

Evolving Models and Ongoing Challenges for HIV Preexposure Prophylaxis Implementation in the United States

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Background: The use of preexposure prophylaxis (PrEP) for HIV prevention was approved by the Food and Drug Administration in 2012, but delivery to at-risk persons has lagged. This critical review analyzes the current state of PrEP implementation in the United States, by reviewing barriers and innovative solutions to enhance PrEP access and uptake.

Setting: Clinical care settings, public health programs, and community-based organizations (CBOs).

Methods: Critical review of recent peer-reviewed literature.

Results: More than 100 papers were reviewed. PrEP is currently provided in diverse settings. Care models include sexually transmitted disease clinics, community health centers, CBOs, pharmacies, and private primary care providers (PCPs). Sexually transmitted disease clinics have staff trained in sexual health counseling and are linked to public health programs (eg, partner notification services), whereas PCPs and community health centers may be less comfortable counseling and feel time-constrained in managing PrEP. However, PCPs may be ideal PrEP providers, given their long-term relationships with patients, integrating PrEP into routine care. Collaborations with CBOs can expand PrEP care through adherence support and insurance navigation. Pharmacies can deliver PrEP, given their experience with medication dispensing and counseling,

and may be more accessible for some patients, but to address other health concerns, liaisons with PCPs may be needed.

Conclusions: PrEP implementation in the United States is moving forward with the development of diverse models of delivery. Optimal scale-up will require learning about the best features of each model and providing choices to consumers that enhance engagement and uptake.

Key Words: HIV prevention, PrEP, primary care, pharmacies, community-based organizations, sexually transmitted diseases

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INTRODUCTION

Clinical trials have demonstrated the efficacy of HIV preexposure prophylaxis (PrEP) using a once-daily oral antiretroviral medication [tenofovir-emtricitabine, (TDF-FTC)] that is safe, well-tolerated, and effective in decreasing HIV incidence in adherent high-risk individuals.^{1–5} Recent demonstration projects have found that PrEP delivery is feasible and effective in “real-world” clinical settings.^{6–8} Although the Centers for Disease Control and Prevention (CDC) has issued clinical practice guidelines for PrEP use in the United States,⁹ numerous implementation barriers remain, including questions about the cost-effectiveness of PrEP, optimal settings for provision, and the most effective ways to motivate health care practitioners to prescribe PrEP. Protocols to identify individuals who are most likely to benefit from PrEP have been developed, but addressing racial, ethnic, and socioeconomic disparities pose additional challenges.^{10,11}

Implementation science involves the study of strategies that accelerate the adoption of evidence-based interventions, such as PrEP, among health organizations by taking into account the unique organizational setting’s barriers and facilitators for sustained service delivery.^{12,13} Each section of this review addresses leverage points that influence PrEP uptake grounded in the practical robust implementation and sustainability model (Figure 1).¹⁴ We describe the organizational structures and the barriers and facilitators to PrEP implementation and then describe how the needs of key vulnerable populations influence PrEP uptake. Finally, we summarize mitigating external factors and lessons learned that will dictate ongoing reach and sustainability.¹

