



New HIV-Prevention Study Focuses on Adherence

Trials of the use of antiretroviral (ARV) drugs to prevent HIV infection have highlighted the importance of consistent use of these methods.

None of the products tested in the recent VOICE trial — tenofovir gel, oral tenofovir or oral Truvada® (a combination of tenofovir disoproxil fumarate and emtricitabine) — proved effective, but the results revealed that most participants did not use the products as directed. In other trials with higher adherence, all three of these products showed effectiveness.

The VOICE results, which mirror those of the PTA-supported FEM-PrEP trial, reinforce the need for better ways to support consistent use of ARV-based HIV prevention methods. Gaining greater understanding of adherence to these regimens is one of the objectives of a study that FHI 360 is conducting in collaboration with the Centre for the AIDS Programme of Research in South Africa (CAPRISA), with results expected in August 2014.

The primary outcome of the study, known as CAPRISA 106, is to assess adherence to tenofovir gel use in CAPRISA 008, an implementation study led by CAPRISA investigators in family planning clinics in Kwazulu-Natal.

Both are follow-up studies to CAPRISA 004, which showed that use of tenofovir gel before and after sex reduced women's risk of acquiring HIV; the Follow-on African Consortium for Tenofovir Studies (FACTS) is conducting a confirmatory trial. The women participating in CAPRISA 008 were participants in CAPRISA 004. The CAPRISA 106 investigators plan to conduct in-depth interviews and focus group discussions with CAPRISA 008 participants, their male partners, men in the study communities, and CAPRISA 008 providers and research staff.

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~ Kate MacQueen, CAPRISA 106 Principal Investigator, FHI 360

One aim of CAPRISA 106 is to qualitatively explore how social context affects the acceptability of and adherence to gel use. Another is to assess CAPRISA's use of a health systems strengthening (HSS) approach, applying quality improvement (QI) methods to integrate the delivery of tenofovir gel into family planning clinics. A costing analysis will estimate the resources used to implement HSS/QI and the cost of adding tenofovir gel provision to family planning services.

Unlike the earlier ARV-based prevention trials, whose participants did not know whether they had been randomly assigned to receive a placebo or an active product of unknown effectiveness, CAPRISA 008 is an open-label study. All participants will be provided with tenofovir gel and information about the promising results of the CAPRISA 004 trial.

“Open-label trials like this one can tell us more about adherence and acceptability than placebo-controlled trials,” says Kate MacQueen, principal investigator for CAPRISA 106. “Women know they are getting an active product that has some evidence of being protective against HIV if used as directed, so we can really begin to understand what motivates and sustains adherence.”

Kenyan Youth Learn “ABCs”

For University of Nairobi student Pinto Kisambi, the training he received through the ABC Project was “a stepping stone in my endeavor to serve my fellow youth as a campus change agent (CCA).”

Kisambi found many students had misconceptions about contraceptives and were embarrassed to seek help for unintended pregnancies, unprotected sex, and drug or alcohol abuse. His training empowered him to offer basic counseling and successfully refer many students to the campus health clinic, where a nurse provided confidential, youth-friendly services.

One of 60 students and staff trained as CCAs in 2012, Kisambi was part of a project that promoted the “ABC” approach (abstain, be faithful and use condoms) to preventing sexually transmitted infection and unintended pregnancy. Aiming to improve sexual and reproductive health (SRH) knowledge, attitudes and practices among youth at several universities in Kenya, the project trained 7,128 peer educators from 2004 to 2012, with PTA’s technical support and funding from USAID.

In September 2011, FHI 360’s Preventive Technologies Agreement (PTA) supported a phase of the ABC Project designed to strengthen peer education and SRH services at the universities of

Nairobi and Kenyatta and the U.S. International University. A total of 175 university students were trained as peer educators. The project offered these students and others previously trained opportunities to enhance their skills. More than 100 peer educators were trained in life skills — specific skills that students can use to put their knowledge of the “ABCs” into practice. Another 61 learned to facilitate behavior change communication (BCC) groups.

The peer educators’ efforts were reinforced through radio programs and special events, which reached 21,686 students.

The project also sought to improve integration of SRH in the universities’ HIV prevention, care and support services. It trained 33 staff members in integration and supported drives where more than 8,000 students were counseled and tested for HIV and 2,215 were screened for breast and cervical cancer.

To sustain this work, both the University of Nairobi and United States International University approved strategic plans for SRH-HIV service integration and began implementing them in 2012. The effectiveness of SRH integration in improving students’ use of life-saving services will be assessed in the project’s next phase.

HELPING HOUSE GIRLS

In Nairobi, the PTA collaborated with the University of Kenyatta to provide training in health and life skills to a group often missed by SRH programs for youth — the domestic servants known as house girls. Formative research by FHI 360 had shown that house girls are at risk of sexually transmitted infections (STIs) and unintended pregnancies because of their poverty, isolation and lack of social support, as well as the low status of their work and their previous experiences with sexual coercion and violence. Reaching this group is difficult because house girls usually have little free time or independence, but the research found that the girls could receive training on Sundays after church services. In a PTA-supported follow-on to earlier phases of the House Girls Health and Life Skills Project (HELP), 144 girls completed 15 training sessions from July 2010 to August 2011. Results of pre- and post-training tests among 88 girls showed increased knowledge of SRH, while still room for additional improvement. For example, those who identified being faithful to one uninfected partner as an STI prevention method increased from 24 to 47 percent. Those who thought it best to wait and see if symptoms go away when suspecting an STI dropped from 32 to 16 percent.

