dynamics of Cycle Beads & Other Methods in CBD Pro	Core	236,134	-	46,224	-	June 2009
ARD	143116	Regional Mini-U for Evidence-Based Programming	FS	115,000	-	39,584	-	June 2009
ARD	123103	USAID Best Practices Package: Development and M&E	GLP	75,000	70,094	11,929	(7,023)	Oct. 2008
ARD	143119	Kenya: CBD of DMPA Promotion	FS	65,000	-	-	67,066	
ARD	113153	CRTU Project Achievements Dissemination	Core	42,942	-	5,055	153,075	April 2010

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Group	FCO	Title	Fund Source	LOSP Budget	CRTU Expenditures Yrs. 1-3	CRTU Expenditures Year 4	CRTU Budget Year 5	Projected End Date
Cross-cutting: General								
EXO	119501	CRTU Monitoring and Evaluation	Core	Annual	628,508	245,764	253,725	April 2010
EXO	119507	RU Assessment: Field Costs	Core		-	28,318	-	
SF	112100	Coordination of CONRAD Activities	Core	Annual	663,302	38,562	-	April 2010
SF	119508	FHI Support for CONRAD NIH-IAA Activities	Core		-	-	-	April 2010
HSR	174001	Cost-Effectiveness Analysis of Assisted Reproductive Technology	CDC	25,739	23,627	4,361	-	Dec. 2008
OIRE	172000	Research Ethics Training Curriculum for Community Representatives	NIH	100,000	170,024	11,916	(81,940)	Dec. 2008
ARD	143103	Kenya DRHCD Follow-on	FS	500,000	254,132	129,161	120,413	April 2010
ARD	143117	Kenya DRHCD Follow-on MAARD		310,000	-	8,004	301,588	
ARD	153102	Building Strategic Information Capacity within NASCOP in Kenya	PEPFAR	670,143	167,512	84,531	418,649	Feb. 2010
ARD	153133	Sub: Building Strategic Information Capacity, NASCOP		263,857	-	58,535	205,493	
		<i>Total</i>		934,000	167,512	143,066	624,142	
BBR	156101	Uganda: Needs Assessment of Male Circumcision	PEPFAR	177,876	89,588	67,267	19,387	Feb. 2010
BBR	156102	Sub to: Uganda Needs Assessment of MC		122,124	95,440	30,036	-	
		<i>Total</i>		300,000	185,028	97,303	19,387	
BBR	156103	Understanding Concurrent Partnerships in Uganda	PEPFAR	250,000	-	134,464	115,534	March 2010
ARD	154103	Uganda: Traditional Male Circumcisers in HIV Prevention	PEPFAR	242,034	-	111,441	130,593	Feb. 2010
ARD	153137	Multiple Enrollment & Flow of Patient Info for ART	PEPFAR	150,000	-	8,436	146,061	Feb. 2010
Cross-cutting: Commodities, Securities and Logistics								
PQC	118101	Technical Leadership: Collab. w/Multi/Bi-Lateral Procurement Agencies	CSL-Core	Annual	191,548	118,410	23,194	April 2010
PQC	118102	Technical Assistance to Field Programs	CSL-Core	Annual	220,316	123,290	32,057	April 2010
PQC	118103	Technical Oversight Committee	CSL-Core	Annual	211,582	69,845	46,701	April 2010
PQC	118104	Inter-Laboratory Trials	CSL-Core	Annual	68,501	56,552	32,975	April 2010
PQC	148101	Production Surveillance – Hormonals and LAPMs	CSL-FS	Annual	480,351	238,361	56,550	April 2010
PQC	X001.PN08	X001.PN08 - SCMS			-	-	-	
HIV and Contraceptive Services								
BBR	112127	Prospective Evaluation of Contraceptive Dynamics in Women	Core	132,799	99,221	29,558	-	Dec. 2009
ARD	113106	Tool Kit to Increase Access to Contraception	Core	360,972	374,284	24,291	-	Oct. 2008
ARD	113131	FP in Context of HIV: Supporting Evidenced-based Practices	Core	470,858	125,561	234,734	87,867	April 2010
HSR	114116	Increasing Access to Postpartum FP Services - Madagascar	Core	125,983	118,999	18,642	-	April 2010
HSR	114132	Sub for: Increasing Access to Postpartum FP Services		64,124	63,879	3,347	-	
		<i>Total</i>		190,107	182,878	21,989	-	
HSR	114115	FP-VCT Integration in Tanzania	Core	329,716	117,754	610	-	Aug. 2008

CRTU Year 4 (July 2008 - June 2009) Expenditures & Year 5 (July 2009 - April 2010) Workplan

