USAID FROM THE AMERICAN PEOPLE

fhi360 THE SCIENCE OF IMPROVING LIVES

PTA PREVENTIVE TECHNOLOGIES AGREEMENT

This PDF is interactive

ENTER HERE

END-OF-PROJECT REPORT

Preventive Technologies Agreement (PTA)

Advancing the Science of HIV Prevention









The U.S. Agency for International Development (USAID) awarded the Preventive Technologies Agreement (PTA) to FHI 360 in 2009. The *PTA End-of-Project Report: Advancing the Science of HIV Prevention* provides an overview of the results and accomplishments of the five-year PTA project.

For additional information on particular activities or technical areas undertaken by the PTA, please see the PTA website at http://www.fhi360.org/projects/preventive-technologies-agreement-pta

Photo credits:

cover and page 2, Jessica Scranton
page 4, Sarah Mullins/FHI 360
cover and page 5, Natasha Mack/FHI 360
page 7, Natasha Mack/FHI 360
cover and page 9, Jessica Scranton
page 10, Michele Lanham/FHI 360
page 11, Natalie Eley/FHI 360
cover and page 12, Michele Lanham/FHI 360
page 15, Jessica Scranton
cover and page 16, Leigh Wynne/FHI 360
cover and page 17, Jessica Scranton
page 18, Ian Taylor
cover and page 22, Sarah Mullins/FHI 360
page 23, James Kilonzo, Courtesy of Photoshare
page 24, Jessica Scranton
cover and page 25, Kim Best
page 26, Kim Best
page 27, Jessica Scranton

Table of Contents

Introduction

According to the Joint United Nations Programme on HIV/AIDS, more than 35 million people worldwide are still living with HIV, and more than 2 million people are being newly infected each year. In 2009, the U.S. Agency for International Development (USAID) awarded FHI 360 the five-year Preventive Technologies Agreement (PTA) to help develop selected HIV prevention technologies and strategies to advance the global HIV prevention and health agenda. FHI 360 and its partners achieved these goals by generating knowledge about biomedical, behavioral, and programmatic solutions to HIV prevention and providing scientific support and technical assistance to governments and nongovernmental organizations in 15 countries.

KEY RESOURCE

» The Preventive Technologies Agreement

Prevention research under the PTA focused on women in sub-Saharan Africa, who have a continuing need for effective woman-controlled methods of HIV prevention. The Joint United Nations Programme on HIV/AIDS reports that 70% of new infections each year happen in this geographic area. A disproportionate 57% of people living with HIV there are women. Gender norms in many cultural contexts translate into women's lack of control over their sexual lives, leaving many unable to negotiate condoms without risking suspicion or even violence from their partners.

During the PTA, FHI 360 brought together a professional team of experts in clinical, epidemiological, behavioral, and operations research and in biostatistics, data management, research ethics, regulatory affairs, research dissemination and utilization, adult education, field program management, and product quality assurance. This multi-disciplinary team — a strength of FHI 360's approach to prevention research — contributed to the PTA's evolving research and research support agenda.

This report summarizes five years of PTA-supported accomplishments in HIV prevention research, the integration of HIV prevention and reproductive health technologies, and technical leadership and support for HIV prevention research, field activities, and product quality and compliance. The appendix at the back of the report lists the more than 150 peer-reviewed journal articles, technical briefs, and practical tools developed and disseminated under the agreement.

HIV Prevention for Women

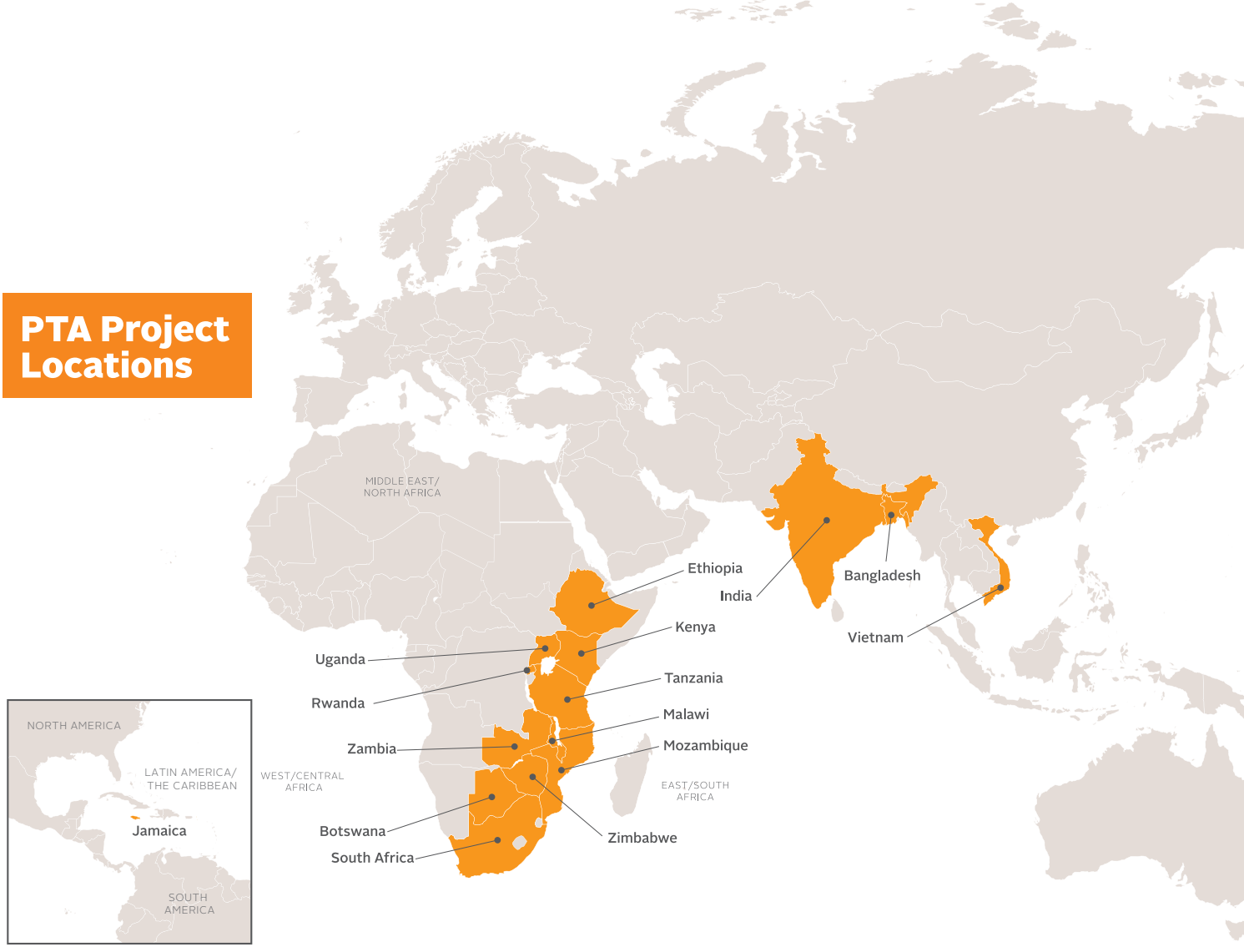
Research to identify an HIV prevention method that women could control, which accounted for the greatest portion of work completed under the PTA, first focused on the efficacy of products containing antiretroviral (ARV) drugs. The PTA supported the CAPRISA 004 study of tenofovir gel in South Africa and implemented FEM-PrEP in three African countries. FEM-PrEP was a randomized controlled trial of oral Truvada — a combination of the ARV drugs tenofovir disoproxil fumurate and emtricitabine used to prevent HIV in an approach known as pre-exposure prophylaxis (PrEP). Both trials included intensive social, behavioral, and community components to address the many challenges of conducting sophisticated randomized controlled trials in resource-poor settings.

Although CAPRISA 004 demonstrated partial effectiveness of tenofovir gel, adherence to the study regimen was a challenge in both CAPRISA 004 and FEM-PrEP. For the FEM-PrEP trial in particular, a question remained: Why did so many women in the trial not use the products? HIV prevention technologies — the focus of the PTA — do not exist in a social vacuum, and their use depends on several contextual factors. For example, life situations that make individuals vulnerable to disease also make it difficult for them to fulfill the requirements of a clinical trial, including product adherence.

With questions about adherence looming large, the attention of PTA-funded HIV prevention research later turned toward more behavioral and social science research in Kenya and South Africa. Both qualitative and quantitative data from the CAPRISA 004 and FEM-PrEP trials were analyzed to better understand women's perceptions of trial participation and HIV risk and their motivations for adherence and study retention. Research with women who did not adhere to the study product during the FEM-PrEP trial was also conducted to find out why these women had not taken Truvada as directed.

During the past five years, studies such as CAPRISA 004, iPrEx, Partners PrEP, the TDF2 trial, and the Bangkok Tenofovir Study have shown the effectiveness or partial effectiveness of ARV-based prevention when used as directed. As part of USAID's shared vision and strategic plan for microbicide introduction, the PTA supported preparation for the eventual rollout of such products into national health systems by exploring personal, social, and structural dynamics likely to influence women's use of the products outside of clinical trials. Studies focused on delivering microbicide services through the health system, creating demand for products through communication activities, and adapting a gender analysis tool to identify and address potential barriers in specific service contexts.

PTA Project Locations



Integration of HIV Prevention and Reproductive Health Technologies

Contraception is a proven strategy for preventing new HIV infections. By preventing unintended pregnancies in women with HIV, contraception can reduce HIV-positive births and, by extension, the number of children needing HIV treatment, care, and support. Contraception in the form of correct and consistent condom use can also prevent the sexual transmission of HIV, thereby contributing to the prevention of HIV both in infants and in the general population. Under the PTA, FHI 360 built on work begun under the USAID-supported Contraceptive and Reproductive Health Technologies Research and Utilization program, by conducting research and research utilization activities to improve the integration of HIV prevention and reproductive health programs. Activities focused on gaining a better understanding of how best to reach women and youth at risk of HIV with family planning (FP) and HIV prevention information and services, determining the cost-effectiveness of specific configurations of services, and providing information and technical assistance to national programs as they move forward with developing models of FP/HIV integration.

Research Support, Field Support, and Product Quality and Compliance

Under the PTA, FHI 360 helped facilitate the HIV prevention research and programs of other USAID cooperating agencies, such as CONRAD, and programs funded by the National Institutes of Health. This was accomplished through technical, clinical, regulatory, quality assurance, data management, biostatistical, communications, and behavioral leadership and support. In addition to supporting core-funded activities, USAID country missions in Botswana, Kenya, Malawi, and South Africa accessed FHI 360's technical assistance for HIV prevention through buy-ins to the PTA on an as-needed basis. To complement this work, FHI 360 provided technical assistance to USAID's contraceptive security and logistics program, ensuring that USAID's reproductive health commodities — including a high volume of condoms — met international quality standards.

HIV Prevention Clinical Trials

Two biomedical HIV prevention clinical trials conducted with support from the PTA — CAPRISA 004 and FEM-PrEP — were instrumental in testing and preparing for the introduction of new HIV prevention options for women. Both were large-scale trials that collected information on the long-term safety and effectiveness of new products, but only after they had passed several other rigorous tests of safety and acceptability. Both CAPRISA 004 and FEM-PrEP examined whether specific formulations of ARV drugs, typically used to treat HIV, could also safely prevent new HIV infections.

Most microbicides for women have been formulated as vaginal gels that are intended to be used daily or to be used around the time of sexual activity. Led by the Centre for the AIDS Programme of Research in South Africa (CAPRISA) at the University of KwaZulu-Natal, CAPRISA 0040 was the first study to show the effectiveness of a vaginal gel (1% tenofovir used before and after sex) in preventing HIV acquisition among women. With support from the PTA, FHI 360 provided technical assistance to the trial, including statistical design and analysis, behavioral assessment, evaluation of safety reports for trial participants, clinical monitoring and project management, ethical and safety oversight, and communications.

ARV drugs can also be formulated as pills and used as PrEP. One example is Truvada, which combines two ARV drugs into a single pill taken once a day. Some clinical trials have shown that Truvada can prevent HIV infection, leading the U.S. Food and Drug Administration in 2012 to approve the drug as PrEP for men and women at high risk of HIV infection. However, because of low adherence to the study pills, two other trials (both among women) were not able to demonstrate the effectiveness of Truvada.

