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## Evolving models and ongoing challenges for HIV pre-exposure prophylaxis implementation in the United States

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### Abstract

**Background**—The use of pre-exposure prophylaxis (PrEP) for HIV prevention was approved by the FDA in 2012, but delivery to at risk persons has lagged. This critical review analyzes the current state of PrEP implementation in the US, by reviewing barriers, and innovative solutions, to enhanced 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 (STD) clinics, community health centers (CHCs), CBOs, pharmacies, and private primary care providers (PCPs). STD clinics have staff trained in sexual health counseling and are linked to public health programs (e.g. partner notification services), while PCPs and CHCs 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

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

**Conclusion**—PrEP implementation in the US 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.

### Keywords

HIV prevention; PrEP; primary care; pharmacies; community-based organizations; sexually transmitted diseases

## Introduction

Clinical trials have demonstrated the efficacy of HIV pre-exposure 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<sup>1–5</sup>. Recent demonstration projects have found that PrEP delivery is feasible and effective in “real-world” clinical settings<sup>6–8</sup>. Although the Centers for Disease Control and Prevention has issued clinical practice guidelines for PrEP use in the United States (US)<sup>9</sup>, numerous implementation barriers remain, including questions about the cost-effectiveness of PrEP, optimal settings for provision, and the most effective ways to motivate healthcare 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<sup>10,11</sup>.

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.<sup>12, 13</sup> Each section of this review addresses leverage points that influence PrEP uptake grounded in the Practical Robust Implementation and Sustainability Model (PRISM) (Figure 1). 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.<sup>1</sup>

## Methods

We searched Pubmed over the past 5 years and major international HIV/AIDS conferences (e.g. 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<sup>15</sup>, presenting opportunities for seamless integration of PrEP alongside existing screening and prevention services. The first US PrEP Demonstration Project<sup>7,16</sup> was conducted at the San Francisco and Miami STD Clinics and found that PrEP implementation among high-risk 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 don’t provide longitudinal care. At the Rhode Island STD Clinic, only 11% of MSM educated about PrEP were ultimately prescribed the medication<sup>17</sup>, consistent with early PrEP implementation efforts in other settings<sup>18–20–23</sup>. The largest patient-level barriers to PrEP uptake included low self-perceived HIV risk, financial challenges, concerns about side effects, and limited access to healthcare. 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<sup>21</sup>. 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<sup>22,23</sup>. Given that other STDs increase the risk of HIV acquisition<sup>24</sup> and are an HIV risk indicator<sup>9, 25, 27</sup>, 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<sup>28</sup>. However, only 13% of those referred for STD care via 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<sup>29,30</sup>, effective PrEP implementation may require a comprehensive approach, integrating related patient services (e.g. 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<sup>31</sup>, 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 (e.g. Chicago<sup>32</sup>, Houston<sup>33</sup>, San Francisco<sup>34</sup>, St. Louis<sup>35</sup>, and Seattle<sup>36,37</sup>) offer examples of different types of successful PrEP-related programs. Programs have used telephone hotlines<sup>35,38–40</sup>, public health services<sup>37,41, 42</sup>, specially-trained PrEP insurance navigators<sup>35</sup>, and/or use internet-based social applications<sup>36,38</sup> 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 US<sup>43</sup> and many are involved with HIV disease management, as well as large-scale rollout of preventive services (e.g. vaccines)<sup>44–47</sup>. Pharmacy-based HIV testing has been cost saving, successfully reaching at-risk populations<sup>45–48–51</sup>. PrEP care delivered by clinical pharmacists has been shown to be feasible when utilizing collaborative drug therapy agreements<sup>49–55</sup>. Clinics within retail pharmacies have begun to pilot PrEP service delivery with the use of nurse practitioners and physician assistants<sup>56</sup>. A Seattle pharmacy reported initiating PrEP in 245 patients, and found 75% patient retention, and a return on investment, within nine months, which included individual consultations with clinical pharmacists and laboratory testing<sup>52,53</sup>. Requirements for establishing pharmacy-based and pharmacist-delivered PrEP clinics include understanding the care provision requirements in each state's collaborative drug therapy policies<sup>57,58</sup>. 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<sup>59,60</sup>. Other advantages are possible ease of integrating PrEP services into locations where HIV testing and linkage to care already occurs<sup>48, 61</sup>, evening and weekend hours of pharmacy operation, pharmacists' ability to prospectively review medication refill gaps to detect non-adherence and to provide adherence counseling<sup>62</sup>, and partnerships with other entities (e.g. health departments or community organizations) to optimize reach to at-risk populations. This model has promise for nation-wide scale up, given that about half of US pharmacies are part of large retail chains<sup>56</sup>. Barriers to this model may encompass not having 1) a private physical space within the pharmacy to conduct HIV risk assessments, 2) onsite comprehensive counseling services and seamless referrals (i.e. 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<sup>61, 62</sup>. 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 US, community health centers (CHCs) are an important source of health care for many populations at increased risk for HIV, particularly those who are poorer and from communities of color<sup>63</sup>. 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.<sup>64</sup> Some CHCs have developed strategies to address economic and logistical challenges that may affect PrEP access and adherence, particularly for patients who are under-insured or uninsured (e.g. 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<sup>65</sup>. 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**

