

Next-Wave HIV Pre-Exposure Prophylaxis Implementation for Gay and Bisexual Men

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Abstract

Data indicate that diffusion of pre-exposure prophylaxis (PrEP) programs for HIV prevention is increasing in the United States; however, persistent disparities in PrEP access remain. Earlier waves of PrEP implementation focused on development (2012–2015) and diffusion (2016–2018). To reduce disparities, the next wave of PrEP implementation should focus on integration; that is, the assimilation of PrEP service as an integral part of HIV prevention, sexual health, and primary care. This review analyzes PrEP implementation literature in the context of three “next-wave” challenges: increasing patient demand, enhancing provider investment and competency, and improving health systems capacity. Our review revealed five activities we consider critical to successful next-wave PrEP implementation efforts: (1) redefining PrEP eligibility assessment, (2) de-emphasizing risk perception as a strategy to increase demand, (3) rejecting risk compensation arguments, (4) altering guidelines to make PrEP follow-up less onerous, and (5) focusing directly on strategies to reduce the cost of PrEP medication. This article ends with a case study of a research–practice partnership designed to instantiate new approaches to integrative implementation efforts.

Keywords: pre-exposure prophylaxis, PrEP, implementation, MSM

Introduction

FOLLOWING THE US Food and Drug Administration (FDA) approval of antiviral medication for HIV pre-exposure prophylaxis (PrEP) in 2012, researchers, advocates, and policy makers began work toward realizing the potential of this game-changing HIV prevention intervention. In the first 3 years after approval (2013–2015), the focus was largely on *development* of clinical guidelines, of pilot programs through PrEP demonstration projects, and of community awareness of PrEP as an HIV prevention strategy.

In the second 3 years since FDA approval (2016–2018), the focus has been on *diffusion*. There have been concentrated efforts by health departments and other actors to both disseminate PrEP information and develop programs for PrEP provision. In tandem with these diffusion efforts, there has been a parallel surge of research on barriers and facilitators to PrEP implementation. Multiple comprehensive literature reviews have been published describing these barriers and facilitators at the patient, provider, and systems levels.^{1–4} In

2018, Pinto et al.⁵ published a particularly useful synthesis of barriers to PrEP implementation across levels, with corresponding strategies designed to address these barriers.

Although they may differ slightly in orientation, almost all the reviews published during this diffusion period focus on two central implementation issues (see the recent special issue in this journal for some examples).⁶ First, they underscore the need for enhanced provider training, both on PrEP delivery (i.e., medical screening, prescription, and follow-up) and on identification of appropriate PrEP candidates within a health care setting. Second, they emphasize the need for patient assistance in navigating health care access, especially costs related to PrEP medication and visits. These two implementation issues have been widely discussed and understood by researchers, advocates, and policy makers, and many specific strategies have been or are being developed to address them.

As a direct result of these efforts, PrEP prescription rates are rising. A recently published analysis documented a 56% estimated annual percentage change in the prevalence of

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PrEP use in the United States from 2012 to 2017.⁷ However, persistent disparities in PrEP access remain, with black and Latino individuals, younger individuals, women, and those residing in the southern states having the lowest access.^{8,9} The next 3-year phase for PrEP implementation (2019–2021) should focus on *integration*, that is, the assimilation of PrEP provision as an integral part of HIV prevention, sexual health, and primary care. Implementation in the third wave will require addressing three central unanswered questions that emerged from the development and diffusion waves. First, how can we increase PrEP demand and interest among patients, especially in the face of a persistent disconnect between objective risk and subjective risk perception? Second, how can we continue to increase PrEP investment among providers, especially those who do not feel that the benefits of a PrEP program outweigh the costs in terms of time, energy, or potential risk compensation? And third, how can we best integrate PrEP capacity into our existing health care system, especially given both its often racist and inequitable structure and the intensive follow-up schedule recommended by clinical guidelines?

The goal of this review is to analyze the existing literature on PrEP implementation in the context of these three challenges from the first two waves—patient demand, provider investment, and health systems capacity—to identify key factors that will be critical to the next wave. We then present some examples from our own research–practice partnership as a case study of ways to instantiate new approaches in integrative implementation efforts.