The PTA-supported FEM-PrEP trial, conducted among women at high risk of HIV infection in Kenya, South Africa, and Tanzania, was among the two trials that were unable to demonstrate effectiveness because of low adherence. However, because of the extensive social, behavioral, and community research conducted as part of FEM-PrEP, the trial was able to contribute much-needed data on factors affecting adherence to the study pills. It was also able to contribute data on how trial participants perceive their HIV risk and on behaviors related to participants that can inform future trials of novel HIV prevention technologies.

KEY RESOURCES

» CAPRISA 004

» FEM-PrEP

CAPRISA 004

CAPRISA 004 was a randomized, placebo-controlled clinical trial that assessed the effectiveness and safety of a vaginal gel containing 1% tenofovir for the prevention of HIV infection in South African women. The study achieved an important scientific breakthrough, providing the first evidence that a microbicide gel can reduce HIV and genital herpes infection in women.

After its results were announced in 2010, the CAPRISA 004 trial gained international attention. *Science Magazine* recognized it as one of the top 10 scientific achievements of 2010, and USAID awarded CAPRISA 004 its prestigious Science and Technology Pioneers Prize in 2014. The prize, established in 2013, recognizes excellence in the use of science and technology to solve the latest challenges in human development.

KEY PARTNERS

Bill & Melinda Gates Foundation

Centre for the AIDS Programme of Research in South Africa

Columbia University

CONRAD

Gilead Sciences

Gladstone Institutes

IMPACT Research and Development Organization

Institute for Tropical Medicine

JOSHA Research

Kilimanjaro Christian Medical Centre

London School of Hygiene & Tropical Medicine

SCT Consulting

Setshaba Research Center

Technology Innovation Agency

University of North Carolina at Chapel Hill

University of KwaZulu-Natal

University of San Francisco

CAPRISA partnered with FHI 360 and CONRAD to conduct the trial, which included 889 women at high risk of HIV infection at an urban site and a rural site in KwaZulu-Natal, South Africa. Women in the trial were randomly assigned either the 1% tenofovir gel or a placebo gel and advised to use it up to 12 hours before sex and again as soon as possible within 12 hours after having sex, for a maximum of two doses within 24 hours.

Results showed that the 1% tenofovir gel was 39% effective in reducing a woman's risk of becoming infected with HIV and 51% effective in preventing herpes simplex virus type-2 infection. These protective effects increased as adherence to the product's dosing regimen increased. For example, women who used the gel in more than 80% of their sex acts had a 54% reduction in HIV infections, whereas those who used the gel in less than half of their sex acts had a 28% reduction in HIV infections.

Tenofovir gel could fill an important HIV prevention gap by empowering women who are unable to successfully negotiate mutual faithfulness or condom use with their male partners. Since women with genital herpes are much more likely to become infected with HIV, the additional protection oftenofovir gel against herpes creates a second mechanism whereby the gel may have an impact in preventing HIV. Should current studies of tenofovir gel confirm the results of CAPRISA 004, widespread use of the gel could prevent more than half a million new HIV infections in South Africa alone over the next decade.

CAPRISA 104 and 106

Because good adherence is necessary for researchers to be able to assess the efficacy of any potential biomedical HIV prevention product and to assure effectiveness if a product is rolled out, FHI 360 in collaboration with CAPRISA sought to better understand adherence to 1% tenofovir gel. The results of two separate PTA-supported studies, both involving participants from CAPRISA's tenofovir gel trials, highlighted the challenges of both supporting and measuring adherence.

CAPRISA 104

In a mixed-method study known as CAPRISA 104, conducted in parallel with the groundbreaking CAPRISA 004 trial, approximately 400 CAPRISA 004 participants were interviewed to explore how variations in their gel use may have influenced the gel's effectiveness. The study demonstrated that nested observational studies allow detailed behavioral data to be collected in real time with large-scale HIV prevention trials. Although statistical modeling was limited because of biases related to self-reported adherence, this approach is promising if combined with measurements of biomarkers. The CAPRISA 104 study also generated descriptive findings on the relationship between adherence and the extent to which women told their male partners that they were participating in the study, that the study was about HIV prevention, and that the study required use of a vaginal gel.

CAPRISA 106

These nuances of partner disclosure led to the design of a second study, known as CAPRISA 106, conducted in parallel with a follow-on 1% tenofovir gel trial called CAPRISA 008. Led by CAPRISA investigators, CAPRISA 008 randomized former CAPRISA 004 participants to receive tenofovir gel either in conjunction with FP services or in the same way they had received the gel in the successful CAPRISA 004 trial. The CAPRISA 106 study, led by FHI 360 in collaboration with CAPRISA, qualitatively examined adherence among women who did and did not disclose information about the trial and the gel to their partners. It also examined the acceptability of the gel among male partners and men in the community, and described the experiences and perspectives of providers and gel recipients regarding the delivery of tenofovir gel in the context of FP.

Unlike most ARV-based prevention trials, whose participants do not know whether they have been randomly assigned to receive a placebo or an active product of unknown effectiveness, CAPRISA 008 was an open-label study. Participants were openly provided with tenofovir gel and information about the promising results of CAPRISA 004. Open-label trials like this one can reveal more about adherence and acceptability than placebo-controlled trials because the women know they are getting an active product that has some evidence of being protective against HIV if used as directed.

Preliminary results of CAPRISA 106 indicated that women and men perceive disclosure of 1% tenofovir gel use as beneficial when it is negotiated and socially supported, and that non-disclosure is practical and acceptable in some relationships. Furthermore, both men and women in the study perceived tenofovir gel as having the potential to address limitations in the current mix of HIV prevention methods.

FEM-PrEP

FEM-PrEP was a randomized, placebo-controlled clinical trial to assess the safety and effectiveness of a daily dose of Truvada to prevent HIV infection among HIV-negative women who were at higher risk of HIV exposure. The trial was conducted in 2010 and 2011 among 2,120 volunteers from four sites in Kenya, South Africa, and Tanzania. Low adherence to the study pills prevented the trial from being able to determine whether Truvada could reduce the risk of HIV infection in the study population. The results did, however, provide a wealth of information that will help guide future clinical trials and programs of PrEP for HIV prevention.

Adherence rates

Although 95% of the FEM-PrEP participants reported that they usually or always took their assigned study pills, objective data suggested otherwise. Analyses of drug concentrations in the blood of a small group of participants found that only 12% had actually achieved good adherence (i.e., were estimated to have taken the study drug at least four times per week in the preceding 28 days). Fear of being terminated from the trial was the main reason participants cited for over-reporting adherence.

Factors affecting adherence

Participants who perceived some HIV risk or liked the color of the pills were more likely to adhere to the study drug. In contrast, the main reasons participants gave for not adhering — and the main reasons partners, the community, and other participants discouraged adherence — were concerns about possible side effects or about taking a drug that had not yet been proven to be effective or safe for HIV prevention. Women using oral contraceptive pills at enrollment had lower adherence to the study pills and a higher rate of pregnancy, suggesting that these women in parti-cular may have had difficulty adhering to a daily pill regimen. These findings reinforced the key role of adherence in HIV prevention studies and the need to determine better approaches to support adherence in future PrEP programs.

Risk perception

Even though 68 participants became infected with HIV during the trial, perceptions of HIV risk were low, particularly among participants from the South African sites. Among all the women who became infected with HIV, more than half reported before seroconversion that they had no chance of becoming infected with HIV in the next four weeks. Future risk-reduction interventions should incorporate women's HIV risk perceptions into the HIV prevention discourse, as they are likely important precursors to any risk-reduction measures.

New way to measure adherence

When Truvada is metabolized in the body, the substances that are produced can be identified in peripheral blood mononuclear cells (PBMCs) — certain kinds of immune cells that need to be isolated from whole blood to be examined. Truvada metabolites in PBMCs have been used as markers of long-term adherence to the drug. However, isolating PBMCs from blood is expensive, complex, and not feasible in many settings. Drug concentrations from upper layer packed cells, which which are much easier to isolate and contain both PBMCs and red blood cells, were compared with drug concentrations from PBMCs alone. The concentrations from the two sources were well correlated, suggesting that drug concentrations in upper layer packed cells could be used as as a new and simpler measure of adherence to ARV drugs. All blood samples for the FEM-PrEP trial were analyzed at the University of North Carolina at Chapel Hill.

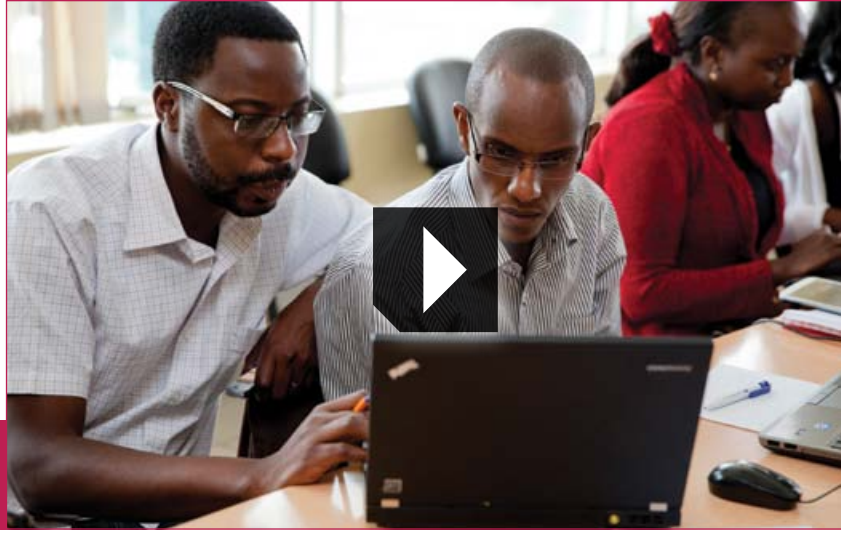
Method for verifying safe drug levels

Chemistry reference ranges (CRRs) are used to interpret drug safety in a particular population. The FEM-PrEP study team used a simple and inexpensive method to verify the CRRs in three of the trial's study sites. The method the team used resulted in different classifications of liver and kidney toxicities than would have been found using CRRs provided by the manufacturer. This finding suggested that verification of CRRs should be standard practice in clinical trials conducted in settings where normal chemistry ranges have not been validated in the local population.

Effectiveness of injectable contraceptives

Many factors may affect the effectiveness of a drug, including the length and conditions of its storage and individual characteristics that could influence a drug's metabolism and action. During FEM-PrEP, levels of medroxyprogesterone acetate in the blood were lower than expected among Kenyan participants who were using the injectable depot-medroxyprogesterone acetate (DMPA). These low levels likely reduced contraceptive efficacy, reflected in the nine pregnancies that occurred among DMPA users in Kenya. The FEM-PrEP investigators could not confirm whether this finding was due to a difference in metabolism by this population of Kenyan women, due to variable quality of the DMPA product, or due to other unknown factors. FHI 360 subsequently tested samples of product from the same manufacturer that was used in the Kenyan study site and found that the samples contained appropriate concentrations of medroxyprogesterone acetate.

Support for HIV Prevention Research



As part of the PTA's efforts to advance research on new HIV prevention and contraceptive methods, FHI 360 provided support to partners and global technical leadership in study design, data management, and biostatistical analysis. FHI 360 also worked with partners to increase the engagement of a wide range of stakeholders in the research process and to improve communication about the conduct of research and its results.

Science Facilitation

Under the PTA, FHI 360 conducted or advised on secondary analyses of data from completed HIV prevention trials, served on the scientific advisory board of the International Partnership for Microbicides, and contributed to the international discussion on how laboratory test results are used to determine an HIV diagnosis. By providing data management and analysis for CONRAD's product development program, the PTA also contributed to clinical evaluation of the safety and effectiveness of microbicide candidates, a pivotal trial of the safety and effectiveness of a new diaphragm, and methodological advances to improve the efficiency of product development.

Safety and effectiveness of microbicide candidates

Once the CAPRISA 004 trial had shown that 1% tenofovir gel could reduce the risk of infection with HIV and herpes simplex virus type-2, CONRAD developed an extensive research portfolio to evaluate the gel and other potential microbicides. (CONRAD and the International Partnership for Microbicides hold the license to develop 1% tenofovir gel for eventual market approval.) Through the PTA, FHI 360 provided data management and biostatistical support for this research, which compared different dosing regimens, assessed whether use at different phases of a woman's menstrual cycle or in conjunction with hormonal contraceptives affected the gel's safety and effectiveness, and evaluated several vaginal tablets containing different ARV drugs.