As many persons at substantial risk for HIV infection will receive healthcare 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<sup>66</sup>, even though the FDA approved TDF-FTC for use as PrEP in 2012 and CDC released comprehensive clinical practice guidelines for PrEP in 2014<sup>67</sup>. 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<sup>66,68–71</sup>. In an earlier study, clinicians felt that provision of PrEP was more appropriate for HIV specialists<sup>72</sup>, but more recently, some PCPs appeared to be more open to learning how to prescribe PrEP<sup>73</sup>. 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<sup>74,75</sup>. However, despite the availability of normative guidelines, didactic lectures and webinars<sup>76</sup>, 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<sup>75</sup>. In New York City, a public health detailing initiative for PrEP was associated with an increase in first-time prescribing of PrEP by PCPs<sup>77</sup>, 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<sup>25,78,79</sup>. 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<sup>80</sup>. 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<sup>80</sup>, 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 (e.g. history of an STD), prescriptions (e.g. use of HIV post-exposure prophylaxis), and laboratory tests (e.g. frequent screening tests for HIV) to develop automated algorithms that can identify persons at increased risk for HIV acquisition<sup>81</sup>. 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<sup>3,4</sup>, and the CDC estimates that 624,000 US heterosexuals are at significant risk and could benefit from PrEP<sup>9, 82</sup>. However, profound racial and ethnic disparities persist, as Blacks and Hispanic/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<sup>83</sup>. PrEP uptake among heterosexuals in the US has been very limited<sup>11</sup>, 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 for HIV because of their sexual networks, even when they have few sexual partners<sup>4,9</sup>. 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 amongst 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<sup>84</sup>. Individual-level barriers to PrEP uptake among at-risk heterosexuals include limited PrEP awareness, medical mistrust, HIV stigma, and low perceived personal risk<sup>85–88</sup>. Structural barriers impeding PrEP use include poverty impeding access to health insurance and care<sup>87,89</sup>, limiting mobility and health literacy<sup>90</sup>. Some at risk women have expressed concerns about PrEP and drug effects on pregnancy outcomes, and infant development during breastfeeding<sup>91</sup>. Thus, strategies to increase appropriate PrEP use among at risk heterosexuals will need to be multi-faceted, 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<sup>67</sup>. Although about 25% of HIV-uninfected MSM between ages 18–59 years who report past-year sex with a man meet indications for PrEP use<sup>9</sup>, 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<sup>92</sup>. Sub-groups 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<sup>1819,93–95</sup>; 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<sup>16,94–96</sup>; and structural-level barriers include limited poverty, language barriers, or lack of insurance coverage<sup>16,87,95,97,98</sup>. Studies have documented MSM who are unwilling to disclose sexual minority identity or behavior to providers<sup>99,100</sup> 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<sup>68,72,101,102</sup>. Structural racism also contributes to barriers to PrEP uptake among MSM of color. While MSM of color face significantly greater lifetime risk of contracting HIV compared to white MSM<sup>103</sup>, these populations may experience distrust of medical institutions as a result of historical abuses<sup>104,105</sup>, as well as inequities in Medicaid and healthcare access programs<sup>106</sup>. PrEP implementation should involve focused, evidence-based and community-engaged methodologies in order to overcome the many obstacles facing racial and ethnic minority high-risk MSM<sup>107,108</sup>.

## Identification of injecting drug using candidates for PrEP

Among HIV-uninfected, adult people who inject drugs (PWID) in the US, about 19% meet indications for PrEP<sup>9</sup>. However, engaging PWID in PrEP care remains a significant challenge. The Bangkok Tenofovir Study demonstrated the efficacy of tenofovir-only PrEP among PWID<sup>2</sup>, 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), though 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<sup>109</sup>. 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<sup>110</sup>. Further study of PrEP implementation among PWID in the US 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<sup>111–114</sup>, and may be similarly applied to promoting PrEP awareness and uptake.

## Supporting PrEP care for poor and under-insured 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<sup>59,87,95,98,115</sup>. Nearly 26 million 18–64 year old Americans, 41% of which are 18–34 years, are currently uninsured<sup>116</sup>; 15% are Black<sup>117</sup> and 28% are Hispanic/Latino<sup>118</sup>. Moreover, 24–18% of the lesbian, gay, bisexual, transgender, and queer population is estimated to be uninsured<sup>119</sup>. The proposed American Health Care Act could cause further setbacks to national PrEP implementation. If the Affordable Care Act (ACA) 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 ACA<sup>10,120</sup>. Other relevant reforms involve changing the employer-required coverage mandate and decreasing federal funding that can specifically lower patient deductible and copayment costs<sup>120</sup>. To overcome these barriers, health policies are needed that allow equal access to affordable and high quality insurance throughout the US 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 (PrEP-AP) in order to address the issue<sup>121–123</sup>. 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 US<sup>124,125</sup>, to CBOs such as Project Inform<sup>126</sup> (see Table Two for additional resources).

## Cost-Effectiveness of PrEP

The current annual medication cost for PrEP in the US 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 US, and reached differing conclusions due to variable assumptions about costs, behaviors, and HIV transmission dynamics<sup>127–131</sup>. 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<sup>132</sup>. 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 One).

## Lessons learned, remaining challenges, and the future of PrEP

Although PrEP was first approved for HIV prevention in the US in 2012, only about 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 five years represents a significant public health accomplishment. This paper has described some of the existing challenges (i.e. 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<sup>30,41</sup>, pharmacy-based PrEP care with relatively low service fees<sup>52–54</sup>, integrating PrEP into routine primary care services at CHCs<sup>32</sup>, and creating programs in HIV/STD service settings through collaborations among health departments and CBOs<sup>133</sup>. The use of point-of-care laboratory testing in certain settings could potentially 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<sup>134</sup>.

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, who are disproportionately at risk for 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<sup>134</sup>. 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<sup>136</sup>. These approaches, as well as the advent of generic tenofovir and emtricitabine could decrease some of the costs associated with PrEP compared to 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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## References

1. Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med*. 2010; 363(27):2587–2599. [PubMed: 21091279]
2. Choopanya K, Martin M, Suntharasamai P, et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet*. 2013; 381(9883):2083–2090. [PubMed: 23769234]
3. Baeten JM, Donnell D, Ndase P, et al. Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women. *New England Journal of Medicine*. 2012; 367(5):399–410. [PubMed: 22784037]
4. Thigpen MC, Kebaabetswe PM, Paxton LA, et al. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *N Engl J Med*. 2012; 367(5):423–434. [PubMed: 22784038]
5. Grohskopf LA, Chillag KL, Gvetadze R, et al. Randomized trial of clinical safety of daily oral tenofovir disoproxil fumarate among HIV-uninfected men who have sex with men in the United States. *J Acquir Immune Defic Syndr*. 2013; 64(1):79–86. [PubMed: 23466649]
6. Grant RM, Anderson PL, McMahan V, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. *Lancet Infect Dis*. 2014; 14(9):820–829. [PubMed: 25065857]
7. Liu AY, Cohen SE, Vittinghoff E, et al. Preexposure Prophylaxis for HIV Infection Integrated With Municipal- and Community-Based Sexual Health Services. *JAMA internal medicine*. 2016; 176(1): 75–84. [PubMed: 26571482]

