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Global Campaign for Microbicides statement on the discontinuation of the FEM-PrEP trial

Johannesburg, South Africa, and Washington, DC, April 19, 2011—FHI yesterday announced its decision to discontinue the [FEM-PrEP](#) study testing oral Truvada (emtricitabine and tenofovir disoproxil fumarate) to prevent HIV infection in women in Africa. This follows a recommendation by the Independent Data Monitoring Committee to stop the trial early on the basis that it would be unlikely to show a definitive result of the effectiveness of Truvada in protecting women from HIV. A statistical interim analysis showed that the same number of HIV infections took place in participants given Truvada compared to those in the placebo arm. Even if the trial were to continue, the data monitoring committee concluded, the number of trial participants would be too small to ascertain a conclusive outcome on the effectiveness of oral daily Truvada.

These early findings from the study are still being reviewed, and detailed scientific analysis over the coming months will help to answer why the study showed comparable levels of infection. Importantly, it will help to determine whether these differences were somehow intrinsic to the population, explained by biological, environmental, or behavioral differences such as adherence. In the mean time, some interesting and unexpected findings from FEM-PrEP have already emerged. For example, a higher rate of pregnancy was noted in the Truvada arm, although the reasons for this are as yet unknown. It may be that participants in the Truvada arm had lower adherence, or perhaps it will be explained by an unexpected interaction between tenofovir and contraceptive hormones taken by the women in the trial.

The results have surprised many given the positive outcome of the [iPrEx](#) trial last year, which showed that the same drug with the same daily regimen used by men who have sex with men can reduce HIV infection. While iPrEx was only one study, and conducted in a very different population, it provided scientific basis—and hope—that this intervention may show a protective effect in women.

FEM-PrEP was one of a number of important studies that seeks to understand whether tenofovir-based oral prevention can help prevent HIV infection in different populations, in this case women at high risk of HIV. “Bear in mind that one out of every five women considered for the FEM-PrEP study could not be included because they already had HIV,” said Samukeliso Dube, Head of Africa Programs at the Global Campaign for Microbicides. “This points to the urgency for us to develop an intervention that works for the women in these communities.”

Three other studies are currently underway that will help to answer if oral Truvada or tenofovir can reduce HIV transmission in those at greatest risk of infection,

including injecting drug users ([CDC 4370](#)), women at high risk (Vaginal and Oral Interventions to Control the Epidemic, [VOICE](#)), and sero-discordant couples (Partners PrEP). Sponsors of these trials do not expect any immediate impact on their ongoing studies and stress the even greater importance to continue the research in order to answer these critical questions about what works, in which communities, and where.

The VOICE trial, being conducted by the Microbicide Trials Network, which is testing whether the daily use of a vaginal gel or oral tablet tenofovir (tenofovir disoproxil fumarate) or Truvada is safe, effective, and preferred by women for preventing HIV, is of particular significance, as it is the only study testing both topical and oral interventions in the same trial. If the results are positive, they are expected to confirm the effectiveness of the tenofovir gel, according to the indication given by the US Food and Drug Administration last year.

Another important milestone in the fight to halt the global HIV epidemic came from the [CAPRISA 004](#) trial, which tested the safety and effectiveness of 1% tenofovir gel among nearly 900 women in South Africa. The study found that using the gel before and after sex reduced the risk of sexually transmitted HIV in women.

“What is important is that we learn lessons from FEM-PrEP—and continue in our search for prevention tools that women can use to help protect themselves from HIV,” said Yasmin Halima, Director of the Global Campaign. “The field has promised, and delivered, some exciting results. This is a setback certainly, but additional studies are already underway, testing Truvada and newer agents with different dosing and delivery mechanisms. As advocates, we have to keep fighting for women and for communities who today still remain biologically, culturally, and economically vulnerable to HIV.”

About the trial

Sponsored by the US Agency for International Development and the Bill & Melinda Gates Foundation, FEM-PrEP was a randomized, placebo-controlled, clinical trial of the effectiveness of daily oral Truvada for HIV prevention among HIV-uninfected women in Kenya, South Africa, and Tanzania. Truvada combines two antiretroviral drugs—emtricitabine and tenofovir disoproxil fumarate—in a single pill that is taken once a day. Truvada has been proven safe and effective as a treatment for HIV-positive people.

About PrEP

Pre-exposure prophylaxis (PrEP) is the use of medicine in advance of exposure to something potentially harmful, such as a disease or condition. Within the context of HIV, it is the use of antiretroviral medicine by HIV-negative people before sexual activity or other high-risk behaviors.

About microbicides

Microbicides are being developed as products that can be topically applied by a receptive sex partner to reduce the risk of becoming HIV infected during sex. Microbicide candidates are being formulated as vaginal gels, melting tablets, and slow-releasing vaginal rings.

About the Global Campaign for Microbicides

The Global Campaign for Microbicides is a civil society organization working to

ensure the ethical and accelerated development of, and widespread access to, new and existing HIV prevention options—especially for women. For more information, please visit www.global-campaign.org or info@global-campaign.org.