Methods

We conducted a literature review of articles indexed in PubMed and published in English from January 1, 2016 to September 30, 2018. The search strategy included “HIV” and “PrEP” in any field, and either “implementation” or “engagement” in the abstract. This search resulted in 230 unduplicated articles. Articles were then removed if they did not report data ($n = 11$), focused on non-oral PrEP ($n = 8$), or were not actually about PrEP implementation ($n = 14$). In addition, 46 articles were excluded because they focused exclusively on populations other than gay, bisexual, or other men who have sex with men (GBMSM). While it is imperative to advance implementation strategies for other populations, including but not limited to cisgender women, transgender women, and injection drug users, we decided to focus this article on GBMSM for two reasons. First, PrEP implementation for other populations had largely lagged behind those for GBMSM, and the literature on early waves of implementation for these groups is not as robust as it is for GBMSM. Accelerated programming, demonstration projects, and research initiatives are urgently needed to support these populations. Second (and relatedly), although many of the specific approaches and strategies necessary to address implementation issues for GBMSM are applicable to other populations, we believe that each population has unique and distinct implementation challenges that need to be addressed in their own right. We were concerned that any attempt to add these issues to this article would recapitulate the past practice of presenting the needs of these populations as merely a corollary to those of GBMSM. There have been several excellent reviews of specific implementation challenges for

cisgender women,¹⁰ transgender women,¹¹ and injection drug users,¹² and we encourage the production of thoughtful analysis regarding the next steps for truly integrative implementation for these individuals.

Upon removing the articles as already specified, we were left with a set of 151 articles reviewed for this article. Our review was informed by implementation science methods from scoping studies and proceeded with a combination of thematic and content analysis.¹³ Each article was read and key findings were extracted corresponding to one or more of the central questions already identified. Once findings were coded, they were grouped into themes, which were discussed and refined by the authors, resulting in the five themes described below. We grounded the thematic review process in our own experiences with PrEP implementation, and focused on analyzing the literature for specific lessons that can inform integrative PrEP implementation in the third wave. Our discussion is primarily focused on the context of PrEP implementation in the United States; however, many of the implementation challenges and imperatives described are relevant internationally.

Results/Discussion

Our review revealed five themes that will be critical to future efforts to increase patient demand, enhance provider investment, and improve health systems capacity.

PrEP “eligibility” assessment needs to be redefined

One of the consistent themes in recent PrEP implementation literature centers on provider concerns about conducting PrEP eligibility assessments. Uncertainty or disagreement about which patients are appropriate for PrEP has been found to be a critical barrier to PrEP access;⁵ in one survey of county and district health department directors, 70% requested training for their municipality on how to identify PrEP candidates.¹⁴ Data also suggest that providers may not be conducting PrEP risk assessments in ways that promote access. Patients report that one of the critical barriers to PrEP uptake is reluctance to talk to providers about sexual health;^{15,16} in one survey, ~40% of GBMSM with a primary care provider reported not feeling comfortable talking to this provider about their sexual behavior.¹⁷ Patients who might be interested in PrEP report feeling that interactions with providers are “scripted” in ways that do not allow full disclosure of sexual behavior or concerns.¹⁸ Men of color are particularly likely to report that providers make false assumptions about their heterosexuality, or relate that fears of “transgressing” masculine norms in health care settings limit their access to preventive care.¹⁸

However, even if PrEP assessment tools were widely disseminated and providers were taught how to administer them effectively, data suggest that there would still be a fundamental problem with this strategy for identifying appropriate PrEP candidates stemming from a disconnect in data about HIV transmission. For a given individual patient, there is no denying that as the number of risk factors (e.g., number of partners, number of sex acts) increases, their risk for HIV exposure increases as well. But at the population level, data demonstrate that individual behavioral factors may not be the best predictors of seroconversion. We know that extremely high percentages of GBMSM contract HIV

from a primary partner (rendering their total number of partners irrelevant), and that disproportionately high rates of HIV incidence among black GBMSM cannot be explained by differences in risk behavior patterns.¹⁹ For these reasons, National Health Behavior Survey data indicate that young black GBMSM—a population arguably at highest risk of HIV infection—are less likely to self-report having indications for PrEP, compared with young GBMSM of other races.²⁰ In a longitudinal study of HIV testing data from 300 young (ages 16–29) black MSM in Chicago, almost half of the YBMSM who HIV seroconverted over the course of the study would not have met Center for Disease Control and Prevention (CDC) eligibility criteria for PrEP.²¹