8. Volk JE, Marcus JL, Phengrasamy T, et al. No New HIV Infections With Increasing Use of HIV Preexposure Prophylaxis in a Clinical Practice Setting. *Clin Infect Dis*. 2015; 61(10):1601–1603. [PubMed: 26334052]
9. Smith DK, Van Handel M, Wolitski RJ, et al. Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition—United States, 2015. *MMWR Morb Mortal Wkly Rep*. 2015; 64(46):1291–1295. [PubMed: 26606148]
10. Laufer FN, O’Connell DA, Feldman I, Mps, Zucker HA. Vital Signs: Increased Medicaid Prescriptions for Preexposure Prophylaxis Against HIV infection—New York, 2012–2015. *MMWR Morb Mortal Wkly Rep*. 2015; 64(46):1296–1301. [PubMed: 26606257]
11. Bush, S., Magnuson, D., Rawlings, MK., Hawkins, T., McCallister, S., Robertino, MG. Racial characteristics of FTC/TDF for pre-exposure prophylaxis (PrEP) users in the US [abstrct 2651]. Paper presented at American Society for Microbiology and Interscience Conference on Antimicrobial Agents and Chemotherapy; June 16–20, 2016; Boston, MA. 2016.
12. Glasgow RE, Vinson C, Chambers D, Khoury MJ, Kaplan RM, Hunter C. National Institutes of Health approaches to dissemination and implementation science: current and future directions. *Am J Public Health*. 2012; 102(7):1274–1281. [PubMed: 22594758]
13. Eccles MP, Mittman BS. Welcome to Implementation Science. *Implement Sci*. 2006; 1:1–1.
14. Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. *Jt Comm J Qual Patient Saf*. 2008; 34(4):228–43. [PubMed: 18468362]
15. Cramer R, Leichliter JS, Gift TL. Are safety net sexually transmitted disease clinical and preventive services still needed in a changing health care system? *Sex Transm Dis*. 2014; 41(10): 628–630. [PubMed: 25211261]
16. Liu A, Cohen S, Follansbee S, et al. Early experiences implementing pre-exposure prophylaxis (PrEP) for HIV prevention in San Francisco. *PLoS Med*. 2014; 11(3):e1001613. [PubMed: 24595035]
17. Chan PA, Glynn TR, Oldenburg CE, et al. Implementation of Preexposure Prophylaxis for Human Immunodeficiency Virus Prevention Among Men Who Have Sex With Men at a New England Sexually Transmitted Diseases Clinic. *Sex Transm Dis*. 2016; 43(11):717–723. [PubMed: 27893604]
18. Krakower DS, Mimiaga MJ, Rosenberger JG, et al. Limited Awareness and Low Immediate Uptake of Pre-Exposure Prophylaxis among Men Who Have Sex with Men Using an Internet Social Networking Site. *PLoS One*. 2012; 7(3):e33119. [PubMed: 22470438]
19. Eaton LA, Driffin DD, Bauermeister J, Smith H, Conway-Washington C. Minimal Awareness and Stalled Uptake of Pre-Exposure Prophylaxis (PrEP) Among at Risk, HIV-Negative, Black Men Who Have Sex with Men. *AIDS Patient Care STDS*. 2015; 29(8):423–429. [PubMed: 26083143]
20. Hood JE, Buskin SE, Dombrowski JC, et al. Dramatic increase in preexposure prophylaxis use among MSM in Washington state. *Aids*. 2016; 30(3):515–519. [PubMed: 26562845]
21. Raifman J, Nunn AS, Oldenburg CE, et al. An evaluation of a clinical pre-exposure prophylaxis education intervention among men who have sex with men. *Health Services Research*.
22. Centers for Disease Control and Prevention. Recommendations for partner services programs for HIV infection, syphilis, gonorrhea, and chlamydial infection. *MMWR Recomm Rep*. 2008; 57(Rr-9):1–83.
23. Wilson TE, Hogben M, Malka ES, et al. A randomized controlled trial for reducing risks for sexually transmitted infections through enhanced patient-based partner notification. *Am J Public Health*. 2009; 99(Suppl 1):S104–110. [PubMed: 18556619]
24. Cohen MS. HIV and sexually transmitted diseases: lethal synergy. *Top HIV Med*. 2004; 12(4):104–107. [PubMed: 15516707]
25. Smith DK, Pals SL, Herbst JH, Shinde S, Carey JW. Development of a clinical screening index predictive of incident HIV infection among men who have sex with men in the United States. *J Acquir Immune Defic Syndr*. 2012; 60(4):421–427. [PubMed: 22487585]
26. Chan PA, Rose J, Maher J, et al. A Latent Class Analysis of Risk Factors for Acquiring HIV Among Men Who Have Sex with Men: Implications for Implementing Pre-Exposure Prophylaxis Programs. *AIDS Patient Care STDS*. 2015; 29(11):597–605. [PubMed: 26389735]

