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Barriers to HIV Pre-exposure Prophylaxis Treatment

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Introduction

Globally, the incidence of human immunodeficiency virus (HIV) continues to remain high despite the implementation of numerous research and prevention strategies. The number of new HIV infections in adults worldwide has not declined since 2010 (USAIDS, 2016). While significant progress has been made in the United States since the discovery of HIV/AIDS in 1981, new infection rates continue to remain higher than expected.

According to the Centers for Disease Control and Prevention (CDC) there are approximately 1.2 million people in the United States infected with HIV, with new diagnoses estimated at 39,513 in 2015 (CDC, 2016). Of these cases, homosexual men accounted for 67%, while African American men having sex with men (MSM) disproportionately made up the largest number of new diagnoses compared to other racial or ethnic communities in the United States. Additionally, the report identified African American heterosexual women as an at-risk population. Although the number of new HIV diagnoses among this group declined from 2004 to 2014, African American heterosexual women accounted for a higher proportion of HIV cases compared to other women of other races or ethnicities (CDC, 2016).

While transmission of HIV among high risk populations continues to remain problematic in the United States, the introduction of pre-exposure prophylaxis (PrEP) treatment is one prevention method that both health care providers and individuals at risk should consider. This article will review the current guidelines for prescribing PrEP and explore possible barriers for both provider and patient regarding increased utilization for prevention HIV treatment.

PrEP Guidelines

HIV pre-exposure prophylaxis (PrEP) provides a promising new approach for slowing the transmission of HIV in the United States (U.S.) and worldwide (McMahon et al., 2014). Truvada® (emtricitabine/tenofovir disoproxil fumarate) is a nucleoside reverse transcriptase inhibitor (NRTI) first approved by the U.S. Food and Drug Administration (FDA) in 2011 for treatment of HIV-1 infection in adults (Truong et al., 2015). In 2012, Truvada® was approved for prophylactic use in at-risk individuals.

A multifaceted approach that includes counseling, continued condom use, and risk reduction is recommended when utilizing Truvada® for PrEP to maximize efficacy (Plosker, 2013). McCormack et al. (2016) conducted the PROUD study to assess the efficacy of Truvada® and relative risk of compensation in PrEP users specifically among men who have sex with men, resulting in a 90% reduction rate in the transmission of HIV with no evidence of an increase in the incidence of other sexually transmitted infections.

Prior to prescribing or starting PrEP, initiation of specific steps are paramount to ensure safety and efficacy. HIV status must be confirmed and documented. Clinical eligibility also includes normal renal and liver function tests, with continued monitoring every six months. PrEP users should be monitored for medication side effects, adherence, pregnancy intent, risk reduction and sexually transmitted infections (STI) at three month intervals. Hepatitis B virus (HBV) status should be confirmed and vaccinations should be given if indicated (U.S. Public Health Service, 2014). Table 1 provides a summary of PrEP guidelines developed by the U.S. Public Health Service.

Table 1: Summary of Guidance for PrEP Use

	Men Who Have Sex with Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection	HIV-positive sexual partner; recent bacterial STI; high number of sex partners; history of inconsistent or no condom use; commercial sex work	HIV-positive sexual partner; recent bacterial STI; high number of sex partners; history of inconsistent or no condom use; commercial sex work; in high-prevalence area or network	HIV-positive injecting partner; sharing injection equipment; recent drug treatment (but currently injecting)
Clinically eligible	Documented negative HIV test result before prescribing PrEP; no signs/symptoms of acute HIV infection; normal renal function; no contraindicated medications; documented hepatitis B virus infection and vaccination status		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply		
Other services	Follow-up visits at least every 3 months to provide the following: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment at 3 months and every 6 months thereafter, assess renal function every 6 months, test for bacterial STIs		
	Do oral/rectal STI testing	Assess pregnancy intent Pregnancy test every 3 months	Access to clean needles/syringes and drug treatment services
STI: sexually transmitted infection			

Source: U.S Public Health Service, 2014

Barriers to PrEP utilization

Although the reported breakthrough in the reduction of HIV transmission with Truvada® has been promising, its use for prevention remains limited among at-risk individuals. At the 21st International AIDS Conference, it was reported that 79,000 individuals used Truvada® as PrEP

between 2012 and 2015 (Anita et al., 2014). However, it was found that some groups were not benefiting as much as others. Barriers to the implementation and utilization of PrEP by at-risk individuals include: lack of awareness, inadequate provider training, limited data regarding long term adverse effects of PrEP, high cost, stigma associated with PrEP and strict regimen of taking the medication daily. (Krakower & Mayer, 2012; Gengiah et al., 2014; Liu et al., 2014).

