

## Pivotal study in Africa finds that HIV medications prevent HIV infection

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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 preexposure 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 <u>HIV prevention</u> 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

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