27. Koblin BA, Husnik MJ, Colfax G, et al. Risk factors for HIV infection among men who have sex with men. *AIDS*. 2006; 20(5):731–739. [PubMed: 16514304]
28. Katz DA, Dombrowski JC, Bell T, Golden MR. STD partner services to monitor and promote PrEP use among men who have sex with men. *AIDS Patient Care STDS*. 2016; 30(5):208–214. [PubMed: 27158848]
29. Mugavero MJ, Amico KR, Horn T, Thompson MA. The state of engagement in HIV care in the United States: from cascade to continuum to control. *Clin Infect Dis*. 2013; 57(8):1164–1171. [PubMed: 23797289]
30. Greenberg AE, Purcell DW, Gordon CM, Barasky RJ, del Rio C. Addressing the challenges of the HIV continuum of care in high-prevalence cities in the United States. *J Acquir Immune Defic Syndr*. 2015; 69(Suppl 1):S1–7. [PubMed: 25867773]
31. Ryan White HIV/AIDS Program: Program Fact Sheet. 2016. Available at: <https://hab.hrsa.gov/sites/default/files/hab/Publications/factsheets/programoverviewfacts2016.pdf>. Accessed June 7, 2017
32. Pre-Exposure Prophylaxis (PrEP), HIV/AIDS Services at Howard Brown. Howard Brown Health. Available at: <http://howardbrown.org/wp/prep/>. Accessed June 7, 2017
33. Flash, CA., Frost, E., Akinbohun, N., Rodriguez, P., Giordano, TP. PrEP Implementation in Houston, TX among high-risk heterosexuals and MSM (abstract ID 1526). Abstract and oral presentation presented at IDWeek; October 07-12, 2014; Philadelphia, PA. 2014.
34. Crouch, P-C. SFAF Magnet PrEP Health Program. 2014. Available at: <http://www.uchaps.org/prep/SanFranciscoPrEPUCHAPS2014.pdf>. Accessed June 7, 2017
35. Patel, R., Wrigley, D., Mayer, K., Powderly, W. High Linkage to PrEP Care in St. Louis Using a Pilot Linkage to PrEP Care Community Partnership Program (abstract ID 5113). National HIV Prevention Conference; 2015; Atlanta, GA.
36. Patel RR, Harrison LC, Patel VV, et al. HIV Pre-exposure Prophylaxis Programs Incorporating Social Applications Can Reach At-Risk Men Who Have Sex With Men for Successful Linkage to Care in Missouri, USA. *J Assoc Nurses AIDS Care*. 2017; 28(3):428–430. [PubMed: 28216178]
37. Chan, G., Katz, DA., Golden, MR., Dombrowski, JC. Utilizing STD Partner Services to Target High-Risk Men Who Have Sex with Men for Pre-Exposure Prophylaxis Referral: Programmatic Experience in King County, Washington [Abstract 1742]. Paper presented at: National HIV Prevention Conference; 2015; Atlanta, GA.
38. PrEP4Love. One Pill. Once a Day. Protect Against HIV. Chicago PrEP Working Group and AIDS Foundation of Chicago; Available at: <http://prep4love.com/>. Accessed May 16, 2017
39. The Chicago Center for HIV Elimination. PrEPLine & PrEP Linkage-to-Care. University of Chicago; 2012. Available at: [https://hivelimination.uchicago.edu/projects/programs/prep\\_hotline\\_linkage\\_to\\_care/](https://hivelimination.uchicago.edu/projects/programs/prep_hotline_linkage_to_care/). Accessed June 7, 2017
40. Mississippi State Department of Health Office of Communications. HIV Pre-Exposure Intervention Call Center Now Available in Mississippi. Mississippi State Department of Health; 2015. [http://www.msdh.state.ms.us/msdhsite/\\_static/23,15994,341,731.html](http://www.msdh.state.ms.us/msdhsite/_static/23,15994,341,731.html). Accessed June 7, 2017
41. Mikati, T., Bahatia, R., Pohl, D. Pilot Implementation of PrEP: active referral model in Chicago public STI Clinic (abstract ID 2063). National HIV Prevention Conference; 2015; Atlanta, GA.
42. American Pharmacists Association F, American Pharmacists A. Consortium recommendations for advancing pharmacists' patient care services and collaborative practice agreements. *J Am Pharm Assoc* (2003). 2013; 53(2):e132–141. [PubMed: 23571636]
43. Saberi P, Dong BJ, Johnson MO, Greenblatt RM, Cocohoba JM. The impact of HIV clinical pharmacists on HIV treatment outcomes: a systematic review. *Patient Prefer Adherence*. 2012; 6:297–322. [PubMed: 22536064]
44. Santschi V, Chiolero A, Burnand B, Colosimo AL, Paradis G. Impact of pharmacist care in the management of cardiovascular disease risk factors: a systematic review and meta-analysis of randomized trials. *Arch Intern Med*. 2011; 171(16):1441–1453. [PubMed: 21911628]
45. Cranor CW, Bunting BA, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. *J Am Pharm Assoc* (Wash). 2003; 43(2):173–184. [PubMed: 12688435]

46. Uscher-Pines L, Harris KM, Burns RM, Mehrotra A. The growth of retail clinics in vaccination delivery in the U.S. *Am J Prev Med*. 2012; 43(1):63–66. [PubMed: 22704748]
47. Weidle PJ, Lecher S, Botts LW, et al. HIV testing in community pharmacies and retail clinics: a model to expand access to screening for HIV infection. *J Am Pharm Assoc* (2003). 2014; 54(5): 486–492. [PubMed: 25216878]
48. Amesty S, Crawford ND, Nandi V, et al. Evaluation of Pharmacy-Based HIV Testing in a High-Risk New York City Community. *AIDS Patient Care STDS*. 2015; 29(8):437–444. [PubMed: 26217930]
49. Dugdale C, Zaller N, Bratberg J, Berk W, Flanigan T. Missed opportunities for HIV screening in pharmacies and retail clinics. *J Manag Care Spec Pharm*. 2014; 20(4):339–345. [PubMed: 24684638]
50. Collins, BC., Bronson, HW., Martin, EG. Assessing the efficacy and feasibility of a retail pharmacy-based HIV testing program [Abstract 962]. Paper presented at: Conference on Retroviruses and Opportunistic Infections; February 13–16, 2017; Seattle, WA.
51. American Pharmacists A, National Association of Chain Drug Stores F. Medication therapy management in pharmacy practice: core elements of an MTM service model (version 2.0). *J Am Pharm Assoc* (2003). 2008; 48(3):341–353. [PubMed: 18595820]
52. Tung, E., Thomas, A., Eichner, A., Shalit, P. Feasibility of a pharmacist-run HIV PrEP clinic in a community pharmacy setting (abstract ID 961). Paper presented at: Conference on Retroviruses and Opportunistic Infections; 2017; Seattle, WA.
53. Kelley-Ross Pharmacy Group. One-Step PrEP®. Available at: <https://www.kelley-ross.com/polyclinic/prep>. Accessed June 7, 2017
54. Scales' Pharmacy. Services. Available at: <https://www.scalespharmacy.com/services/>. Accessed June 7, 2017
55. Gateway Apothecary. Available at: <https://gatewayapothecary.winrxrefill.com>. Accessed June 7, 2017
56. Walgreens Healthcare Clinics to Offer Testing Services for Sexually Transmitted Infections, Including HIV, Hepatitis and Others [press release]. Apr 18. 2017 Available at: <http://news.walgreens.com/press-releases/walgreens-healthcare-clinics-to-offer-testing-services-for-sexually-transmitted-infections-including-hiv-hepatitis-and-others.htm>. Accessed June 7, 2017
57. Centers for Disease Control and Prevention. State Law Fact Sheet: Select Features of State Pharmacist Collaborative Practice Laws. 2013. Available at: [https://www.cdc.gov/dhdsppubs/docs/pharmacist\\_state\\_law.pdf](https://www.cdc.gov/dhdsppubs/docs/pharmacist_state_law.pdf). Accessed June 7, 2017
58. Centers for Disease Control and Prevention. A Program Guide for Public Health: Partnering with Pharmacists in the Prevention and Control of Chronic Diseases. 2012. Available at: [www.cdc.gov/dhdspp/programs/nhdsp\\_program/resources.htm](http://www.cdc.gov/dhdspp/programs/nhdsp_program/resources.htm). Accessed June 7, 2017
59. Arnold T, Brinkley-Rubinstein L, Chan PA, et al. Social, structural, behavioral and clinical factors influencing retention in Pre-Exposure Prophylaxis (PrEP) care in Mississippi. *PLoS One*. 2017; 12(2):e0172354. [PubMed: 28222118]
60. Ferrell KW, Woodard LM, Woodard TJ. Role of medication therapy management in preexposure prophylaxis therapy for HIV prevention. *J Pharm Pract*. 2015 Feb; 28(1):10–2. [PubMed: 25500557]
61. Thygeson M, Van Vorst KA, Maciosek MV, Solberg L. Use And Costs Of Care In Retail Clinics Versus Traditional Care Sites. *Health Affairs*. 2008; 27(5):1283–1292. [PubMed: 18780912]
62. Bruno C, Saberi P. Pharmacists as providers of HIV pre-exposure prophylaxis. *International Journal of Clinical Pharmacy*. 2012; 34(6):803–806. [PubMed: 23073703]
63. National Association of Community Health Centers. Research Fact Sheets And Infographics. National Association of Community Health Centers; Available at: <http://www.nachc.org/research-and-data/research-fact-sheets-and-infographics/>. Accessed June 7, 2017
64. Mayer K, Appelbaum J, Rogers T, Lo W, Bradford J, Boswell S. The Evolution of the Fenway Community Health Model. *American Journal of Public Health*. 2001; 91(6):892–894. [PubMed: 11392929]