Group	FCO	Title	Fund Source	LOSP Budget	CRTU Expenditures Yrs. 1-3	CRTU Expenditures Year 4	CRTU Budget Year 5	Projected End Date
BBR	112136	Safety of Implant Use Among Women on ARVs	Core	298,252	80,496	60,213	88,763	April 2010
BBR	112141	Sub: UNITID Safety of Implant Use Among Women on ARV's		91,146	9,839	16,592	35,014	
		<i>Total</i>		<u>389,398</u>	<u>90,335</u>	<u>76,805</u>	<u>123,777</u>	
BBR	112139	Do ARVs Affect the Efficacy of COCs	Core	532,380	48,595	238,868	118,866	April 2010
BBR	112145	Sub: U Witwatersrand		244,089	-	39,110	185,450	
BBR	112146	Sub: Makerere University		149,474	-	17,408	35,374	
BBR	112147	Sub: SCT Consulting		52,293	-	9,064	25,260	
		<i>Total</i>		<u>978,236</u>	<u>48,595</u>	<u>304,449</u>	<u>376,632</u>	
ARD	113104	Providing Global Leadership-FP-HIV Integration Efforts	Core	655,270	300,218	281,724	47,227	April 2010
ARD	123100	Providing Global Leadership-FP-HIV Integration Efforts	GLP	175,000	149,725	(535)		June 2008
HSR	114145	Developing & Testing FP for PMTCT Phase II	Core	165,049	-	62,551	-	April 2010
HSR	114144	Sub: WHRU Developing & Testing FP for PMTCT		197,141	-	83,855	55,400	
		<i>Total</i>		<u>362,190</u>	<u>-</u>	<u>146,406</u>	<u>55,400</u>	
HSR	114130	Youth Integrated FP and HIV Service Delivery Models	Core	264,101	29,553	200,610	75,823	April 2010
HSR	114136	Facilitated Referrals to Promote Contraceptive Access Among HIV+ Wom	Core	280,425	10,505	99,237	100,203	April 2010
HSR	114151	Sub: Muhimbili Univ. for Facilitated Referrals		86,197	0	23,487	59,287	
		<i>Total</i>		<u>366,622</u>	<u>10,505</u>	<u>122,724</u>	<u>159,490</u>	
HSR	114147	Assessing Male Circumcision for Male Involvement in FP	Core	145,500	-	25,394	126,671	April 2010
ARD	113147	Programmatic Guidance for Integrating FP & HIV Services	Core	200,000	-	28,967	115,300	April 2010
ARD	113151	Journal Supplement on Family Planning & HIV Integration	Core	133,497	-	3,252	129,569	April 2010
ARD	123102	Scale-up & Global Dissem. of Kenya's FP/VCT Integration Package	GLP	88,628	128,322	(60,679)	-	Sept. 2008
ARD	113126	Scale-up & Global Dissem. of Kenya's FP/VCT Integration Package	Core	146,001	141,217	7,350	-	June 2008
HSR	114114	Integration of FP into Comprehensive Care Centers	Core	675,693	71,884	131,228	368,922	April 2010
HSR	124104	Integration of FP into Comprehensive Care Centers	GLP	134,000	33,481	122,278	19,102	April 2010
HSR	114124	Country Assessments: Documenting Promising FP/HIV Models	Core	459,470	470,255	(10,454)	-	June 2008
HSR	114135	Sub to: ISAE: Country Assessments: FP-HIV Integration Models		49,467	49,925	(442)	-	Jan. 2009
		<i>Total</i>		<u>508,937</u>	<u>520,179</u>	<u>(10,896)</u>	<u>-</u>	
HSR	124106	Country Assessments: Documenting Promising FP/HIV Models	GLP	375,400	385,563	(5,809)	252	June 2008
HSR	124107	Sub to: Progressus: Country Assessments: FP-HIV Integration		42,042	21,545	22,235	16,220	Feb. 2009
HSR	124108	Sub to: MACRO: Country Assessments: FP-HIV Integration Models		159,008	83,709	72,674	-	Dec. 2008
		<i>Total</i>		<u>576,450</u>	<u>490,817</u>	<u>89,100</u>	<u>16,472</u>	
ARD	113127	FP & HIV Service Integration: SA Network of Champions	Core	129,005	132,085	6,074	-	May 2008
ARD	153130	FP & HIV Service Integration: SA Network of Champions	PEPFAR	358,293	27,500	206,456	281,752	Dec. 2009
HSR	114104	Improving Use of FP in VCT in Kenya	Core	446,239	126,322	228,492	58,640	April 2010
ARD	153103	PEPFAR: Improving Use of Family Planning in VCT	PEPFAR	52,900	73,469	-	-	Oct. 2006

CRTU Year 4 (July 2008 - June 2009) Expenditures & Year 5 (July 2009 - April 2010) Workplan

Group	FCO	Title	Fund Source	LOSP Budget	CRTU		Projected End Date	
					Expenditures Yrs. 1-3	Expenditures Year 4		CRTU Budget Year 5
HSR	114143	Monitoring Status FP/HIV Integration Efforts	Core	455,005	-	342,421	139,344	April 2010
HSR	114153	Sub: FP/HIV Integration Efforts	Core	-	-	-	17,788	April 2010
		<i>Total</i>		<u>455,005</u>	<u>-</u>	<u>342,421</u>	<u>157,132</u>	
HSR	184000	Monitoring Status FP/HIV GHAI	Core-OHA	200,000	-	28,884	171,117	April 2010
HSR	124100	Examining the FP Needs of Women Targeted for HIV Services	GLP	189,518	198,425	(3,554)	-	Dec. 2008
HSR	124105	Examining the FP Needs of Women Targeted for HIV Services		79,784	77,940	7,474	-	Jan. 2009
		<i>Total</i>		<u>269,302</u>	<u>276,364</u>	<u>3,921</u>	<u>-</u>	
HSR	124102	Assessing Provision of FP and RH Services in Commercial Sector	GLP	114,599	69,570	7,514	-	April 2009
BBR	172010	Devel Collab Study Contra Use - HIV + Women	NIH	74,006	19,905	12,607	41,481	March 2010
ARD	143110	Support to the MOH for Increased Access to FP in Uganda	FS	200,000	43,171	139,589	17,240	April 2010
ARD	143106	Integration of FP Services into VCT Sites in the DRC	FS	940,604	172,843	562,041	185,511	April 2010
ARD	143112	Sub: Centre de Ret Integration of FP into CT		14,375	-	12,007	-	
ARD	143113	Sub: HGR: Integration of FP into CT		14,375	-	14,404	-	
ARD	143114	Sub: Integration FP/CT - Ville Basse & Tabac Congo		30,646	-	8,799	4,000	
ARD	143121	Sub: Integration FP/CT- HGR Kinkanda		13,435	-	-	13,435	
ARD	143122	Sub: Integration FP/CT- HGR Panda		13,435	-	-	13,435	
ARD	143123	Sub: Integration FP/CT- HGR Matadi		13,435	-	-	13,435	
		<i>Total</i>		<u>1,040,305</u>	<u>172,843</u>	<u>597,250</u>	<u>229,816</u>	
HSR	144101	FP/PMTCT Integration Assessment	FS	49,958	51,786	1,076	-	June 2008
HSR	154101	FP/PMTCT Integration Assessment	PEPFAR	400,132	115,553	107,435	177,052	April 2010
ARD	153104	Enhancing PMTCT Performance Improvement in South Africa	PEPFAR	1,261,511	509,052	425,983	342,179	April 2010
ARD	153122	SA: Integrated Community Palliative Care Project (ICPC) (Parent)	PEPFAR	757,873	395,646	614,032	(250,000)	April 2010
ARD	153123	SA: Integrated Palliative Care Project (ICPC)		32,463	3,376	29,786	-	
ARD	153124	SA: Integrated Palliative Care Project (HPCT)		197,948	120,695	137,073	(60,000)	
ARD	153125	SA: Integrated Palliative Care Project: FICPC		53,868	7,104	27,130	19,633	
ARD	153126	SA: Integrated Palliative Care Project: CICPC		36,092	7	24,680	11,403	
ARD	153127	SA: Integrated Palliative Care Project: SICPC		71,756	9,658	28,178	41,168	
ARD	153139	Integrated Community Palliative Care (ICPC) (Parent - MAARD)		695,627	-	9,786	639,869	
ARD	153136	SA: Integrated Palliative Care Project: Guateng (MAARD)		225,000	-	79,809	142,265	
ARD	153140	SA: Integrated Palliative Care Project: PICPC (MAARD)		40,000	-	-	40,000	
ARD	153142	SA: Integrated Palliative Care Project: SARCS (MAARD)		23,500	-	-	23,500	
ARD	153143	SA: Integrated Palliative Care Project: MK Umbrella (MAARD)		33,000	-	-	33,000	
		<i>Total</i>		<u>2,167,127</u>	<u>536,486</u>	<u>950,476</u>	<u>640,838</u>	

