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Successful Implementation of HIV Preexposure Prophylaxis: Lessons Learned From Three Clinical Settings

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Abstract The past 3 years have marked a transition from research establishing the safety and efficacy of HIV preexposure prophylaxis (PrEP) to questions about how to optimize its implementation. Until recently, PrEP was primarily offered as part of randomized controlled trials or open-label studies. These studies highlighted the key components of PrEP delivery, including regular testing for HIV and other sexually transmitted infections (STIs), adherence and risk-reduction support, and monitoring for renal toxicity. PrEP is now increasingly provided in routine clinical settings. This review summarizes models for PrEP implementation from screening through initiation and follow-up, focusing on the strengths and weaknesses of three delivery systems: a health maintenance organization, an STI clinic, and a primary care practice. These early implementation experiences demonstrate that PrEP can be successfully delivered across a variety of settings and highlight strategies to streamline PrEP delivery in clinical practice.

Keywords Preexposure prophylaxis (PrEP) · PrEP delivery · PrEP implementation · Human immunodeficiency virus (HIV) · Implementation · Sexually transmitted infections · Delivery of health care · Science of prevention · Review

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Introduction

In July 2012, the US Food and Drug Administration (FDA) approved the use of daily oral emtricitabine/tenofovir (FTC/TDF, Truvada©) as preexposure prophylaxis (PrEP) for the prevention of sexually acquired HIV infection. This landmark decision was based on data from multi-national, placebo-controlled trials demonstrating the safety and efficacy of FTC/TDF PrEP in men who have sex with men (MSM) and heterosexual men and women [1–3], and was followed by a trial demonstrating the safety and efficacy of PrEP in people who inject drugs [4]. The Centers for Disease Control and Prevention (CDC) endorse PrEP as a critical element of a combination approach to HIV prevention and released guidelines for its use in adults at risk of HIV acquisition in 2014 [5].

The past 3 years have marked a transition from research establishing the safety and efficacy of PrEP to questions about how to optimize its implementation and maximize its public health impact. Until recently, PrEP was primarily delivered in the USA in settings that offered time-limited access, such as placebo-controlled trials [3], open-label extension studies [6•], and demonstration projects [7•, 8]. PrEP is now increasingly being provided in a variety of clinical settings that aim to offer ongoing access. While early reports suggested that PrEP use outside of research contexts was low [9], recent surveys suggest that PrEP use is increasing throughout the USA [10–12]. Questions have now arisen about optimal settings for PrEP delivery, such as sexually transmitted infection (STI) clinics, by HIV specialists, or in primary care.

This review focuses on implementation models that represent the future of PrEP provision. We discuss three examples of PrEP delivery systems, summarizing published data where available and highlighting the advantages and disadvantages of each setting with respect to the PrEP continuum of care. Lastly, we discuss what local health departments can do to support PrEP implementation in their jurisdiction.

What Is the Continuum of Care for PrEP Delivery?

Here, we define the continuum of care for PrEP delivery as (1) the *identification* of individuals at risk for HIV infection; (2) *linkage* of individuals at risk for HIV to a site of PrEP delivery and a PrEP provider; (3) *initiation* of PrEP, which includes baseline laboratory tests and identifying a mechanism for paying for PrEP medication; and (4) *engagement* in PrEP care (i.e., clinical monitoring, maintenance of adherence, risk-reduction counseling, and retention in care) throughout periods of HIV risk (Fig. 1).