65. Parsons JT, Millar BM, Moody RL, Starks TJ, Rendina HJ, Grov C. Syndemic Conditions and HIV Transmission Risk Behavior Among HIV-Negative Gay and Bisexual Men in a U.S. National Sample. *Health Psychol.* 2017
66. Smith DK, Mendoza MC, Stryker JE, Rose CE. PrEP Awareness and Attitudes in a National Survey of Primary Care Clinicians in the United States, 2009-2015. *PLoS One.* 2016; 11(6):e0156592. [PubMed: 27258374]
67. Smith, DK., Koenig, LJ., Martin, M., et al. Preexposure prophylaxis for the prevention of HIV infection in the United States – 2014: a clinical practice guideline. US Public Health Service, Centers for Disease Control and Prevention; 2014. Available at: <https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf>. Accessed June 7, 2017
68. Krakower DS, Maloney KM, Grasso C, Melbourne K, Mayer KH. Primary care clinicians' experiences prescribing HIV pre-exposure prophylaxis at a specialized community health centre in Boston: lessons from early adopters. *J Int AIDS Soc.* 2016; 19(1):21165. [PubMed: 27733238]
69. Calabrese SK, Magnus M, Mayer KH, et al. Putting PrEP into Practice: Lessons Learned from Early-Adopting U.S. Providers' Firsthand Experiences Providing HIV Pre-Exposure Prophylaxis and Associated Care. *PLoS One.* 2016; 11(6):e0157324. [PubMed: 27304883]
70. Krakower DS, Oldenburg CE, Mitty JA, et al. Knowledge, Beliefs and Practices Regarding Antiretroviral Medications for HIV Prevention: Results from a Survey of Healthcare Providers in New England. *PLoS One.* 2015; 10(7):e0132398. [PubMed: 26146824]
71. Blumenthal J, Jain S, Krakower D, et al. Knowledge is Power! Increased Provider Knowledge Scores Regarding Pre-exposure Prophylaxis (PrEP) are Associated with Higher Rates of PrEP Prescription and Future Intent to Prescribe PrEP. *AIDS Behav.* 2015; 19(5):802–810. [PubMed: 25616837]
72. Krakower D, Ware N, Mitty JA, Maloney K, Mayer KH. HIV providers' perceived barriers and facilitators to implementing pre-exposure prophylaxis in care settings: a qualitative study. *AIDS Behav.* 2014; 18(9):1712–1721. [PubMed: 24965676]
73. Krakower DS, Ware NC, Maloney KM, Wilson IB, Wong JB, Mayer KH. Differing Experiences with Pre-Exposure Prophylaxis in Boston Among Lesbian, Gay, Bisexual, and Transgender Specialists and Generalists in Primary Care: Implications for Scale-Up. *AIDS Patient Care STDS.* 2017
74. Patel, RR., Ahsan, K., Krakower, D., Mayer, K., Harrison, L. Brief didactic educational session increases willingness to prescribe HIV pre-exposure prophylaxis among health professionals (abstract ID 5635). International AIDS Conference; July 24-26, 2017; Paris, France.
75. Soumerai SB, Avorn J. Principles of educational outreach ('academic detailing') to improve clinical decision making. *JAMA.* 1990; 263(4):549–556. [PubMed: 2104640]
76. National Coordinating Resource Center: Pre-Exposure Prophylaxis. Available at: <https://www.aidsetc.org/topic/pre-exposure-prophylaxis>. Accessed May 30, 2017
77. Edelstein, Z., Salcuni, P., Restart, A., Myers, J., Tsoi, B., Daskalakis, D. Early Adopters and Incident PrEP Prescribing in a Detailing Campaign, 2014–2015 [Abstract 892]. Paper presented at: Retroviruses and Opportunistic Infections; February 22-25, 2016; Boston, MA.
78. Menza TW, Hughes JP, Celum CL, Golden MR. Prediction of HIV acquisition among men who have sex with men. *Sex Transm Dis.* 2009; 36(9):547–555. [PubMed: 19707108]
79. Hoenigl M, Weibel N, Mehta SR, et al. Development and validation of the San Diego Early Test Score to predict acute and early HIV infection risk in men who have sex with men. *Clin Infect Dis.* 2015; 61(3):468–475. [PubMed: 25904374]
80. Jones J, Hoenigl M, Siegler AJ, Sullivan PS, Little S, Rosenberg E. Assessing the Performance of 3 Human Immunodeficiency Virus Incidence Risk Scores in a Cohort of Black and White Men Who Have Sex With Men in the South. *Sex Transm Dis.* 2017; 44(5):297–302. [PubMed: 28407646]
81. Krakower, D., Gruber, S., Menchaca, JT., et al. Automated Identification of Potential Candidates for HIV Pre-Exposure Prophylaxis using Electronic Health Record Data [Abstract 860]. Paper presented at: IDWeek; October 24-30, 2016; New Orleans, LA.
82. Centers for Disease Control and Prevention. HIV in the United States: at a glance. Dec 2. 2016 Available at: <https://www.cdc.gov/hiv/statistics/overview/ataglance.html>. Accessed June 7, 2017