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Group	FCO	Title	Fund Source	LOSP Budget	CRTU Expenditures Yrs. 1-3	CRTU Expenditures Year 4	CRTU Budget Year 5	Projected End Date
ARD	153128	Expansion of Strengthen Linkages Between HBC, FP, ARV	PEPFAR	624,604	126,063	1,365,213	(376,000)	April 2010
ARD	153129	Sub to: SA: Expansion of Strengthen Linkages Between HBC, FP, ARV		765,426	369,873	(94,580)	-	
ARD	153138	Mobile Services Unit/HBC Linkages (MAARD)		1,179,971	-	741	1,160,789	
		<i>Total</i>		<u>2,570,001</u>	<u>495,936</u>	<u>1,271,373</u>	<u>784,789</u>	
HSR	154100	Risk of HIV and Feasibility Research Among House Girls (MAARD)	PEPFAR	448,107	309,263	50,528	80,943	April 2010
HSR	154102	Sub Kenyatta Univ: Intervention for House Girls in Bahaiti Martyrs Church, Nairobi		434,894	84,721	25,105	338,475	
HSR	154104	Nairobi: Risk of HIV & Feasibility Research Among Housegirls		42,747	-	-	42,472	
HSR	154105	Sub: Risk of HIV & Feasibility Research Among Housegirls		157,253	-	-	157,255	
		<i>Total</i>		<u>1,083,001</u>	<u>393,984</u>	<u>75,633</u>	<u>619,145</u>	
ARD	156100	Understanding Fertility Knowledge & Desire of Women on ART	PEPFAR	450,000	146,979	89,405	220,808	Feb. 2010
ARD	153134	Kenya: Fertility Desires and FP Needs of HIV+ Women - RU	PEPFAR	50,000	-	2,625	48,881	
Hormonals								
BBR	116105	Development & Evaluation of Campaign to Increase Continuation	Core	413,556	144,353	150,277	63,623	April 2010
BBR	116110	Development & Evaluation of Campaign to Increase Continuation		258,946	64,981	93,923	-	
ARD	113149	Sub:Radio Ramoji		51,993	-	14,632	45,040	
		<i>Total</i>		<u>724,495</u>	<u>209,334</u>	<u>258,831</u>	<u>108,663</u>	
BBR	146002	Support for HC Continuation Campaign (Non-MAARD)	FS	30,000	-	69,838	(39,838)	
BBR	146003	Support for the HC Continuation Study (MAARD)	FS		-	-	90,001	
		<i>Total</i>		<u>30,000</u>	<u>-</u>	<u>69,838</u>	<u>50,163</u>	
BBR	112118	Continuous vs. Cyclic Use of COC Pills	Core	486,642	291,616	158,656	70,643	April 2010
BBR	112130	Guatemala: Continuous vs. Cyclic Use of COC Pills - APROFAM		90,050	30,113	(8,494)	-	
BBR	112142	Sub: Profamilia: Continuous vs. Cyclic Use of COC		126,313	-	46,453	82,293	
BBR	112144	Sub: Profamilia: Continuous vs. Cyclic Use of COC		86,765	-	624	-	
		<i>Total</i>		<u>789,770</u>	<u>321,729</u>	<u>197,238</u>	<u>152,936</u>	
ARD	113107	Pregnancy Provider Checklists and Reference Guide 2005	Core	189,076	188,984	(897)	-	July 2008
ARD	113108	Promoting DMPA Provision by Community Health Providers	Core	956,537	437,314	278,504	233,518	April 2010
ARD	113135	Expanding Access to Hormonals via Drug Outlets in Tanzania	Core	328,756	107,727	30,020	72,009	Dec. 2009
ARD	113155	Sub: NIMR: Drug Shops as Sales Outlets		42,942	-	-	42,942	
		<i>Total</i>		<u>371,698</u>	<u>107,727</u>	<u>30,020</u>	<u>233,951</u>	
HSR	114102	Improving Continuation Rates for Injectable Contraceptives	Core	308,275	192,977	70,482	84,518	April 2010
HSR	114126	South Africa: Women's Health Research Unit - University of Cape Town		236,520	199,433	441	-	
		<i>Total</i>		<u>544,795</u>	<u>392,410</u>	<u>70,923</u>	<u>84,518</u>	
HSR	114111	Improving Service Delivery of CBD of DMPA in Uganda	Core	166,454	155,109	21,643	-	June 2009
HSR	114129	Sub Uganda: Improving Service Delivery of Community-Based Distribution of DMF		31,324	21,509	(8,444)	-	
		<i>Total</i>		<u>197,778</u>	<u>176,618</u>	<u>13,199</u>	<u>-</u>	