Safety and effectiveness of the SILCS diaphragm

The PTA supported CONRAD's trial of the safety and contraceptive effectiveness of the SILCS diaphragm (being marketed in Europe as the Caya diaphragm) by assisting with data management and biostatistical analysis, providing regulatory audits, and monitoring several study sites. The PTA also supported the preparation of a submission to request the approval of the U.S. Food and Drug Administration to market the SILCS diaphragm as a medical device in the United States. The SILCS diaphragm, developed by PATH, differs from traditional diaphragms in that it is made of silicone (which is more durable than latex) and comes in only one size, which makes it easier to provide.

KEY RESOURCES

- » Communications Handbook for Clinical Trials
- » Stakeholder Engagement Toolkit for HIV Prevention Trials

Methodological advances for microbicide trials

The PTA also worked with CONRAD on a methodological study exploring subtle changes in biological markers of inflammation that could signal problems with the safety of vaginal microbicide products. These biomarkers could help researchers identify, early in product development, the microbicide candidates that

could fail later safety evaluations.

Good Communication Practices

Effective communication can build public support for research, enabling studies to proceed and paving the way for the acceptance of new products or interventions. But too often, the need for a communication strategy is overlooked until a crisis arises or a study ends. Through the Good Communication Practices for Microbicides initiative, FHI 360 sought to integrate communication planning and ongoing communication support into its microbicide research from the beginning.

Communication strategies and dissemination

FHI 360's communication specialists worked with multidisciplinary teams at FHI 360 to develop and implement comprehensive communication strategies for PTA-supported microbicide and PrEP trials and to disseminate the results of those trials. Monitoring of media coverage revealed that coverage of the trials was extensive and largely balanced and accurate, regardless of whether the trial results were positive or negative.

Communications handbook for clinical trials

The PTA spearheaded an effort, in collaboration with the multi-partner Microbicides Media and Communications Initiative (MMCI), to document and share the lessons the group's members had learned about communication in HIV prevention trials. The result was the *Communications Handbook for Clinical Trials*, published by FHI 360 and the MMCI in 2010. Offering practical guidance on how to anticipate and respond to the special communication challenges posed by clinical research, the handbook features more than 40 contributions from researchers and communication experts who share ideas, tips, and lessons learned from their experiences in Africa, Asia, Europe, Latin American, and the United States.

More than 2,000 copies of the *Communications Handbook* were distributed to individuals working on HIV prevention trials in more than 125 organizations in 33 countries. In a survey of handbook users that the PTA conducted with AVAC in 2013, respondents said they found the handbook useful and easy to use. Almost 82% agreed that the topics covered in the handbook helped them do their job.

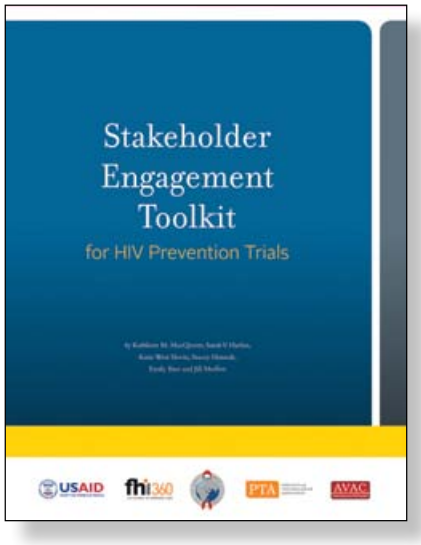
FHI 360 worked with the MMCI to promote the use of the handbook and to enhance the resource based on feedback from users. A CD version was launched at the International AIDS Conference in 2012. And in 2014, the PTA produced a user-friendly online version of the handbook, with additional resources such as videos, slide presentations, and new case studies.

Assuring Stakeholder Involvement

Many people have a stake in the conduct and outcome of a clinical trial, from members of the communities where the research is done to policymakers and regulatory officials. The benefits of involving these groups at every stage of a trial are widely recognized, but little systematic guidance is available on how to

engage stakeholders effectively and efficiently.

Under the PTA, FHI 360 collaborated with AVAC to fill that gap by developing a *Stakeholder Engagement Toolkit for HIV Prevention Trials.* The 200-page toolkit offers research teams a step-by-step guide to working with a wide range of stakeholders before, during, and after a trial. Based on best practices and the experience of clinical trial experts and community-based advocates, the toolkit was designed to help research teams deepen their relationships with partners, measure stakeholder engagement, and address community concerns in ways that create opportunities for dialogue.



Launched at the International AIDS Conference in 2012, the toolkit was disseminated widely in pdf format on flash drives to research teams in the field. Based on user feedback, it was also made available in print, on CD, and on the FHI 360 website, along with the *Toolkit Quick Guide* — a new electronic resource developed to accompany the toolkit. The quick guide includes hyperlinks to tools and other resources in the toolkit, including Microsoft Word or Excel files of all the tools, which allow users to adapt them as needed.

Under the PTA, FHI 360 also developed a half-day training session on the use of the *Stakeholder Engagement Toolkit.* The session was pilot-tested at the annual meeting of the HIV Prevention Trials Network in 2014, providing members of this global research network with enhanced skills, systems, and tools for ensuring stakeholder involvement in HIV prevention research.

KEY PARTNERS

AVAC

CONRAD

International Partnership for Microbicides

Microbicides Media and Communications Initiative

PATH

Population Council

Microbicide Implementation

KEY RESOURCES

- » Gender and Male Engagement in Microbicide Introduction
- » Communicating about Microbicides with Women in Mind

Now that several clinical trials have shown the effectiveness of oral PrEP — and CAPRISA 004 has shown that a vaginal microbicide gel can reduce women's risk of infection, with a confirmatory study under way — the next challenge will be to ensure access to the products and encourage their use. USAID's shared vision and strategic plan for microbicide introduction, which includes a variety of work conducted under the PTA, aims to speed that process by beginning now to prepare for eventual microbicide introduction.

Gender and Male Engagement in Microbicide Introduction

Microbicides hold promise as an HIV prevention method that women could control, or at least initiate, if an effective product is licensed for introduction. However, women are still likely to face gender-related barriers to accessing and using microbicides. Furthermore, male partners will likely play a role in the effective use of the technology. During the PTA, FHI 360 and partners implemented gender analyses in two countries to identify gender-related barriers to access and use, and ways to address them. They also worked with partners to collect and analyze data on male engagement and to develop recommendations for engaging men in future microbicide research and product introduction.

Addressing gender

FHI 360 took USAID's approach to gender analysis, adapted it to the context of microbicide introduction, and conducted gender analyses in Kenya and South Africa (in partnership with Sonke Gender Justice). Each gender analysis included a desk review of relevant literature and population-level data, a policy analysis, and interviews with more than 30 key stakeholders.

Stakeholders thought microbicides should be an option for all women, particularly when they experience difficulty negotiating condom use. They warned that marketing only to women at the highest risk of HIV infection could stigmatize microbicide products. To maximize access, stakeholders recommended that microbicides be made available free of charge and through health services that women and youth already access.

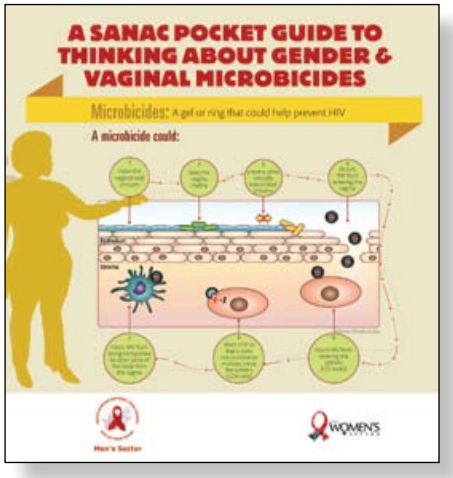
Most stakeholders acknowledged that support from male partners could facilitate access to, acceptance of, and consistent use of microbicide products, and they recommended promoting positive male engagement. The stakeholders affirmed, however, that women have the right to choose whether to tell male partners about microbicide use and thought health care providers should be trained to help women decide whether and how to do so.

Based on recommendations from stakeholder meetings in both Kenya and South Africa, FHI 360 and partners developed products — including advocacy materials and technical briefs — to facilitate use of the findings and promote attention to gender issues in future microbicide programs. The team also produced a guide to support replication of the gender analyses in other countries that may be planning for microbicide introduction.

Engaging men

How can programs balance the promotion of microbicides as a method that is revolutionary because it does not require men's involvement with the reality that a man often plays an important role in its effective use? With support from USAID, FHI 360 and partners explored this question during the PTA.

A consultation involving 22 experts in FP, community health, HIV prevention, and male engagement in women's health programs convened in January 2013 to help guide the design of formative research to identify the best strategies for engaging men in microbicide programs without disempowering women. FHI 360 and colleagues from the Kenya Medical Research Institute then conducted 98 interviews and two focus group discussions with women, men, health care providers, and community advisory board members in Kisumu, Kenya — many of whom had been directly involved in microbicide trials. FHI 360 also partnered with researchers from the University of Amsterdam, Population Council, and RTI International to explore qualitative data they had collected on male engagement during the previous MDP 301, Carraguard, and VOICE microbicide trials, respectively.



In November 2013, FHI 360 convened another PTA-supported expert consultation to review the findings from these studies and the formative research in Kenya. Key findings included that women in steady partnerships preferred to have their partners agreement to use microbicides. Women used several strategies to obtain partner approval, including using the product for a while before telling their partners, giving men information gradually, and continuing to bring up microbicides until resistant partners acquiesced.

Among men who were aware of a partner's microbicide use, involvement ranged from opposition to agreement (or non-interference) to active support. Both men and

women expressed a desire for men to have access to information and to be able to talk with a health care provider about microbicides. However, men rarely went to the clinic during the trials because of their work schedules, fear of HIV testing, and stigma. Based on these findings, the team developed a detailed summary of the evidence on male engagement in microbicides and recommendations for engaging men in future microbicide research and product introduction.

Communicating about Microbicides with Women in Mind

The PTA's Communicating about Microbicides with Women in Mind project explored how to market a microbicide gel so that women at risk of acquiring HIV could use it in a variety of contexts — from intimate relationships to commercial sex — while avoiding the association with infidelity that often stigmatizes condom use.

Developing microbicide messages and materials

After reviewing the literature on microbicides and HIV prevention for women and meeting with experts, FHI 360 worked with partners in Kenya to develop audience-centered communication strategies, messages, and materials about a microbicide gel. Development of the materials involved extensive consultations with potential users of microbicides and with other key stakeholders in four Kenyan cities. In-depth interviews, focus group discussions, and a message development workshop with members of the local project advisory committee were all part of the consultations.

The literature review, meetings with experts, and consultations guided the design of all materials. A

Local Project Advisory Committee

Representatives of:

Kenya National AIDS & STI Control Programme (Chair)

Department of Health Promotions, Ministry of Public Health and Sanitation

Family Health Options of Kenya

International AIDS Vaccine Initiative

Kenya Medical Research Institute

LVCT Health

National AIDS Control Council, Ministry of State in the Office of the President

National Organization of Peer Educators

Network of People Living with HIV and AIDS in Kenya

PSI Kenya

Sex Workers Outreach Programme

Kenyan firm, Artful Eyes Productions, developed prototype materials for awareness-raising (posters, TV storyboards, and radio spots), in-depth education (flip charts, an informational brochure, and a counseling algorithm), and digital media (website and social media concepts). Awareness-raising materials were framed in two ways: HIV-framed materials highlighted the HIV prevention benefit of microbicides, and materials that were not HIV-framed focused primarily on other benefits such as empowerment, greater intimacy, and increased sexual pleasure.

Assessing the impact of the materials

After two rounds of pretesting and subsequent revision of the materials, FHI 360 conducted a study to assess the potential impact of the materials and their messages. In a survey of 600 women and 200 men who previewed the awareness-raising materials, interest in using a microbicide gel was high. Almost 80% said they would be somewhat or very interested in using the gel if it were available.

The assessment revealed that the way the materials framed the benefits of microbicides had important effects on the attitudes of some groups. For example, messages about sexual pleasure and other benefits generated more interest in use than messages about HIV prevention for men and women who identified themselves as married and monogamous. Among younger participants and those who were married, materials that focused on the HIV prevention messages generated more negative attitudes toward microbicides than did materials that were not HIV-framed. Older, single participants were the least affected by the way the materials were framed.