In part, a desire to use eligibility assessment to identify appropriate PrEP candidates stems from a desire to be most effective and efficient in targeting PrEP resources by applying an epidemiologic lens. Some modeling data suggest that providing PrEP only to highest risk GBMSM is the most cost-effective strategy for HIV prevention.²² But there are some data to the contrary. A recent study found that, especially in settings with lower baseline incidence, a nontargeted strategy (i.e., setting a low threshold for recruitment of GBMSM) was more effective in averting new infections than a strategy that restricted PrEP to GBMSM in distinct high-risk categories.²³ Other studies have found that the greater the coverage of the PrEP program (i.e., higher percentages of GBMSM adopting PrEP), the larger both the benefit (i.e., infections averted) and the cost savings, and when PrEP is concentrated only on highest risk individuals, cost saving is slightly higher, but number of infections averted is slightly lower.²⁴ It is also important to note that most modeling studies do not include potential complications of targeting strategies in their models, for example, the increased cost associated with identifying eligible individuals, or the extent to which targeting may have the paradoxical effect of decreasing uptake among eligible individuals by increasing stigma.²³ There is evidence for both of these dynamics in the current PrEP implementation efforts,³ which need to be considered in our evaluation of optimal methods for eligibility assessment.

We (J.M.) have previously published an article drawing analogies between PrEP implementation and rollout of oral contraceptive pills in the 1960s.²⁵ That analogy may prove a particularly useful thought experiment in this case: can we imagine a sexually active woman entering a gynecologist's office and being asked to complete a pregnancy "risk assessment" before being offered contraceptive options? PrEP implementation programs and research often articulate PrEP as part of a comprehensive strategy for HIV prevention that includes multiple options, such as condom use, regular testing, or asking the HIV and treatment status of partners. Yet true comprehensive HIV prevention would present PrEP as an option to any sexually active GBMSM, and focus not on determining "eligibility" (which suggests that some patients have a risk profile appropriate for PrEP while others do not) but on determining whether PrEP is a good option for a given patient, based on whether the patient feels PrEP is the prevention strategy he is able to use most effectively and consistently. This approach to PrEP "options counseling," rather than "eligibility," shifts the focus away from any PrEP-specific risk assessment checklist. Instead, it considers PrEP education and counseling as an opportunity to reboot our approach to sexual history taking. Data indicate that high

percentages of providers are uncomfortable taking a sexual history and acknowledge the need for greater training in this area.²⁶ Some of this discomfort may stem from the assumption that a sexual history needs to focus on what patients *do*, rather than on what they need and want. An alternative approach to sexual history for GBMSM might start with the assumption that all individuals need an HIV prevention plan, and focus on eliciting from the patient what strategy might be best for them and why. This strategy starts by ensuring that information and options are provided to patients, and then pivots to focus on which method might fit best with their individual sexual lifestyle, de-emphasizing the role of the provider as arbiter of this decision in the process. While it might abandon the idea of a risk score, this strategy is likely to result in a deeper understanding of which patients are good candidates for PrEP. Anecdotal evidence suggests that some providers are already adopting this approach; however, there is need for wider scale implementation of these efforts, especially among populations with historic disparities in access.

Focusing on HIV risk perception is not a sustainable strategy for increasing PrEP demand

Related to the issue mentioned is the question of how to encourage PrEP uptake among individuals who are likely to benefit from it. PrEP implementation research consistently cites inadequate risk perception as a barrier to PrEP interest and uptake, and many studies call for strategies to increase risk perception among PrEP-eligible individuals.^{27–30} However, there are significant concerns about whether this approach is effective or sustainable as a strategy for increasing PrEP demand. Data demonstrate a pervasive disconnect between individuals' objective risk of HIV infection and their subjective risk perception.²⁹ In one study of GBMSM recruited at a community testing site, >68% of high-risk patients (identified by staff based on behavioral risk assessment scores) did not believe themselves to be at high or even moderate risk of HIV infection.³¹ In an even more extreme example, GBMSM diagnosed with rectal chlamydia or gonorrhea at a sexually transmitted disease clinic did not perceive themselves to be at high risk of HIV infection and were not more likely to report interest in PrEP compared with other GBMSM attending the clinic.³² Perhaps the problem is a reliance on the construct of "high risk." We (S.G.) have written elsewhere about the ways in which "high-risk" language and messaging can be stigmatizing and antithetical to increasing PrEP demand.³ If efforts to heighten risk perception are alienating to patients, it will be difficult, if not impossible, to promote PrEP use to them.

