

Pre-Exposure Prophylaxis for HIV Prevention

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HIV remains a major public health threat in the United States and globally. As of December 2013, an estimated 1.2 million people aged 13 years and older were living with HIV in the United States, approximately 13% of whom were unaware that they were infected [1]. In recent years, new infections have been stable at about 50,000 per year. HIV significantly impacts minorities and people with low socioeconomic status, particularly in the Southeastern United States. The majority of new infections continue to occur in men who have sex with men (MSM), with African American and Latino MSM being 8 times and 6 times more likely to acquire HIV, respectively, compared to white MSM [1]. Injection drug users (IDUs) are also at high risk of contracting HIV, although new infections in this group have decreased in the past decade. The Centers for Disease Control and Prevention (CDC) estimates that 1 in 4 gay and bisexual males, 1 in 5 IDUs, and 1 in 200 heterosexual men and women are at substantial risk for acquiring HIV during their lifetime [2].

In addition, new infections are not equally distributed geographically. The South bears a high burden of established and new HIV infections. In 2014, approximately 44% of people living with HIV and 52% of newly infected individuals lived in the South, a region that accounted for 52% of deaths directly attributed to HIV and AIDS diagnoses in that year [1]. In addition, the South differs in where new infections are happening. In most of the United States, new infections tend to occur in major metropolitan areas. However, in the Southern United States, new infections occur primarily in smaller metropolitan areas and rural areas. North Carolina, like the rest of the

South, bears a high burden of HIV, being ranked 9th for the number of new infections. Estimates suggest that 1 in 93 North Carolinians are at risk of being diagnosed with HIV at some point during their lifetime, which is higher than the average lifetime risk for the rest of the US population (1 in 99) [3].

Several strategies for the prevention of HIV have been shown to have varying degrees of effectiveness. Pre-exposure prophylaxis (PrEP) was found to be highly effective in the prevention of HIV among MSM [4], IDUs [5], and heterosexual couples [6] who are at risk for HIV. In 2012, the US Food and Drug Administration (FDA) approved the fixed-dose combination tablet of tenofovir plus emtricitabine (Truvada) daily for PrEP. The CDC recommends PrEP for people who are at substantial risk for acquiring HIV including MSM and heterosexuals who are in a relationship with an HIV-positive partner, MSM who have had multiple partners or sexually transmitted diseases in the past 6 months, and IDUs who share needles with an HIV-positive partner [7].

The main predictor of the effectiveness of PrEP is adherence. In the iPrEX study, PrEP provided overall protection from HIV of 40% [4]. However, patients who had Truvada drug levels suggestive of taking the medication only 4 times per week had 92% protection, while patients who were highly adherent and took the medication daily had 99% reduction in their risk of acquiring HIV. The CDC recommends that PrEP be offered as part of a comprehensive program that also addresses adherence, screening for sexually transmitted diseases, and risk reduction behavior. In spite of its effectiveness, a recent survey by the CDC

showed that only 1 in 3 primary care providers had ever heard of PrEP [4].

Truvada is well tolerated and has been used to treat established HIV infection for decades. Patients taking PrEP may experience a “startup syndrome” during the first week, with symptoms that include gastrointestinal upset and headache. Most of these symptoms resolve after 1 week. Rare side effects include nephrotoxicity due to tenofovir, which can lead to tubular damage and Fanconi syndrome. A decline in bone mineral density has also been observed in patients who took Truvada for PrEP, but this decline was reversible, with bone mineral density returning to baseline levels within 6-18 months after discontinuation of the drug.

Several challenges have risen in the provision of PrEP. Most importantly, the cost of medication and health care visits can be a barrier for patients, especially those who are uninsured or underinsured. Gilead Sciences offers a patient assistance program that can provide eligible patients with Truvada free for up to 6 months. However, the cost of medical visits and laboratory testing can still be a burden to patients. Another concern about patients on PrEP is the possibility of an increase in high-risk behaviors that can lead to an increase in the rate of sexually transmitted diseases other than HIV. Despite this concern, such an increase has not been shown in clinical trials and demonstration projects of PrEP.

Most infectious disease and HIV clinics are well suited to administer PrEP, since the challenges encountered by these patients are similar to those encountered by HIV-infected patients. Ideally PrEP should be offered in primary care settings, but because of the aforementioned challenges, uptake in this setting has been slow. A list of clinics currently administering PrEP in North Carolina is available at the North Carolina AIDS Training and Education Center’s website. NCMJ

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