The study also included a series of focus groups with young women and female sex workers (FSWs) to assess the effectiveness of the flipcharts for community education. Following these discussions, interest in gel use increased from 40% to 57% among the young women and from 65% to 83% among the FSWs. The desire to abandon condoms for use of a less effective gel decreased among the young women and remained low among the FSWs after participating in the educational sessions. In-depth interviews with health care providers suggested that the materials that had been developed would help them effectively counsel women about microbicides.

Based on the study's results, FHI 360 drafted recommendations for developing communication strategies and a guide that describes how programs can adapt the awareness-raising materials for use in other countries or with other HIV prevention products. Strategic development of communication materials will help ensure that everyone who might benefit from new HIV prevention products can do so.

Preparing for Microbicide Delivery: Assessing Integration of Services

Preparing health care providers and systems for microbicide introduction will require a better understanding of service integration. In Kenya, the Ministry of Health's decision to introduce a package of integrated reproductive health, HIV, and AIDS services in public health facilities nationwide offered an opportunity to study what happens in the real world when health facilities are charged with integrating an additional service.

In collaboration with the Ministry of Health's National AIDS & STI Control Programme and its Reproductive Health and Maternal Services Unit, FHI 360 documented the extent to which integrated services were being delivered in 15 public health facilities in Kenya and the factors that facilitated or impeded service delivery.

The results highlighted several challenges common to integrating HIV testing and counseling into FP and outpatient services and to integrating reproductive health, infectious disease, and psychosocial support into services for HIV-positive clients who are not eligible for antiretroviral treatment (ART). Lack of HIV test kits, overburdened staff, insufficient training, and issues of privacy and space all made integration difficult.

The data were shared with key stakeholders in March 2014 at a workshop in Nairobi, where participants discussed the challenges of integration and proposed recommendations for overcoming them. Implementation of these recommendations will help improve the current rollout of integrated services and will prepare public health facilities for the introduction of additional services, such as provision of microbicides and other forms of ARV-based prevention, when they become available.

KEY PARTNERS

Kenya Medical Research Institute

Kenya Ministry of Health

Kenya National AIDS & STI Control Programme

Population Council

RTI International

Sonke Gender Justice

University of Amsterdam

Other Social Behavioral Evidence

With PTA support, FHI 360 provided information and data on knowledge, attitudes, and protective and risk behaviors related to the prevention of HIV and sexually transmitted infections (STIs) among populations who are vulnerable to HIV infection. One study examined the impact of messages about abstinence among Jamaican women with curable STIs. Another investigated clinical trial participants' comprehension of informed consent, the results of which were used to create a tool to help overcome barriers to comprehension.

KEY RESOURCE

» A Toolkit for Developing Bilingual Lexicons for International HIV Prevention Clinical Trials

KEY PARTNERS

National Institute for Medical Research in Tanzania

Population Council

University of North Carolina at Chapel Hill

U.S. Centers for Disease Control and Prevention

Evaluating Messages about Abstinence

In a randomized controlled trial among 300 Jamaican women with curable STIs or other reproductive tract infections, the women were assigned to abstinence-only or abstinence-plus-condoms messaging during counseling. During the week after STI treatment, researchers evaluated the level of prostate-specific antigen (a biomedical marker for semen exposure) in the blood to compare the levels of unprotected intercourse between the two groups. The findings showed no statistical evidence supporting the effectiveness of one counseling message over the other for helping women avoid unprotected sex during the treatment period. Rather, the effectiveness of a particular message may be associated with a woman's previous experience. For example, women with recent condom experience may benefit more from an abstinence-plus-condoms message, and women without this experience may benefit from an abstinence-only message. Ultimately, providers should weigh condom history when determining the most appropriate counseling message for an individual patient.

Addressing Barriers to Informed Consent

Even for well-educated clinical trial volunteers who are familiar with the research process, comprehension of informed consent materials may be challenging. Add in the language barriers and unique technical terms that are common in HIV prevention research, and comprehension becomes even more difficult.

Researchers from FHI 360, the Population Council, the University of North Carolina at Chapel Hill, and the National Institute for Medical Research in Tanzania collaborated to develop a way to ensure that important technical terms do not lose their meaning when translated into local languages for use in HIV prevention trials. Through focus group discussions with women in Tanzania, the researchers identified four questioning techniques that are all important to use when deciding how to best translate technical terms.

FHI 360 and the Population Council used the study results to create a toolkit to help other researchers improve the translation of clinical research terms. The toolkit includes seven steps that researchers can use to create a bilingual lexicon of technical terms for their specific HIV prevention trial. The researchers can then use their lexicon to translate informed consent forms and to facilitate all other important communication with trial volunteers.

Family Planning and HIV Integration

Under the PTA, FHI 360 conducted biomedical, behavioral, and programmatic research to broaden the evidence base on how the FP and HIV fields intersect and how they can be better integrated in practice. FHI 360 also implemented a portfolio of research utilization activities to ensure that emerging or underused evidence was communicated to and used by audiences globally and at the country level. A large portion of this work focused on youth and their unique sexual and reproductive health needs.

KEY RESOURCES

- » AIDS Journal Supplement: Family Planning and HIV
- » Prezi: Integrating Family Planning into HIV Programs
- » Interagency Youth Working Group
- » Select Family Planning and HIV Integration Resources

Biomedical Research

Biomedical research conducted under the PTA contributed evidence on the safety and effectiveness of contraceptive methods for women living with HIV, including women on ART. FHI 360 and partners conducted a non-randomized clinical trial in South Africa and Uganda to investigate whether ART affects the effectiveness of oral contraceptives. The trial enrolled 196 women who were taking both combined oral contraceptives and ART containing the drug nevirapine, as well as 207 women who were taking combined oral contraceptives but were ineligible for ART. Comparison of ovulation rates and pregnancy rates between the two groups showed similar rates of both, suggesting that ART containing nevirapine has no notable effect on contraceptive effectiveness.

Behavioral Research

Behavioral research focused on understanding the contraceptive needs and preferences of key populations. A study in Kenya found that infrastructure, provider-client interaction, and couple dynamics were the top three barriers preventing FSWs from obtaining contraceptives. Drop-in centers were the most preferred model of service delivery, mobile clinics were the least preferred model, and participants strongly supported the provision of contraceptives from peer educators. In Bangladesh, formative assessments among FSWs and women who inject drugs revealed that

Contraceptive need and use — FSWs in Bangladesh

	Hotel FSWs (n=354) %	Street FSWs (n=323) %
Contraceptive need		
Unmet need	25	36
Met need	67	55
No need	8	9
Non-condom modern method use	47	35
Consistent condom use (5 of 5 most recent acts with each partner type)	33	25
Doesn't want a child within the next year	84	86

contraceptive knowledge and use was high among women who for the most part did not want to get pregnant in the near future. For instance, more than 90% of the FSWs were using condoms, and 37% were using dual methods — primarily condoms with either oral contraceptive pills or injectables. However, the findings also showed that condom use was inconsistent. Although important, increased access to FP information and services might not be enough to alleviate this problem, as FSWs and women who inject drugs both felt they had little control when a partner did not want to use condoms.

KEY PARTNERS

Ashokti Punorbashon Nibash

Bangladesh Women's Health Coalition

Community Health, Rehabilitation, Education, and Awareness

CONRAD

Durjoy Nari Shangha

Elizabeth Glaser Pediatric AIDS Foundation

Gold Star-Kenya

Interagency Task Team on Prevention of HIV in Pregnant Women, Mothers, and their Children

Kenya Ministry of Health

South Africa National Department of Health

Southern Africa Development Community

Uganda Ministry of Health

University of Washington

Women's Health Research Unit

World Health Organization

Zambia Prevention, Care, and Treatment Partnership II

Programmatic Research

PTA-supported programmatic research generated evidence about effective, feasible models for delivering integrated FP/HIV services in both clinic- and community-based contexts and measured the impact of the models on a range of contraceptive-related outcomes. Integrated service delivery interventions were also evaluated to determine how well they were being implemented, to document the technical and financial support required to meet quality standards, and to inform strategies for scale-up and replication.

Community-based integration

In Uganda, where HIV prevalence is rising but testing rates remain low, village health teams offer a nationwide government-supported platform for community-based reproductive health services. Under the PTA, FHI 360 collaborated with the Uganda Ministry of Health to evaluate an intervention in which village health teams that were already providing FP services (including injectable contraceptives) were trained to offer HIV testing and counseling. Between May 2012 and September 2013, 36 trained members of village health teams delivered HIV testing and counseling services. The findings suggested that the practice was safe, effective, and acceptable to the community. During dissemination meetings in April 2014, stakeholders agreed that key policymakers and technical experts should help refine and adapt the approach, which could inform the revision of Uganda's national village health team strategy.

HIV care and treatment centers

An evaluation of a "facilitated referral" model for FP/HIV integration at 12 HIV care and treatment centers (CTCs) in Tanzania found that the model had a positive overall effect on FP use among CTC clients. Among sexually active female clients, dual method use increased by 16% after the intervention. All CTC providers stated that FP integration was feasible and a good addition, although there were implementation challenges. In stakeholder discussions during dissemination of the research, the chief medical officer of the Ministry of Health and Social Welfare

expressed his support for moving forward with scaling up integrated FP and HIV care and treatment services in Tanzania. He endorsed the direct provision of FP methods — condoms, oral contraceptive pills, injectables, and implants — by service providers at all HIV CTCs in the country.

Prevention of mother-to-child transmission

Two studies supported by the PTA — one in South Africa and one in Uganda — evaluated the effect of interventions to increase contraceptive use among postpartum clients of prevention of mother-to-child transmission (PMTCT) services. In South Africa, a counseling intervention did not substantially improve knowledge and attitudes related to long-acting and permanent methods of contraception among postpartum women; use of the methods was low at baseline and remained unchanged. In Uganda, results of an intervention to involve men in FP/PMTCT services also had a limited effect on FP outcomes. Only 14% of male and female clients interviewed in facilities where the intervention was implemented reported dual method use, defined as using condoms along with another contraceptive method. Less than a third reported using condoms every time they had sex. More favorably, among men in the community who participated in a study-sponsored educational workshop, the percentage who reported that they had accompanied their wives to a health facility or had ever been tested for HIV increased after the workshop. The results of both studies revealed valuable information about the health systems challenges that must be overcome to support effective, sustainable integrated services. To broaden contraceptive options for PMTCT clients, providers must be equipped with the competence, motivation, and management support to offer an expanded range of services.

Research Utilization

Throughout the PTA, FHI 360 implemented strategic research utilization activities to increase support for and use of FP/HIV integration evidence among HIV policymakers, donors, opinion leaders, and implementers. These efforts galvanized support among funders and policymakers for more widespread implementation of FP/HIV integration in generalized epidemics. They also drew attention to issues that have been underrepresented in the global FP/HIV dialogue, such as preconception care for women living with HIV and the contraceptive needs of key populations living in countries with concentrated epidemics.

Journal supplements

Representatives of FHI 360 and the University of Washington guest edited an *AIDS* journal supplement dedicated to expanding the evidence on how the fields of FP and HIV are interrelated and how they can be better integrated in policies and programs. Produced with support from the PTA, the October 2013 supplement offered original research, cutting-edge reviews, and thought-provoking opinion pieces on topics ranging from the effects of hormonal contraception on HIV to promising practices in the integration of FP and HIV services. The PTA also supported a supplement to the *Journal of the International AIDS Society,* highlighting challenges and opportunities associated with women's use of ARV-based prevention technologies. The supplement will be published in September 2014.

Family planning and HIV integration at scale

The Zambia Prevention, Care, and Treatment Partnership II is a large HIV program funded by the U.S. President's Emergency Plan for AIDS Relief that has scaled up FP/HIV integration in an intentional and substantial way. For this reason, FHI 360 sought to document this program's experiences. By describing how the program undertook FP/HIV integration, including identifying factors that facilitated success and obstacles that hampered progress, the case study offered practical guidance to HIV implementers on how to put FP/HIV integration goals into widespread practice.

Webinar series

FHI 360 hosted a series of webinars on current topics related to reproductive health and HIV integration: FP/HIV

integration in Asia, safer contraception for women living with HIV, and hormonal contraception and HIV. The webinars provided technical updates on the topics, addressed pressing questions from the perspective of experts in the field, and engaged participants in interactive discussions. Each webinar had 20 to 60 live participants, made up primarily of technical experts, donors, government representatives, implementing partners, health care providers, and researchers. Many more people accessed the webinar content via archived materials and video streams on YouTube.