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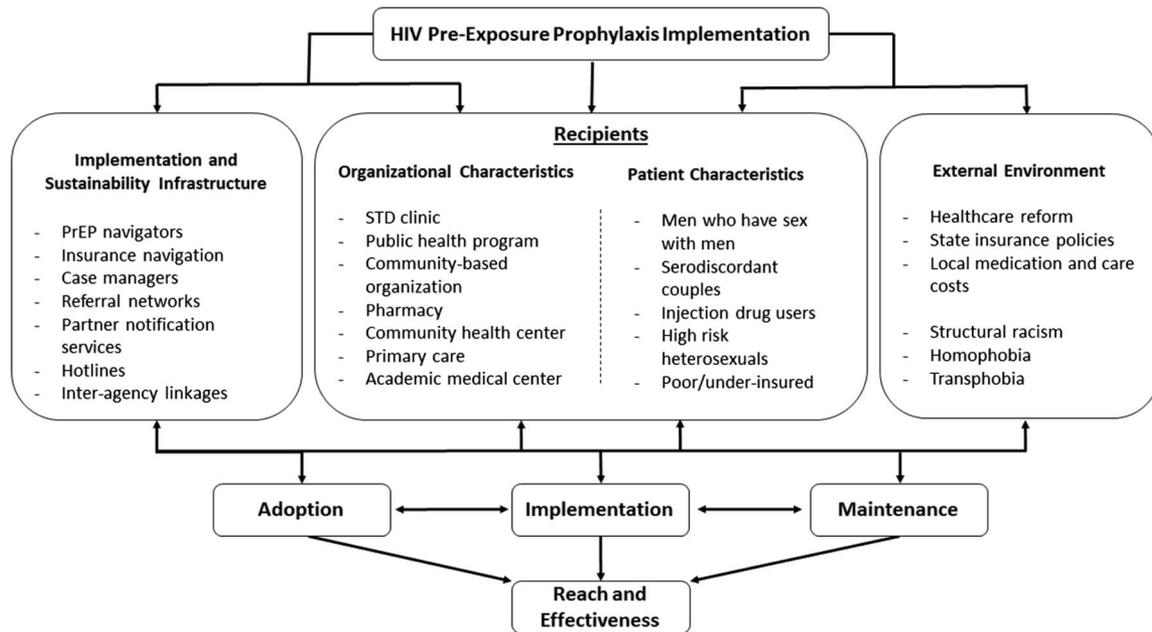


FIGURE 1. Ecosocial model of factors involved in PrEP implementation.

METHODS

We searched Pubmed over the past 5 years and major international HIV/AIDS conferences (eg, IAS and CROI meetings) using a combination of terms including “PrEP,” “Implementation,” “Heterosexual,” “IDU,” “MSM,” “women,” “Black/African American,” “Hispanic/Latino,” “Primary Care,” “STD Clinics,” “Partner Notification,” “Uninsured,” “Health insurance,” “Medicaid,” “Affordable Care Act,” “Pharmacy,” “Pharmacist,” “Community Organizations,” “Hotlines,” “Disease Intervention Specialists,” “Health Department,” “Referral,” “Linkage to Care,” and “Navigators.” We also cross-referenced the terms “PrEP” (n = 1841 in total) with “cost-effectiveness” (n = 107), “healthcare provider or provider” (n = 115), “decision support” (n = 34), “risk screening” (n = 135), or “community health center” (n = 98) between 2012 and 2017. We then focused on studies describing PrEP implementation in real-world settings.

PrEP IMPLEMENTATION IN STD CLINICS AND OTHER PUBLIC HEALTH PROGRAMS

In many US jurisdictions, publicly-funded sexually transmitted disease (STD) clinics provide prevention-oriented, safety-net services to high-risk populations,¹⁵ presenting opportunities for seamless integration of PrEP alongside existing screening and prevention services. The first US PrEP Demonstration Project^{7,16} was conducted at the San Francisco and Miami STD Clinics and found that PrEP implementation among high-risk men who have sex with men (MSM) was feasible, with high levels of acceptability and sustained adherence. Findings from other real-world PrEP programs demonstrate some of the limitations of PrEP implementation in STD clinics, many of which face financial constraints and do not provide longitudinal care. At the

Rhode Island STD Clinic, only 11% of MSM educated about PrEP were ultimately prescribed the medication,¹⁷ consistent with early PrEP implementation efforts in other settings.^{18–23} The largest patient-level barriers to PrEP uptake included low self-perceived HIV risk, financial challenges, concerns about side effects, and limited access to health care. Brief educational sessions integrated into routine HIV and STD screening may be effective in raising awareness and PrEP uptake in STD clinics, and deserves further study.²¹ In addition to STD clinics, other implementation efforts in the public health sector have included promoting PrEP through partner notification services (PNS, also known as contact tracing), which has been shown to be an effective public health intervention^{22,23} Given that other STDs increase the risk of HIV acquisition²⁴ and are an HIV risk indicator,^{9,25–27} engaging individuals who undergo PNS in PrEP education is a logical step. In Washington State, high-risk individuals are referred to PrEP services through PNS.²⁸ However, only 13% of those referred for STD care through PNS attended a PrEP assessment visit, demonstrating the need for further study of barriers and facilitators to PrEP uptake after PNS referral.