PTA Presents New Opportunities in Microbicides

At the 2013 USAID Microbicide Cooperating Agencies' Meeting, FHI 360 presented an overview of its HIV microbicide research, including two studies currently underway: Communicating Microbicides with Women in Mind and Gender Analysis for Microbicide Introduction. Both of these studies address elements of USAID's Shared Vision for Microbicide Introduction, specifically Element 3, Comprehensive Communication and Element 6, Advocacy Strategy and Gender Analysis Tools.

In the Communicating Microbicides with Women in Mind study, researchers aim to develop a comprehensive communications strategy for introducing microbicide gels to women, with audience-specific processes, messages and materials. The social and behavioral health sciences study team held consultations with policymakers, program implementers and other stakeholders in Kenya to learn about the issues related to the introduction of PrEP and other microbicides. The researchers are currently working with a Kenyan firm to develop communications materials, such as TV spots, posters, and charts, that will be tested in-country. The

assessment of these materials and messages will provide evidence for the development of future campaigns related to microbicide introduction.

Similarly, the Gender Analysis for Microbicide Introduction study aspires to answer how gender relations affect women's access to and use of a microbicide and how its introduction affects the inequalities of women and men. Based on a literature review and key informant interviews, the research utilization study team adapted USAID's current gender analysis methodology and tools, which are being pilot tested in Kenya and South Africa. From these pilots, the team will discern the best approaches for introducing microbicides to women.

"We're trying to understand how microbicides fit into a woman's life," said FHI 360's Rose Wilcher, a technical advisor in research utilization and part of the gender analysis study team.

The teams are working together to share data, and the gender analysis team is using existing primary data not previously analyzed.

Research and Toolkit Aim to Improve Comprehension of Informed Consent

Even for well-educated clinical trial volunteers who are familiar with the research process, comprehension of informed consent forms 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 through a focus group process.

FHI 360 and the Population Council are using the results of the study to create a toolkit to help other researchers improve the translation of clinical research terms. The article "Lost in Translation: assessing effectiveness of focus group questioning techniques to develop improved translation of terminology used in HIV prevention clinical trials," was accepted for publication in the open-access journal [PLOS ONE](#).

"The toolkit includes seven steps that researchers can use to create a bilingual lexicon of technical terms for their specific HIV prevention trial," says Scientist Natasha Mack of FHI 360. "They can then use the lexicon to translate informed consent forms and to facilitate all other important communications with trial volunteers." The toolkit, which also includes case studies and an example lexicon in English and Swahili, will be available in late July 2013.

PTA Provides Technical Guidance on Sexuality Education in Kenya

In partnership with UNESCO, FHI 360 provided technical assistance to Kenya Ministry of Education (MOE) and Kenya Institute of Education (IOE) to strengthen sexuality education using UNESCO's *International Technical Guidance on Sexuality Education*. This process of implementing the guidance document's basic minimum package on sexuality education in Kenya included stakeholder engagement, field work, comparative analysis, and advocacy. Field work was used to determine stakeholders' opinions on what should be taught in sexuality education as well as information about what was currently being implemented. The comparative analysis looked at what was reported to be implemented and compared that to the UNESCO guidance to identify gaps.

As a result of these activities, FHI 360 and UNESCO have helped Kenya's MOE and IOE to establish a more up-to-date evidence base on sexuality education. The MOE and IOE have agreed that there is a need for sexuality education in schools and that the UNESCO Guidance offers adaptable benchmarks for both content and implementation as Kenya strives to strengthen its sexuality education program. In response to recommendations set forth by FHI 360 and UNESCO, a group of local stakeholders, including MOE and the IOE, generated local recommendations on ways to strengthen sexuality education in Kenya.

FHI 360 developed a lessons learned document on this project, which is available [here](#).

TWO NEW BRIEFS ON YOUTH SRH DEVELOPED BY THE IWYG

The Interagency Youth Working Group (IWYG), funded by USAID and managed by FHI 360, recently produced two new issues of *YouthLens*, a series of briefs that summarizes the latest research and programmatic information on key issues regarding reproductive health and HIV prevention among youth ages 10 to 24. The first brief is titled *The Intersection of Economic Empowerment and Youth Sexual and Reproductive Health*. Addressing young people's economic vulnerability has been cited as a promising strategy for improving their sexual and reproductive health (SRH), because poverty is both a cause and a consequence of negative SRH outcomes. This brief reviews various types of economic empowerment approaches, discusses some promising programs, and talks about next steps needed to take this relatively new approach forward. The second new brief is called *Mobile Technology for Health*. Mobile health, also known as mHealth, is a relatively new field that uses the incredible advances and growth in text messaging and other mobile technologies to help deliver health care. The brief covers a number of innovative programs, including an FHI 360 program, funded by the USAID cooperative agreement PROGRESS, in Tanzania and Kenya that allows mobile phone users to access tailored information about family planning at their convenience. These two briefs were disseminated to approximately 5,400 people globally and are available on the [IWYG's website](#).



To learn more about how the Preventive Technologies Agreement (PTA) is Advancing the Science of HIV Prevention, please visit fhi360.org/projects/preventive-technologies-agreement-pta or write to PTAinfo@fhi360.org.

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