Synthesis of evidence-based practices

Evidence for the effective integration of FP and HIV services is growing, and a broad array of guidance documents and tools are available to support integrated programming. With support from the PTA, FHI 360 reviewed research findings, program experiences in the field, and technical guidance to identify and synthesize evidence pertaining to the rationale for integrating FP and HIV services, facilitators of and barriers to successful integration, and the impact of integrated FP and HIV services. A 12-page brief and narrated web-based Prezi were developed to summarize this evidence and make recommendations for institutionalizing and scaling up integrated FP and HIV services.

Integration in southern Africa

Interest in FP/HIV integration by the Southern Africa Development Community grew substantially during the PTA. To build the capacity of local stakeholders in this region to advance effective integration, an expert in FP/HIV integration from FHI 360's research utilization team was paired with a representative of Kenya's Ministry of Health who had helped lead Kenya's own integration efforts. The two visited ministries of health, implementing partners, funders, and FHI 360 staff in three key countries — Botswana, Mozambique, and South Africa — to share evidence, experiences, and lessons learned on FP/HIV integration. As a result of the visit to Botswana, the Botswana Ministry of Health sent a delegation of eight staff to Kenya in a follow-on south-to-south exchange, to inform the development of Botswana's own national integration strategy. As a result of the visit to South Africa, FHI 360 provided technical assistance to South Africa's National Department of Health between 2011 and 2013 to develop a new national policy on contraception. The policy supports the integration of FP and HIV services.

Monitoring integration

Recognizing the need to measure the implementation of integrated services, FHI 360 tested the feasibility of using existing data sources (such as service registers and routine reports) to monitor service delivery and calculate integration-related indicators. The study was conducted in four African countries: Ethiopia, Rwanda, Tanzania, and Uganda. Results showed three indicators as the most feasible for PMTCT programs to collect: the proportion of service delivery points that offer integrated FP/HIV services, the proportion of HIV-positive women who receive a FP method, and the proportion of women who are tested for HIV when accessing FP services. Widespread endorsement of these indicators could increase support for FP/HIV integration and increase the amount of data produced from routine monitoring to document the extent and impact of integrated FP/HIV services.

Youth

On average, it can take 10 to 15 years for new research results to be put into practice. With UNICEF estimating that 2,500 young people become infected with HIV each day and the World Health Organization estimating that 16 million girls give birth each year, 10 to 15 years is too long. Through the PTA, FHI 360 quickly put research results related to youth sexual and reproductive health into the hands of people with the means to use them and the will to help institutionalize new, improved practices.

Interagency Youth Working Group

During the PTA, FHI 360 managed the technical content for USAID's Interagency Youth Working Group (IYWG) — the only source of global information about preventing both unintended pregnancy and HIV among youth. On behalf of the IYWG, FHI 360's research utilization youth team synthesized evidence-based information, developed new resources and tools, and disseminated these materials to audiences around the world. Combined with strong internal and external partnerships, these activities helped highlight promising programs and approaches across sectors and geographic locations and reached a broad audience using a variety of innovative approaches to sharing knowledge.

IYWG Knowledge Management Stats

InfoNet – more than 100 issues distributed twice monthly to more than 5,000 individuals

YouthLens – 21 issues

IYWG website – visited by 30,000 people from 199 countries

E-forums – hosted 9 e-forums with a total of 5,812 participants

Twitter – 1,181 followers

Facebook – 564 "likes"

Answer the Call campaign Facebook page – 1,876 "likes"

Blog – 200 posts

IYWG resources – distributed more than 2,500 copies

FHI 360 developed the content for the IYWG website and blog, produced Youth InfoNet (a twice-monthly electronic summary of new journal articles and other publications on youth), produced YouthLens (a series of briefs on trending topics related to youth sexual and reproductive health), hosted global technical meetings and e-forum discussions, and managed the IYWG social media accounts. The resources that were developed, which are all available on the IYWG website, include *Positive Connections: Leading Information and Support Groups for Adolescents Living with HIV, It's About More than Just Sex: Curricula and Educational Materials to Help Young People Achieve Better Sexual and Reproductive Health, Promoting Partner Reduction, Evidence-Based Guidelines for Youth Peer Education,* and *Young People Most at Risk of HIV.*

Research on adolescents living with HIV

A PTA-supported study conducted by FHI 360 and three ART clinics in the Copperbelt Province of Zambia sought to better understand the sexual and reproductive health of adolescents (ages 15 to 19) living with HIV and the experiences and concerns they have with HIV care and treatment. Little was known about the HIV prevention behaviors of adolescents on ART in sub-Saharan Africa before this study, the results of which can be used to strengthen HIV care and treatment services for this important group of youth.

Interviews with adolescents living with HIV, their families, and their health care providers showed that adolescents face barriers to adhering to ART and practicing safe sex, such as fear of stigma and rejection if they disclose their HIV status. The results also showed that alcohol use was related to ART adherence and that adolescents who lived in homes where their HIV status was known were more likely to report better adherence. Overall, these findings support strengthening programs to address adolescents' self-management skills with a focus on alcohol use and family engagement. Culturally acceptable strategies are clearly needed to address the sexual and reproductive health needs of adolescents living with HIV and support HIV prevention behaviors.

Support for Field Activities

Through the PTA, FHI 360 provided local technical support to USAID field missions and their implementing partners to study and evaluate prevention technologies and strategies and to implement evidence-based programs. In Botswana, an integrated behavioral and biological surveillance survey among key populations resulted in updates to the country's national STI guidelines. A similar survey was conducted in Malawi, but the data were still being analyzed as of June 30, 2014. In Kenya, outreach workers conducted more than 12,000 door-to-door outreach activities to reach domestic workers with HIV prevention information. In South Africa, mobile service units, technical assistance to the national PMTCT program, and support to a program for newly diagnosed people living with HIV ensured access to reproductive health and HIV services for thousands of people. Furthermore, a palliative care project demonstrated the importance of community health workers in providing palliative care as an integral component of comprehensive care for people living with HIV.

KEY RESOURCE

» Botswana Behavioral and Biological Surveillance Survey

Botswana

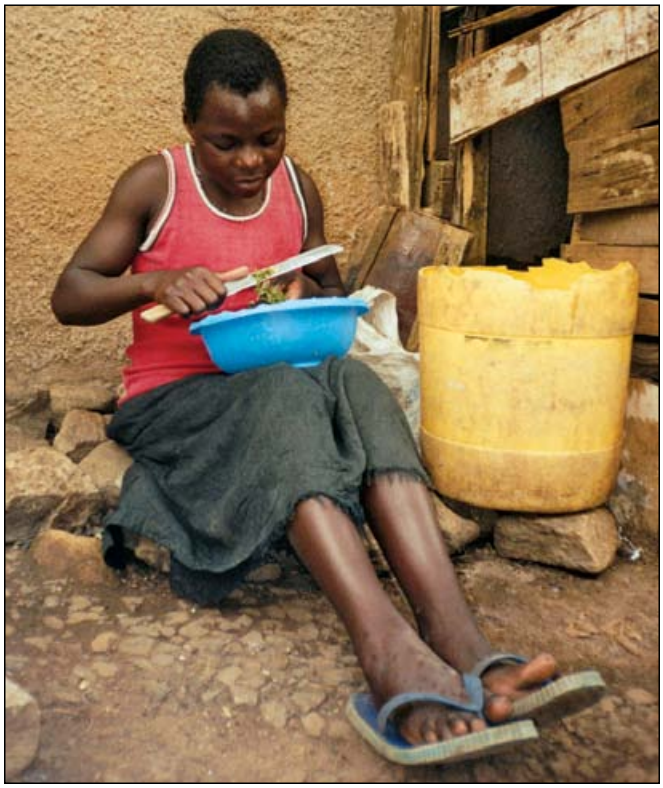
In Botswana, the estimated HIV prevalence in the general population is one of the highest in the world. In 2012, the Botswana Ministry of Health, with technical assistance from FHI 360, set out to estimate the population sizes and HIV and STI prevalences among FSWs and men who have sex with men in three districts. The results of the integrated behavioral and biological surveillance survey suggested that both FSWs and men who have sex with men (whose behaviors are stigmatized and illegal in Botswana) could be contributing to the generalized HIV epidemic and are in urgent need of better access to HIV and STI services. The study was historic, for the first time presenting findings on HIV and STI disease burden in these key populations, raising awareness of this burden, and contributing to the government's commitment to expanded action. Based on the survey's findings, Botswana's national STI treatment guidelines were updated to encourage clinicians to perform anal examinations and collect comprehensive sexual histories for men who have sex with men. The Ministry of Health also appointed a local nongovernmental organization to provide HIV and STI services directly to key populations, and additional policy and programmatic changes based on the results are possible.

Kenya

According to the Kenya Union of Domestic, Hotels, Educational Institutions, Hospitals and Allied Workers (KUDHEIHA), an estimated 1.8 million domestic workers are employed in Kenya. Because domestic work takes place in private homes, the house girls, house boys, drivers, gardeners, and guards who typically perform the work may not have access to the sexual and reproductive health information and services they need. To raise awareness about sexual and reproductive health and to equip domestic workers with life skills for making informed sexual and reproduc-

tive health decisions, the Domestic Workers Sexual and Reproductive Health project was initiated in Nairobi in May 2013. Implemented by the National Organization of Peer Educators in collaboration with KUDHEIHA and with technical assistance from FHI 360, the project provided training for domestic workers to become peer educators, sensitized health practitioners to the sexual and reproductive health needs of domestic workers, and conducted sexual and reproductive health outreach activities.

During the PTA, more than 500 domestic workers were trained to serve as peer educators, and outreach workers conducted more than 12,000 door-to-door meetings with domestic workers. The project resulted in a key health systems change: selected government health facilities extended their hours, allowing domestic workers increased access to sexual and reproductive health prevention and treatment services. The project also identified youth as an important population to target, enabling the project to address sensitive sexual and reproductive health issues that affect young domestic workers. Through the capacity building efforts of FHI 360 and the National Organization of Peer Educators, KUDHEIHA hopes to continue the project and eventually support additional efforts to address the sexual and reproductive health needs of domestic workers in Kenya.



Malawi

In 2013, with technical assistance from FHI 360, the Malawi Ministry of Health and National Statistical Office (NSO) conducted the country's third national biological and behavioral surveillance survey to better understand the HIV epidemic and maximize the use of available resources for HIV prevention. Data were collected on size estimation, HIV prevalence, STI prevalence, and risk factors among FSWs and other key populations at high risk of infection in 14 districts from three regions. The results will be used to inform strategic decisions, policies, and ongoing efforts to prevent HIV and other STIs in Malawi.

KEY PARTNERS

Botswana Ministry of Health

I Choose Life

Joint United Nations Programme on HIV/AIDS

Kenya Union of Domestic, Hotels, Educational Institutions, Hospitals and Allied Workers

Malawi Ministry of Health

Makhuduthamaga Umbrella

National AIDS Commission in Malawi

National Organization of Peer Educators in Kenya

National Statistical Office of Malawi

South Africa National Department of Health

U.S. Centers for Disease Control and Prevention

Wits Health Consortium

South Africa

With PTA support, FHI 360 in South Africa used mobile service units to ensure access to reproductive health and HIV services for more than 30,000 people, provided technical assistance to the national PMTCT program, helped coordinate a program to support newly diagnosed people living with HIV, and strengthened palliative care services.

Mobile service units

FHI 360 converted four Toyota minivans into spaces for counseling, testing, and client examinations and trained home-based care volunteers to use the spaces to provide integrated reproductive health and HIV services. These mobile service units traveled long distances to provide integrated services to four remote and underserved

provinces, reaching more than 30,000 individuals within short distances from their homes. Based on requests from the district health offices, the minivans expanded their services to include a range of comprehensive primary care services — HIV and STI prevention and education, tuberculosis screening, STI treatment, cervical cancer education, and treatment for minor ailments. In September 2013, FHI 360 transitioned the four mobile service units to three Provincial Departments of Health, which continue to provide the traveling services.

Prevention of mother-to-child transmission services

In collaboration with South Africa's National Department of Health, FHI 360 improved the overall performance of selected PMTCT sites by promoting FP counseling and referrals through training and technical assistance. Using South African and international standards for PMTCT quality assurance and improvement processes, FHI 360 refined the current training course for auxiliary nurses and lay counselors. The new training course equips these health care providers with the knowledge and skills necessary to strengthen PMTCT services, including HIV testing and counseling, provision of ARV prophylaxis, counseling and support for safe infant feeding practices, and counseling on FP.

