Implementation of HIV Preexposure Prophylaxis in a Homeless Primary Care Setting at the Veterans Affairs

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Abstract
Objective: Oral preexposure prophylaxis (PrEP) is highly effective in preventing HIV-1 acquisition, yet it is underutilized among at-risk populations. In this pilot quality improvement (QI) initiative, we sought to identify barriers to PrEP implementation and create interventions to improve access to PrEP in a primary care clinic for homeless veterans. Methods: The setting was a large homeless primary care clinic at the Veterans Affairs in an urban area with high HIV prevalence. A root cause analysis was performed to identify barriers to PrEP expansion in the primary care clinic. Targeted interventions to improve provider knowledge and patient access to PrEP were implemented by the QI team. Results: Root cause analysis revealed 3 primary barriers to PrEP expansion in the primary care clinic: institutional limitations for prescribing PrEP, inconsistent screening and recognition of eligible patients by clinic staff, and lack of clinic workflow processes to support PrEP prescription. A multidisciplinary focus group found low levels of PrEP awareness and knowledge, with only 22% of providers reporting comfort discussing PrEP with patients. This improved to 40% of providers following targeted clinic educational interventions. The QI team also developed a pathway for primary care providers to obtain institutional PrEP prescribing privileges and used work groups to develop clinic workflows and protocols for PrEP. At the end of the intervention, at least 50% of primary care providers in the clinic had initiated PrEP in a new patient. Conclusions: We describe a multidisciplinary QI model to implement PrEP within a primary care setting serving Veterans and persons experiencing homelessness. Our program successfully addressed provider knowledge deficits and improved primary care capacity to prescribe PrEP. The primary care clinic can be a viable and important clinical setting to improve access to PrEP for HIV prevention, especially for vulnerable populations.

Keywords
human immunodeficiency virus, prevention, preexposure prophylaxis (PrEP), homeless, primary care, veterans, quality improvement, underserved communities

Introduction
Oral preexposure prophylaxis (PrEP) is a highly effective strategy for the prevention of HIV infection. Clinical studies have shown efficacy among at-risk men who have sex with men (MSM), heterosexual men and women, and people who inject drugs (PWID). Currently, the only Food and Drug Administration–approved medications for PrEP are daily administration of the fixed-dose pill combinations tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) or tenofovir alafenamide/emtricitabine.

In 2014, the Centers for Disease Control and Prevention (CDC) released recommendations for universal screening of all patients for HIV risk factors and initiating oral PrEP for all eligible patients. The United States Preventive Services Task Force (USPSTF) reinforced this in June 2019 with a grade A recommendation that clinicians offer PrEP to persons at high risk of HIV acquisition. Despite national recommendations, it is estimated that only 15% of those at risk receive PrEP.

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risk in the United States currently use PrEP. Increasing access to PrEP is a key tenet of the recent HHS initiative to ending the HIV epidemic in the United States.

The addition of highly effective oral PrEP to comprehensive HIV prevention efforts has not yet produced a significant reduction in the rate of HIV transmission. The annual number of new HIV infections in the United States has remained relatively stable since 2010, with just over 39,000 new infections in 2016. This plateau may be related to inadequate prevention outreach for certain high-risk groups. Though MSM continue to account for most new HIV infections in the United States, 25% of new infections are through heterosexual sexual exposure and 10% in PWID. HIV also disproportionately affects economically disadvantaged and rural populations, which may be related to lack of access to prevention services.

The Veteran Health Administration (VHA) is the largest provider of HIV care in the United States as well as the largest single provider of healthcare services to the homeless population. It is well established that persons experiencing homelessness have worse health outcomes and higher mortality rates than the general population. A recent study found that those who acquire HIV while homeless have 27-fold higher independent odds of death compared to those with housing. While the prevalence of HIV varies widely among homeless subgroups, homeless veterans are affected at a rate of 3.4 times that of the general veteran population and 3.6 times that of the US population overall.

