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# Implementation of PrEP Protocol in Primary Care

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#### **Executive Summary**

# **Introduction of the Problem**

Human immunodeficiency virus (HIV) is an incurable condition that continues to be a public health threat. Approximately 38 million people live with the disease worldwide (World Health Organization, 2020). According to the latest statistics provided by the Centers for Disease Control and Prevention (CDC), roughly 1.2 million individuals in the United States were infected with the virus at the end of 2018 (CDC, 2021). In addition, 37,968 people were classified as newly acquired cases (CDC, 2020e). Furthermore, according to HIV.gov (2020b), one out of seven individuals living with the disease are unaware that they have it.

Pre-exposure prophylaxis (PrEP) is a medication that can be prescribed to individuals at risk of acquiring HIV. PrEP is highly effective and reduces one's risk by 99% if taken as directed (CDC, 2020c). The Food and Drug Administration (FDA) has approved Truvada and Descovy as medications for daily use as PrEP (Hunt, 2019).

Pre-exposure prophylaxis can be prescribed by any healthcare provider when they deem a patient high risk for acquiring HIV. However, at a primary care practice in central Illinois, the department of infectious disease continuously received numerous referrals for PrEP initiation. The practice's department of internal medicine previously had no protocol for initiation of PrEP, which contributed to the increased referrals for PrEP. The department of infectious disease wanted to increase PrEP prescribing in the department of internal medicine by implementing a PrEP protocol.

# **Literature Review**

Human immunodeficiency virus first appeared in the United States in the 1970s. The virus is thought to have originated in chimpanzees and then spread to human hosts because of

humans ingesting the infected meat (CDC, 2020a). Human immunodeficiency virus is spread through the exchange of infected bodily fluids such as blood, semen, rectal fluid, and breast milk from persons who have a detectable viral load (HIV.gov, 2020a). Once HIV is contracted, it advances in three stages: stage one, acute HIV; stage two, chronic HIV; and stage three, acquired immunodeficiency syndrome (CDC, 2020a). No cure for HIV exists, so it is important to identify and treat high risk individuals prophylactically to prevent new infections. New cases of HIV often arise due to high-risk behavioral factors by men who have sex with men, intravenous drug users, and/or sex workers (CDC, 2019). Primary care providers should be aware of these highrisk groups as potential candidates for PrEP initiation.

Barriers inhibiting PrEP initiation by primary care doctors are complex and multifactorial, consisting of different layers surrounding lack of knowledge and education. Providers' concerns related to the cost of antiretroviral medications and uncertainty about insurance coverage, along with the high cost of continued medical monitoring of patients prevent them from prescribing PrEP (Krakower et. al, 2014). Perceived barriers for PrEP prescription by family practice and primary care practices include lack of specialized training, preparation, and tools to prescribe PrEP which leads to lower comfort levels in prescribing the medication (Henry et. al, 2019).

While PrEP has been implemented into settings such as HIV clinics and STI clinics, there is limited data on why PrEP is not implemented into primary care settings more often (Edelman et. al, 2020). An estimated 1.2 million Americans are eligible for PrEP initiation, but only about 90,000 individuals were prescribed it in 2016 (Edelman et. al, 2020). Underhill, Operario, Skeer, Mimiaga, and Mayer (2010) proposed a framework outlining key components for the implementation of PrEP in clinical practices or community settings. The five components consist

of: (a) PrEP medication; (b) safety screening and repeat HIV testing; (c) maintaining PrEP; (d) development of strategies to help users and prescribers of PrEP; and (e) population monitoring (Underhill et. al, 2010). Such a framework can optimize the initiation and use of PrEP for high-risk populations by providing ongoing assistance in addition to an established clinical guideline for PrEP use (Underhill et. al, 2010). Studies suggested that integration of proper protocols into clinical practices, including education of providers and staff will improve comfort with PrEP prescribing (Arnold et. al, 2012). Improved uptake of prescribing PrEP will lead to improved outcomes through decreased HIV transmission rates and new diagnosis of HIV infections.

# **Project Methods**

The purpose of this DNP project was to optimize PrEP uptake by providers in a primary care practice and as a result, decrease referrals to the department of infectious disease. Specific objectives of this project included determining what barriers were preventing providers from prescribing PrEP. Provider knowledge, comfort level, and bias related to initiating PrEP were explored and guidelines reviewed for PrEP initiation. This was done to create an evidence-based protocol that was then utilized in the primary care practice. The project was submitted to Southern Illinois University Edwardsville and SIU Medicine IRBs. The project was deemed quality improvement (QI) and was not subjected to further IRB approval.