PrEP IMPLEMENTATION THROUGH COMMUNITY-BASED ORGANIZATION REFERRALS

Based on successful HIV treatment models,^{29,30} effective PrEP implementation may require a comprehensive approach, integrating related patient services (eg, behavioral health insurance navigation, etc.) with PrEP care, requiring extensive collaboration among local stakeholders. However, the lack of dedicated federal funds for PrEP care, such as the Ryan White HIV/AIDS Program for HIV-infected individuals,³¹ has posed challenges to developing comparable integrated programs for

PrEP delivery. The staff and funding for such services usually come from a variety of sources. Partnerships between academic centers, health departments, and community organizations in many cities (eg, Chicago,³² Houston,³³ San Francisco,³⁴ St. Louis,³⁵ and Seattle^{36,37}) offer examples of different types of successful PrEP-related programs. Programs have used telephone hotlines,^{35,38–40} public health services,^{37,41,42} specially-trained PrEP insurance navigators,³⁵ and/or use internet-based social applications^{36,38} to enhance local PrEP uptake. Studies that identify the core components of effective programmatic partnerships are needed, so that normative guidance can be developed to promote best practices for local PrEP implementation programs.

PrEP IMPLEMENTATION IN PHARMACIES

There are over 60,000 pharmacies in the United States⁴³ and many are involved with HIV disease management as well as large-scale rollout of preventive services (eg, vaccines).^{44–47} Pharmacy-based HIV testing has been cost saving, successfully reaching at-risk populations.^{47–50} PrEP care delivered by clinical pharmacists has been shown to be feasible when using collaborative drug therapy agreements.^{50–55} Clinics within retail pharmacies have begun to pilot PrEP service delivery with the use of nurse practitioners and physician assistants.⁵⁶ A Seattle pharmacy reported initiating PrEP in 245 patients, and found 75% patient retention and a return on investment within 9 months, which included individual consultations with clinical pharmacists and laboratory testing.^{52,53} Requirements for establishing pharmacy-based and pharmacist-delivered PrEP clinics include understanding the care provision requirements in each state's collaborative drug therapy policies.^{57,58} Facilitators of this care model include fee-for-service charges, irrespective of insurance coverage, that may allow individuals to overcome cost barriers to obtaining PrEP.^{59,60} Other advantages are possible ease of integrating PrEP services into locations where HIV testing and linkage to care already occurs,^{48,61} evening and weekend hours of pharmacy operation, pharmacists' ability to prospectively review medication refill gaps to detect nonadherence and to provide adherence counseling,⁶² and partnerships with other entities (eg, health departments or community organizations) to optimize reach to at-risk populations. This model has promise for nationwide scale-up, given that approximately half of the US pharmacies are part of large retail chains.⁵⁶ Barriers to this model may encompass not having (1) a private physical space within the pharmacy to conduct HIV risk assessments, (2) on-site comprehensive counseling services and seamless referrals (ie, mental health and substance use), and (3) pharmacists trained in sexual risk counseling to determine PrEP eligibility. Pharmacies can overcome such barriers by training pharmacists and creating robust local referral networks for patient counseling needs.^{61,62} Expansion of this approach requires that state policymakers promote pharmacist collaborative practice laws conducive to scale-up of PrEP services and pharmacies increase staff education about PrEP delivery, including risk assessments and related counseling.