While the VHA has excelled in providing care across the HIV care continuum, the uptake of PrEP across the VHA has been variable. In one recent analysis of VHA data, a potential barrier for PrEP uptake was that initiation and management of PrEP across the VHA has been historically restricted to infectious disease specialists. Consequently, in 2018, 76% of all PrEP prescriptions in the VHA were initiated by infectious disease specialists compared with 13% initiated in the primary care setting. A recent review of medical records in multiple VHA sites also identified provider knowledge gaps and attitudes about PrEP as significant barriers to access.

We wanted to examine limitations to PrEP uptake among high-risk homeless veterans at one VHA site in a high HIV prevalence urban setting. Herein we describe a multidisciplinary pilot initiative to improve education and access to PrEP services in a VA primary care clinic serving veterans experiencing homelessness.

Methods

Setting

The VA Greater Los Angeles Healthcare System (VAGLAHS) is among the largest VA medical centers and is located in Los Angeles, California. During the project period from September 2018 to August 2019, the VAGLAHS served approximately 3600 homeless veterans at 3 Homeless Patient Aligned Care Team (HPACT) clinics designated to address the complex medical, mental health, and social needs of veterans experiencing homelessness. Established in 2012, the West Los Angeles (WLA) HPACT cares for approximately 2200 veterans and is the largest HPACT nationwide. WLA HPACT employs more than 60 permanent staff and serves as an interprofessional training site for nurse practitioner residents, clinical pharmacy residents, social workers, psychology fellows, and resident physicians in internal medicine and psychiatry. In Fall 2018, WLA HPACT interdisciplinary trainees and faculty formed a quality improvement (QI) team to improve uptake of PrEP in the primary care setting. This evaluation was categorized as an operation improvement activity based on Veterans Health Administration Handbook 1058.05 where information generated is used for business operations and quality improvement. The overall project was subject to administrative oversight rather than oversight from a human subjects institutional review board.

Root Cause Analysis

At the start of the QI initiative, the multidisciplinary team accessed an internal clinical dashboard to help assess the number of potential PrEP candidates in the clinic not receiving PrEP. The QI team then used focus group and key informant interviews to understand the existing institutional process and barriers for patients to obtain PrEP prescriptions. Identified barriers were graphed in a fish bone diagram and became the focus of intervention for the next year.

Measures and Analyses

An interprofessional focus group of 23 clinic staff and trainees was convened to determine baseline awareness, knowledge, and attitudes about discussing HIV risk behavior and prescribing PrEP. With this information, the QI team identified “champions” within each discipline to help facilitate staff education and developed a series of training tools. At the end of the 9-month project period, the focus group reconvened to assess changes in knowledge, comfort, and willingness to prescribe PrEP following the educational interventions.

Results

Root Cause Analysis

PrEP utilization among potentially eligible veterans was first assessed using the PrEP dashboard (an internal VA data tracking tool). We found low utilization of PrEP in the HPACT clinic, with only 8% of eligible Veterans currently...
prescribed PrEP. Root cause analysis identified the following barriers to PrEP implementation in the clinic: (1) institutional limitations of PrEP prescribing privileges to the Infectious Disease Service, (2) underidentification of homeless patients with significant risk for HIV acquisition who may be eligible for PrEP, and (3) no current process for PrEP management within the HPACT clinic (Figure 1).

**Institutional Prescription Restrictions**

Specialty medications such as certain antineoplastic drugs, biologics, antibiotics, and antiretroviral drugs including TDF/FTC are restricted to specialist prescribers by the VA National Formulary. This is done to ensure safe use of these medications and avoid overuse. Local facilities can then modify medication restrictions to meet patient needs. In partnership with the Infectious Disease and Pharmacy Services, the QI team developed a new institutional process allowing primary care and pharmacy providers to prescribe TDF/FTC (which was the only Food and Drug Administration–approved medication for PrEP at the time of this QI initiative). In order to obtain approval to prescribe PrEP, interested providers completed a 1-hour VA-specific PrEP prescriber training (using the established VHA Talent Management System for employee trainings course #36785) and submitted training documentation to the local Pharmacy and Therapeutics committee. This process allowed primary care providers (PCPs) and clinical pharmacists to become approved PrEP prescribers in the health care system, and receive appropriate education on the indications, risks/side effects of TDF/FTC, and proper safety laboratory monitoring. To ensure continued availability of PrEP services in the primary care clinic, this training is now part of the standard onboarding process for all new clinic prescribing staff and trainees.

