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Pivotal HIV prevention trial in Africa continues, but makes crucial change What does this mean for HIV prevention for women?

Johannesburg, South Africa, and Washington, DC, September 28, 2011—A pivotal trial testing the use of oral and topical prophylaxis to help prevent HIV has been modified, according to an announcement made today by the Microbicide Trials Network. The VOICE study (Vaginal and Oral Interventions to Control the Epidemic) sponsored by the National Institute of Allergy and Infectious Diseases, part of the US National Institutes of Health, is evaluating the safety and efficacy of two antiretrovirals (tenofovir and Truvada[®]) taken daily as oral pre-exposure prophylaxis (PrEP) in women, as well as a vaginal microbicide containing tenofovir in gel form. The study is taking place at sites in South Africa, Uganda, and Zimbabwe.

A meeting of the independent Data Safety Monitoring Board (DSMB) last week recommended that the trial continue, but that women assigned to the tenofovir tablet should discontinue use of the study product. It is important to note that the decision to stop oral tenofovir does not reflect safety concerns associated with that regimen; the DSMB concluded that the study would not be able to show a difference in effectiveness between tenofovir and placebo. The study will continue to evaluate whether Truvada[®] and the vaginal gel are effective in preventing HIV compared to their respective placebos.

In their review, the VOICE DSMB also considered recent results from two previous clinical studies of tenofovir and Truvada[®], which showed striking evidence that oral PrEP can help reduce HIV infection. In the Partners PrEP study, sero-discordant couples (i.e., in which only one partner had known HIV) showed 62 percent fewer infections in those taking tenofovir and a 73 percent HIV risk reduction in participants randomized to Truvada[®]. In the US Centers for Disease Control and Prevention TDF2 study in Botswana of sexually active men and women, researchers found a 62 percent risk reduction of HIV infection in men and women taking Truvada[®] as compared to those in the placebo arm.

Responding to this change, Yasmin Halima, Director of the Global Campaign for Microbicides, stressed the value of VOICE: “With the good news that PrEP has been shown in studies to reduce HIV risk in men who have sex with men, sero-discordant couples, and sexually active heterosexual men and women, the key question remains—do we have sufficient evidence that PrEP works in women? For this reason, VOICE continues to be an exceptionally important study. Not only does it include both oral PrEP and a vaginal microbicide in the same trial, but VOICE, we hope, will help provide the evidence we need to bring us closer to delivering two more options for women.”

Other trials also underway testing oral and topical PrEP include a study of the tenofovir tablet for HIV prevention in injecting drug users in Thailand, and the

FACTS 001 trial, which plans to test tenofovir gel used by women before and after sex. These additional studies will add to our level of knowledge and provide additional safety and insight to use and adherence in different population groups.

“As advocates, we are mindful of these studies and their progress—and their potential for impact on the communities we serve,” said Samukeliso Dube, Head of Africa Programs for the Global Campaign for Microbicides. “While this is an important decision, we are pleased that VOICE will continue, as it will help answer critical questions about PrEP in women. Most of all, we applaud the women who volunteer for such trials—without their courage, we would not be able to develop the tools we so urgently need to help protect women from HIV.”

The Global Campaign for Microbicides remains committed to making available a variety of tools that women in Africa can use to protect themselves from HIV, including microbicides and slow-releasing vaginal rings, in addition to other prevention options.

About the trials

[VOICE](#)

[Q&A](#) about the modification of VOICE

[Partners PrEP](#)

CDC [TDF2](#) study

About pre-exposure prophylaxis

Pre-exposure prophylaxis, or 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 could 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, suppositories, 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 further information, please visit www.global-campaign.org, or contact us at info@global-campaign.org.