

NIH-funded analysis estimates effective PrEP dosing

September 13 2012

Several large clinical trials have demonstrated that a daily oral dose of one or two antiretroviral drugs used to treat HIV infection can prevent infection in an approach known as pre-exposure prophylaxis, or PrEP. The level of protection, however, depends on taking the drugs regularly.

For instance, the [landmark iPrEx study](#) found that overall, men who have sex with men who received a daily dose of tenofovir plus [emtricitabine \(Truvada\)](#) had a 44 percent lower risk of HIV infection compared with those who received a daily [placebo pill](#). But for the subset of participants who had detectable drug in their blood—indicating that they were actually taking Truvada regularly—the risk of HIV infection was 92 percent less than for the [placebo group](#).

Led by study chair Robert M. Grant, M.D., of the Gladstone Institute of Virology and Immunology, the iPrEx team recently set out to estimate what [drug concentration](#) in blood cells was associated with a 90 percent reduction in HIV infection risk, and how many Truvada doses per week would achieve that concentration. The research was funded by the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Mental Health, the National Center for Research Resources and the National Center for Advancing Translational Sciences, all part of the National Institutes of Health.

The scientists examined data from the iPrEx study to determine the concentrations of tenofovir diphosphate, the active form of tenofovir, associated with different levels of protection from [HIV acquisition](#).

They focused on tenofovir diphosphate because it is believed to be the most important component of Truvada for PrEP. The researchers also conducted a small study to determine the blood concentrations of tenofovir diphosphate that resulted from taking a Truvada pill 2, 4 and 7 days per week. Through their analyses, the scientists found that to achieve the 90 percent risk reduction in HIV acquisition, participants needed to take Truvada at least 4 days per week (which would achieve a concentration of roughly 16×10^{-15} moles of tenofovir diphosphate per million blood cells). The researchers also estimated that taking Truvada daily would lead to a 99 percent reduction in HIV infection risk.

The authors caution that the findings of this study, which are relevant to men who have sex with men (the iPrEx study population), may not be applicable to other populations, such as heterosexuals. This is because the minimum protective drug concentration in the blood and the number of tablets per week required to achieve that concentration in target tissues may differ depending on the route and frequency of exposure to HIV.

More information: Anderson et al. Emtricitabine-tenofovir concentrations and pre-exposure prophylaxis efficacy in men who have sex with men. *Science Translational Medicine*. [DOI: 10.1126/scitranslmed.3004006](https://doi.org/10.1126/scitranslmed.3004006) (2012).

Provided by NIH/National Institute of Allergy and Infectious Diseases

Citation: NIH-funded analysis estimates effective PrEP dosing (2012, September 13) retrieved 27 February 2023 from <https://medicalxpress.com/news/2012-09-nih-funded-analysis-effective-prep-dosing.html>

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