**Identification of PrEP eligible patients**

The initial focus group interviews revealed poor knowledge of PrEP and perceived discomfort prescribing PrEP among clinic staff. At baseline, only 22% of providers stated they were comfortable talking about PrEP with patients. Identified barriers included lack of adequate knowledge to answer patient questions (10 providers) or being completely unaware of PrEP (6 providers). As a group, only 30% of staff were able to correctly identify all appropriate candidates for PrEP when provided clinical scenarios.

To address these gaps the QI team developed educational interventions. All HPACT staff received an hour-long interactive lecture-based training on HIV risk assessment and PrEP indications. Prescribing providers were also asked to complete the previously described VA-specific PrEP training in order to obtain local approval for PrEP prescribing. To reinforce these trainings, a pocket tool was developed and distributed to clinic staff (Figure 2). The pocket tool included a condensed PrEP protocol for clinical assessment and laboratory testing as well as specific questions to help providers elicit a comprehensive sexual and injection drug use risk assessment. At the completion of the educational interventions, all HPACT PCPs and clinical pharmacy staff had received institutional approval to prescribe PrEP.

Three months after the educational trainings, the focus group reconvened to assess changes in PrEP knowledge and
PrEP in Primary Care

Pre-exposure prophylaxis (PrEP) is an effective way to prevent HIV infection for people who are at high risk.

The FDA approved medication for PrEP consists of tenofovir (TDF) 300 mg and emtricitabine (FTC) 200 mg (Truvada) combined into a single tablet taken once daily.

To prescribe PrEP at WLA VA, prescribers need to complete TMS training #36785 then submit certificate for approval. Prescribers will be notified when approved.

- Discuss sexual health and practices
- Discuss injection drug use

Indications for PrEP

- Any Veteran who has sex and/or shares injection equipment with HIV infected or HIV status unknown individuals

Assess for CURRENT HIV Infection

- Order HIV testing. Negative test must result within 1 week of starting PrEP
- Check for s/sx of acute HIV infection
- **Do NOT use PrEP in Veterans with positive HIV testing or strong suspicion for recent exposure***

Check Other Baseline Labs

- Creatinine clearance (Consider PrEP only in Veterans with CrCl >= 60 mL/min.)
- STIs: gonorrhea/chlamydia (GC/CT), syphilis (RPR)
- Pregnancy status (not a contraindication)
- Hep B/C (not a contraindication but may need additional evaluation)

Prescribe PrEP

- Truvada 1 tab PO daily
- INITIATE with no more than 30-day supply & REFILL with no more than 90-day supply
- Adherence determines efficacy

Follow-up

- 1 month: Repeat HIV test
- Q 3 months: HIV status
- Q 6 months: STI and Creatinine clearance
- Annually: Reassess need

Sexual History Questions: The Five P’s

- **Partners**
  - Do you have sex with men, women, or both?
  - In the past 6 months, have you had unprotected sex? With anyone who’s HIV status you did not know?
  - Is it possible that any of your sex partners in the past year had sex with someone else while they were still in a sexual relationship with you?

- **Practices**
  - Can you describe the type of sex you have with your partner(s)?
  - Do you use barrier protection (condoms, denta dams, rubber gloves, etc.) or other types of protection? If not, why not? If sometimes, in what situations do you use protection?
  - Have you ever had sex in exchange for something you needed (food, shelter, drugs, $$)?
  - Is there anything else I should know about your sexual practices?

Protection from and Past history of sexually transmitted infections (STIs)

- Do you know your HIV status?
- Past history of STIs? Are you concerned about getting an STI?
- How do you protect yourself from STIs and HIV?
- Have any of your partners had STIs?

Pregnancy

- What are your plans regarding pregnancy?
- What (if anything) are you doing to prevent pregnancy?

Injection Drug History Questions

Put questions in context: “Some of my patients have used drugs, such as heroin, cocaine or methamphetamine— have you ever used drugs?”