PrEP IMPLEMENTATION IN COMMUNITY HEALTH CENTERS

In the United States, community health centers (CHCs) are an important source of health care for many populations at increased risk of HIV, particularly those who are poorer and from communities of color.⁶³ Thus, these centers could serve as a useful point of access to PrEP provision. Several CHCs with specialized expertise in providing care to sexual and gender minorities have been at the forefront of developing comprehensive approaches to implementing PrEP in primary care settings, and these centers could help train other CHCs in PrEP provision.⁶⁴ Some CHCs have developed strategies to address economic and logistical challenges that may affect PrEP access and adherence, particularly for patients who are underinsured or uninsured (eg, assisting with insurance navigation), but CHCs in states that have not embraced health reform may encounter challenges in supporting patients' PrEP expenses. Health centers care for some patients whose HIV risk behaviors would suggest they could benefit from PrEP.⁶⁵ The availability of integrated behavioral health care, including on-site and accessible mental health professionals and system navigators, could improve PrEP adherence and effectiveness.

INCREASING PrEP PRESCRIBING BY PRIMARY CARE PROVIDERS: DEVELOPMENT OF DECISION SUPPORT AND TRAINING

Because many persons at substantial risk of HIV infection will receive health care from generalist primary care providers (PCPs), it is important to train and engage this large clinical workforce in PrEP provision. However, awareness and utilization of PrEP among PCPs remain limited, with national surveys of PCPs suggesting that only about 7% of these clinicians have ever prescribed PrEP,⁶⁶ although the FDA approved TDF-FTC for use as PrEP in 2012 and CDC released comprehensive clinical practice guidelines for PrEP in 2014.⁶⁷ Studies of PCPs have identified several practical barriers to prescribing PrEP, including inexperience and discomfort prescribing HIV medications, uncertainty about how to identify individuals who are most likely to benefit from PrEP, concerns about medication toxicities and selection of drug-resistant HIV, and concerns about insurance and other financial barriers.^{66,68–71} In an earlier study, clinicians felt that provision of PrEP was more appropriate for HIV specialists,⁷² but more recently, some PCPs seemed to be more open to learning how to prescribe PrEP.⁷³ PCP concern about not being sufficiently trained to deliver PrEP could be overcome by educational interventions and access to user-friendly decision-support tools for use during clinical encounters.^{74,75} However, despite the availability of normative guidelines, didactic lectures, and webinars,⁷⁶ PrEP prescription remains uncommon among most PCPs. To accelerate the use of PrEP by PCPs, some public health authorities have launched innovative educational outreach programs known as academic detailing, which entail PrEP experts conducting focused, 1-on-1, interactive educational visits with PCPs at their practice sites to educate them about PrEP and to help them

develop solutions to perceived barriers to PrEP provision.⁷⁵ In New York City, a public health detailing initiative for PrEP was associated with an increase in first-time prescribing of PrEP by PCPs,⁷⁷ suggesting that dissemination of this strategy could help expand the number of PrEP prescribing PCPs.

Several brief HIV risk screening tools have been developed to help PCPs to identify persons who might benefit from PrEP, including algorithms to risk-stratify MSM and persons who inject drugs.^{25,78,79} Although these tools are simple to use and are recommended for use by clinical practice guidelines, their predictive performance may be suboptimal when used in populations in which they were not initially developed.⁸⁰ For example, risk screening tools for MSM that were developed using data from predominantly white samples had low predictive accuracy when applied to a cohort of black MSM in Atlanta,⁸⁰ and will likely be inadequate for use in screening women as well. Few studies have assessed the degree to which these tools are used by practicing clinicians; so, the impact of these tools on PrEP uptake remains unknown. Another innovative decision-support strategy is to use data from electronic health records such as diagnoses (eg, history of an STD), prescriptions (eg, use of HIV postexposure prophylaxis), and laboratory tests (eg, frequent screening tests for HIV) to develop automated algorithms that can identify persons at increased risk of HIV acquisition.⁸¹ This innovative approach could provide an objective and efficient means to assess HIV risk in large numbers of patients; so, studies to determine the most effective ways to use these algorithms are needed.