Initial PrEP studies shed light on factors along the PrEP continuum of care that contribute to effective PrEP delivery. Demonstration projects have shown that PrEP uptake is high across a distribution of age, race/ethnicity, and education levels, but that some subgroups, including MSM of color, are less likely to seek out PrEP or achieve high levels of adherence and retention [7•, 8, 13•]. Trials have illustrated that adherence drives PrEP efficacy [6•, 14–16] yet presents challenges for measurement [17, 18], while demonstration projects are testing strategies to support adherence among PrEP users [19–21]. Trial results also demonstrated the importance of diagnosing HIV, including acute HIV infection, at PrEP initiation and during PrEP use to reduce the risk of drug resistance [22–24]. Small reductions in creatinine clearance [14, 15] and bone mineral density [25, 26] were noted among PrEP trial participants [27, 28], highlighting the need for ongoing monitoring of renal function during PrEP use and education regarding bone health at PrEP initiation. Increases in sexual risk behavior or STI incidence were not observed in placebo-controlled trials [29–31] or open-label studies [6•, 13•, 32, 33], despite fears that risk compensation would reduce or negate the protective benefits of PrEP [34]. However, rates of STIs, including hepatitis C, have been high among PrEP users in open-label studies [8, 35••] and clinical practice [36•, 37]. Risk-reduction counseling is recommended during PrEP use, along with frequent screening and treatment for STIs to minimize the risk of HIV acquisition and other sequelae [5].

While PrEP studies to date have provided guidance on the clinical components of PrEP delivery, they have been less informative about operational aspects of implementation, including how to identify patients at risk for HIV infection in a clinical setting; how to increase patient and provider awareness of PrEP; how to identify providers who are knowledgeable about and able to prescribe PrEP; how to address gaps in insurance coverage for PrEP and improve affordability; how to optimize engagement in a PrEP program and deliver adherence support, risk-reduction counseling, and laboratory tests in a busy clinical setting; and the staff capacity required to deliver PrEP, including the types of staff (e.g., clinicians, nurses, counselors, pharmacists) who should be involved.

What Are Current Models for Ongoing PrEP Implementation?

PrEP is currently being delivered across a variety of settings in the USA [38, 39], including community-based HIV/STI testing sites; health maintenance organizations (HMOs); HIV clinics; lesbian, gay, bisexual, and transgender health clinics; primary care; and STI clinics, with each offering strengths and weaknesses with respect to the PrEP continuum of care (Table 1). Here, we describe PrEP delivery in three clinical settings in San Francisco: an HMO, an STI clinic, and a primary care clinic.

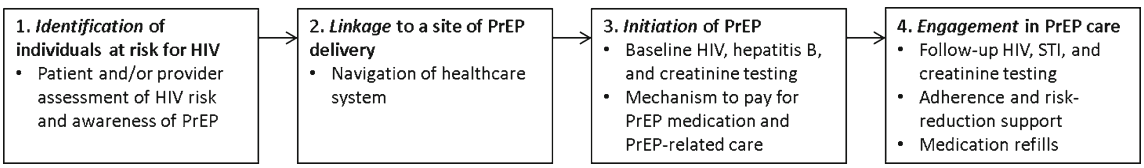

Fig. 1 Continuum of care for PrEP delivery. *PrEP* preexposure prophylaxis, *STI* sexually transmitted infection