- Have you ever injected drugs that were not prescribed for you or in a way other than were prescribed to you by a health care provider? If yes:
  - When did you last inject drugs that were not prescribed for you?
  - In the past 6 months, have you injected using needles, syringes, or other drug preparation equipment that had already been used by another person?
  - In the past 6 months, have you been in a methadone, buprenorphine/naloxone, or other medication-based drug treatment program?

***At minimum, a sexual health hx should be performed on an annual basis OR when NEW risk factors are identified***

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**Figure 2.** Pocket card created for primary care clinic staff following preexposure prophylaxis (PrEP) educational training. This reference included brief PrEP clinical protocol as well as framework for sexual and drug use history.
attitudes (Figure 3). The percentage of staff that were able to accurately identify patients as eligible PrEP candidates increased from 30% to 55%. There remained, however, knowledge gaps in all disciplines particularly around risk associated with injection drug use. Importantly, the number of PCPs who stated they felt comfortable talking about PrEP with their patients increased to 40%. At the time of the second focus group, more than 50% of permanent staff had either initiated or overseen initiation by a trainee of a new PrEP prescription.

**PrEP workflow implementation within the clinic**

Incorporating tools created by the VHA National PrEP Working Group, we collaborated with our local electronic health record team to build tools to assist PCPs in identifying potential PrEP candidates and support ongoing management of PrEP. These electronic health record tools included a yearly PrEP clinical reminder to assess HIV risk, a PrEP in primary care order set, and note templates.

The QI team also developed a clinic workflow process map for any staff member who identified a Veteran with HIV risk to either initiate PrEP or refer to the appropriate prescribing provider (Figure 4). The new workflow was shared with and refined by clinic staff through iterative process. In this process, the role each discipline can play in identifying and reducing HIV acquisition risk in the homeless population was emphasized. For example, mental health providers and social workers often elicit patient behaviors that convey increased HIV risk and can then communicate risks to prescribing team members.

**Discussion**

PrEP is an important HIV prevention tool and is underutilized among many high-risk populations including persons experiencing homelessness. Our pilot QI initiative identified institutional, knowledge, and clinic workflow barriers to PrEP implementation in a VA homeless primary care clinic. Many patients have strong trusting relationships with their PCPs, and therefore may be more comfortable having discussions of sexual health, substance use, and risk behavior in this setting. Failure by the PCP to initiate and normalize sensitive risk behavior discussions can result in missed HIV prevention opportunities. We showed that with relatively minimal training and resources, PCPs are willing to prescribe PrEP. Similar findings have been seen in multiple settings in other studies as well.

Our PrEP interventions received significant support from nonprescribing clinic staff and trainees. The inclusion of multiple health care professions and ancillary support staff in this process is unique, but important to ensure widespread impact and ongoing success of PrEP in the homeless primary care setting. We believe this could serve as a model for successful PrEP implementation for homeless veterans and other underresourced populations in primary care clinic settings.
Data on the impact of the implementation effort on increasing PrEP prescriptions and ultimately reducing new HIV infections will be collected over the ensuing years. This will include tracking data on number of eligible veterans receiving PrEP, source of PrEP prescription (primary care or ID), and incidence of new HIV diagnoses. Additionally, we will monitor the appropriate use of TDF/FTC, to ensure that releasing the prescription restrictions has not resulted in overuse or unintended harm. Future clinic efforts will also focus on optimizing the electronic health record to support best practice.

Conclusions
This pilot implementation project describes a model for incorporating PrEP within a primary care setting serving veterans experiencing homelessness; highlighting the roles multidisciplinary team members can assume in improving PrEP education and workflow in the primary care clinic. Increasing capacity to prescribe PrEP in the primary care clinic capitalizes on the strengths of the longitudinal therapeutic alliance between patients and their primary care team while potentially reducing patient barriers to PrEP access including specialist referrals, cost, and inconvenience of additional appointments. Continued focus on expanding the capacity of primary care to provide PrEP and other HIV prevention strategies will be important for ending the HIV epidemic, particularly in high-risk vulnerable populations such as the homeless.

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