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Group	FCO	Title	Fund Source	LOSP Budget	CRTU Expenditures Yrs. 1-3	CRTU Expenditures Year 4	CRTU Budget Year 5	Projected End Date
HSR	114113	Assessment of Late DMPA Client Management	Core	184,347	125,244	42,930	-	April 2009
HSR	114137	Sub to: MA: Assmnt of Late DMPA Client Management		52,421	37,934	8,272	-	
		<i>Total</i>		236,768	163,179	51,202	-	
HSR	114128	Increasing FP Uptake Among PP Women-Testing Supply & Demand	Core	448,026	139,218	203,347	136,941	April 2010
BBR	112137	Pregnancy Testing: Depo Now in Africa	Core	69,171	55,916	12,935	-	Sept. 2008
HSR	114131	Drug Shops as Sales Outlets for Injectable Contraception	Core	121,000	20,629	36,864	76,361	April 2010
HSR	114149	Sub for 114131: Save the Children: Drug Shops		-	-	-	-	
		<i>Total</i>		121,000	20,629	36,864	76,361	
HSR	114134	Taking CBD of DMPA to Scale: Process, Cost and Outcome Evaluation	Core	203,389	10,525	53,345	-	June 2009
HSR	114141	Madagascar: Immunization Services as an Entry Point to FP	Core	272,788	-	65,483	-	June 2009
HSR	114148	Sub: INSPC: Immunization as Entry for FP		-	-	-	-	
		<i>Total</i>		272,788	-	65,483	-	
ARD	113142	Expanding the Global Evidence Base of CBD-DMPA Intro to N. Nigeria	Core	85,809	-	33,701	55,723	April 2010
ARD	113152	Sub: ARFH: CBD of DMPA in Nigeria		65,946	-	-	65,948	
		<i>Total</i>		151,755	-	33,701	121,671	
HSR	114152	Population Level Impact of Injectables	Core	117,984	-	-	118,300	April 2010
SF	172014	CONRAD: Development of LNG-B	NIH	-	-	-	-	April 2010
SF	172015	Sub: CONRAD: Development of LNG-B		212,375	-	-	212,377	
		<i>Total</i>		212,375	-	-	212,377	
BBR	TBD	Planned Funding for Meeting on Progestins and Endometrial Bleeding	NIH	24,500	-	-	24,500	April 2010
ARD	143104	Evidence-based Child Intervention Development in Northern Nigeria	FS	250,000	150,533	(3,044)	22,130	April 2010
BBR	146001	Nigeria: Evidence-based Child Spacing Intervention Development for Northern-Nig		-	53,984	23,892	-	
		<i>Total</i>		250,000	204,517	20,848	22,130	
ARD	143109	Taking CBD of DMPA to scale in Madagascar	FS	539,144	168,187	264,643	-	June 2009
ARD	143107	Taking the Best Practices Package to scale in Madagascar	FS	250,952	2,249	36,774	-	June 2009
ARD	143108	Operationalizing National RH Norms & Procedures	FS	104,902	18,943	28,323	-	June 2009
ARD	143115	Uganda: Advocacy for CBD of DMPA	FS	200,000	-	21,779	178,221	Feb. 2010
Long-Acting and Permanent Methods								
BBR	116100	Vasectomy Accept. Among Clients/Providers in Uttar Pradesh	Core	222,710	159,625	59,279	22,907	April 2010
BBR	116111	Sub: Vasectomy Accept. Among Clients/Providers in Uttar Pradesh		103,106	80,370	38,702	-	
		<i>Total</i>		325,816	239,995	97,981	22,907	
BBR	116108	Malawi: Male Motivators in Malawi	Core	179,900	106,075	30,536	100,344	April 2010
BBR	116109	Sub to Save the Children: Malawi Educators Project		139,347	44,317	66,973	-	
		<i>Total</i>		319,247	150,392	97,509	100,344	
BBR	112107	USAID Fin. Support to Develop a Female NSS Method w/Erythromycin	Core	351,445	113,398	21,658	14,404	April 2010

CRTU Year 4 (July 2008 - June 2009) Expenditures & Year 5 (July 2009 - April 2010) Workplan

Group	FCO	Title	Fund Source	LOSP Budget	CRTU Expenditures Yrs. 1-3	CRTU Expenditures Year 4	CRTU Budget Year 5	Projected End Date
BBR	112124	Implant Provision thru the Private Sector	Core	384,592	151,070	56,029	127,184	April 2010
BBR	112148	Sub PAAL: Assessing Implant Provision			-	-	53,184	
		<i>Total</i>			151,070	56,029	180,368	
BBR	112125	Collaborative Research on Implants	Core	893,758	461,724	183,122	192,164	April 2010
BBR	112135	Sub WHO: Collaborative Research on Implants		166,294	165,991	-	-	
		<i>Total</i>		1,060,052	627,714	183,122	192,164	
BBR	112129	Improved Counseling on Implants to Reduce Unintended Pregnancy	Core	407,039	86,572	87,709	57,966	April 2010
BBR	112140	Sub: UNITID - Improve Counsel on Implants to Prevent Pregnancy		88,593	7,059	20,497	16,620	
		<i>Total</i>		495,632	93,631	108,206	74,586	
ARD	113109	Global Advocacy and Stakeholder Engagement for LAPMs	Core	587,665	335,036	123,439	135,512	April 2010
ARD	113110	Repositioning FP-Revitalizing LAPMs in Uganda	Core	219,351	235,476	17,977	-	July 2008
ARD	113111	Kenya IUD Revitalization-Transition Phase and M&E	Core	300,548	276,888	15,011	-	April 2009
BBR	112128	RCT of Three Vasectomy Techniques	Core	250,000	200,927	57,401	-	Mar. 2009
ARD	113112	MAQ IUD Subcommittee & IUD Checklist Production & Dissemination	Core	401,115	373,159	18,525	17,997	Dec. 2008
ARD	113136	IUD Revitalization in India	Core	208,960	155,339	(36,487)	102,265	April 2010
ARD	113150	Sub: FPAI: Cyclofem		50,885	-	-	50,885	
HSR	114138	India: Private Sector Assessment for FP		211,418	18,162	71,484	170,080	
HSR	114150	Sub: ORG Center for Social Research		54,527	-	10	36,922	
		<i>Total</i>		525,790	173,501	35,006	360,152	
ARD	143111	India: IUD revitaliation in India, FS	FS	136,479	3,548	130,024	2,907	
ARD	143120	Sub FPAI: Cyclofem FS		63,521	-	-	63,520	
		<i>Total</i>		200,000	3,548	130,024	66,427	
BBR	172012	Non-Invasive Approaches to Male Sterilization	NIH	6,000	-	1,201	4,799	April 2010
BBR	172013	Sub: UNC-Charlotte	NIH	209,425	-	15,277	194,396	
		<i>Total</i>		215,425	-	16,478	199,195	
Youth								
HSR	114146	Strengthening RH Counseling for Youth Seeking PAC	Core	248,355	-	105,866	139,413	April 2010
ARD	113144	Global Knowledge Management: Phase II	Core	300,000	-	202,182	99,583	April 2010
ARD	183000	Global Knowledge Management: Phase II	Core-OHA	400,000	-	178,359	22,859	
ARD	113143	Promising Practices and Materials for RH/HIV for Youth	Core	300,000	-	97,028	202,972	April 2010
ARD	183001	Promising Practices and Materials for RH/HIV for Youth	Core-OHA	400,000	-	70,466	129,534	
ARD	125005	Global Knowledge Management: Youth RH/HIV Prevention	GLP-HIV	400,000	264,050	55,741	66,609	Nov. 2008
ARD	125001	Global Knowledge Management: Youth RH/HIV Prevention	GLP	400,000	489,639	2,940	(66,683)	July 2008
ARD	125003	Global Knowledge Management: Youth Reports	GLP-HIV	300,000	174,124	130,519	9,369	Nov. 2008
ARD	125002	Global Knowledge Management: Youth Reports	GLP	300,000	255,957	17,648	123	