Table 1 Strengths and weaknesses of models for ongoing PrEP implementation

Delivery setting	Strengths	Weaknesses
Community-based HIV/STI testing sites	• Serve a population at risk for HIV • Providers are aware of PrEP • Staff are accustomed to assessing HIV risk and providing risk-reduction counseling	• Lack infrastructure for continuity of care and creatinine testing • May need to rely on copayment assistance program to cover PrEP • May not be prepared to provide adherence support • May lack a prescribing provider and/or medical liability insurance to cover the prescribing
Health maintenance organizations	• Infrastructure for continuity of care and STI, HIV, and creatinine testing • Most patients' plans cover a portion of the cost of PrEP • Capacity to conduct panel management activities	• HIV risk assessments may not be routinely conducted • Providers may lack awareness of PrEP or be unwilling to prescribe it • May not be prepared to provide risk-reduction or adherence support • Benefits navigation may be needed to avoid high copayments
HIV clinics	• Serve a population at risk for transmitting or acquiring HIV • Providers are aware of PrEP • Staff are accustomed to providing risk-reduction counseling • May be accustomed to providing adherence support	• May need to rely on copayment assistance program to cover PrEP cost for uninsured patients • May not have HIV-uninfected clients or funding to provide care to HIV-uninfected clients • Possible stigma associated with attending an HIV clinic
LGBT clinics	• Serve a population at risk for HIV • Providers are aware of PrEP • Staff are accustomed to assessing HIV risk, screening/treating STIs, and providing risk-reduction counseling	• May not be prepared to provide risk-reduction and adherence counseling • May need to rely on copayment assistance program to cover PrEP cost for uninsured patients • Lack infrastructure for continuity of care and creatinine testing
Primary care (private practice or publicly funded)	• Infrastructure for continuity of care and STI, HIV, and creatinine testing • Most insurance plans cover a portion of the cost of PrEP	• HIV risk assessments may not be routinely conducted • Providers may lack awareness of PrEP or be unwilling to prescribe it • May not be prepared to provide risk-reduction or adherence support • Benefits navigation may be needed to avoid high copayments
STI clinics	• Serve a population at risk for HIV • Providers are aware of PrEP • Staff are accustomed to assessing HIV risk and providing risk-reduction counseling	• May need to rely on copayment assistance program to cover PrEP • Lack infrastructure for continuity of care and creatinine testing • May not be prepared to provide adherence support

LGBT lesbian gay bisexual transgender, *PrEP* preexposure prophylaxis, *STI* sexually transmitted infection, *PCP* primary care provider

PrEP Implementation in an HMO Setting

Kaiser Permanente's San Francisco Medical Center (KPSF) is an HMO serving more than 170,000 adult members. A recent report from KPSF described a large and rapidly growing specialized PrEP program [36•]; nearly 1000 patients have initiated PrEP at KPSF as of July 2015. Notably, there have been no HIV seroconversions in this population [36•]. The program is staffed by three infectious disease (ID) physicians, each with up to 6 hours per week of clinical time dedicated to PrEP, as well as part-time support from a nurse, two pharmacists, a health educator, and a program assistant. PrEP visits are coded as "prophylaxis" (International Classification of Disease, Version 9 [ICD-9] code: V07.8; ICD-10 code: Z41.8).

Steps 1 and 2: Identification and Linkage The majority of referrals to the PrEP program are initiated by patients during in-person or telephone visits with a provider or through secure email messages sent by patients to primary care providers (PCPs). A minority of referrals are initiated by clinicians based on a sexual risk assessment, STI diagnosis, or use of non-occupational post-exposure prophylaxis (nPEP). To educate PCPs at KPSF about PrEP and the availability of the program, an ID physician has given grand rounds and reminded PCPs through emails and department meetings to consider PrEP for HIV-uninfected individuals with rectal STI or syphilis diagnoses.

Step 3: Initiation After being referred to the KPSF PrEP program, patients are seen by an ID physician or an ID-trained pharmacist who conducts an in-person intake visit, with a review of the patient's medical history, a risk assessment, and education about PrEP, including side effects, required monitoring, and adherence. Clinical follow-up is done by the ID

physician or pharmacist who conducted the intake visit, with physician support for the pharmacist for symptomatic STIs or abnormal laboratory tests. Some patients (18 %) have elected to not start PrEP after this intake visit, citing a variety of reasons, including low risk for HIV, concern about cost, and not wanting to adhere to the required follow-up [36•].

Prior to initiating PrEP, KPSF patients have blood drawn for HIV antibody and viral load, syphilis, and creatinine testing at the onsite laboratory. A baseline urinalysis is done, and patients are provided swabs and a urine kit for self-collection of specimens to screen for pharyngeal, rectal, and urethral gonorrhea and chlamydia [40, 41]. Patients are also tested for hepatitis A, B, and C, and vaccination for hepatitis A and B is offered if indicated based on laboratory results. Alanine aminotransferase is tested at baseline and quarterly thereafter to monitor for incident hepatitis C infections. Most laboratory tests, with the exception of the HIV viral load, are completed before the intake visit. After the viral load and any outstanding tests are done, the patient goes to the onsite pharmacy to receive a 30-day supply of FTC/TDF, with 90 days of medication provided with subsequent refills.

