

## **VOICE study will continue as it considers what action to take after results of two trials**

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Today, researchers from two major HIV prevention trials announced favorable results of an approach called oral pre-exposure prophylaxis, or PrEP. One of these trials, the Partners PrEP Study, has provided the strongest evidence yet of PrEP's effectiveness.

Information from both studies will need to be fully evaluated before it can be determined what impact they will have on another major trial that is ongoing. [Investigators](#) for VOICE – Vaginal and Oral Interventions to Control the Epidemic, and the study's sponsor, the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH), hope to complete their evaluation as soon as possible. In the meantime, the five-arm study involving more than 5,000 women in sub-Saharan Africa will continue as currently designed.

PrEP involves the use of antiretroviral (ARV) drugs commonly used in the treatment of [HIV](#) by individuals who are not infected. In the Partners PrEP Study, researchers from the University of Washington and their collaborators in Uganda and Kenya, evaluated the safety and effectiveness of daily use of two ARVs – tenofovir and Truvada®, the brand name for a tablet combining tenofovir and emtricitabine – among men and women in a discordant relationship with a partner who is HIV-positive. The study enrolled 4,758 serodiscordant couples.

There were 62 percent fewer HIV infections among participants assigned to take the ARV tenofovir daily compared to participants who took a placebo tablet, and 73 percent fewer infections among those who

took Truvada. In statistical terms, the results leave little doubt they are not due to chance. However, the study was not able to say whether Truvada or tenofovir works better than the other in preventing HIV.

The results came to light during a review conducted by Partner PrEP's independent Data Safety and Monitoring Board (DSMB) just a few days ago, on July 10. The DSMB found the results so compelling that it recommended that it stop testing in the placebo group. The research team will be making arrangements so that participants who had been randomly assigned to take a placebo tablet can instead receive one of the study's active study products. Participants in the other two groups will continue to be followed.

In the second study, a smaller trial that involved 1,200 heterosexual men and women in Botswana, researchers from the U.S. Centers for Disease Control and Prevention (CDC) found that 62.6 percent fewer HIV infections had occurred in the group of participants assigned to take Truvada than in the placebo group. The CDC team will be reporting more details about the findings of the study, known as TDF2, at the International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention in Rome next week.

Both sets of results bolster the findings of iPrEx, which late last year provided the first evidence that oral PrEP can help prevent HIV. iPrEx found Truvada – together with a comprehensive [HIV prevention](#) package – was safe and 44 (43.8) percent more effective than a placebo tablet for protecting against HIV in men who have sex with men. The two studies' favorable results also raise more questions about what happened with FEM-PrEP. Two months ago, researchers announced the trial would be stopping earlier than planned because an interim review of the study's progress by its data monitoring committee determined that even if the study were to continue, it would not be able to conclude whether or not Truvada is

effective in its population of women. The study team is still collecting data. A final report is not expected until late this year or early 2012.

Few conclusions can be drawn from the CDC study concerning the effectiveness of Truvada specifically in women. And although Partners PrEP found tenofovir and Truvada worked well for both men and women, the study provides more information about how these drugs can protect heterosexual men from getting infected than it does about how these drugs can protect women from getting infected from a partner with HIV. That's because in most of the 4,758 couples enrolled (62 percent) it was the male who was the uninfected partner.

VOICE involves 5,029 women from Uganda, South Africa and Zimbabwe. VOICE is testing not only daily use of an ARV tablet – Truvada or tenofovir, but also a vaginal microbicide containing tenofovir in gel form. VOICE is the only trial evaluating both a tablet and a gel in the same study. This design is important for determining how each product works compared to its control (placebo gel or placebo tablet) and which approach women may prefer.

VOICE began in September 2009, completed enrollment in June 2011 and remains on target to complete follow-up in June 2012. By that time, all women will have used their study product for at least one year, some for nearly three years. Women will then be followed for an additional two months. Results are anticipated to be available in early 2013.

Leading the VOICE study are Zvavahera Mike Chirenje, M.D., of the University of Zimbabwe in Harare, and Jeanne Marrazzo, M.D., M.P.H., from the University of Washington in Seattle, U.S.

VOICE is the flagship study of the Microbicide Trials Network (MTN), an HIV/AIDS clinical trials network funded by NIAID with co-funding from the Eunice Kennedy Shriver Institute for Child Health and Human

Development and the National Institute of Mental Health, all components of the NIH. MTN principal investigator is Sharon Hillier, Ph.D., and co-principal investigator is Ian McGowan, M.D., Ph.D.

Women make up half of the more than 33 million people living with HIV/AIDS worldwide. In sub-Saharan Africa, six out of 10 new HIV infections in adults occur in women. In several southern African countries, young women aged 15 to 24 are at least three times more likely than their male peers to be infected with HIV. Among women, unprotected sex with an infected male partner remains the primary risk factor for HIV infection, and in many parts of the world, heterosexual intercourse is the driving force of the epidemic. Women are twice as likely as their male partners to acquire HIV during sex. Although correct and consistent use of male condoms has been shown to prevent HIV infection, often [women](#) are not able to choose if they are used.

Provided by Microbicide Trials Network

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