83. Hodder SL, Justman J, Hughes JP, et al. HIV acquisition among women from selected areas of the united states: A cohort study. *Annals of Internal Medicine*. 2013; 158(1):10–18. [PubMed: 23277896]
84. Adimora AA, Schoenbach VJ, Floris-Moore MA. Ending the epidemic of heterosexual HIV transmission among African Americans. *Am J Prev Med*. 2009; 37(5):468–471. [PubMed: 19840704]
85. McMahon JM, Myers JE, Kurth AE, et al. Oral pre-exposure prophylaxis (PrEP) for prevention of HIV in serodiscordant heterosexual couples in the United States: opportunities and challenges. *AIDS Patient Care STDS*. 2014; 28(9):462–474. [PubMed: 25045996]
86. Flash CA, Stone VE, Mitty JA, et al. Perspectives on HIV prevention among urban black women: a potential role for HIV pre-exposure prophylaxis. *AIDS Patient Care STDS*. 2014; 28(12):635–642. [PubMed: 25295393]
87. Patel RR, Mena L, Nunn A, et al. Impact of insurance coverage on utilization of pre-exposure prophylaxis for HIV prevention. *PLoS ONE*. 2017; 12(5):e0178737. [PubMed: 28558067]
88. Eisingerich AB, Wheelock A, Gomez GB, Garnett GP, Dybul MR, Piot PK. Attitudes and acceptance of oral and parenteral HIV preexposure prophylaxis among potential user groups: a multinational study. *PLoS One*. 2012; 7(1):e28238. [PubMed: 22247757]
89. Khawcharoenporn T, Kendrick S, Smith K. HIV risk perception and preexposure prophylaxis interest among a heterosexual population visiting a sexually transmitted infection clinic. *AIDS Patient Care STDS*. 2012; 26(4):222–233. [PubMed: 22404427]
90. Wingood GM, Dunkle K, Camp C, et al. Racial differences and correlates of potential adoption of preexposure prophylaxis: results of a national survey. *J Acquir Immune Defic Syndr*. 2013; 63(Suppl 1):S95–101. [PubMed: 23673895]
91. Auerbach JD, Kinsky S, Brown G, Charles V. Knowledge, attitudes, and likelihood of pre-exposure prophylaxis (PrEP) use among US women at risk of acquiring HIV. *AIDS Patient Care STDS*. 2015; 29(2):102–110. [PubMed: 25513954]
92. Jenness SM, Goodreau SM, Rosenberg E, et al. Impact of the Centers for Disease Control’s HIV Preexposure Prophylaxis Guidelines for Men Who Have Sex With Men in the United States. *The Journal of Infectious Diseases*. 2016; 214(12):1800–1807. [PubMed: 27418048]
93. Arnold EA, Hazelton P, Lane T, et al. A qualitative study of provider thoughts on implementing pre-exposure prophylaxis (PrEP) in clinical settings to prevent HIV infection. *PLoS One*. 2012; 7(7):e40603. [PubMed: 22792384]
94. Golub SA, Gamarel KE, Rendina HJ, Surace A, Lelutiu-Weinberger CL. From efficacy to effectiveness: facilitators and barriers to PrEP acceptability and motivations for adherence among MSM and transgender women in New York City. *AIDS Patient Care STDS*. 2013; 27(4):248–254. [PubMed: 23565928]
95. Brooks RA, Kaplan RL, Lieber E, Landovitz RJ, Lee SJ, Leibowitz AA. Motivators, concerns, and barriers to adoption of preexposure prophylaxis for HIV prevention among gay and bisexual men in HIV-serodiscordant male relationships. *AIDS Care*. 2011; 23(9):1136–1145. [PubMed: 21476147]
96. Calabrese SK, Underhill K. How Stigma Surrounding the Use of HIV Preexposure Prophylaxis Undermines Prevention and Pleasure: A Call to Destigmatize “Truvada Whores”. *Am J Public Health*. 2015; 105(10):1960–1964. [PubMed: 26270298]
97. Doblecki-Lewis S, Liu A, Feaster D, et al. Healthcare Access and PrEP Continuation in San Francisco and Miami After the US PrEP Demo Project. *J Acquir Immune Defic Syndr*. 2017; 74(5):531–538. [PubMed: 27861236]
98. Chan PA, Mena L, Patel R, et al. Retention in care outcomes for HIV pre-exposure prophylaxis implementation programmes among men who have sex with men in three US cities. *J Int AIDS Soc*. 2016; 19(1):20903. [PubMed: 27302837]
99. Bernstein KT, Liu KL, Begier EM, Koblin B, Karpati A, Murrill C. Same-sex attraction disclosure to health care providers among New York City men who have sex with men: implications for HIV testing approaches. *Arch Intern Med*. 2008; 168(13):1458–1464. [PubMed: 18625927]
100. Underhill K, Morrow KM, Collieran C, et al. A Qualitative Study of Medical Mistrust, Perceived Discrimination, and Risk Behavior Disclosure to Clinicians by U.S. Male Sex Workers and Other

Men Who Have Sex with Men: Implications for Biomedical HIV Prevention. *J Urban Health*. 2015; 92(4):667–686. [PubMed: 25930083]

