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Preventing New Human Immunodeficiency Virus Infections with Pre-exposure Prophylaxis

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ABSTRACT

Human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) with emtricitabine/tenofovir (TDF/FTC) can reduce HIV infection risk by 92% in people at high risk for HIV. TDF/FTC was approved for HIV PrEP by the Food and Drug Administration in 2012. Primary care nurse practitioners (NPs) have not embraced this tool for the prevention of new HIV infection. A number of barriers exist that may prevent primary care NPs from prescribing HIV PrEP for patients in need. This article clarifies current recommendations for HIV PrEP and provides practical guidance for primary care NPs to incorporate this tool into their routine practice.

Keywords: harm reduction, human immunodeficiency virus prevention, injection drug users, pre-exposure prophylaxis, sexual/gender minority

The Centers for Disease Control and Preventions (CDC) estimates that there were 37,600 new human immunodeficiency virus (HIV) infections in 2014.[1] Pre-exposure prophylaxis (PrEP) is a highly effective tool for the prevention of new HIV infections that was approved by the Food and Drug Administration (FDA) in 2012.[2] PrEP is largely underused by primary care providers.[3] This clinical feature will address provider barriers that impede prescribing PrEP to high-risk patients and provide a straightforward approach for nurse practitioners (NPs) to offer PrEP in the primary care setting.

BACKGROUND

The CDC estimates that 1.1 million people are infected with HIV in the United States, with 1 in 7 people unaware of his or her HIV status.[1] Of the new diagnoses of HIV in the US in 2015,[1] 82% are men who have sex with men (MSM). Black people make up the majority (45%) of new HIV diagnoses followed by whites and Hispanics.[1] Most troubling about new cases of HIV in the US is the fact that if current HIV incidence rates persist, 1 in 2 black MSM and 1 in 4 Latino MSM will be diagnosed with HIV during their lifetime.[4] The overall lifetime risk of HIV diagnosis in the US among all MSM is now 1 in 99.[4] Among women with a new diagnosis of HIV, 61% are black, 19% are white, and 15% are Hispanic. Heterosexual black women represent the largest group of new HIV infections among women.[1]

Thirty-five years after the HIV/AIDS epidemic was first identified, effective treatments have dramatically decreased the number of deaths from HIV/AIDS. More than 6,000 people still died from HIV-related illnesses in 2014.[1] Although life expectancy and quality of life have increased markedly for people living with HIV (PLWH), the reality remains that, if not treated, HIV can lead to devastating health consequences and death. PLWH have the potential to transmit the infection to others through sexual contact and shared injection drug paraphernalia.

Antiretroviral therapies have improved the quality and quantity of life for PLWH. HIV is now viewed as a chronic disease in high-resource countries.[5]

Although the care of PLWH has shifted to primary care settings, services for the prevention of new HIV infections in these settings remain incomplete. The tool kit of many NPs for the prevention of new HIV infections remains the same—condoms, safer sex education, and clean needles. Lacking from this tool kit for many NPs are newer strategies that have been found to be most effective in preventing new HIV infections including universal HIV testing and linkage to care,[6] HIV treatment and viral load suppression to reduce transmission,[7] and PrEP for those at high risk of HIV acquisition.[8]

PREVENTING NEW HIV INFECTIONS

The first combination drug for HIV PrEP was approved by the FDA in 2012.[2] Emtricitabine/tenofovir (FTC/TDF) is a fixed-dose combination of 2 nucleoside reverse transcriptase inhibitors. Used for the treatment of HIV since 2004, FTC/TDF was shown to be effective as a daily treatment for the prevention of HIV infection.[2] Although evidence of the safety and efficacy of FTC/TDF as HIV PrEP has been demonstrated in numerous trials, prescribers should be familiar with 2 large-scale clinical trials on which approval of the treatment was based. The first trial focused on serodiscordant heterosexual couples (Partners PrEP) and the other focused on MSM (Pre-Exposure Prophylaxis Initiative [iPrEx]).

In the Partners PrEP trial,[9] serodiscordant heterosexual couples in 2 countries were randomized to receive tenofovir, FTC/TDF, or placebo. Treatment in the FTC/TDF arm of the trial was associated with a 75% reduction in HIV acquisition, but researchers observed a 90% reduction in those who had detectable drug levels in their system. The trial was originally intended to last up to 36 months but stopped 18 months early after an interim analysis showed statistically significant efficacy in the FTC/TDF group compared with the other 2 groups.[9]

The iPrEx trial[10] was a randomized, double-blind, placebo-controlled study in 6 countries, enrolling 2,499 individuals. In this trial, MSM and transgender women were randomized to receive daily FTC/TDF or placebo. The study showed a 44% reduction in HIV acquisition within the TDF/FTC treatment arm, despite low adherence to the study drug (51% as evaluated by serum drug levels). None of the participants who had a new diagnosis of HIV had serum therapeutic levels of FTC/TDF, suggesting treatment nonadherence as opposed to treatment failure was the cause of HIV acquisition.

There is compelling evidence to support PrEP as an effective tool to reduce HIV infections.[8-10] NPs should begin incorporating this strategy into their overall approach to preventing new HIV infections. Primary care NPs are ideally situated to be at the forefront of the movement to eliminate new HIV infections in this generation.

NP' BARRIERS TO PrEP PRESCRIBING

Health care providers report a number of barriers to incorporating PrEP in their practice.[3] Patient-level barriers include concerns that patients receiving PrEP will engage in higher-risk behaviors and/or not adhere to treatment. Additionally, NPs may be concerned about drug toxicity of PrEP. System-level barriers include concerns about an NP's ability to appropriately prescribe PrEP and the overall cost of treatment.

Patient Risk Behaviors

A common concern that NPs have regarding PrEP is the perception that a PrEP prescription will increase risk-taking behavior and/or reduce safer sex practices. On the contrary, the clinical literature does not support this concern. Data from the iPrEx trial confirm that participants were, in fact, more likely to engage in sexual risk reduction behaviors while receiving PrEP.[11] Additionally, PrEP is a component of a larger risk reduction program, which requires regularly scheduled provider follow-up. These follow-up encounters are opportunities to further engage patients in an overall program of risk reduction.

It may be helpful to consider HIV PrEP in the context of other strategies for PrEP. For a patient traveling to a malaria-endemic part of the world, the NP will prescribe appropriate antimalarial medication, in addition to teaching strategies to avoid being bitten by mosquitoes. For the patient who is unwilling or unable to use insect repellent, the NP would not withhold antimalarials because doing so would cause harm. Similarly, withholding PrEP from a patient at high risk for HIV increases the patient's risk for HIV