KPSF is a combined insurance plan and healthcare organization; the patient's share of cost for PrEP at KPSF depends on the specifics of the patient's plan. While copayments for PrEP are less than $50 per month for the majority of KPSF members, some plans have high deductibles or require substantial copayments for laboratory tests or clinic visits. Patients are informed of the copayment assistance program offered by Gilead Sciences, the company that produces Truvada, which provides FTC/TDF for PrEP at no cost to US residents who earn <500 % of the federal poverty level [42]. However, because the copayment card cannot be used at KPSF pharmacies, patients must purchase the medication and then seek reimbursement. In addition, not all KPSF members, such as those with Medicare Part D, are eligible for the copayment assistance program. Thus, while the majority of KPSF patients can access PrEP at an affordable cost, barriers remain even in this HMO context.

Step 4: Engagement Although the intake visit is conducted in person to create a comfortable environment for discussing sexual risk, most follow-up visits are over the telephone or through secure email messages. Patients request refills online, and the medication is picked up in the pharmacy or mailed to the patient. Patients are advised to complete their quarterly follow-up laboratory testing (i.e., HIV antibody, STIs, and creatinine) at the same time the medication is refilled. More frequent STI and HIV testing is available if desired by patients, who are advised to visit the laboratory without an appointment, including on evenings and weekends, for these tests as often as monthly. Patients are informed that they will be contacted if an HIV test is positive; all other test results are viewable online. While treatment of STIs is part of the PrEP program, patients receive other primary care services from their PCP.

Strengths and Weaknesses HMO settings such as KPSF have the infrastructure to provide continuity of care to PrEP patients. KPSF leverages its robust electronic health record (EHR) to conduct panel management activities to facilitate engagement in PrEP care. For example, PrEP program staff receive a biweekly list with the names of patients who have not refilled their prescription, or had HIV or creatinine testing, in more than 100 days. These patients are contacted by a member of the PrEP delivery team, who provides brief adherence counseling, a reassessment of HIV risk, and a reminder of the importance of regular laboratory testing. Self-collection of specimens for STI testing—available at most Kaiser Permanente Northern California laboratories, including KPSF—facilitates this telemedicine approach to PrEP follow-up, which decreases programmatic costs and provides flexibility to patients.

The KPSF experience also reveals some of the challenges of PrEP implementation in an HMO setting. Most of the PrEP referrals have been initiated by patients rather than providers. Furthermore, most patients receiving PrEP at KPSF are white, and 99 % are MSM. To identify potential PrEP candidates who do not recognize their risk for HIV infection, do not know about PrEP, or do not have the agency to seek out PrEP, PCPs must routinely ask patients about their sexual orientation, gender identity, sexual history, and drug use, a practice that is underperformed in many clinical practice settings [43–45]. Despite training non-physician staff to assist in many aspects of PrEP delivery, including adherence and risk-reduction counseling, the KPSF PrEP program was initially strained by the demand for PrEP, and additional provider staffing was needed to minimize wait time for appointments and manage the growing cohort of patients on PrEP. Finally, at KPSF, stopping and restarting PrEP is common as a result of changing risk or gaps in insurance coverage, and resources are needed to assist patients and providers in navigating these transitions.

PrEP Implementation in an STI Clinic Setting

STI clinics in San Francisco (i.e., San Francisco City Clinic [SFCC]) and Miami (i.e., Miami-Dade County Downtown STD Clinic) have provided PrEP as part of time-limited demonstration projects [46]. Baseline data from the open-label US PrEP Demonstration Project (The Demo Project) indicated that interest in PrEP was high in a diverse population of eligible MSM attending STI clinics [7•]. Adherence was excellent in The Demo Project, with 80–86 % of participants tested having drug levels consistent with taking at least four doses of FTC/TDF per week across study visits [13•]; such drug levels have been estimated to reduce HIV risk by over 96 % [16]. Similar to the KPSF PrEP program, demand for PrEP as part of The Demo Project at SFCC exceeded clinic capacity, resulting in a waitlist for interested individuals [47]—and, like

KPSF, The Demo Project found that a commonly reported reason for declining PrEP was not having enough time for participation [7•].