CRTU Year 4 (July 2008 - June 2009) Expenditures & Year 5 (July 2009 - April 2010) Workplan

Group	FCO	Title	Fund Source	LOSP Budget	CRTU Expenditures Yrs. 1-3	CRTU Expenditures Year 4	CRTU Budget Year 5	Projected End Date
ARD	143101	Evaluation of What's New and Cool for Youth Booklet	FS	520,721	314,568	48,952	155,193	April 2010
ARD	143118	<u>Evaluation of What's New and Cool for Youth Booklet (FS)</u>		<u>95,000</u>	<u>-</u>	<u>-</u>	<u>98,016</u>	
		<i>Total</i>		<i>615,721</i>	<i>314,568</i>	<i>48,952</i>	<i>253,209</i>	
ARD	153131	S Africa: ABC Approach Youth Univ Campuses 2008	PEPFAR	97,889	72,165	(22,381)	79,264	Dec. 2010
ARD	153132	Sub to: BBIT: ABC Approach Youth Univ Campuses		145,671	25,106	140,665	-	
ARD	153135	<u>Sub to: Hope Africa: ABC Approach Youth Univ Campuses</u>		<u>150,441</u>	<u>-</u>	<u>80,439</u>	<u>70,001</u>	
		<i>Total</i>		<i>394,001</i>	<i>97,271</i>	<i>198,724</i>	<i>149,265</i>	
ARD	153147	Care and Prevention among Positive Youth	PEPFAR	9,780	-	-	9,780	April 2010
ARD	153146	<u>Sub: SACBC Youth Desk: Care Prev Positive Youth</u>		<u>65,300</u>	<u>-</u>	<u>35,291</u>	<u>30,008</u>	
		<i>Total</i>		<i>75,080</i>	<i>-</i>	<i>35,291</i>	<i>39,788</i>	

TOTAL (Core Funds)	25,469,786	10,468,565	9,313,997
TOTAL (GLP Funds)	2,676,770	380,302	48,702
TOTAL (Venture Capital Funds)	110,369	21,186	(18,554)
TOTAL (Core-OHA)	-	277,709	323,510
TOTAL (FS Funds)	1,931,504	1,625,847	1,492,190
TOTAL (PEPFAR Funds)	5,243,339	4,157,866	4,953,258
TOTAL (NIH-IAA Funds)	1,079,248	289,310	660,711
TOTAL (CDC-IAA Funds)	199,884	60,745	326,931
TOTAL (CSL-Core Funds)	875,334	459,458	151,877
TOTAL (CSL-FS Funds)	6,308,295	1,978,808	494,753
GRAND TOTAL	43,894,528	19,719,795	17,747,374

CRTU Year 4 (July 2008 - June 2009) Expenditures and Year 5 (July 2009 - April 2010) Workplan
Microbicide Activities

Group	FCO	Title	CRTU Expenditures Years 1-3	CRTU Expenditures Year 4	CRTU Budget Year 5	PTA FCO	PTA Budget Year 1	TOTAL CRTU Year 5 + PTA Year 1
BBR	Total	SAVVY (Nigeria & Ghana)	5,540,902	109,222	1,766		-	1,766
BBR	Total	CAPRISA Phase IIB	4,065,808	4,982,897	2,145,158	Total	2,063,382	4,210,306
BBR	Total	Case Control Analysis of Microbicide Use	164,875	174,869	56,650	Total	317,964	374,614
BIOS	139101	Statistical support-microbicides	131,424	59,426	13,529	805241	30,467	43,996
BBR	Total	Next Steps for New Female Condoms	731,950	133,893	6,739	805234	24,252	30,991
BBR	Total	SIDI	5,122,860	8,434,282	1,574,367	Total	679,469	2,253,836
BBR	Total	FEM-PrEP	3,645,637	4,968,780	2,645,674	Total	7,165,108	9,810,782
ARD	133101	Good Communication Practices for M'cide Studies	120,667	156,645	43,075	806201	53,609	96,683
BBR	Total	Evaluating Informed Consent	8,365	123,171	55,968	Total	211,194	267,162
HSR	Total	Improved Measure, Pregnancy Intent	8,836	55,913	-	Total	-	-
BBR	136115	Assuring Stakeholder Involvement in New M'cide Studies	22,738	192,746	21,344	805212	44,658	66,001
ARD	133100	South Africa ECP Implementation	218,913	148,594	6,251	806200	18,751	25,002
SF	132109	CONRAD: Assessment of Soluble & Cellular Markers	128,257	144,287	20,618	805243	5,600	26,218
SF	132111	CONRAD: UC-781 Male Tolerance	74,045	39,676	8,249	805244	3,169	11,418
SF	132149	CONRAD: Biomarkers of semen exposure	19,386	52,515	62,618	805238	22,517	85,135
SF	132147	CONRAD: UC-781 PK Study	2,188	360	53,381	805239	26,288	81,669
SF	132176	CONRAD Coordination	-	139,885	155,249	805236	58,918	214,167
SF	132177	CONRAD: SILCS Diaphragm	-	230,249	275,381	805235	118,697	394,078
SF	n/a	CONRAD: Mucosal Studies	-	-	-	805237	44,350	44,350
SF	n/a	CONRAD: UC-781 Pilot Studies	-	-	-	805240	44,608	44,608
SF	n/a	CONRAD: Biomarkers Interference	-	-	-	TBD	-	-
PAR	n/a	Reporting, Monitoring and Evaluation	-	-	-	806202	50,000	50,000
Subtotal			20,006,850	20,147,409	7,146,017		10,983,001	18,132,782
Completed Activities								
BBR	132129	Carraguard HC-HIV Analysis	12,189	112,258	-			
SF	132101	Independent monitoring, CONRAD	18,045	42	-			
SF	132112	CONRAD MRI Microbicide Formulation	1,932	242	-			
SF	132148	CONRAD: Ph. I Study of Q-2 Vaginal Gel	1,242	218	-			
SF	Total	CONRAD: Diaphragm plus microbicide	-	1,163,000	-			
BBR	136103	Use of DHS Data for Site ID Recruitment	1,497	34,296	-			
BBR	Total	New Delivery Device	461,592	118,063	-			
BBR	Total	Microbicides Acceptability in India	287,283	152,211	-			
BBR	Total	CS Phase III Study	6,061,237	55,567	-			
Total			27,659,270	21,776,835	7,146,017		10,983,001	18,132,782



APPENDIX A

**Family Health International
List of CTR/CRTU – Supported Publications
July 1, 2008 – June 30, 2009**

Appendix A

List of CTR/CRTU-Supported Publications

July 1, 2008- June 30, 2009

Since the 2007-2008 CRTU Annual Report, FHI's Library has documented the publication of 40 new articles or other writings authored or coauthored by FHI staff and/or investigators, and supported—in whole or in part—by either the CTR or the CRTU. These publications serve to disseminate research results, synthesize what is known, and respond to current concerns regarding family planning and reproductive health.