IDENTIFICATION OF HETEROSEXUAL CANDIDATES FOR PrEP

Clinical trials demonstrated PrEP efficacy in preventing HIV acquisition by heterosexuals,^{3,4} and the CDC estimates that 624,000 US heterosexuals are at significant risk and could benefit from PrEP.^{9,82} However, profound racial and ethnic disparities persist because blacks and Hispanics/Latinos comprise a disproportionate fraction of new infections. These disparities are particularly accentuated among women, with black women accounting for two thirds of new HIV infections in American women.⁸³ PrEP uptake among heterosexuals in the United States has been very limited,¹¹ suggesting a need to scale-up strategies to increase PrEP access for those at risk. One of the greatest challenges is that economically disenfranchised people living in high HIV prevalence communities have excess risk of HIV because of their sexual networks, even when they have few sexual partners.^{4,9} Traditional HIV risk assessment that emphasizes sexual orientation and number of sexual partners may underestimate risk in vulnerable populations. A new STD diagnosis, anal sex among heterosexuals, partner concurrency, and presence of a partner or partners with known HIV, history of incarceration, drug use, or sex trade should prompt consideration of PrEP.⁸⁴ Individual-level barriers to PrEP uptake among at-risk heterosexuals include limited PrEP awareness, medical mistrust, HIV stigma, and low perceived

personal risk.^{85–88} Structural barriers impeding PrEP use include poverty impeding access to health insurance and care,^{87,89} limiting mobility and health literacy.⁹⁰ Some at-risk women have expressed concerns about PrEP and drug effects on pregnancy outcomes and infant development during breastfeeding.⁹¹ Thus, strategies to increase appropriate PrEP use among at-risk heterosexuals will need to be multifaceted, including individual, provider, and community-level interventions to assist in the identification of those who could benefit the most from PrEP, and will need to provide trusted information about the safety and benefits of PrEP as well as the development of programs that address their economic challenges.

IDENTIFICATION OF SOCIALLY MARGINALIZED MSM CANDIDATES FOR PrEP

Current guidelines and recommendations for PrEP use include MSM as one of the priority populations for PrEP implementation.⁶⁷ Although approximately 25% of HIV-uninfected MSM aged between 18 and 59 years who report past-year sex with a man meet indications for PrEP use,⁹ current PrEP treatment coverage is well below the half million who are eligible. A modeling study of PrEP use based on CDC guidelines suggests that 40% uptake would avert 33% of new infections among MSM.⁹² Subgroups of MSM may experience diverse barriers to PrEP uptake. Individual-level barriers include limited knowledge, low self-efficacy, negative attitudes toward the health care system, and low HIV risk perception^{18,19,93–95}; social-level barriers include internalized stigma related to sexual behavior or identity, racial stigma, and fear of being perceived as sexually promiscuous or HIV-infected^{16,94–96}; and structural-level barriers include limited poverty, language barriers, or lack of insurance coverage.^{16,87,95,97,98} Studies have documented MSM who are unwilling to disclose sexual minority identity or behavior to providers^{99,100} because of internalized or experienced homophobia, posing a substantial barrier to PrEP uptake. Patients' unwillingness to disclose sexual identity is mirrored by providers' discomfort in discussing patients' sexual history.^{68,72,101,102} Structural racism also contributes to barriers to PrEP uptake among MSM of color. Although MSM of color face significantly greater lifetime risk of contracting HIV compared with white MSM,¹⁰³ these populations may experience distrust of medical institutions as a result of historical abuses^{104,105} as well as inequities in Medicaid and health care access programs.¹⁰⁶ PrEP implementation should involve focused, evidence-based, and community-engaged methodologies to overcome the many obstacles facing racial and ethnic minority high-risk MSM.^{107,108}