Integrated access to care and treatment

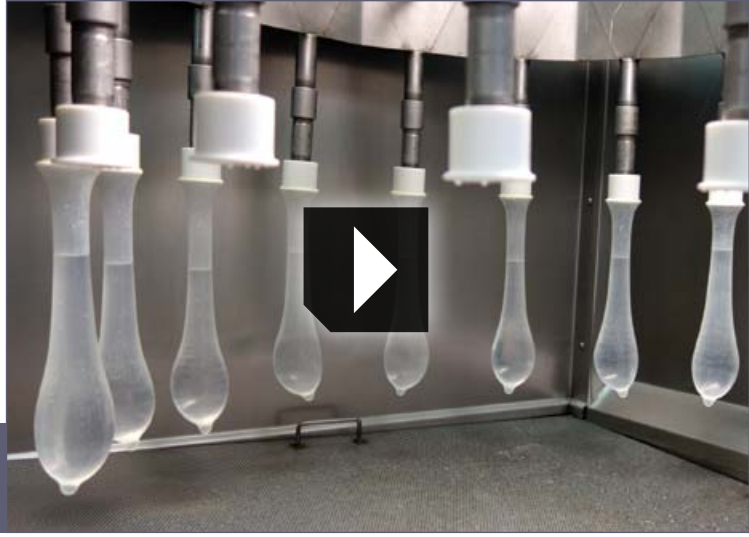
In collaboration with the Department of Health, FHI 360 helped coordinate the Integrated Access to Care and Treatment (I-ACT) program in Northern Cape Province. I-ACT is a national program that supports newly diagnosed people living with HIV who are not yet eligible for ART. The I-ACT program helps people living with HIV connect to care and support, which can help delay the need to initiate ART. A large component of this involves maintaining a network of community-based support groups and well-trained support-group facilitators. Apart from providing psychosocial support, I-ACT support groups offer six core educational sessions to give newly diagnosed people living with HIV opportunities to network with other newly diagnosed individuals. Through its involvement in the I-ACT program, FHI 360 trained more than 400 support-group facilitators and other members of the program.

Palliative care

The Integrated Community Palliative Care project was developed to link South Africa's existing health systems with support mechanisms for community care, such as home-based care, hospice, and support groups. The project integrated these support mechanisms throughout primary health care facilities and their multidisciplinary teams, ART sites and their interdisciplinary care teams, community home-based care groups, and communities and families themselves. This integrated service delivery contributed to the provision of a continuum of palliative care from diagnosis to wellness support to end-of-life care.

FHI 360 partnered with the Wits Health Consortium to support the project's pilot model in the primary health care sites of Charlotte Maxeke Johannesburg Academic Hospital. The Wits Health Consortium provides comprehensive palliative care services, including pain management, to all hospital wards and disciplines across all illnesses, including HIV and AIDS. The consortium also provides clients and families with continuous holistic support through its home visit services, hospice, and ART site. In Limpopo Province, FHI 360 provided training and technical assistance to the Makhuduthamaga Umbrella organization, which then built the capacity of four community-based organizations and four clinics to provide palliative care. Training activities focused on strengthening the capacity of community health workers, nurses, spiritual leaders, and traditional healers to provide the care.

Product Quality and Compliance



Through the PTA, FHI 360's Product Quality and Compliance (PQC) Division provided comprehensive product quality assurance and technical assistance to USAID's contraceptive security and logistics program. A variety of activities were conducted to ensure that USAID's reproductive health commodities were of the highest quality and met international quality standards.

Development of International Standards

Donor organizations use internationally recognized product-performance standards when procuring products for use in developing countries. During the PTA, the PQC Division represented USAID's interests in the standards community by leading technical committee meetings of the International Organization for Standardization and ASTM International. Through this work, FHI 360 helped guide new and revised performance standards for male and female condoms, intrauterine devices, synthetic condoms, and diaphragms.

Capacity Building

In collaboration with the World Health Organization and the United Nations Population Fund, the PQC Division supported in-country national quality assurance laboratories through in-country workshops focused on training laboratory staff to test condoms and contraceptives. These trainings were conducted in Botswana, Djibouti, Dominican Republic, Ecuador, Ethiopia, Fiji, Ghana, Kenya, Namibia, Tanzania, Thailand, and Zambia.

Production Surveillance

Evaluating and monitoring manufacturers, sampling and testing products, conducting audits and providing technical assistance, and handling product complaints and investigations all ensure low risk and protection for condom and contraceptive users. During the PTA, more than 3 billion male condoms (7,818 lots) were distributed through USAID programs, with the PQC Division testing all lots prior to shipment. An additional 492 lots of female condoms, lubricants, intrauterine devices, and hormonal contraceptives were similarly evaluated. Several lots of contraceptives were also tested for product stability.

Surveillance Stats

Products evaluated for compliance with USAID contract specifications:*

- **7,818** lots of male condoms
- **131** lots of female condoms
- **148** lots of lubricants
- **122** lots of intrauterine devices
- **36** lots of oral contraceptive pills
- **34** lots of injectable contraceptives
- **21** lots of the implant Jadelle

* Lot size varied depending on the product and the size of the order. For male and female condoms, the maximum size reached more than 400,000 products per lot.

Field Concerns

By effectively responding to field concerns, the PQC Division has gained the reputation as the go-to independent third-party laboratory for investigating complaints about product quality. In response to complaints about

cracked oral contraceptive pills in Bangladesh, the PQC Division tested 68 lots, determining that exposure to high heat and humidity had likely caused the cracking. Tests also showed that the pharmaceutical efficacy of the product had not been affected. However, the PQC Division advised that the product be destroyed to maintain a low risk for USAID and potential consumers. In a different scenario in Ghana, the PQC Division worked with USAID, the World Health Organization, and the Global Fund to prevent the distribution of more than 20 million poor-quality condoms procured through non-USAID funds. This was achieved by providing results of a third-party investigation to Ghana's national testing laboratory, which had initially identified the problem.

KEY PARTNERS

American National Standards Institute

ASTM International

International Organization for Standardization

John Snow, Inc. (USAID|DELIVER PROJECT)

Muhimbili University of Health and Applied Sciences

Supply Chain Management Systems

United Nations Population Fund

World Health Organization

Inter-Laboratory Proficiency Trials

Annual PTA-supported inter-laboratory proficiency trials for male condoms were conducted among national, manufacturer, and independent testing laboratories. The trials were essential for understanding competencies within the laboratories, which can help USAID and the PQC Division manage product complaints raised by a country and can serve as a valuable reference for USAID and missions to respond with sound statistical data. At least 27 laboratories participated in each annual trial, and the 2011 trial was completed with a record 34 laboratories participating.

Innovative Techniques for Quality Assurance

The PQC Division in collaboration with Supply Chain Management Systems and Muhimbili University of Health and Applied Sciences in Tanzania was instrumental in the development of near-infrared spectroscopy screening libraries for cotrimoxazole tablets. This collaboration led the PQC Division to develop screening libraries for all contraceptive pharmaceuticals.

Moving Forward

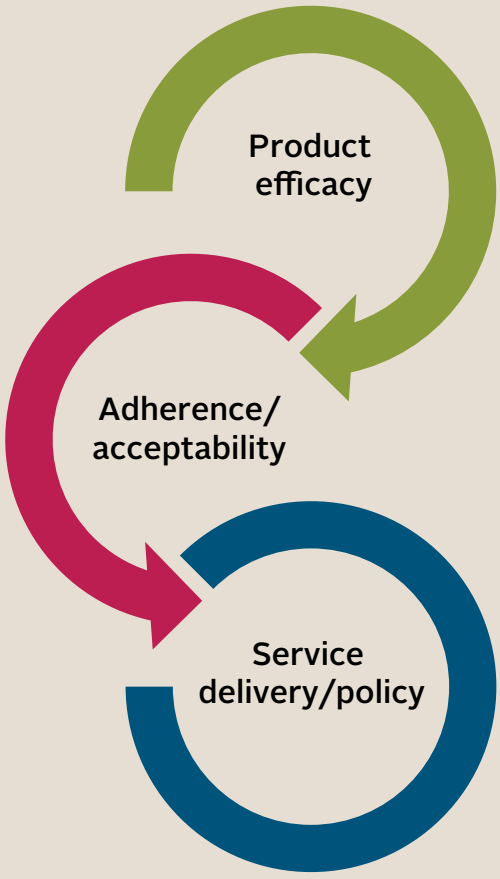
USAID's funding of the PTA over the past five years enabled FHI 360 and its partners to conduct research and to support activities that helped mold the evolving field of HIV prevention technologies. As a result, the field is better prepared for the eventual rollout of microbicide products and the implementation of HIV prevention services to women in sub-Saharan Africa.

It is clear from research supported through the PTA and other funding sources that there is no silver bullet for HIV prevention. Effective HIV prevention efforts that rely on biomedical technologies will require improved understanding of the interplay among biological, social, and behavioral aspects of HIV transmission. Social and economic inequalities that increase women's vulnerabilities to HIV infection in resource-poor countries must also be identified and addressed through policy and programs at the community, national, and global levels if dramatic reductions in the number of people infected with HIV are to be achieved.

FUTURE RESEARCH

- Identification of better measurements of adherence (already under way) to help clarify what adherence will look like outside of placebo-controlled clinical trials
- Continued development of new ARV-based technologies that meet the varying needs of women in different circumstances and different stages of life, rather than a focus solely on products that reduce user involvement
- Evaluation of social and structural interventions (including adherence support) to complement biomedical interventions
- More exploration of how to promote interventions for women with different HIV prevention needs, including adolescents
- Implementation science to identify models of high-quality integrated FP/HIV services that national health programs will be able to scale up

Evolving Research Agenda



Appendix: Publications

Below is a list of PTA-supported publications, organized by topic and type of document. For journal articles, the first three authors are listed. Only those documents that were published or accepted for publication by August 11, 2014, are reported here. Additional resources published after that date may be found on the PTA project page.

HIV Prevention Clinical Trials		
Title	Authors	Journal
Journal Articles – CAPRISA 004		
» *Effectiveness and safety of tenofovir gel, an antiretroviral microbicide, for the prevention of HIV infection in women*	Abdool Karim, Q., S.S. Abdool Karim, J.A. Frohlich	Science
» *Contraceptive choices, pregnancy rates, and outcomes in a microbicide trial*	Sibeko, S., C. Baxter, N. Yende	American Journal of Obstetrics & Gynecology
» *Recruitment of high risk women for HIV prevention trials: baseline HIV prevalence and sexual behavior in the CAPRISA 004 tenofovir gel trial*	Karim, Q.A., A.B. Kharsany, J.A. Frohlich	Trials
» *Epidemiological impact of tenofovir gel on the HIV epidemic in South Africa*	Williams, B.G., S.S. Abdool Karim, Q.A. Karim	Journal of Acquired Immune Deficiency Syndromes
» *Co-enrollment in multiple HIV prevention trials — experiences from the CAPRISA 004 Tenofovir gel trial*	Karim, Q.A., A.B. Kharsany, K. Naidoo	Contemporary Clinical Trials
» *Drug concentrations after topical and oral antiretroviral pre-exposure prophylaxis: implications for HIV prevention in women*	Karim, S.S., A.D. Kashuba, L. Werner	Lancet
» *Antiretroviral prophylaxis: a defining moment in HIV control*	Karim, S.S., A.D. Kashuba, L. Werner	Lancet
» *A drug evaluation of 1% tenofovir gel and tenofovir disoproxil fumarate tablets for the prevention of HIV infection*	Gengiah, T.N., C. Baxter, L.E. Mansoor	Expert Opinion on Investigational Drugs
» *Design challenges facing clinical trials of the effectiveness of new HIV-prevention technologies*	Grobler, A.C., S.S. Abdool Karim	AIDS
» *Safety of tenofovir gel, a vaginal microbicide, in South African women: results of the CAPRISA 004 Trial*	Sokal, D.C., Q.A. Karim, S. Sibeko	Antiviral Therapy
» *Monitoring microbicide gel use with real-time notification of the container's opening events: results of the CAPRISA Wisebag study*	Gengiah, T.N., M. Upfold, A. Naidoo	AIDS and Behavior
» *Assessing adherence in the CAPRISA 004 tenofovir gel HIV prevention trial: results of a nested case-control study*	Macqueen, K.M., M.A. Weaver, F. van Loggerenberg	AIDS and Behavior

