Interim PrEP Recs Now Available for At-Risk Heterosexuals

August 10, 2012 By Tim Horn

As a follow-up to preliminary guidance regarding pre-exposure prophylaxis (PrEP) for men who have sex with men (MSM), the U.S. Centers for Disease Control and Prevention (CDC) have issued interim recommendations for heterosexually active adults. According to the agency, health care providers looking to prescribe Truvada (tenofovir plus emtricitabine) as PrEP should ensure their patients are confirmed to be uninfected prior to use and provided regular testing and other key prevention services.

“With 50,000 new HIV infections every year in the United States, we urgently need additional prevention options,” said Kevin Fenton, MD, director of CDC’s National Center for HIV/AIDS, Viral Hepatitis, STD and Tuberculosis Prevention. “To facilitate the safe and effective use of PrEP as an additional tool, the guidance we’re releasing today gives health care providers information to help them evaluate and support its use for their patients who may be considering this method.”

The guidance is based on the results of two large international clinical trials (Partners PrEP ad TDF2) in which PrEP was found to significantly reduce the risk of HIV infection through heterosexual sex. The CDC notes, however, that in a third clinical trial (FEM-PrEP) involving heterosexual women, PrEP was not found to be effective, and results are pending in a fourth study (the VOICE study).

“The conflicting trial results for efficacy of [Truvada] in heterosexual women can be partially explained by the low medication adherence in FEM-PrEP compared with the higher adherence in Partners PrEP and TDF2,” the CDC writes. “As yet unidentified factors also might have influenced the results.”

The interim guidelines for heterosexual men and women note several cautions and recommendations, similar to those released in January for MSM. These include:

- PrEP should be targeted to individuals at very high risk for HIV infection, such as those with a sex partner who is HIV-positive.
- It is critical that those using PrEP take the daily medication consistently, as the level of protection has been shown to be closely related to levels of adherence

- Concerning women who are pregnant or trying to conceive, health care providers should discuss available information about potential risks and benefits of beginning or continuing PrEP so that an informed decision can be made. While no adverse effects have been found among infants exposed to TDF/FTC during pregnancy, most of the relevant data have been collected among children born to HIV-positive women using the drug for treatment. Data are incomplete for children of HIV-negative women who become pregnant while using PrEP.
- PrEP is not a stand-alone solution: It should be delivered as part of a comprehensive package of prevention services, including counseling to reduce risk behavior and encourage adherence to the daily pill regimen, access to condoms, and management of other sexually transmitted infections.
- Individuals prescribed PrEP must be confirmed to be HIV negative prior to use, and their HIV status, experience of side effects, adherence, and risk behaviors must be monitored regularly during use.

“PrEP could help to reduce new HIV infections in the United States, if it is used consistently and effectively in combination with all available prevention strategies,” said Jonathan Mermin, MD, director of CDC’s Division of HIV/AIDS Prevention. “Its overall impact will also be determined by acceptability and access among the populations at highest risk and whether programs implemented in community settings can achieve the key requirements for success, including ensuring regular HIV testing, maintaining high levels of medication adherence, and preventing increases in risk behavior.”

Demonstration projects and research studies by CDC and others are now underway in several U.S. cities and other countries to begin to assess these and other key implementation questions. Outcomes of these studies of PrEP use in real-world settings will help determine how PrEP can most effectively be used in the United States.

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