IDENTIFICATION OF INJECTING DRUG USING CANDIDATES FOR PrEP

Among HIV-uninfected adult people who inject drugs (PWID) in the United States, approximately 19% meet indications for PrEP.⁹ However, engaging PWID in PrEP care remains a significant challenge. The Bangkok Tenofovir Study

demonstrated the efficacy of tenofovir-only PrEP among PWID,² but few studies have evaluated PrEP effectiveness among PWID in real-world settings. A Canadian study of HIV-uninfected PWID found low acceptability of PrEP (35% of the sample reported willingness to use PrEP), although individuals with greater HIV risk, such as those engaged in transactional sex and those reporting a higher number of recent sexual partners, were more likely to report willingness to use PrEP.¹⁰⁹ Qualitative findings from a multinational sample of PWID found that acceptability of PrEP was generally high but was tempered by concerns such as the feasibility of obtaining it and the ethics of promoting PrEP over other harm-reduction services.¹¹⁰ Further study of PrEP implementation among PWID in the United States is necessary. Implementation efforts in this population should draw lessons from other successful HIV prevention interventions among PWID. Peer-based interventions to promote harm reduction services have successfully reduced incidence of HIV and high-risk behaviors among PWID,^{111–114} and may be similarly applied to promoting PrEP awareness and uptake.

SUPPORTING PrEP CARE FOR POOR AND UNDERINSURED PATIENTS

Inadequate insurance coverage, including lack of insurance, high copayments, and/or deductibles for office visit and laboratory procedures, contributes to disparities in PrEP utilization.^{59,87,95,98,115} Nearly 26 million 18–64-year-old Americans, 41% of which are 18–34 year old, are currently uninsured¹¹⁶; 15% are black¹¹⁷ and 28% are Hispanic/Latino.¹¹⁸ Moreover, 24%–18% of the lesbian, gay, bisexual, transgender, and queer population is estimated to be uninsured.¹¹⁹ The proposed American Health Care Act could cause further setbacks to national PrEP implementation. If the Affordable Care Act is repealed, more than 20 million people over the next decade may lose insurance, the majority (17 million) from changes to Medicaid policy; this could impact PrEP use in states that expanded Medicaid under the Affordable Care Act.^{10,120} Other relevant reforms involve changing the employer-required coverage mandate and decreasing federal funding that can specifically lower patient deductible and copayment costs.¹²⁰ To overcome these barriers, health policies are needed that allow for equal access to affordable and high-quality insurance throughout the United States for all age groups. Some states and cities have created special PrEP service reimbursement programs, such as New York State’s Pre-Exposure Prophylaxis Assistance Program to address the issue.^{121–123} Several web resources are available for consumers and providers to determine how to access PrEP in different settings, ranging from Gilead, the company that manufactures TDF-FTC in the United States,^{124,125} to community-based organizations such as Project Inform¹²⁶ (Table 1 for additional resources).

COST-EFFECTIVENESS OF PrEP

The current annual medication cost for PrEP in the United States generally exceeds \$10,000 per person. Total

PrEP costs are substantially greater when additional expenses associated with clinical care and laboratory monitoring are considered. In an era of constrained public health resources and insurance-related impediments, cost-effectiveness analyses can help inform policies to ensure that PrEP is implemented in an equitable and sustainable manner. Several groups have examined the cost-effectiveness of daily oral PrEP in the United States, and reached differing conclusions because of variable assumptions about costs, behaviors, and HIV-transmission dynamics.^{127–131} They agree that PrEP is cost-effective when prescribed preferentially to the highest risk individuals with the greatest adherence, but the broad use of PrEP may not be cost-effective at current costs, particularly if adherence is suboptimal.¹³² These findings suggest that efforts to improve accurate HIV risk assessments could enhance the cost-effectiveness of PrEP, which in turn could increase its overall public health impact. The next major inquiry is which settings are best-suited for PrEP implementation (Table 2).