In contrast, data suggest that there may be other strategies for making PrEP attractive to potential users that are both easier to implement and more likely to be effective. These strategies focus on the benefits users derive from PrEP in addition to merely lowering their risk of potential infection. For example, worry about HIV infection is a potent predictor of PrEP interest,^{30,33} and PrEP users cite reduction in HIV-related anxiety as a critical benefit of PrEP use.^{34,35} Other benefits of PrEP use have been documented from GBMSM on PrEP, including increasing feelings of intimacy with partners, improving one's sex life, and enhancing feelings of agency over sexual health.^{33,34,36,37} Our own work (S.G.) indicates that PrEP use can have ancillary benefits of

reducing HIV-related stigma among its users.³⁸ To complement sexual history conversations that focus on what patients want and need, it may be critical to talk to patients directly about the benefits of PrEP for their overall sexual health and well-being.

Risk compensation is a red herring

Almost all data related to provider willingness to prescribe PrEP include concerns about risk compensation, that is, the possibility that PrEP users will increase their risk behavior after going on PrEP, undermining the potential benefit. In surveys of provider attitudes toward PrEP prescription across countries, risk compensation concerns remain paramount,^{39,40} and are associated with both prescribing and referring patients for PrEP in primary care.⁴¹

Data on the existence of risk compensation effects are equivocal. On the one hand, some analyses indicate increases in number of condomless anal sex partners⁴² or condomless sex acts⁴³ among PrEP users 6 months after PrEP initiation. In Australia, significant decreases have been documented in consistent condom use in the years after PrEP rollout.⁴⁴ On the other hand, multiple large-scale demonstration projects indicate no increase in condomless sex or other risk behavior after PrEP uptake.^{45,46} And yet there was evidence for an increase in condomless sex *before* widespread PrEP availability or use.^{47,48} Across studies, inconsistent condom use is associated with *interest* in PrEP,^{49–51} and reporting condomless sex is associated with higher PrEP drug levels (i.e., greater adherence behavior) in both adult and adolescent samples.^{28,52} These data indicate that PrEP users are aware of their sexual behavior patterns and are consciously using PrEP to protect themselves during inconsistent condom use.

Modeling data show the potential promise of PrEP implementation to impact the sexual health of priority populations. In a modeling study contrasting the potential increase in sexually transmitted infections (STIs) from risk compensation in comparison with the potential decrease in STIs from better screening and earlier treatment, data suggest that PrEP uptake will significantly decrease cumulative infections. Even when risk compensation was 100% (i.e., complete elimination of condom use), there was a net reduction in new STIs when PrEP coverage exceeded 50% of eligible individuals. PrEP provision according to CDC guidelines was estimated to result in a 40% reduction in gonorrhea and 40% reduction in chlamydia infection in the next 10 years.⁵³ In another modeling analysis, PrEP remains a cost-effective strategy even if STI rates double.²⁴

At first glance, we might be tempted to recommend educating providers about the data on risk compensation, with the assumption that they would be more likely to prescribe PrEP if they were convinced that its benefits as a prevention strategy outweigh these particular risks. But research indicates that this strategy does not merit such attention, as the concept of risk compensation is a red herring. First, much of the negative rhetoric around PrEP stigmatizes PrEP users for *wanting* to have condomless sex, regardless of whether this behavior actually results in negative outcomes, such as an STI.^{54,55} And second, presenting these data legitimizes the consideration of risk compensation as a rationale for limiting PrEP implementation, when it should be irrelevant. Even if PrEP were associated with an increase in STI risk, it is un-

equivocally associated with a decrease in HIV infection risk. HIV is the STI with the most serious short- and long-term consequences for patients, and prevention of HIV infection is the primary outcome of interest in PrEP implementation efforts. Providers should, and do, care deeply about the comprehensive sexual health of their patients, and it remains critical to develop novel and synergistic strategies to decrease STI rates. But withholding PrEP from a patient—that is, preventing them from protecting themselves from HIV—because of fears that they may reduce their condom use and require future STI treatment is not only against the best interests of the patient, but it is also unethical and bad medical practice.