HIV Prevention Clinical Trials		
Title	Authors	Journal
» *Adherence in the CAPRISA 004 tenofovir gel microbicide trial*	Mansoor, L.E., Q. Abdool Karim, N. Yende-Zuma	AIDS and Behavior
» *Impact of an adherence intervention on the effectiveness of tenofovir gel in the CAPRISA 004 trial*	Mansoor, L.E., Q. Abdool Karim, N. Yende-Zuma	AIDS and Behavior
» *Disclosure of microbicide gel use to sexual partners: influence on adherence in the CAPRISA 004 trial*	A.C. Grobler	AIDS and Behavior
» *Measuring adherence by visual inspection of returned empty gel applicators in the CAPRISA 004 microbicide trial*	Gengiah, T.N., L.E. Mansoor, M. Upfold	AIDS and Behavior
Journal Articles – FEM-PrEP		
» *Preexposure prophylaxis for HIV infection among African women*	Van Damme, L., A. Corneli, K. Ahmed	New England Journal of Medicine
» *Adherence support approaches in biomedical HIV prevention trials: experiences, insights and future directions from four multisite prevention trials*	Amico, K.R., L.E. Mansoor, A. Corneli	AIDS and Behavior
» *Elevated liver transaminases, human immune deficiency virus (HIV) seroconversion and rapid progression to AIDS in a HIV prevention clinical trial participant: a case report*	Ahmed, K., M. Malahleha, J. Deese	Journal of AIDS and HIV Research
» *Neurological syndrome in an HIV-prevention trial participant randomized to daily tenofovir disoproxil fumarate (300 mg) and emtricitabine (200 mg) in Bondo, Kenya*	Owino, F., J. Mandala, J. Ambia, K. Agot	International Medical Case Reports Journal
» *Implementing good participatory practice guidelines in the FEM-PrEP Preexposure Prophylaxis Trial for HIV Prevention among African Women: a focus on local stakeholder involvement*	Mack, N., S. Kirkendale, P. Omullo	Open Access Journal of Clinical Trials
» *Barriers and facilitators to pre-exposure prophylaxis (PrEP) eligibility screening and ongoing HIV testing among target populations in Bondo and Rarieda, Kenya: results of a consultation with community stakeholders*	Mack, N., J. Odhiambo, C.M. Wong	Journal of the International AIDS Society
» *FEM-PrEP: adherence patterns and factors associated with adherence to a daily, oral study product for pre-exposure prophylaxis*	Corneli, A., J. Deese, M. Wang	Journal of the International AIDS Society
» *Widow cleansing and inheritance among the Luo in Kenya: the need for additional women-centered HIV prevention options*	Perry B., L. Oluoch, K. Agot	Journal of the International AIDS Society
» *Tenofovir diphosphate and emtricitabine triphosphate concentrations in blood cells compared with isolated peripheral blood mononuclear cells: a new measure of antiretroviral adherence?*	Adams J.L., C. Sykes, P. Menezes	Journal of Acquired Immune Deficiency Syndrome
» *Accuracy of Self-Report and Pill-Count Measures of Adherence in the FEM-PrEP Clinical Trial: Implications for Future HIV-Prevention Trials*	Agot, K., D. Taylor, A. Corneli	AIDS and Behavior

HIV Prevention Clinical Trials		
Title	Authors	Journal
Journal Articles – Site Identification and Development Initiative		
» *Correlation of prospective and cross-sectional measures of HIV type 1 incidence in a higher-risk cohort in Ho Chi Minh City, Vietnam*	Sexton, C.J., E.C. Costenbader, D.T. Vinh	AIDS Research and Human Retroviruses
» *HIV prevalence and incidence among women at higher risk of infection in Addis Ababa, Ethiopia*	Combes, S.L., A. G-Yohannes, A. Kidane	AIDS Research and Human Retroviruses
» *Determinants of prevalent HIV infection and late HIV diagnosis among young women with two or more sexual partners in Beira, Mozambique*	Zango, A., K. Dube, S. Kelbert	PLoS One
» *HIV incidence and prevalence among cohorts of women with higher risk behaviour in Bloemfontein and Rustenburg, South Africa: a prospective study*	Feldblum, P.J., M.H. Latka, J. Lombaard	BMJ Open
» *HIV incidence in a cohort of women at higher risk in Beira, Mozambique: prospective study 2009-2012*	Dube, K., A. Zango, J. van de Wijgert	PLoS One
» *Prevalence, incidence and determinants of herpes simplex virus type 2 infection among HIV-seronegative women at high-risk of HIV infection: a prospective study in Beira, Mozambique*	Meque, I., K. Dube, P.J. Feldblum	PLoS One
» *Assortativity coefficient-based estimation of population patterns of sexual mixing when cluster size is informative*	Young, S.K., R.H. Lyles, L.L. Kupper	Sexually Transmitted Infections
» *HIV prevalence and incidence in a cohort of women at higher risk for HIV acquisition in Chokwe, southern Mozambique*	Feldblum, P.J., S. Enosse, K. Dube	PLoS One
» *Pregnancy incidence and correlates in a clinical trial preparedness study, North West province South Africa*	Chetty-Makkan, C.M., K. Fielding, P.J. Feldblum	PLoS One
Journal Articles – All Other Studies		
» *Sexual behavior before and after pregnancy detection in four microbicide trials*	Rountree, W., P.J. Feldblum, D. Taylor	AIDS and Behavior
» *An adaptive design to bridge the gap between Phase 2b/3 microbicide effectiveness trials and evidence required for licensure*	Taylor, D.J., A. Grobler, S.S. Abdool Karim	Clinical Trials
» *Sexual behavior before and after pregnancy detection in four microbicide trials*	Rountree, W., P.J. Feldblum, D. Taylor	AIDS and Behavior
» *Performance of a rapid and simple HIV testing algorithm in a multicenter phase III microbicide clinical trial*	Crucitti, T., D. Taylor, G. Beelaert	Clinical and Vaccine Immunology
» *Predictors of pregnancy in microbicide trials*	Halpern, V., C.C. Lie, P. Feldblum	Contraception
» *Notes on the frequency of routinely collected and self-reported behavioral data in HIV prevention trials*	Taylor, D.J., C.C. Lie, M.A. Weaver	AIDS and Behavior

HIV Prevention Clinical Trials		
Journal Articles – All Other Studies		
» *Baseline factors associated with incident HIV and STI in four microbicide trials*	Feldblum, P.J., C.C. Lie, M.A. Weaver	Sexually Transmitted Diseases
» *Adherence and its measurement in phase 2/3 microbicide trials*	Tolley, E.E., P.F. Harrison, E. Goetghebeur	AIDS and Behavior
» *Heterosexual anal intercourse has the potential to cause a significant loss of power in vaginal microbicide effectiveness studies*	McGowan, I., D.J. Taylor	Sexually Transmitted Diseases
» *What predicts non-retention in microbicide trials?*	Feldblum, P.J., V. Halpern, C.C. Lie	Contemporary Clinical Trials
» *Practice makes perfect: reduction in female condom failures and user problems with short-term experience in a randomized trial*	Beksinska, M., J. Smit, C. Joanis	Contraception
Brief – CAPRISA 106		
» *CAPRISA 106 Tenofovir Gel Social and Health Systems Research Study*		
Briefs – Site Identification and Development Initiative		
» *Family Health International's Site Identification and Development Initiative (SIDI)*		
» *Combined Cross-Sectional and Prospective HIV Incidence Study: The Site Identification and Development Initiative (SIDI)*		
» *Josha Research Centre Bloemfontein, South Africa*		
» *Rustenburg Research Centre of The Aurum Institute Rustenburg, South Africa*		
» *Multiple and Concurrent Partners (MCP) Research: HIV Prevention*		
» *Site Identification and Development Initiative (SIDI) Mozambique HIV Incidence Studies*		
» *Expanded Cross-Sectional and Prospective Study for Measurement of HIV incidence in Chokwe, Mozambique*		
Brief – All Other Studies		
» *SCOPE: Strategies to Combine PrEP with Prevention Efforts*		
Reports – FEM-PrEP		
» *HIV Services Inventory Final Report: Sociobehavioral Research & Community Planning to Develop Site-Specific Pilot Intervention Plans for PrEP Rollout, Soshanguve, Pretoria, South Africa*		
» *HIV Services Inventory Final Report: Sociobehavioral Research & Community Planning to Develop Site-Specific Pilot Intervention Plans for PrEP Rollout, Bondo and Rarieda, Nyanza Province, Kenya*		
» *Considerations for Rolling Out Oral PrEP to Target Populations through Social Marketing in Bondo and Rarieda, Kenya*		
» *Final Report: Sociobehavioral Research & Community Planning to Develop Site-Specific Pilot Intervention Plans for PrEP rollout, Soshanguve, Pretoria, South Africa*		
Reports – CAPRISA 106		
» *CAPRISA 106 Tenofovir Gel Social and Health Systems Research Study End of Study/Lessons Learned Report*		

Support for HIV Prevention Research		
Title	Authors	Journal
Journal Articles – Science Facilitation		
» *Baseline variation and associations between subject characteristics and five cytokine biomarkers of vaginal safety among healthy non-pregnant women in microbicide trials*	Fichorova, R.N., J.J. Lai, J.L. Schwartz	Cytokine
» *Colposcopy: still useful in microbicide safety trials?*	Mauck, C.K., D.H. Weiner, J.J. Lai	Sexually Transmitted Diseases
» *Three new female condoms: which do South-African women prefer?*	Joanis, C., M. Beksinska, C. Hart	Contraception
» *Toward early safety alert endpoints: exploring biomarkers suggestive of microbicide failure*	Mauck, C., J.J. Lai, D.H. Weiner	AIDS Research and Human Retroviruses
Report – Good Communication Practices		
» *Communications Handbook for Clinical Trials: Strategies, Tips, and Tools to Manage Controversy, Convey Your Message, and Disseminate Results*		
Tool – Good Communication Practices		
» *Communications Handbook for Clinical Trials*		
Tool – Assuring Stakeholder Involvement		
» *Stakeholder Engagement Toolkit for HIV Prevention Trials*		

Microbicide Implementation
Title
Brief – Preparing for the Delivery of Microbicides
» *Preparing for the Delivery of Microbicides: Lessons from the Implementation of Integrated Reproductive Health and HIV Services in Kenya*
Web Page – Communicating about Microbicides with Women in Mind
» *Communications about Microbicides with Women in Mind Project*
Web Page – Gender and Male Engagement in Microbicide Introduction
» *Microbicides and Gender*

Other Social Behavioral Evidence		
Title	Authors	Journal
Journal Articles – Evaluating Messages About Abstinence		
» *Exploring discordance between biologic and self-reported measures of semen exposure: a qualitative study among female patients attending an STI clinic in Jamaica*	Carter, M.W., A. Bailey, M.C. Snead	AIDS and Behavior
» *Randomized controlled trial on the effectiveness of counseling messages for avoiding unprotected sexual intercourse during sexually transmitted infection and reproductive tract infection treatment among female sexually transmitted infection clinic patients*	Anderson, C., M.F. Gallo, T. Hylton-Kong	Sexually Transmitted Diseases
» *Biological markers of sexual activity: tools for improving measurement in HIV/sexually transmitted infection prevention research*	Gallo, M.F., M.J. Steiner, M.M. Hobbs	Sexually Transmitted Diseases
» *Intravaginal cleansing among women attending a sexually transmitted infection clinic in Kingston, Jamaica*	Carter, M., M. Gallo, C. Anderson	West Indian Medical Journal
Journal Article – Addressing Barriers to Informed Consent		
» *Lost in translation: assessing effectiveness of focus group questioning techniques to develop improved translation of terminology used in HIV prevention clinical trials*	Mack, N., C.B. Ramirez, B. Friedland	PLoS One
Tool – Addressing Barriers to Informed Consent		
» *A Toolkit for Developing Bilingual Lexicons for International HIV Prevention Trials*		