Final cost objective (FCO) numbers are provided following the citation to show first what funding supported time spent in writing the publication and secondly, if applicable, what funding supported the original research addressed by the article. The articles are grouped by the order in which they were reported to the Library.

- 2008-81 MacQueen KM, Alleman P. International perspectives on the collection, storage, and testing of human biospecimens in HIV research. *IRB Ethics Human Res* 2008 Jul-Aug; 30 (4): 9-14. (FCO-116103) (FCO-617)
- 2008-82 McCarraher D, Cuthbertson C, Kung'u D, Otterness C, Johnson L, Magiri G. Sexual behavior, fertility desires and unmet need for family planning among home-based care clients and caregivers in Kenya. *AIDS Care* 2008 Oct; 20 (9): 1057-65. (FCO-114106) (FCO-9503)
- 2008-84 Grimes DA, Lopez LM. Within subject variance and estimating degrees of confidence that 0 sperm is the true value? (author reply) *Fertil Steril* 2008 May; 89 (5): 1277-8. (FCO-112112)
- 2008-85 Grimes DA, Lopez LM. Reining in diversity--at what risk? (author reply) *Fertil Steril* 2008 May; 89 (5): 1278-9. (FCO-112112)
- 2008-97 Grimes DA. The nomogram epidemic: resurgence of a medical relic. *Ann Intern Med* 2008 Aug 19; 149 (4): 273-5. (FCO-112120)
- 2008-98 Schwartz JL, Ballagh SA, Creinin MD, Rountree RW, Kilbourne-Brook M, Mauck CK, Callahan MM. SILCS diaphragm: postcoital testing of a new single-size contraceptive device. *Contraception* 2008 Sep; 78 (3): 237-44. (FCO-112100 / 112101) (FCO-2281)
- 2008-99 Ramjee G, Doncel GF, Mehendale S, Tolley EE, Dickson K. Microbicides 2008 Conference: from discovery to advocacy. *AIDS Res Ther* 2008 Aug 15; 5 (Article No. 19): 14 p. Online. Available:<http://www.aidsrestherapy.com/content/5/1/19>. (FCO 116103)
- 2008-100 Reynolds HW, Janowitz B, Wilcher R, Cates W Jr. Contraception to prevent HIV-positive births: current contribution and potential cost savings in PEPFAR countries. *Sex Transm Infect* 2008 Oct; 84 (Suppl II): ii49-53. (FCO-113104)
- 2008-101 Wilcher R, Petruney T, Reynolds HW, Cates W Jr. From effectiveness to impact: contraception as an HIV prevention intervention. *Sex Transm Infect* 2008 Oct; 84 (Suppl II): ii54-60. (FCO113104)

- 2008-102 Aradhya KW. Microbicides for HIV prevention. *Mera* 2008 Jul; (36): iii-vi. (FCO-113118)
- 2008-103 Steward B, Hays M, Sokal D. Diagnostic accuracy of an initial azoospermic reading compared with results of post-centrifugation semen analysis after vasectomy. *J Urol* 2008 Nov; 180 (5): 2119-23. (FCO-5352) (FCO-2239)
- 2008-107 Helmerhorst FM, Lopez LM, Kaptein AA. Premenstrual syndrome (letter). *Lancet* 2008 Aug 9; 372 (9637): 446. (FCO172002)
- 2008-113 Mauck CK, Ballagh SA, Creinin MD, Weiner DH, Doncel GF, Fichorova RN, Schwartz JL, Chandra N, Callahan MM. Six-day randomized safety trial of intravaginal lime juice. *J Acquir Immune Defic Syndr* 2008 Nov 1; 49 (3): 243-50. (FCO-2295 / 132110)
- 2008-116 Rickert VI, Grimes DA. Start now or start something else? (editorial). *J Adolesc Health* 2008 Nov; 43 (5): 419-20. (FCO-112120)
- 2008-121 Van Damme L, Taylor D. Cellulose sulfate for prevention of HIV infection (authors' reply). *N Engl J Med* 2008 Nov 6; 359 (19): 2067-8. (FCO139101)
- 2008-122 Shears KH, Aradhya KW. Helping women understand contraceptive effectiveness. *Mera* 2008 Sep; (37): iii-iv. (FCO-113118)
- 2008-124 Aradhya KW. Meeting the reproductive health needs of women with HIV. *Mera* 2008 Nov; (38): iii-v. (FCO113118)
- 2008-127 Denison JA, Higgins DL, Sweat MD. Chapter 19, HIV testing and counseling. In: Mayer KH; Pizer HF, editors. *HIV prevention: a comprehensive approach*. London: Academic Press; 2008 Oct; 524-49. (FCO-058 / 116103)
- 2008-129 MacQueen KM, McLoughlin K, Alleman P, Burke HM, Mack N. Partnering for care in HIV prevention trials. *J Empir Res Hum Res Ethics* 2008 Dec; 3 (4): 5-18. (FCOs-116103, 644)
- 2008-130 Schwartz JL, Barnhart K, Creinin MD, Poindexter A, Wheelless A, Kilbourne-Brook M, Mauck CK, Weiner DH, Callahan MM. Comparative crossover study of the PATH Woman's Condom and FC Female Condom®. *Contraception* 2008 Dec; 78 (6): 465-73. (FCO-112100)
- 2008-131 Stanback J, Krueger K. Letter to the editor, re: self-administration of injectable contraceptives. *Contraception* 2008 Dec; 78 (6): 514. (FCO-114106)
- 2008-132 Cates W, Feldblum P. HIV prevention research: the ecstasy and the agony (commentary) *Lancet* 2008 Dec 6; 372 (9654): 1932-3. (FCO116103)
- 2008-134 Nanda K, Amaral E, Hays M, Viscola MA, Mehta N, Bahamondes L. Pharmacokinetic interactions between depot medroxyprogesterone acetate and combination antiretroviral therapy. *Fertil Steril* 2008 Oct; 90 (4): 965-71. (FCO-112118)
- 2008-137 Taylor DJ, Kupper LL, Johnson BA, Kim S, Rappaport SM. Statistical models for exposure-biomarker relationships with measurement error and censoring. *J Agric Biol Environ Stat* 2008 Dec; 13 (4): 367-87. (FCO-119100)

