

Study finds first evidence that PrEP can reduce HIV risk among people who inject drugs

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The Centers for Disease Control and Prevention today released the first evidence that daily medication used to treat HIV infection can also reduce the risk of HIV acquisition among people who inject drugs. The new data are published online in the *Lancet*.

The findings come from the Bangkok Tenofovir Study, conducted by CDC in collaboration with the Bangkok Metropolitan Administration and the Thailand Ministry of Public Health. Since daily PrEP has already been proven to reduce sexual transmission of HIV among both heterosexuals and gay/bisexual men, the new findings complete the picture of PrEP efficacy – PrEP is now proven to prevent HIV transmission among all populations at high risk.

The study included more than 2,400 men and women at Bangkok city-run drug treatment clinics. Participants were randomly assigned to receive a daily oral pill containing either the antiretroviral medication tenofovir or placebo, and all participants were provided a package of proven HIV prevention tools and services.

Key Trial Findings

- Overall, daily oral tenofovir reduced the risk of contracting HIV by 49 percent
- Participants who took the medication consistently saw a 74 percent reduction in HIV transmission, underscoring the importance of adherence
- There were no significant safety concerns and no one who became infected with HIV during the trial developed drug resistance, consistent with previous studies

In response to the trial outcomes, CDC is also releasing interim clinical guidance to healthcare professionals who wish to prescribe pre-exposure prophylaxis (PrEP) for HIV prevention among people who inject drugs.

Daily HIV medications now proven to prevent HIV among all groups at high risk

A daily dose of a medication used to treat HIV infection reduced the risk of HIV acquisition among people who inject drugs by 49 percent. Those who took the medication most consistently had even higher levels of protection, according to a new study announced today by the Centers for Disease Control and Prevention – in collaboration with the Bangkok Metropolitan Administration (BMA) and the Thailand Ministry of Public Health (MOPH).

This is the first evidence that pre-exposure prophylaxis (PrEP) offers significant protection to

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individuals exposed to HIV through injection drug use. The findings were published online today in the *Lancet*.

"This is a significant step forward for HIV prevention. We now know that PrEP can work for all populations at increased risk for HIV," said Jonathan Mermin, M.D., director of CDC's Division of HIV/AIDS Prevention. "Injection drug use accounts for a substantial portion of the HIV epidemic around the world, and we are hopeful that PrEP can play a role in reducing the continued toll of HIV infection in this population."

The findings are from the Bangkok Tenofovir Study, a clinical trial launched in 2005 involving more than 2,400 men and women at Bangkok city-run drug treatment clinics. Injection drug use accounts for eight percent of new HIV infections in the United States and approximately ten percent of new HIV infections worldwide. In some regions of the world, such as Eastern Europe and Central Asia, this route of transmission accounts for up to 80 percent of new infections.

Daily PrEP with tenofovir – alone or in combination with emtricitabine – has been proven to reduce the risk of sexual transmission of HIV among heterosexuals and men who have sex with men. This trial is the first to examine efficacy among people who inject drugs.

Study Findings

A total of 2,413 men and women were enrolled in the study and randomly assigned to take a daily dose of tenofovir disoproxil fumarate (TDF) or placebo. Two participants were determined to have been HIV-infected before enrollment and were excluded from analysis, which included the remaining 2,411 HIV-negative participants. All participants in the study were provided HIV prevention counseling, a risk reduction package for both sexual and drug-related risks, and monthly HIV testing.

In the primary analysis, among the 1,204 participants taking TDF, there were 17 HIV infections, compared with 33 infections among the 1,207 participants taking placebo. This translates into a statistically significant 49 percent reduction in risk of HIV acquisition overall.

The researchers also conducted a separate analysis to better understand the level of protection for those who adhered most closely to the daily regimen. This analysis was among participants who chose to be on directly observed therapy, met pre-established criteria for high adherence (taking TDF at least 71 percent of days and not missing more than two consecutive days) and had detectable levels of TDF in their blood. In this adherent population, HIV acquisition risk was reduced by 74 percent.

"These findings add to the mounting scientific evidence that high adherence to PrEP is essential to achieve the greatest benefit," said Mermin. "When used consistently and in conjunction with other proven prevention measures, PrEP can provide important additional protection for many people who remain at high risk for HIV, including those who inject drugs."

Consistent with prior studies, the Bangkok trial did not identify any significant safety concerns associated with PrEP use, although participants assigned to the TDF group were more likely

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than those in the placebo group to report nausea, which typically resolved after two months.

Risk behaviors, including injecting drugs, sharing needles, and having sex with more than one partner, decreased substantially during the course of the trial in both the TDF and placebo arms of the study. No tenofovir resistance was detected among participants who become infected with HIV during the trial.

"We are grateful for the extraordinary dedication of our Thai trial volunteers over many years and salute Thailand's leadership in HIV prevention research," said Michael Martin, M.D., Chief of HIV Clinical Research for the Thailand MOPH – U.S. CDC Collaboration, and the lead CDC investigator on the study. "Their efforts have provided hope that many HIV infections can be prevented, saving lives here in Bangkok and around the world."

Implementation Next Steps

Many important questions remain about how best to implement PrEP in conjunction with other proven prevention measures for people who inject drugs. The best way for people who inject drugs to reduce their risk for HIV is to stop using injection drugs. However, for people who will not or cannot stop injecting, PrEP may complement other available tools, including access to new sterile needles and syringes and regular HIV testing. Key implementation questions that CDC and its partners will examine for the United States include acceptability, strategies to support adherence in less controlled settings than a clinical trial, and the best settings for delivery of PrEP for this population.

Tomorrow, CDC will publish initial guidance in the weekly Morbidity and Mortality Weekly Report, recommending that providers who wish to prescribe PrEP to people who inject drugs follow the same cautions and procedures in CDC's existing interim clinical guidance on the use of PrEP to prevent sexual transmission and deliver PrEP in combination with other proven prevention services to reduce both sexual and drug-related transmission risks. CDC is currently working to finalize full Public Health Service clinical guidelines on PrEP use, which the agency anticipates publishing later this year.

In Thailand, trial participants will now be offered access to TDF for HIV prevention for one year as part of a follow-on study which will provide additional data to help assess use and effectiveness outside of a trial setting. CDC will also support BMA and MOPH as they work to determine how to best incorporate PrEP into HIV prevention efforts locally.