101. Petroll AE, Mosack KE. Physician awareness of sexual orientation and preventive health recommendations to men who have sex with men. *Sex Transm Dis*. 2011; 38(1):63–67. [PubMed: 20706178]
102. Walsh JL, Petroll AE. Factors Related to Pre-exposure Prophylaxis Prescription by U.S. Primary Care Physicians. *American Journal of Preventive Medicine*. 2017; 52(6):e165–e172. [PubMed: 28363410]
103. Hess, K., Hu, X., Lansky, A., Mermin, J., Hall, HI. Estimating the lifetime risk of a diagnosis of HIV infection in the United States [Abstract 52]. Paper presented at: Conference on Retroviruses and Opportunistic Infections; February 22-25, 2016; Boston, MA.
104. Landrine H, Klonoff EA. The schedule of racist events: a measure of racial discrimination and a study of its negative physical and mental health consequences. *J Black Psychol*. 1996; 22(2):144–168.
105. Philbin MM, Parker CM, Parker RG, Wilson PA, Garcia J, Hirsch JS. The Promise of Pre-Exposure Prophylaxis for Black Men Who Have Sex with Men: An Ecological Approach to Attitudes, Beliefs, and Barriers. *AIDS Patient Care STDS*. 2016; 30(6):282–290. [PubMed: 27220036]
106. Clark CR, Ommerborn MJ, B AC, Pham do Q, Haas JS. Income Inequities and Medicaid Expansion are Related to Racial and Ethnic Disparities in Delayed or Forgone Care Due to Cost. *Med Care*. 2016; 54(6):555–561. [PubMed: 26974677]
107. Auerbach JD, Hoppe TA. Beyond “getting drugs into bodies”: social science perspectives on pre-exposure prophylaxis for HIV. *J Int AIDS Soc*. 2015; 18(4 Suppl 3):19983. [PubMed: 26198346]
108. Penner LA, Blair IV, Albrecht TL, Dovidio JF. Reducing Racial Health Care Disparities: A Social Psychological Analysis. Policy insights from the behavioral and brain sciences. 2014; 1(1):204–212. [PubMed: 25705721]
109. Escudero DJ, Kerr T, Wood E, et al. Acceptability of HIV Pre-exposure Prophylaxis (PrEP) Among People Who Inject Drugs (PWID) in a Canadian Setting. *AIDS Behav*. 2015; 19(5):752–757. [PubMed: 25086669]
110. Guise A, Albers ER, Strathdee SA. ‘PrEP is not ready for our community, and our community is not ready for PrEP’: pre-exposure prophylaxis for HIV for people who inject drugs and limits to the HIV prevention response. *Addiction*. 2017; 112(4):572–578. [PubMed: 27273843]
111. Latkin CA. Outreach in natural settings: the use of peer leaders for HIV prevention among injecting drug users’ networks. *Public Health Reports*. 1998; 113(Suppl 1):151–159. [PubMed: 9722820]
112. Latkin CA, Sherman S, Knowlton A. HIV prevention among drug users: Outcome of a network-oriented peer outreach intervention. *Health Psychology*. 2003; 22(4):332–339. [PubMed: 12940388]
113. Tobin KE, Kuramoto SJ, Davey-Rothwell MA, Latkin CA. The STEP into Action study: a peer-based, personal risk network focused HIV prevention intervention with injection drug users in Baltimore, Maryland. *Addiction (Abingdon, England)*. 2011; 106(2):366–375.
114. Weeks MR, Li J, Dickson-Gomez J, et al. Outcomes of a peer HIV prevention program with injection drug and crack users: the Risk Avoidance Partnership. *Subst Use Misuse*. 2009; 44(2):253–281. [PubMed: 19142824]
115. Mayer KH, Hosek S, Cohen S, et al. Antiretroviral pre-exposure prophylaxis implementation in the United States: a work in progress. *J Int AIDS Soc*. 2015; 18(4 Suppl 3):19980. [PubMed: 26198345]
116. U.S. Census Bureau. Selected Characteristics of the Uninsured in the United States: 2015 American Community Survey 1-Year Estimates. 2015
117. U.S. Census Bureau. Health Insurance Coverage Status by Age (Black or African American Alone). Universe: Black or African American alone civilian noninstitutionalized population. 2015 American Community Survey 1-Year Estimates. 2015

118. U.S. Census Bureau. Health Insurance Coverage Status by Age (Hispanic or Latino). Universe: Hispanic or Latino civilian noninstitutionalized population. 2015 American Community Survey 1-Year Estimates. 2015
119. Gates, GJ. US, LGBT More Likely Than Non-LGBT to Be Uninsured. 2014. Available at: <http://www.gallup.com/poll/175445/lgbt-likely-non-lgbt-uninsured.aspx>. Accessed June 7, 2017
120. Congressional Budget Office Cost Estimate: American Health Care Act. 2017. p. 1-37. Available at: <https://www.cbo.gov/sites/default/files/115th-congress-2017-2018/costestimate/americanhealthcareact.pdf>. Accessed June 7, 2017
121. Pre-Exposure Prophylaxis Assistance Program (PrEP-AP): Program Summary. Available at: <https://www.health.ny.gov/diseases/aids/general/resources/adap/prep.htm>. Accessed June 7, 2017
122. Pre-Exposure Prophylaxis Drug Assistance Program (PrEP DAP). Available at: <http://www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIVAIDS/HIVCareClientServices/PrEPDAP>. Accessed June 7, 2017
123. San Francisco City Clinic: Pre-Exposure Prophylaxis (PrEP). Available at: <http://www.sfcityclinic.org/services/prep.asp>. Accessed June 7, 2017
124. Eligible Patients May Save on the Cost of TRUVADA for PrEP. Available at: <https://start.truvada.com/hcp/prep-cost>. Accessed June 7, 2017
125. HIV Prevention and Treatment. Available at: <https://panfoundation.org/index.php/en/patients/assistance-programs/hiv-prevention-and-treatment>. Accessed June 7, 2017
126. Getting PrEPped. Available at: [https://www.projectinform.org/pdf/PrEP\\_Flow\\_Chart.pdf](https://www.projectinform.org/pdf/PrEP_Flow_Chart.pdf). Accessed June 7, 2017
127. Bernard CL, Brandeau ML, Humphreys K, et al. Cost-Effectiveness of HIV Preexposure Prophylaxis for People Who Inject Drugs in the United States. *Ann Intern Med*. 2016
128. Juusola JL, Brandeau ML, Owens DK, Bendavid E. The Cost-Effectiveness of Preexposure Prophylaxis for HIV Prevention in Men Who Have Sex with Men in the United States. *Annals of internal medicine*. 2012; 156(8):541–550. [PubMed: 22508731]
129. Paltiel AD, Freedberg KA, Scott CA, et al. HIV preexposure prophylaxis in the United States: impact on lifetime infection risk, clinical outcomes, and cost-effectiveness. *Clin Infect Dis*. 2009; 48(6):806–815. [PubMed: 19193111]
130. Gomez GB, Borquez A, Case KK, Wheelock A, Vassall A, Hankins C. The cost and impact of scaling up pre-exposure prophylaxis for HIV prevention: a systematic review of cost-effectiveness modelling studies. *PLoS medicine*. 2013; 10(3):e1001401. [PubMed: 23554579]
131. Kessler J, Myers JE, Nucifora KA, et al. Evaluating the impact of prioritization of antiretroviral pre-exposure prophylaxis in New York. *Aids*. 2014; 28(18):2683–2691. [PubMed: 25493594]
132. Jacobsen MM, Walensky RP. Modeling and Cost-Effectiveness in HIV Prevention. *Current HIV/AIDS reports*. 2016; 13(1):64–75. [PubMed: 26830283]
133. National HIV PrEP Summit. HIV PrEP Implementation Models: Expanding Access to Priority Populations. Available at: <http://hivprepsummit.org/index.php/hiv-prep-implementation-models-expanding-access-to-priority-populations/>. Accessed May 16, 2017
134. Schneider, J. Insurance Coverage Expansion (ICE): A Collaboration to Increase and Strengthen Access to Care Among Men and Their Networks. 2016. Available at: [https://projectreporter.nih.gov/project\\_info\\_description.cfm?aid=9224776&icde=34305607&ddparam=&ddvalue=&ddsub=&cr=8&csb=default&cs=ASC&pball=](https://projectreporter.nih.gov/project_info_description.cfm?aid=9224776&icde=34305607&ddparam=&ddvalue=&ddsub=&cr=8&csb=default&cs=ASC&pball=). Accessed June 7, 2017, 2017
135. Molina J-M, Capitant C, Spire B, et al. On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection. *New England Journal of Medicine*. 2015; 373(23):2237–2246. [PubMed: 26624850]
136. www.avac.org. AIDS Vaccine Advocacy Coalition website. accessed, October 9, 2017.