Appendix A– List of Supported Publications

- 2008-146 Harrison P et al including, Cates W, Coletti AS, Dorflinger LJ, Feldblum P, Halpern VG, Taylor D, Tolley EE, Van Damme L. Challenges in HIV-prevention microbicide research (e-letter) *Science* 2008 Dec 17; 6 p. Online.
Available:<http://www.sciencemag.org/cgi/eletters/321/5888/532#11839>. (FCO116103)
- 2008-148 Gallo MF, Grimes DA, Lopez LM, Schulz KF, d'Arcangues C. Combination injectable contraceptives for contraception. *Cochrane Database Syst Rev* 2008 Oct 8; (4): CD004568, 31 p. (FCO-2703)
- 2008-149 Gallo MF, Lopez LM, Grimes DA, Schulz KF, Helmerhorst FM. Combination contraceptives: effects on weight. *Cochrane Database Syst Rev* 2008 Oct 8; (4): CD003987, 57 p. (FCO-5206 / 172002 / 112112)
- 2008-150 Gallo MF, Nanda K, Grimes DA, Lopez LM, Schulz KF. 20 mcg versus >20 mcg estrogen combined oral contraceptives for contraception. *Cochrane Database Syst Rev* 2008 Oct 8; (4): CD003989, 46 p. (FCO-5206)
- 2009-06 Morrison CS, Turner AN, Jones LB. Highly effective contraception and acquisition of HIV and other sexually transmitted infections. *Best Pract Res Clin Obstet Gynaecol* 2009 Apr; 23 (2): 263-284. (FCO-116103)
- 2009-08 Lopez LM, Tolley EE, Grimes DA, Chen-Mok M. Theory-based interventions for contraception. *Cochrane Database Syst Rev* 2009 Jan 21; (1): CD007249, 74 p. (FCO-112112 / 172002)
- 2009-10 Moffett J. Improving women's access to injectable contraceptives. *Mera* 2009 Jan; (39): iii-iv. (FCO-113118)
- 2009-11 Yotebieng M, Turner AN, Hatzell Hoke T, Van Damme K, Rasolofomanana JR, Behets F. Effect of consistent condom use on 6-month prevalence of bacterial vaginosis varies by baseline BV status. *Trop Med Int Health* 2009 Apr; 14 (4): 480-6. (FCO-114106) (FCO-9368)
- 2009-18 Schwingl PJ, Meirik O, Kapp N, Farley TM, HRP Multicenter Study of Prostate Cancer and Vasectomy. Prostate cancer and vasectomy: a hospital-based case-control study in China, Nepal and the Republic of Korea. *Contraception* 2009 May; 79 (5): 363-8. (FCO-5287)
- 2009-19 Mauck CK, Weaver MA, Schwartz JL, Walsh T, Joanis C. Critical next steps for female condom research -- report from a workshop. *Contraception* 2009 May; 79 (5): 339-344. (FCO-112100) (FCO-119100)
- 2009-20 Chin-Quee D, Otterness C, Wedderburn M, McDonald O, Janowitz B. One versus multiple packs for women starting oral contraceptive pills: a comparison of two distribution regimens. *Contraception* 2009 May; 79 (5): 369-74. (FCO-114106) (FCO-9335)
- 2009-21 Aradhya K, Petruney T, Shears K, Lasway C. Four strategies to help women use combined oral contraceptives. *Mera* 2009 Mar; (40): iii-vi. (FCO-113118)
- 2009-29 Lopez LM, Tolley EE, Grimes DA, Chen-Mok M. Theory-based strategies for improving contraceptive use: a systematic review. *Contraception* 2009 Jun; 79 (6): 411-7. (FCO-112112 / 172002)
- 2009-30 Deans EI, Grimes DA. Intrauterine devices for adolescents: a systematic review. *Contraception* 2009 Jun; 79 (6): 418-23. (FCO-112112) (FCO-112112)

Appendix A– List of Supported Publications

- 2009-38 McCormack S, Taylor D, Richardson B, Darbyshire J, Sattentau Q, Karim QA, Karim SS, Kharsany A, Lacey C, Nunn A, Weber J. Re: "Enhancement of HIV infection by cellulose sulfate," by Tao et al (letter) *AIDS Res Hum Retroviruses* 2009 Mar; 25 (3): 373.
(FCO 139101)
- 2009-45 Aradhya K. Family planning for breastfeeding women. *Mera* 2009 May; (41): iii-iv.
(FCO-113118)



APPENDIX B

Subprojects by Region/Country and Current FCO(s)

AFRICA

Africa Regional

Assessing Provision of Family Planning and Reproductive Health Services in Commercial Sector HIV/AIDS Programs	124102
FP in Context of HIV: Supporting Evidence-Based and Promising Practices in Africa	113131
Improving Measurement of Pregnancy Intentions	134000/134001
Increasing Family Planning Uptake among Postpartum Women: Testing Supply and Demand Solution	112137/114128/890030
Sociobehavioral Research and Community Planning to Develop Site-Specific Pilot Intervention Plans for PrEP Rollout	136123
Technical Assistance to Improve Family Planning Uptake	113133
Truvada FEMPrEP Phase III Clinical Trial	12302/12322/12341/132146/132157/ 132158/132159/132168/132169/132170/132179/132180
Truvada FEMPrEP: Social, Behavioral & Community Activities	12354/12355/136109/136117/ 136121/136122

Democratic Republic of Congo

Integration of FP Services into Counseling and Testing Sites	143106/143112/143113/143113/ 143121/143122/143123
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Ghana

Evaluation of Integrating Family Planning into ART Services in Ghana Savvy® Phase III RCT,	124101 2278/132105/ 132121/132140/132141/132144
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Kenya