Family Planning and HIV Integration		
Title	Authors	Journal
Journal Articles – Biomedical Research		
» *Nevirapine-based antiretroviral therapy does not reduce oral contraceptive effectiveness*	Nanda, K., S. Delany-Moretlwe, K. Dube	AIDS
Journal Articles – Programmatic Research		
» *Integrating family planning services into HIV care and treatment clinics in Tanzania: evaluation of a facilitated referral model*	Baumgartner, J.N.	Health Policy and Planning
» *Factors impacting knowledge and use of long acting and permanent contraceptive methods by postpartum HIV positive and negative women in Cape Town, South Africa: a cross-sectional study*	Crede, S., T. Hoke, D. Constant	BMC Public Health
» *Expanding contraceptive options for PMTCT clients: a mixed methods implementation study in Cape Town, South Africa*	Hoke, T., J. Harries, S. Crede	Reproductive Health
Journal Articles – Research Utilization		
» *Family planning and HIV: two steps forward*	Wilcher, R., W. Cates Jr., J.M. Baeten	AIDS
» *Meeting the contraceptive needs of key populations affected by HIV in Asia: an unfinished agenda*	Petruney, T., S.N. Minichiello, M. McDowell	AIDS Research and Treatment
» *The importance of addressing gender inequality in efforts to end vertical transmission of HIV*	Ghanotakis, E., D. Peacock, R. Wilcher	Journal of the International AIDS Society
» *The role of family planning in elimination of new pediatric HIV infection*	Wilcher, R., T. Petruney, W. Cates	Current Opinion in HIV and AIDS
» *Integration of family planning into HIV services: a synthesis of recent evidence*	Wilcher, R., T. Hoke, S.E. Adamchak	AIDS
Journal Articles – All Other Studies		
» *Progestogen-only contraceptive use among breastfeeding women: a systematic review*	Kapp, N., K. Curtis, K. Nanda	Contraception
» *Update to CDC's U.S. Medical Eligibility Criteria for Contraceptive Use, 2010: revised recommendations for the use of hormonal contraception among women at high risk for HIV infection or infected with HIV*	Centers for Disease Control and Prevention	Morbidity and Mortality Weekly Report
» *Evaluating the competing risks of HIV acquisition and maternal mortality in Africa: a decision analysis*	Rodriguez, M., M. Reeves, A. Caughey	BJOG
» *The World Health Organization-United Nations Population Fund Strategic Partnership Programme's implementation of family planning guidelines and tools in Asia-Pacific countries*	Mody, S.K., K. Ba-Thike, M.E. Gaffield	Journal of Obstetrics and Gynecological Research
» *Initiation of progestogen-only injectables on different days of the menstrual cycle and its effect on contraceptive effectiveness and compliance: a systematic review*	Kapp, N., M.E. Gaffield	Contraception

Family Planning and HIV Integration		
Title	Authors	Journal
» *Advance supply of emergency contraception: a systematic review*	Rodriguez, M.I., K.M. Curtis, M.L. Gaffield	Contraception
» *Retention of intrauterine devices in women who acquire pelvic inflammatory disease: a systematic review*	Tepper, N.K., M.W. Steenland, M.E. Gaffield	Contraception
» *When can a woman have an intrauterine device inserted? A systematic review*	Whiteman, M.K., C.P. Tyler, S.G. Folger	Contraception
» *Hormonal contraceptive use and female-to-male HIV transmission: a systematic review of the epidemiologic evidence*	Polis, C.B., S.J. Phillips, K.M. Curtis	AIDS
» *Effect of hormonal contraceptive methods on HIV disease progression: a systematic review*	Phillips, S.J., K.M. Curtis, C.B. Polis	AIDS
» *Postpartum education for contraception: a systematic review*	Lopez, L.M., J.E. Hiller, D.A. Grimes	Obstetrical & Gynecological Survey
» *Hormonal contraceptives for contraception in overweight or obese women*	Lopez, L.M., D.A. Grimes, M. Chen-Mok	Cochrane Database of Systematic Reviews
» *Pericoital oral contraception with levonorgestrel: a systematic review*	Raymond, E.G., V. Halpern, L.M. Lopez	American Journal of Obstetrics & Gynecology
» *Strategies to improve adherence and acceptability of hormonal methods of contraception (updated review)*	Halpern, V., L.M. Lopez, D.A. Grimes	Cochrane Database of Systematic Reviews
» *Progestin-only contraceptives: effects on weight*	Lopez, L.M., A. Edelman, M. Chen-Mok	Cochrane Database of Systematic Reviews
» *Quadriphasic versus monophasic oral contraceptives for contraception*	Van Vliet, H.A., M. Raps, L.M. Lopez	Cochrane Database of Systematic Reviews
» *Combination contraceptives: effects on weight*	Gallo, M.F., L.M. Lopez, D.A. Grimes	Cochrane Database of Systematic Reviews
» *Oral contraceptives for functional ovarian cysts*	Grimes, D.A., L.B. Jones, L.M. Lopez	Cochrane Database of Systematic Reviews
» *Theory-based interventions for contraception*	Lopez, L.M., E.E. Tolley, D.A. Grimes	Cochrane Database of Systematic Reviews
» *Triphasic versus monophasic oral contraceptives for contraception*	Van Vliet, H.A., D.A. Grimes, L.M. Lopez	Cochrane Database of Systematic Reviews
» *Combined oral contraceptive pills for treatment of acne (updated review)*	Arowojolu, A.O., M.F. Gallo, L.M. Lopez	Cochrane Database of Systematic Reviews
» *Steroidal contraceptives and bone fractures in women: evidence from observational studies (updated review)*	Lopez, L.M., M. Chen, S. Mullins	Cochrane Database of Systematic Reviews
» *Education for contraceptive use by women after childbirth (updated review)*	Lopez, L.M., J.E. Hiller, D.A. Grimes	Cochrane Database of Systematic Reviews
» *Expectant care versus surgical treatment for miscarriage (updated review)*	Nanda, K., L.M. Lopez, D.A. Grimes	Cochrane Database of Systematic Reviews
» *Hormonal and intrauterine methods for contraception for women aged 25 years and younger*	Tang, J.H., L.M. Lopez, S. Mody	Cochrane Database of Systematic Reviews

Family Planning and HIV Integration		
Title	Authors	Journal
» *Pain management for tubal sterilization by hysteroscopy*	Kaneshiro, B., D.A. Grimes, L.M. Lopez	Cochrane Database of Systematic Reviews
» *Steroidal contraceptives: effect on carbohydrate metabolism in women without diabetes mellitus*	Lopez, L.M., D.A. Grimes, K.F. Schulz	Cochrane Database of Systematic Reviews
» *Oral contraceptives containing drospirenone for premenstrual syndrome*	Lopez, L.M., A.A. Kaptein, F.M. Helmerhorst	Cochrane Database of Systematic Reviews
» *Behavioral interventions for improving contraceptive use among women living with HIV*	Lopez, L.M., D. Hilgenberg, M. Chen	Cochrane Database of Systematic Reviews
» *Behavioral interventions for improving condom use for dual protection*	Lopez, L.M., C. Otterness, M. Chen	Cochrane Database of Systematic Reviews
» *Assessing the effect of hormonal contraception on HIV acquisition in observational data: challenges and recommended analytic approaches*	Polis, C.B., D. Westreich, J.E. Balkus	AIDS
» *Effect of concurrent use of anti-retroviral therapy and levonorgestrel sub-dermal implant for contraception on CD4 counts: a prospective cohort study in Kenya*	Hubacher, D., J. Liku, J. Kiarie	Journal of the International AIDS Society
» *Pregnancy outcomes with an IUD in situ: a systematic review*	Brahmi, D., M.W. Steenland, R.M. Renner	Contraception
» *Changes in contraceptive use following integration of family planning into ART Services in Cross River State, Nigeria*	McCarraher, D.R., G. Vance, U. Gwarzo	Studies in Family Planning
Briefs – Behavioral Research		
» *Do Female Sex Workers in Dhaka Need Family Planning Information and Services?*		
» *Do Female Injecting Drug Users in Dhaka Need Family Planning Information and Services?*		
Briefs – Programmatic Research		
» *Delivery of Integrated Family Planning and HIV Testing and Counseling Services by Village Health Teams*		
» *Integrating Family Planning Services into HIV Care and Treatment Clinics through the Facilitated Referral Model*		
Title		
Briefs – Research Utilization		
» *Strengthening Family Planning in a Large-Scale PEPFAR-Supported HIV Program*		
» *Integrating Family Planning into HIV Programs: Evidence-Based Practices*		
» *Preventing Unintended Pregnancies and HIV*		
» *Family Planning and HIV Services: Increased Efficiency and Impact through Integration*		
» *Prevention of Mother-to-Child Transmission of HIV: FHI 360's Strategic Approach*		

Family Planning and HIV Integration
Briefs – Youth
» *Adolescents Living with HIV in Zambia: An Examination of HIV Care and Treatment and Family Planning*
» *HIV Prevention and Family Planning Use among Adolescents on ART: Preliminary Results from the Qualitative Phase*
» *Challenges and Potential Strategies for Supporting Adolescents Living with HIV in Ndola, Zambia: Results from a Study Dissemination Meeting*
Report – Research Utilization
» *Making the Case for Integration: Tides Foundation's Africa Family Planning and HIV Integration Fund*
Report – Youth
» *Navigating Challenges, Charting Hope. A Cross-Sector Situational Analysis on Youth in Uganda. Volume 1: Main Report; Volume 2: Annexes; Executive Version*
Tool – Research Utilization
» *Prezi: Integrating Family Planning into HIV Programs*
Tools – Youth
» *Positive Connections*
» *It's About More than Just Sex*
» *Promoting Partner Reduction*
» *Evidence-Based Guidelines for Youth Peer Education*
» *Young People Most at Risk of HIV*
Website, Blog, and Other Information – Youth
» *IYWG*
» *Half the World*
» *Youth InfoNet*
» *YouthLens*

Support for Field Activities		
Title		
Journal Articles – Botswana		
» *HIV/Sexually Transmitted Infection Prevalence and Sexual Behavior of Men Who Have Sex With Men in 3 Districts of Botswana: Results From the 2012*	Tafuma, T.A., M. Merrigan, L. Okui	Sexually Transmitted Diseases
» *HIV Prevalence and Risk Behaviors Among Female Sex Workers in Botswana: Results from the 2012 HIV/STI Bio-Behavioral Study*	Merrigan, M., T.A. Tafuma, L. Okui	AIDS and Behavior
Brief – South Africa		
» *Integrated Community Palliative Care: Impact of a Pilot Project in South Africa*		
Brief – Kenya		
» *Training in the Use of Data for Decision Making Improves Kenya's Health System*		
» *Assessment of a sexual and reproductive health intervention for domestic workers in Nairobi, Kenya*		
» *Providing integrated sexual and reproductive health services at Kikuyu Campus, University of Nairobi: Assessment of a new reproductive health unit*		
Report – Botswana		
» *2012 Mapping, Size Estimation & Behavioral and Biological Surveillance Survey (BBSS) of HIV/STI among Select High-Risk Sub-Populations in Botswana*		
Reports – Kenya		
» *Testing the A-B-C Approach for Infection Prevention and Averting Unintended Pregnancies among Youth in Institutions of Higher Learning: Assessment Report*		
» *ABC PTA I, End of Project Report, May 2012*		
» *ABC PTA II, End of Project Report, October 2012*		
» *Life Skills Education in Kenya – A Comparative Analysis and Stakeholder Perspectives*		
» *Health and Life Skills Project (HELP) among House Girls in Nairobi: An Evaluation of the Effect of HELP on House Girls' Vulnerability towards STI/HIV and Unintended Pregnancy*		
» *Minimum Package for Reproductive Health (RH) & HIV Integrated Services*		
» *Development and Operationalization of the Minimum Package for Reproductive Health (RH) and HIV Integrated Services*		
Report – India		
» *Fulfilling the Contraceptive Needs of Sex Workers: Family Planning and HIV Integration in the Aastha Project*		
Reports – South Africa		
» *Mobile Services Unit Project: Lessons for Health Systems Strengthening*		
» *Theory of Change: Integrated Access to Care and Treatment, 2011 - 2014*		

PTA PREVENTIVE TECHNOLOGIES AGREEMENT

This work is made possible by the generous support of the American people through the U.S. Agency for International Development (USAID). Financial assistance was provided by USAID to FHI 360 under the terms of the Preventive Technologies Agreement (PTA), GHO A 00 09 00016-00. The contents of this report do not necessarily reflect the views of USAID or the United States Government.

FHI 360/HEADQUARTERS
359 Blackwell Street, Suite 200
Durham, NC 27701 USA
Tel: 1.919.544.7040 Fax: 1.919.544.7261
Website: www.fhi360.org