Based on the feasibility demonstrated by The Demo Project and ongoing demand from patients, SFCC initiated its "PrEP navigation program" in May 2014. SFCC is the only municipal STI clinic in San Francisco and conducts approximately 19,000 visits per year, with 48 % of the patients being MSM [48]. Clinical care is provided primarily by nurse practitioners (NPs). Funding has been provided to SFCC by the San Francisco Department of Public Health for additional staff (one coordinator, a counselor, and a half-time NP) and to pay for creatinine testing and hepatitis B screening, two services that were not previously offered at the clinic. As of July 2015, over 500 patients have received PrEP counseling and navigation, and 185 have initiated PrEP. Of those initiating PrEP, 48 % were uninsured; of the uninsured patients initiating PrEP, 38 % have subsequently enrolled in comprehensive health insurance coverage. Compared with the cohort who enrolled in The Demo Project at SFCC, PrEP navigation program clients are younger (median age 30 vs. 35 years) and more likely to be non-white (63 vs. 38 %). While STI rates have been high, there have been no seroconversions among clients who are regularly receiving PrEP.

Steps 1 and 2: Identification and Linkage Clients are identified as PrEP candidates during the STI visit by the clinician, who conducts a standardized risk assessment prompted by questions in the EHR, or come into the clinic specifically to request PrEP. They are provided brief PrEP education by the clinician and referred to the PrEP program coordinator or counselor. Patients who are insured and have a PCP are provided information about how to talk to their provider about PrEP, how to determine what their out-of-pocket costs for PrEP would be, and how to access the copayment assistance program. Uninsured patients or those who have difficulty accessing PrEP in primary care are offered PrEP at the STI clinic.

Step 3: Initiation Prior to PrEP initiation, an NP takes a medical history, assesses for signs or symptoms of acute HIV infection, reviews concurrent medications and allergies, discusses potential side effects and toxicities of FTC/TDF, and provides patient educational materials on PrEP (see supplementary material in [47]). Patients are tested for HIV (rapid HIV antibody and pooled RNA [49]) and STIs, and blood is drawn for creatinine, hepatitis B surface antigen, and a hepatitis C antibody test. Insured patients are given a prescription for 30 days of FTC/TDF with no refills. While patients are not responsible for the cost of laboratory tests and clinic visits associated with PrEP, program staff assist uninsured patients with applying for the medication assistance program to cover the cost of the medication. In addition, uninsured patients are counseled regarding eligibility for health insurance and are encouraged to enroll in a health insurance plan that covers PrEP. Insured patients who have faced barriers in accessing PrEP (e.g., report feeling uncomfortable speaking to their provider about sexual health or being denied PrEP by their provider) are provided a list of local PrEP-knowledgeable providers [38].

Step 4: Engagement Patients are seen 1 month after PrEP initiation for a brief in-person visit to discuss side effects and adherence, be tested for HIV, and receive their next PrEP prescription. After the 1-month follow-up visit, patients are seen quarterly. At each quarterly visit, an NP performs an STI evaluation, assesses for signs or symptoms of acute HIV infection, orders a creatinine test for kidney function monitoring, and writes a prescription for FTC/TDF. Non-clinician PrEP program staff disclose the rapid HIV-antibody result, provide brief adherence and risk-reduction counseling, provide the prescription for FTC/TDF, schedule the follow-up visit, and reassess the patient's insurance status. Non-clinician PrEP staff conduct reminder calls prior to appointments and for missed appointments, manage communication with the medication assistance program (which includes ordering refills on a monthly basis and submitting appeals for patients who are denied access), flag abnormal creatinine results for clinician review, and provide referrals to psychosocial services. At each follow-up visit, non-clinician staff reassess the patient's access to care, as the ultimate goal is to bridge clients to a primary care setting where they can receive PrEP.

