

Pre-Exposure Prophylaxis (PrEP) to Prevent HIV Infection: Clinical Considerations from the Department of Veterans Affairs National HIV Program, in the HIV, Hepatitis and Public Health Pathogens Program, Office of Patient Care Services

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Please send questions or comments about this document to the Director, HHPHP, by email at VHAHHPHP@va.gov

PURPOSE

These clinical considerations provide current scientific evidence about and recommendations for the use of pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection for HIV-negative adults at high risk of acquiring HIV infection. This document also provides information to inform VHA clinicians and Pharmacy Directors on compliance with applicable Federal and pharmacy protocols and regulatory standards.

BACKGROUND

Despite many preventive and therapeutic advances, HIV infection remains a major public health problem, both for the United States (U.S.) and VHA. The U.S. Centers for Disease Control and Prevention (CDC) estimates that over 1.1 million Americans are infected with HIV, with approximately 50,000 new infections occurring annually¹.² In 2014, there were 27,405 Veterans in care with HIV infection, making VHA the largest single provider of care to HIV-infected individuals in the country³.

In July 2012, the U.S. Food and Drug Administration (FDA) approved the use of a fixed-dose combination of two antiretroviral drugs, tenofovir (TDF) and emtricitabine (FTC), in combination with safer sex practices, for PrEP against HIV-1 infection in high-risk adults. TDF-FTC is marketed in the U.S. under the trade name Truvada.

Chronic administration of TDF, whether by itself or in combination with FTC, is associated with risk of clinical toxicities⁴. These include renal impairment, decreases in bone mineral density, and acute exacerbations of chronic hepatitis B virus (HBV) infection in patients with HIV/HBV co-infection if TDF-FTC is stopped.

Emergence of HIV resistance is a particularly serious risk if PrEP with TDF-FTC is administered by itself to an individual with undiagnosed HIV infection, whether acquired before or after PrEP is initiated. Emergence of HIV resistance has been observed in clinical trials of PrEP with TDF-FTC, both among individuals who had HIV infection at baseline and those who acquired HIV infection while on PrEP^{5,6,7}.

On May 14, 2014, the U.S. Public Health Service, led by the Surgeon General and the Department of Health and Human Services, released the first comprehensive clinical practice guidelines for PrEP⁸. The new Federal guidelines recommend that

PrEP be considered for individuals who engage in behaviors that lead to increased risk of HIV-1 transmission. Populations for whom PrEP should be considered include:

- Sexually active men who have sex with men (MSM) at substantial risk of HIV acquisition.
- Heterosexually active men and women at substantial risk of HIV acquisition.
- Adult injection drug users (IDU) at substantial risk of HIV acquisition.
- Heterosexually active men and women whose partners are known to have HIV infection.

Behaviors or conditions that place an individual at substantial risk of HIV acquisition include:

- Commercial sex work.
- Having an HIV-positive sexual partner.
- Sexually transmitted infection (STI) diagnosed or reported in the last 6 months.
- High number of sex partners.
- History of inconsistent condom use.
- HIV-positive injecting partner.
- Sharing injection equipment.

RECOMMENDATIONS

PrEP should be considered as one of several prevention options for sexually active MSM at substantial risk of HIV acquisition, heterosexually active men and women at substantial risk of HIV acquisition, adult IDUs at substantial risk of HIV acquisition.

The efficacy of PrEP without concurrent safer sex practices (such as condom use) is unknown. In addition, PrEP does not confer any protection against other sexually transmitted diseases (e.g., syphilis or gonorrhea). Thus, safer sex practices (including condom use) and risk reduction should continue to be an important part of HIV prevention counseling and care.

VA recommends following CDC guidelines particularly with respect to HIV testing and determination of HIV risk prior to initiation of PrEP, routine clinical and lab monitoring (e.g. renal function, hepatitis B virus infection), potential drug-drug interactions, counseling about safer sex practices, routine STI testing, pregnancy tests for women, and discontinuation of treatment⁹. If testing indicates HIV infection,

the patient should be informed of the results and referred to an HIV specialist immediately for evaluation. The CDC guidelines are available at <http://www.cdc.gov/hiv/guidelines/>.

After obtaining the patient's consent, perform HIV testing in the week before initiating PrEP, ideally using 4th-generation HIV tests³. Other appropriate HIV screening tests include serum and point-of-care fingerstick antibody tests. Oral rapid tests are not sufficiently sensitive when considering PrEP use, nor should patient-reported results or anonymous test results be used. The VHA National Center for Ethics in Health Care has provided guidance on informed consent for the series of repeat HIV screening tests conducted in the context of PrEP therapy¹⁰.

Prior to prescribing PrEP, consultation with an infectious diseases or HIV clinician may be helpful.

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9. Centers for Disease Control and Prevention. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. June 2014. Available at <http://www.cdc.gov/hiv/pdf/HIVtestingAlgorithmRecommendation-Final.pdf>. **NOTE:** *This linked document is outside VA control and may or may not conform to Section 508 of the Americans with Disabilities Act.*
10. Veterans Health Administration. National Center for Ethics in Health Care. *Frequently Asked Questions, Informed Consent Requirements for HIV Testing*, updated March 13, 2015. Available at: http://vaww.ethics.va.gov/docs/policy/FAQ_Informed%20Consent%20for%20HIV%20testing_3.13.15.pdf. **NOTE:** *This is an internal VA Web site that is not available to the public.*