LESSONS LEARNED, REMAINING CHALLENGES, AND THE FUTURE OF PrEP

Although PrEP was first approved for HIV prevention in the United States in 2012, only approximately 10% of those who might be expected to benefit have initiated the medication. Nonetheless, scaling up from zero to over 100,000 PrEP initiators in less than 5 years represents a significant public health accomplishment. This article has described some of the existing challenges (ie, external factors such as state insurance policies or organizational-level barriers) to optimizing PrEP scale-up and some creative responses that can facilitate PrEP delivery. Programmatic examples include incorporating insurance navigation and health education into services offered at clinics,^{30,41} pharmacy-based PrEP care with relatively low service fees,^{52–54} integrating PrEP into routine primary care services at CHCs,³² and creating programs in HIV/STD service settings through collaborations among health departments and community-based organizations.¹³³ The use of point-of-care laboratory testing in certain settings could potentially

TABLE 1. Resources Related to PrEP Provision

Financial issues
Patient assistance network: http://www.panfoundation.org/hiv-treatment-and-prevention
Gilead patient assistance program: https://start.truvada.com/hcp/prep-cost
Project Inform: https://www.projectinform.org/pdf/PrEP_Flow_Chart.pdf
Educational resources
https://www.cdc.gov/hiv/risk/prep/
https://www.projectinform.org/prep/
http://www.avac.org/prevention-option/prep
http://www.whatisprep.org/
www.thefenwayinstitute.org
http://www.siecus.org/index.cfm?fuseaction=page.viewPage&pageID=1555
https://aidsetc.org/topic/pre-exposure-prophylaxis

TABLE 2. Common Barriers and Facilitators to Prescription of PrEP in Different Health Care Settings

Setting	Where to Provide PrEP?	
	Barriers	Facilitators
STD clinics	Do not provide 1° care	See high-risk populations
	High patient volume	Sexual health focus
	Limited counseling time	PNSs
CHCs	Clinicians not trained in sexual health care	Opportunity to integrate care
	Busy clinical practices	Ongoing relationship
	Need to address 1° care issues	Safety-net insurance programs
	Limited counseling staff	May be medical home for at-risk, underserved patients
Community-based organizations	Lack of clinical support	Work with at-risk populations
	Often limited resources	Able to do community outreach
	Need to link to clinicians, who may or may not be responsive	May have peer navigators
Pharmacies	Prescriber often not on site	Experience with medications and adherence counseling
	May not be able to address other health concerns	Collaborative drug therapy agreements
	Lack of private physical space for counseling	Extended operating hours
		Potentially low service fees
PCPs	Generalist	Able to integrate other primary care issues
	Busy schedule	Long-term patient relationship common
	Discomfort discussing sexual behaviors	“One-stop shopping”
	Discomfort using new medications	

further reduce costs and procedural burden. Interventions that integrate insurance enrollment with HIV testing services for at-risk individuals and their networks hold promise for optimizing PrEP implementation among uninsured PrEP seekers.¹³⁴

A major looming question is whether the momentum can be maintained or accelerated in a time of uncertainty about federal support of health care for disenfranchised populations,¹³⁴ who are disproportionately at risk of HIV, as well as lack of clarity about whether changes in required coverage by insurers could make PrEP even less accessible to those who could benefit the most. Pericoital use of PrEP has also been demonstrated to be efficacious for MSM and could reduce the total pill burden required to achieve protection for individuals with intermittent exposures to HIV.¹³⁵ New technological advances, such as parenteral formulations of injectable antiretrovirals and infusible antibodies, may increase the simplicity of PrEP delivery, potentially requiring injections or infusions every few months.¹³⁶ These approaches, as well as the advent of generic tenofovir and

emtricitabine could decrease some of the costs associated with PrEP compared with daily regimens, but await rigorous comparisons with daily regimens, to determine long-term relative benefits.

To be able to fully scale-up PrEP delivery, providers need to be trained to readily identify the most appropriate PrEP candidates. Optimization of PrEP screening requires cultural competence training, so that providers can elicit sensitive information comfortably from those who could benefit from PrEP, who often are from ethnic, racial, and sexual and/or gender minority communities. Mechanisms to support the costs of medication for those who are uninsured and underinsured as well as the costs of associated care, laboratory monitoring, and related behavioral health services are also needed. This review has described multiple creative programs that have been developed to increase PrEP uptake and adherence, and if brought to scale, these efforts could further check the spread of HIV in the United States. But dissemination of best practices to a larger cadre of providers, and stable fiscal support, will be needed to achieve the optimal impact of this evidence-based HIV prevention intervention.

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