Strengths and Weaknesses STI clinics serve a population that is at higher risk for HIV infection than individuals accessing care in primary care settings, making these clinics ideal for reaching a PrEP-eligible population. As safety net providers, STI clinics typically serve underserved populations that may not have access to primary care. In addition, STI clinic staff are well-prepared to provide HIV risk assessment and ongoing risk-reduction counseling to potential and active PrEP users, as well as linkage to care for clients who are diagnosed with HIV. As demonstrated by the SFCC PrEP navigation program, PrEP can serve as an incentive for sexual health services and a bridge to primary care. STI clinics that offer nPEP have experience with prescribing antiretroviral therapy for HIV prevention and may be particularly well-suited to offer PrEP. However, few STI clinics offer nPEP [50], and unlike primary care settings, STI clinics do not have systems for providing continuity of care, with patients typically visiting the clinic on a drop-in or episodic basis. Thus, STI clinics may need to modify their practices to allow for the longitudinal care that is required for PrEP delivery.

PrEP Implementation in a Primary Care Setting

One Medical Group (OM) is a multi-site primary care practice with offices across the USA, including 14 offices serving 71,948 adult members in San Francisco. OM accepts a wide range of private insurance plans, including some plans offered under the Affordable Care Act, and Medicare, but does not accept Medicaid. An estimated 791 patients are currently on PrEP at OM in San Francisco. Initially, PrEP was primarily provided by PCPs who provide HIV care. PCPs with less experience with FTC/TDF and sexual health received additional training about PrEP through case-based conferences and peer-to-peer communication, and most PCPs at OM now prescribe PrEP as part of their practices. Providers code PrEP visits in a standardized fashion [ICD-9 code: V01.79; ICD-10 code: Z20.6], such that the medical leadership can identify PrEP users for quality assurance.

Steps 1 and 2: Identification and Linkage PrEP is offered to patients who specifically request it from their PCPs and those who are identified as having elevated risk for HIV infection during a sexual risk assessment. PCPs have been encouraged to consider PrEP for patients diagnosed with an STI, those who have used nPEP (particularly those who have used it multiple times), and those with an HIV-infected partner.

Step 3: Initiation The PCP provides basic PrEP education, screens for symptoms of acute HIV infection, and orders baseline laboratory tests, including a fourth-generation HIV antibody/antigen assay, creatinine, hepatitis B surface antigen, and STI screen. Phlebotomy is available onsite; a medical assistant collects a pharyngeal swab and the patient self-collects a rectal swab for gonorrhea and chlamydia. An HIV RNA test is ordered for patients with recent exposures or symptoms of acute infection. The PCP receives test results through the EHR, communicates with the patient by secure email or phone, and sends a 90-day prescription of FTC/TDF with no refills to the patient's preferred pharmacy. Administrative staff assist with prior authorizations, which can be routed back to the PCP for review and signature through the EHR. Providers or administrative staff also assist patients with enrolling in the copayment assistance program.

Step 4: Engagement After initiating a patient on PrEP, the PCP uses the EHR to prepare an email to be delivered 1 month after PrEP initiation to inquire about how the patient is doing on PrEP, side effects, and adherence. The patient is typically seen in person 3 and 6 months after PrEP initiation; after this, in-person visits may occur less frequently, depending on the patient's medical conditions or psychosocial needs. However, all patients are required to be seen in the office at least annually for continued refills of their medication. Patients are instructed to come in for an evaluation if they have symptoms of acute HIV or have been off FTC/TDF for more than 7 days. To decrease the administrative burden on PCPs, refill requests for all medications are reviewed by a "virtual medical team," consisting of physicians, NPs, physician assistants, and registered nurses. Refills are only provided if the required quarterly laboratory testing (i.e., HIV, STIs, and creatinine) has been completed and the results are within the acceptable range.

