



UNIVERSITY OF WASHINGTON
INTERNATIONAL CLINICAL RESEARCH CENTER
PARTNERS PrEP STUDY

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**PIVOTAL STUDY FINDS THAT HIV MEDICATIONS ARE HIGHLY EFFECTIVE AS
PROPHYLAXIS AGAINST HIV INFECTION IN MEN AND WOMEN IN AFRICA**

Seattle, WA – In a result that will fundamentally change approaches to HIV prevention in Africa, an international study has demonstrated that individuals at high risk for HIV infection who took a daily tablet containing an HIV medication – either the antiretroviral medication tenofovir or tenofovir in combination with emtricitabine – experienced significantly fewer HIV infections than those who received a placebo pill. These findings are clear evidence that this new HIV prevention strategy, called pre-exposure prophylaxis (or PrEP), substantially reduces HIV infection risk.

The study is led by the University of Washington’s International Clinical Research Center and involves 4,758 HIV serodiscordant couples, in which one partner has HIV and the other does not, from nine research sites in Kenya and Uganda. “This study is the largest study to date looking at the effectiveness of PrEP,” said Dr. Connie Celum, a UW professor of global health and medicine and the principal investigator of the study, known as the Partners PrEP Study. The study is funded by the Bill & Melinda Gates Foundation.

“This study demonstrates that antiretrovirals are a highly potent and fundamental cornerstone for HIV prevention and should become an integral part of global efforts for HIV prevention,” said Celum.

Study results through May 31, 2011 were reviewed on July 10, 2011 by the Partners PrEP Study Data and Safety Monitoring Board (DSMB), an independent group of experts that monitored the study’s conduct, safety, and effect of PrEP on preventing HIV infections on an ongoing basis. Due to the strong HIV prevention effect seen, the DSMB recommended that the Partners PrEP Study results be made public and the placebo arm of the study be discontinued. The DSMB also recommended that the study continue: those receiving tenofovir (TDF) and tenofovir combined with emtricitabine (FTC/TDF) PrEP will remain on those medications and those receiving placebo will start receiving TDF or FTC/TDF PrEP.

Through May 31, 2011, a total of 78 HIV infections occurred in the study: 18 among those assigned TDF, 13 among those assigned to FTC/TDF, and 47 among those assigned placebo. Thus, those who received TDF had an average of 62% fewer HIV infections (95% CI 34 to 78%, $p=0.0003$) and those who received FTC/TDF had 73% fewer HIV infections (95% CI 49 to 85%, $p<0.0001$) than those who received placebo.

“This is an extremely exciting finding for the field of HIV prevention. Now, more than ever, the priority for HIV prevention research must be on how to deliver successful prevention strategies, like PrEP, to populations in greatest need,” said Dr. Jared Baeten, co-chair of the study and a

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UW associate professor of global health and medicine. “We are incredibly grateful to the investigators, site teams, participants, and communities for their dedication to this research and to HIV prevention. The level of investment and motivation from each of these groups was tremendous.”

TDF and FTC/TDF were statistically similar in their levels of protection against HIV and reduced HIV risk in both women and men. Importantly, PrEP was found to be safe: the rate of serious medical events was similar for those assigned to TDF, FTC/TDF, and placebo. Ten percent of women annually became pregnant during the study and they were discontinued from the study medication during pregnancy; pregnancy rates were similar across the three arms and there was no evidence that TDF or FTC/TDF was associated with pregnancy complications.

The study was designed to find out whether TDF or FTC/TDF would reduce the risk of acquiring HIV for persons who had an HIV infected sexual partner. Of the 4,758 couples enrolled in the study, one-third of the HIV uninfected partners were randomly allocated to receive TDF, one-third FTC/TDF, and one-third a matching placebo. The study was double-blinded, meaning that both study participants and the researchers who interacted with them did not know which treatment the participants were receiving. All study participants received a comprehensive package of HIV prevention services, which included intensive safer sex counseling (both individually and as a couple), HIV testing, free condoms, testing and treatment for sexually transmitted infections, and monitoring and care for HIV infection.

In the study, adherence to the daily PrEP medication was very high – more than 97% of dispensed doses of the study medications were taken. More than 95% of participants were retained in study follow-up.

The medications used in the Partners PrEP Study, TDF (300 mg) and combination FTC (200 mg) / TDF (300 mg), are marketed by Gilead Sciences, Inc. under the brand names Viread® and Truvada®. They are available generically in many countries at prices as low as approximately 25 cents (U.S.) per tablet. Gilead Sciences donated study medication for, but did not provide funding or otherwise participate in the design, implementation, or analysis of the Partners PrEP Study.

HIV serodiscordant couples, where one partner has HIV and the other does not have HIV infection, are in urgent need of prevention strategies. In sub-Saharan Africa, a substantial fraction of new HIV infections occur among HIV serodiscordant couples. The Partners PrEP Study is the first to show that PrEP reduces HIV risk in heterosexual men and women; the results are critically important for Africa, where the majority of new HIV infections occur. Over the past year, studies of PrEP have suggested great promise for this emerging HIV prevention strategy, and important studies of TDF, FTC/TDF, and a vaginal microbicide gel containing tenofovir are ongoing. Results from the full panel of completed and ongoing studies of PrEP will together provide key information about the ultimate prevention benefits of PrEP in different populations.

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Additional information about the Partners PrEP Study and about PrEP:

- Frequently Asked Questions
(http://depts.washington.edu/uwicrc/research/studies/files/PrEP_FAQ.pdf)
- Backgrounder
(http://depts.washington.edu/uwicrc/research/studies/files/PrEP_Backgrounder.pdf)
- [AVAC website](http://www.avac.org) (<http://www.avac.org>)

*The **International Clinical Research Center (ICRC)**, within the University of Washington Department of Global Health, was established in October 2007 to provide the essential framework and coordination for streamlining the implementation of multi-center international infectious disease prevention trials. The mission of the ICRC is to expand clinical research trial capacity for infectious disease interventions of public health importance. The ICRC facilitates collaborations; implements observational cohort studies and clinical trial operations; and provides repositories of biologic specimens and reagents for future scientific investigations for pathogenesis and prevention research related to HIV and other infectious diseases. More information can be found at www.uwicrc.org*

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