Additional barriers identified were low risk perception, partner nondisclosure, influence of partner beliefs on product use, pregnancy, dosing frequency, type of drug formulation and poor comprehension of product use instructions (Gengiah. et al, 2014).

Implementation of measures to decrease or remove financial burden is paramount in increasing PrEP utilization. In 2015, Laufer et al. published a study on HIV trends and PrEP use in the state of New York, revealing that the incidence of HIV infection substantially decreased among medicaid recipient PrEP users due to collaborative efforts of the state and local health department to increase the availability of Truvada® for prophylaxis. State medicaid agency coverage of PrEP is crucial in the long-term prevention of HIV. Currently, several states have adopted the medicaid expansion program to cover Truvada® as PrEP. Vouchers and other subsidies can be especially beneficial in reducing cost. For those individuals that do not qualify for medicaid benefits, some private insurances cover Truvada® as PrEP with prior authorization.

Providers' Perspectives

Providers play a pivotal role in HIV prevention. Following reports of PrEP efficacy, Tellalian et al. (2013) conducted an online survey of 189 providers to assess awareness, attitudes, and prescribing practices surrounding PrEP. The survey revealed that the majority of the respondents 90% (n=133) were aware of the results of these studies and 78% (n=147) were familiar with CDC's guidelines for PrEP use. However, only 19% (n= 36) had prescribed PrEP,

citing the development of antiretroviral resistance, potential increase in high risk behavior, and poor medication adherence as deterrent factors in prescribing. Similarly, a study conducted among Massachusetts area physicians found differences in the comprehension and interpretation of the results which tended to vary according to specialty, with HIV specialists showing greater awareness than primary care providers (Mimiaga et al., 2014). Hesitancy to prescribe PrEP has also been attributed to provider concerns regarding efficacy and safety, as well as funding.

Patients' Perspectives

The examination of knowledge and perception of individuals who are considered high risk remains imperative to decrease and eliminate barriers preventing Truvada® use. Auerbach et al. (2015) concluded that women in the U.S. consider PrEP an important method to prevent HIV and would consider using the medication if the cost is covered, side effects are minimal, the efficacy of the drug is reasonable and PrEP is delivered by trusted providers in trusted venues. This study also revealed that the participants felt that PrEP was not widely offered because providers were equally unaware of PrEP use, which resulted in a decreased patient trust of the medical system.

Stigmas can create apprehension and misunderstandings between the provider and patient, therefore, limiting the likelihood of Truvada® use. Potential prep users recognize that some of their peers are already aware of what Truvada® is for and will be judged or labeled if they were to take it. In a qualitative study with the MSM population, 80% of men qualified for PrEP treatment, but 78% who qualified declined due to the stigma associated with taking PrEP (Calabrese & Underhill, 2015). Stigmas surrounding PrEP may play a large role in preventing high risk individuals from asking about and ultimately using PrEP.

Solutions to PrEP barriers

It is essential that clinicians receive proper education in both the identification of high risk individuals and Truvada® when used as PrEP. Thorough education will increase clinician comfort level when discussing Truvada® with patients, which may increase utilization and lower the number of new HIV cases. Additionally, it is imperative to educate individuals that Truvada® must be used with safe sex practices for maximum efficacy. Health care providers can update their knowledge of PrEP through conferences, continuing education articles and online courses to increase knowledge and acceptance.

Conclusion

Understanding Truvada®'s efficacy in the reduction of HIV transmission and the barriers to its utilization should facilitate the development of strategies to address continued troubling trends. PrEP implementation should be a global effort to identify and implement appropriate methods to minimize these barriers by increasing provider confidence in prescribing, and enhancing patient acceptance and adherence. Increasing public awareness, ensuring access to HIV services, providing provider training and increasing support services for targeted populations could help reduce these barriers and increase PrEP utilization.

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