Strengths and Weaknesses The OM model demonstrates that PrEP can be successfully delivered as part of routine primary care services by non-HIV specialists. Administrative support from the virtual medical team increases the efficiency of PrEP delivery at OM, and as at KPSF, self-collection of rectal swabs for STI screening facilitates a telemedicine approach to PrEP follow-up. While some PCPs at OM were initially reluctant to prescribe PrEP, demand from patients and training by colleagues has spurred many to become comfortable with PrEP delivery, and those who remain uncomfortable with PrEP delivery can internally refer patients to a PrEP provider. This integration of PrEP into primary care settings may facilitate the normalization of PrEP and provision of sexual health services in routine primary care.

The OM experience also demonstrates some of the challenges of delivering PrEP in a primary care practice. All adherence and risk-reduction counseling is delivered by the PCP. Patients who initiate PrEP but miss a follow-up appointment may not come to the attention of the PCP and thus may be lost to follow-up without an opportunity to assess barriers or support engagement in PrEP care. Lastly, in this private practice setting, financial sustainability requires delivering billable services; conducting PrEP follow-up by email and phone is efficient for the patient but not reimbursable for the provider, and some PCPs may thus not have the time or administrative support to deliver PrEP in this manner, especially as uptake increases.

Conclusions

These early implementation experiences demonstrate that PrEP can be successfully delivered in a diverse array of clinical settings, including primary care. However, the need to streamline delivery is clear. Although PrEP appears to be reaching a population at high risk for HIV acquisition, MSM of color, adolescent MSM, people who inject drugs, and transgender women and men are underrepresented among PrEP users and may benefit from additional outreach. PrEP is being successfully delivered by some PCPs, but most PrEP users in

primary care settings are self-referred; building capacity among PCPs to take a sexual history and identify potential PrEP candidates is important for reaching patients who do not know about PrEP or are not comfortable with initiating a conversation about sexual health with their provider. The burden of PrEP on the healthcare system may be reduced by leveraging existing EHRs; providing a self-collection option for STI testing; and training nurses, health educators, and pharmacists to administer aspects of PrEP care. Finally, although most private insurance companies cover PrEP, cost continues to present a barrier to access for some individuals.

In some cases, PrEP programs are implementing more frequent laboratory testing compared with what is recommended in the CDC guidelines [5]. The high rates of STIs [8, 36•] among PrEP users suggest that quarterly rather than semiannual or annual screening for these infections may be appropriate. Furthermore, quarterly laboratory testing allows patients to obtain 90-day medication refills at the same time as laboratory testing in some settings, thus streamlining PrEP follow-up. Which HIV diagnostic tests to use at PrEP initiation and follow-up (e.g., HIV antibody and/or RNA tests), whether and how to screen for HCV infection, and how best to monitor for renal toxicity are unclear. Determining the frequency and components of laboratory testing to maximize safety and optimize cost-effectiveness should be an ongoing focus of PrEP implementation research.

Local health departments could support PrEP implementation and address these systemic gaps in several ways. First, health departments may consider offering PrEP in municipal STI clinics, which already reach a population at risk for HIV. Second, health department staff could train community-based organizations that currently provide HIV counseling and testing to provide PrEP education, navigation services, and ongoing risk reduction and adherence counseling to PrEP users. Third, health education campaigns could be used to increase awareness of PrEP in the community, with a focus on vulnerable populations with lower PrEP awareness, and among healthcare providers, particularly in primary care settings. Fourth, health departments can partner with AIDS education and HIV/STD-prevention training centers to generate lists of PrEP-knowledgeable providers and offer trainings to providers across a range of disciplines to increase the number of PrEP providers in the jurisdiction. Fifth, gaps in PrEP access can be filled by programs modeled after the AIDS Drug Assistance Program, an approach that has been adopted by state health departments in Washington and New York [51, 52]. Finally, health departments may play a role in establishing a surveillance system to monitor PrEP use and its population-level impact.

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Compliance with Ethical Standards

Conflict of Interest Julia L. Marcus reports grants from Merck.

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- • Of importance
- •• Of major importance

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