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**FACTSHEET**

**CAPRISA 008 TENOFOVIR GEL IMPLEMENTATION TRIAL**

According to the UNAIDS 2011 Global Report, an estimated 34.2 million people globally are living with HIV. HIV is the leading cause of death of women of reproductive age. Globally, young women 15–24 years old are most vulnerable to HIV infection, with infection rates up to eight times as high as men of the same age. In sub-Saharan Africa, women, who account for 60% of all infected adults, are more vulnerable than men to acquiring HIV during sex.

Despite their vulnerability, young women have few options to protect themselves from acquiring HIV. Women are often unable to convince their male partners, especially husbands and regular partners, to use condoms or to be monogamous or faithful. Given that women bear a disproportionate burden of HIV, prevention options that they can use and control remains an important goal.

The CAPRISA 004 tenofovir gel trial demonstrated 39% reduction in HIV infection, providing proof-of-concept that an antiretroviral-based microbicide can prevent sexual transmission of HIV. A confirmatory study, the FACTS 001 trial, is currently underway in several sites across South Africa. FACTS 001 is using the same dosing strategy as CAPRISA 004 and is expected to report its results in mid to late 2014. If it confirms the CAPRISA 004 trial findings it may provide the information needed to support licensure of tenofovir gel for HIV prevention. Hence, the next 2-3 years are a critical window of opportunity to prepare for and devise effective strategies for the future policy and programmatic scale-up of tenofovir gel provision.

In addition to providing post trial access to previous CAPRISA 004 trial participants, the CAPRISA 008 trial aims to address how rapid scale-up can be achieved once tenofovir gel is licensed. One potential programmatic approach to making tenofovir gel available within the public health sector is to integrate its provision into family planning services using a quality improvement (QI) approach. This methodology utilizes small scale rapid cycles of improvement designed by local providers to develop reliable processes for service delivery.

Integrating HIV prevention and family planning services using a health systems strengthening approach has several advantages:

* Large numbers of sexually active women, who would benefit from tenofovir gel provision, already utilize family planning services at regular intervals
* Family planning staff are knowledgeable about reproductive health and have experience providing counseling and adherence support
* With minimal additional resources, the existing family planning service delivery systems could be substantially enhanced using a QI approach
* HIV prevention services could help strengthen family planning services and utilization.

Empiric evidence is needed to assess whether integrating tenofovir gel into family planning services can achieve similar levels of effectiveness as observed in the CAPRISA 004 trial.

CAPRISA 008 will include about 370 consenting sexually active, HIV-uninfected South African women aged 18 years and older who previously participated in the CAPRISA 004 study. The study is being conducted at the CAPRISA Vulindlela and eThekwini Clinical Research sites in KwaZulu Natal, South Africa and adjacent family planning clinics. Participants were randomized to receive tenofovir gel through either family planning services with 2-3 monthly provision and monitoring of the gel, together with QI to promote reliable service delivery (intervention arm) or through the CAPRISA research clinics with monthly provision and monitoring of tenofovir gel (control arm). All women in the trial are provided with tenofovir in pre-filled applicators, as well as the standard package of HIV prevention and reproductive health services.

The CAPRISA 004 before and after dosing strategy is utilized wherein the first dose of tenofovir gel in inserted vaginally within 12 hours **b**efore anticipated intercourse and a second dose as soon as possible but within 12 hours **a**fter intercourse, with a maximum of **t**wo doses of gel in a **24**-hour period (BAT-24).

CAPRISA 008 is conducted by a team of South African scientists led by CAPRISA’s Professor Quarraisha Abdool Karim (principal investigator) and Professor Salim S Abdool Karim and Dr Leila E Mansoor (co-principal investigators). Funding for the study is provided by United States Agency for International Development (USAID) through CONRAD, MACAIDS Fund through the Tides Foundation, and The South African Department of Science and Technology (DST) through the Technology Innovation Agency (TIA). The study product, tenofovir gel, is supplied by CONRAD and Gilead Sciences. Collaborating support is provided by FHI360 and Institute for Health Care Improvement. Additional care and support needs of participants when needed is provided through the KwaZulu-Natal Department of Health.

***CAPRISA*** *(www.caprisa.org) is a multi-institutional AIDS research organization, with its headquarters at the University of KwaZulu-Natal in Durban, South Africa. CAPRISA is a designated UNAIDS Collaborating Centre for HIV Prevention Research. The main goal of CAPRISA is to undertake globally relevant and locally responsive research that contributes to understanding HIV pathogenesis, prevention and epidemiology, as well as the links between tuberculosis and AIDS care. CAPRISA comprises four research programmes: HIV pathogenesis & vaccines, HIV and TB treatment, Microbicides, and HIV prevention and epidemiology. For more information, go to www.caprisa.org.*

***FHI360*** *(*[*www.fhi.org*](http://www.fhi.org)*) is a global health and development organization whose rigorous, science-based approach builds programs that create lasting change. Founded in 1971, FHI maintains offices and staff worldwide, helping to forge strong local relationships that enable us to make measurable progress against disease, poverty, and inequity—improving lives for millions. FHI* *was the primary recipient of USAID funds for the project and provided scientific and operational expertise to the South African scientists in the CAPRISA 004 trial.*

***CONRAD*** *(*[*www.conrad.org*](http://www.conrad.org)*) was established in 1986 and is a Division of the Department of Obstetrics and Gynaecology at Eastern Virginia Medical School (EVMS) in Norfolk, VA, where it has laboratories and a clinical research center. The main office is located in Arlington, VA with additional offices in West Chester, PA and collaborators around the world. CONRAD is committed to improving reproductive health by expanding the contraceptive choices of women and men and by helping to prevent the transmission of HIV/AIDS and other sexually transmitted diseases. CONRAD provided the gel formulation of the microbicide in the CAPRISA 004 trial and the CAPRISA 008 studies.*

***KwaZulu-Natal Department of Health*** *(*[*www.kznhealth.gov.za*](http://www.kznhealth.gov.za)*) seeks to deliver a sustainable, co-ordinated, integrated and comprehensive health system at all levels, based on the primary health care approach through the district health system.*

***Technology Innovation Agency*** *(*[*www.tia.org.za*](http://www.tia.org.za)*)**TIA is mandated by the South African Department of Science and Technology to stimulate and intensify technological innovation in order to improve economic growth and the quality of life of all South Africans by developing and exploiting technological innovations. To this end, TIA is set up to be a world class innovation agency that supports and enables technological innovation to achieve socio-economic benefits for South Africa through leveraging strategic partnerships.*

***USAID*** *(www.usaid.gov) is an independent federal government agency that receives overall foreign policy guidance from the Secretary of State. With headquarters in Washington, D.C., USAID's strength is its field offices around the world. We work in close partnership with private voluntary organizations, indigenous organizations, universities, American businesses, international agencies, other governments, and other U.S. government agencies. USAID has working relationships with more than 3,500 American companies and over 300 U.S.-based private voluntary organizations.*

***MACAIDS Fund*** *(*[*www.macaidsfund.org*](http://www.macaidsfund.org)*) was developed to support people who are living with* [*HIV/AIDS*](http://en.wikipedia.org/wiki/HIV/AIDS) *worldwide. As well as donating funds to communities that offer services and help to and prevent the* [*HIV/AIDS*](http://en.wikipedia.org/wiki/HIV/AIDS) *through educational programs and services.*

***Institute for Health Care Improvement*** *(www.ihi.org) is an independent not-for profit-organization which focuses on motivating and building the will for change; identifying and testing new models of care in partnership with both patients and health care professionals; and ensuring the broadest possible adoption of best practices and effective innovations.*