Assessing the Future Role of Implants	112122
Building Strategic Information Capacity within NASCOP	153102
Development and Evaluation of a Campaign to Increase Continuation of Hormonal Methods	116105/116110
Evaluating the Young Men as Equal Partners Project	114100/114122/114123
Examining the Family Planning Needs of Women Traditionally Targeted for HIV/STI Services	124100/124105
Improved Counseling on Implants to Reduce Unintended Pregnancy	112129
Improving FP Counseling of Clients	144102
Improving Use of Family Planning in VCT	114104/153103
Integration of Family Planning into Comprehensive Care Centers	114114/124104
Kenya Division of Reproductive Health Capacity Development: Follow-on Activity	143103
Kenya FP/PMTCT Integration Assessment	144101/154101
Kenya Field Support Management	143100
Kenya IUD Revitalization - Transition Phase and M & E	113111
Kenya Information Management: Hormonals & HIV	143102
Kenya PEPFAR Management	153106
Kenya: Enhanced Country Program Implementation	113122
Kenya: Evaluation of What's New & Cool for Youth" Booklet	143101
Kenya: Sub: ABC Approach for Infection Prevention and Averting Unintended Pregnancies Among Youth in Institutions of Higher Learning	153110/153111
Risk of HIV and Feasibility Research Among House Girls in Nairobi	154100/154102/154104/154505
Safety of Implant Use among Women on ARVs	112136
Scale-up and Global Dissemination of Kenya's FP/VCT Integration Package	113126/123102

Site Identification, Assessment & Development	1041/132113/132118/132145
Understanding Fertility Desires and Demand for Contraceptive	
Use of Women on Antiretroviral Therapy in Comprehensive Care Centers	153134/156100
Youth Integrated FP and HIV Service Delivery Models	114130
Madagascar	
Assessment of Late DMPA Client Management	114113
Immunization Services as an Entry Point to Family Planning	114141/114148
Increasing Access to Postpartum Family Planning Services	114116/114132
Introductory Trial of Community-based Distribution of Enhanced Country Program	113129
Malawi	
Using Male Educators to increase Family Planning use among young married couples in Malawi	116108
Nigeria	
Expand Global Evidence Base CBD-DMPA Introduction	113142/113152
Evidence-based Child Spacing Intervention Development for Northern Nigeria	143104/146001
Rapid Programmatic Assessment for FP/VCT Integration	113105
Operations Research: Male Motivators Promoting Family Planning in the Nigeria Police Force	114109
Randomized Controlled Trial of Cellulose Sulfate (CS) Gel and HIV	2266/132100/132122/132123/ 132124/132125/132143
Savvy Phase III RCT	2277/132104/132126/132127/132128/ 132139
South Africa	
ABC Approach for Youth on University Campuses	153101
Acidform Behavioral Data Analysis	116101
Enhancing PMTCT Performance	153104
Expansion of Strengthening Linkages Between HBC, FP, ARV	153128/153129/153138
Evidence for Extending the DMPA Re-Injection Interval	114118
Family Planning & HIV Service Integration: South Africa Network of Champions	113127
Feasibility of Randomized Trial to Evaluate the Effect of DMPA on STI	112119/112132/ 112133/112134
Formative Research to Determine the Feasibility of Recruitment for "True Efficacy" Trials	116104/116107/116112
Improving Continuation Rates for Injectable Contraceptives	114102/114126
Next Steps for Clinical Research of New Female Condoms	112111/132114/132142
RCT of Tenofovir Gel	132108/132119/132120
Savvy: Phase III HIV Study	132116
Savvy® Phase III RCT, Ghana	2278/132105/132121/132140/132141/132144
Advance Account	113101
PEPFAR Management	153107
Case Control Study Analysis of Microbicide Use and HIV Infection	136104/136107
Enhanced Country Program Implementation	113123/133100
Integrated Community Palliative Care Project (ICPC)	153122/153123/153124//153125/ 153126/153127/153136/153139/153140/153142/153143
Microbicides: Carraguard Phase III Trial Interim Analysis for DSMB	139100

Tanzania

Expanding Access to Hormonal Contraceptives through Drug Shops	113135/113155
Facilitated Referrals to Promote FP Access Among HIV-Positive Women at HIV Care and Treatment Centers	114136/114151
Implementing and Evaluating FP and VCT Services Integration	114115
Risk Reduction through Role Models for Young Men: Intervention, Adaptation and Testing	114117

Uganda

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Evaluating the Young Men as Equal Partners" Project	114100/114122/114123
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ADVISORY COMMITTEE ROSTERS

July 2008 through June 2009

FAMILY HEALTH INTERNATIONAL

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- | | | | |
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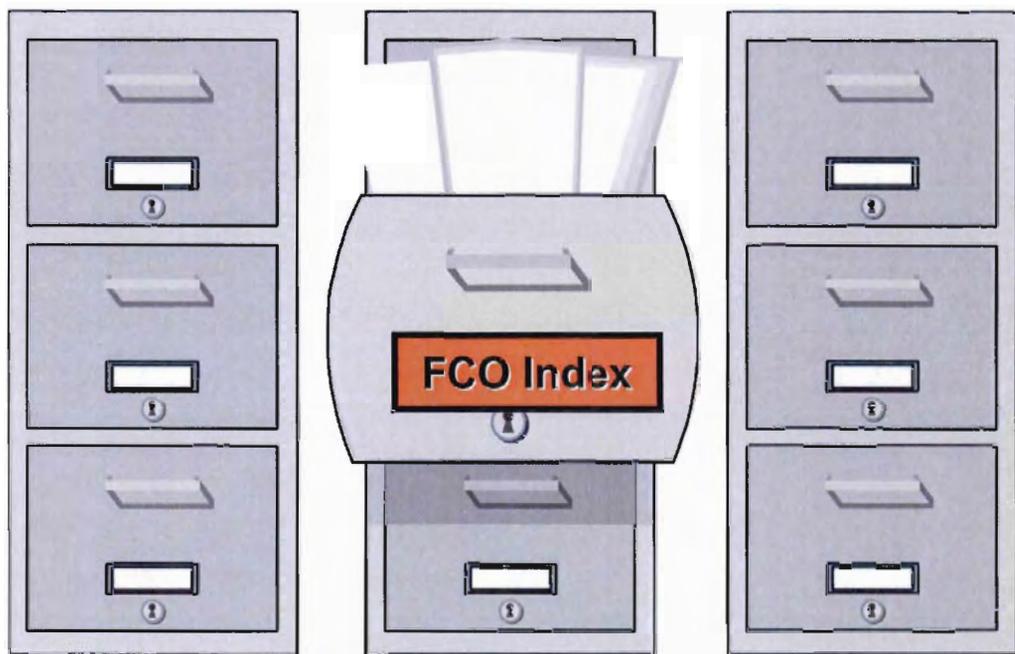
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