The implementation process started in September 2021. The pre-and post-intervention surveys were designed with a combination of quantitative Likert Scale and multiple-choice questions. The pre- and post-intervention surveys had the same questions. The pre-intervention survey was distributed via e-mail and then by *SurveyMonkey* to assess providers' baseline knowledge and to identify any barriers to prescribing PrEP. In October 2021, a meeting was held with the providers via Webex. At that time, PrEP education was provided and the standardized

protocol was introduced and explained. PrEP educational packets and a copy of the PrEP protocol were created and displayed in the clinic rooms and in providers' offices for reference. In addition, patient education brochures discussing PrEP were distributed to providers to hand-out to patients.

Initially, the post-intervention survey was supposed to be evaluated six-weeks after implementation of the protocol. The post-intervention surveys were distributed in December 2021 via *SurveyMonkey* to assess the effectiveness of the protocol and providers' knowledge and attitudes surrounding PrEP. Project leaders were unable to go into clinic due to COVID-19 restrictions, which delayed post-intervention survey distribution.

#### Evaluation

The project was evaluated by analyzing providers' responses from their pre- and postintervention surveys. The primary care practice had 10 providers, a group composed of two nurse practitioners and eight physicians. 60% (n=6) of providers completed the pre-intervention surveys, while only 30% (n=3) of the providers completed both the pre- and post-intervention surveys. Consequently, there was a small sample size when comparing providers responses.

The first part of the surveys was assessed using five quantitative Likert Scale questions. Responses showed that 67% (n=2) of providers did increase in familiarity of prescribing PrEP after the intervention. A majority (67%, n=2) of providers' responses also revealed an increase in comfort of prescribing PrEP from their pre-intervention survey response. None of the provider's response changed when assessing whether they thought prescribing PrEP was out of their scope of practice. Thus, they all knew prior that they could implement PrEP. When asked if they refer patients to the department of infectious disease, all post-intervention responses indicated less likelihood of referral. Two of three providers (67%) disagreed with the statement "I prescribe PrEP in my practice" and did not have a change to their response after the intervention. One provider (33%) did have an increase, but the response (neither agree or disagree) did not definitively state whether PrEP was being prescribed in their practice.

The second part of the survey consisted of eight multiple choice questions. The NP was the only provider who demonstrated an increase in score after the implementation of the intervention. Initially, the NP, MD1, and MD2 scored 87.5%. The NP's score increased to 100%, while MD1 and MD2 remained the same. Both of their missed questions pertained to their knowledge of when PrEP treatment should be discontinued. This indicated that further education in regards to when to discontinue PrEP treatment may be necessary.

# Limitations

The COVID-19 pandemic contributed to project limitations substantially. Originally, the Webex meeting was supposed to be face-to-face. The pre-intervention surveys were supposed to be distributed amongst providers at the scheduled in person meeting. However, due to COVID-19 restrictions, project leaders were not able to be in the clinic. This significantly impacted the number of pre-intervention surveys obtained. Project leaders had to send the pre-intervention survey electronically via email, but did not receive many surveys back. Then, project leaders switched to *SurveyMonkey*, but still many providers did not respond. Project leaders extended the time between initial distribution of surveys to give more time to providers to respond, but were still unsuccessful.

The same process was supposed to be repeated for the post-intervention survey. Project leaders were eventually able to go into the clinic to hand-out the post-intervention surveys. Many more providers were willing to fill out the post-intervention survey. However, half of the providers who did complete the post-intervention survey did not complete pre-intervention survey, resulting in project leaders only being able to compare three providers' responses.

Other limitations included not being able to retrieve the number of referrals to the infectious disease department for PrEP. Due to the delicacy of patient information surrounding HIV and PrEP, access to referrals were not granted. Consequently, it was unclear if there was an actual decrease in referrals to infectious disease after the implementation of the protocol.

# **Impact on Practice**

There was little push back from providers regarding the practice change. By the end of the implementation period, providers were more aware of the protocol and understood how they could implement the protocol into an at-risk patient's care plan. This was a relatively simple practice change that ultimately has the ability to improve patient outcomes by increasing access to preventative services for high-risk populations. Furthermore, it decreases delay in prophylactic treatment as no treatment referral is needed, and overall aids in the reduction of new HIV cases. The use of the protocol is being continued at this practice with plans to develop a clinic solely for PrEP patients.

# Conclusion

HIV is an epidemic in the United States, therefore measures for reducing new diagnoses are of paramount importance. PrEP is a medication that can be used to combat new infections of HIV in high-risk, HIV-negative people. It is important to educate providers on the benefits of initiating PrEP and having a protocol in a primary care setting to help guide providers with highrisk populations and initiating PrEP.