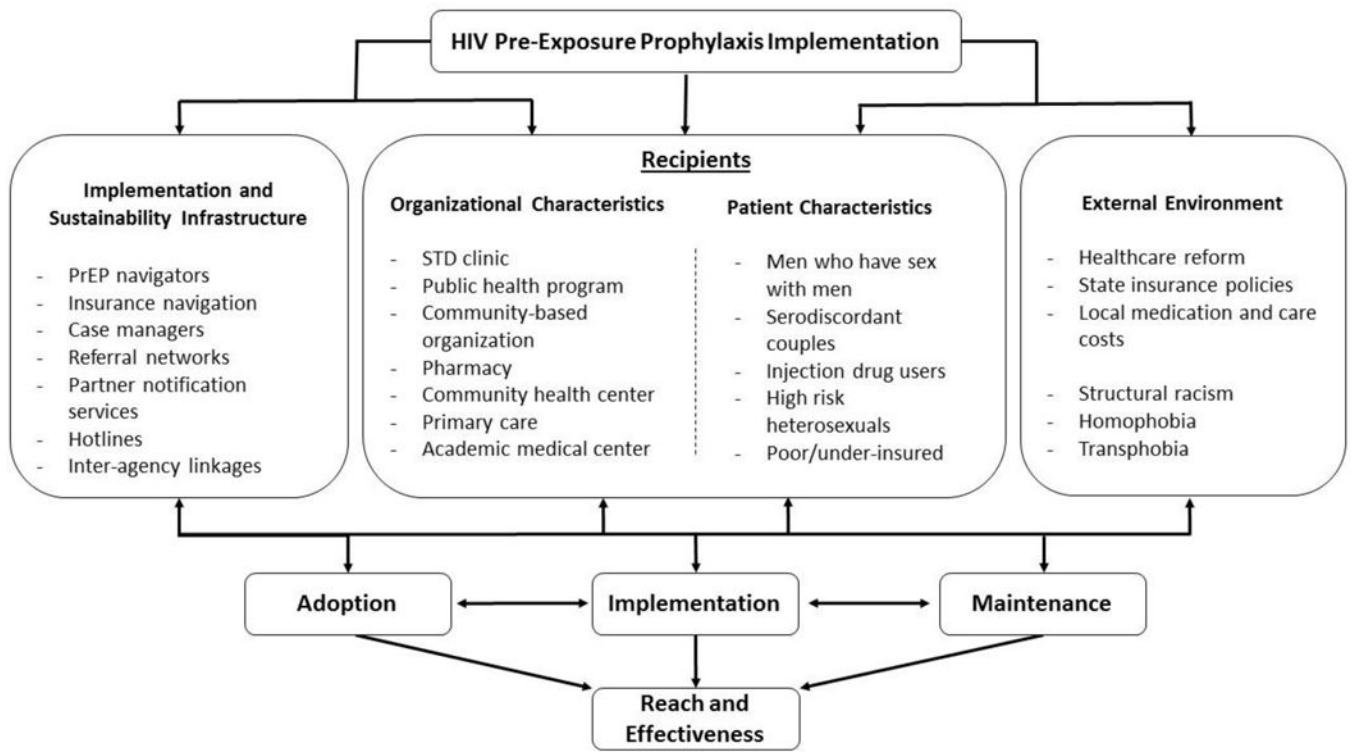


Figure 1.

**Table One**

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

Where to provide PrEP?		
Setting	Barriers	Facilitators
STD Clinics	<ul style="list-style-type: none"> <li><input type="radio"/> Don't provide 1° care</li> <li><input type="radio"/> High patient volume</li> <li><input type="radio"/> Limited counseling time</li> </ul>	<ul style="list-style-type: none"> <li><input type="radio"/> See high risk populations</li> <li><input type="radio"/> Sexual health focus</li> <li><input type="radio"/> Partner notification services</li> </ul>
Community Health Centers	<ul style="list-style-type: none"> <li><input type="radio"/> Clinicians not trained in sexual health care</li> <li><input type="radio"/> Busy clinical practices</li> <li><input type="radio"/> Need to address 1° care issues</li> <li><input type="radio"/> Limited counseling staff</li> </ul>	<ul style="list-style-type: none"> <li><input type="radio"/> Opportunity to integrate care</li> <li><input type="radio"/> Ongoing relationship</li> <li><input type="radio"/> Safety net insurance programs</li> <li><input type="radio"/> May be medical home for at risk, underserved patients</li> </ul>
Community-Based Organizations	<ul style="list-style-type: none"> <li><input type="radio"/> Lack of clinical support</li> <li><input type="radio"/> Often limited resources</li> <li><input type="radio"/> Need to link to clinicians, who may or may not be responsive</li> </ul>	<ul style="list-style-type: none"> <li><input type="radio"/> Work with at-risk populations</li> <li><input type="radio"/> Able to do community outreach</li> <li><input type="radio"/> May have peer navigators</li> </ul>
Pharmacies	<ul style="list-style-type: none"> <li><input type="radio"/> Prescriber often not on site</li> <li><input type="radio"/> May not be able to address other health concerns</li> <li><input type="radio"/> Lack of private physical space for counseling</li> </ul>	<ul style="list-style-type: none"> <li><input type="radio"/> Experience with medications and adherence counseling</li> <li><input type="radio"/> Collaborative drug therapy agreements</li> <li><input type="radio"/> Extended operating hours</li> <li><input type="radio"/> Potentially low service fees</li> </ul>
Primary Care Providers	<ul style="list-style-type: none"> <li><input type="radio"/> Generalist</li> <li><input type="radio"/> Busy schedule</li> <li><input type="radio"/> Discomfort discussing sexual behaviors</li> <li><input type="radio"/> Discomfort using new medications</li> </ul>	<ul style="list-style-type: none"> <li><input type="radio"/> Able to integrate other primary care issues</li> <li><input type="radio"/> Long-term patient relationship common</li> <li><input type="radio"/> "One-stop shopping"</li> </ul>

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**Table Two**

## Resources Related to PrEP Provision

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- ❑ 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](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.thefenwayinstitute.org)
    - ❑ <http://www.siecus.org/index.cfm?fuseaction=page.viewPage&pageID=1555>
    - ❑ <https://aidsetc.org/topic/pre-exposure-prophylaxis>
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