Current guidelines for PrEP prescription and follow-up may be too onerous

Multiple studies of PrEP implementation demonstrate concerns from providers about the implementation of PrEP protocols. In one survey of county and district health department directors, lack of formal PrEP protocols was one of the largest barriers to PrEP implementation in their municipality.¹⁴ From the provider perspective, data suggest that full compliance with the current guidelines may not occur in practice.⁵⁶ In one study, less than a third of PrEP-using gay and bisexual men reported receiving comprehensive care according to CDC guidelines at their last PrEP visit.⁵⁷ Data also indicate significant drop-offs in PrEP retention by 6 months, and patients cite difficulties returning to medical visits as a barrier to engagement in programs.⁵⁸

Initial PrEP guidelines were based on very different data than those available now, after 6 years of PrEP implementation,⁵⁹ including new data showing that event-driven PrEP is effective.⁶⁰ Concerns about undetected HIV infection among PrEP users, either because of medication failure or poor adherence, have been greatly reduced,⁶¹ as have concerns about renal toxicity that compelled regular metabolic screening.^{62–65} Data indicate that STI testing at every follow-up visit is a critical component of sexual health care for PrEP patients,^{53,66} but there are arguments to be made about whether failure to come in for such screening—or any of these screenings—should be a reason to withhold PrEP refill, especially for patients who have been successfully using PrEP for a period of time. Especially since individuals with fewer resources—logistical, financial, and time—are less likely to be able to accommodate follow-up visit schedules, current guidelines may have the impact of limiting access to these groups and exacerbating PrEP disparities. Even the practice of having patients return for a prescription visit after confirming normal results from baseline laboratory testing might introduce barriers that can lead to failure to initiate or sustain PrEP use. Providers are making modifications to the guidelines in the practice already, including same-day initiation based on point-of-care testing in the absence of an acute retroviral syndrome,⁶⁷ but it will be critical to make some of these practice modifications more explicit in guidance to make PrEP seem easier to administer and maintain for both patients and providers. After all, it is not logical for PrEP engagement to be more onerous than HIV treatment, and yet the monitoring (and the visit frequency it implies) proposed in the current guidelines exceeds what is often required of patients who are HIV infected yet stably maintained on therapy.^{68,69}

Addressing PrEP disparities will require political will and institutional change

Perhaps the most pervasive finding in the PrEP implementation literature to date is the importance of financial and health care access barriers in limiting PrEP uptake.⁷⁰ Insurance status remains a critical determinant of PrEP access;⁷¹ in one study of GBMSM in three US states, uninsured patients were over four times less likely to be taking PrEP compared with those who were insured.¹ Financial concerns impact not only access to PrEP but also shape perceptions of its merits as a prevention strategy. Financial barriers have been cited as one of (if not the) largest barriers to PrEP acceptability among patients and providers.^{54,72,73} Cost concerns are most strongly associated with PrEP acceptability for people of color.⁷⁴ Analyses of barriers to PrEP implementation at the systems level note that reducing financial burden related to medication is paramount for the feasibility and sustainability of PrEP programs.^{75,76} In modeling studies, cost of PrEP medication is a critical factor in shortening the time horizon for the cost effectiveness of PrEP as an intervention.^{24,77} And reviews of implementation efforts demonstrate that PrEP rollout is successful when government provides financial support and is impeded when such support is lacking.⁷⁸

Recommendations for systems-level intervention strategies include expanded funding for medication costs generally,⁵ and specifically lowering the price of PrEP medication itself.⁴ Current implementation efforts include supporting patients in navigating PrEP payment options,⁷⁹ which includes state-run programs that cover PrEP-related medical out-of-pocket costs in conjunction with the manufacturer's copayment assistance program for medications; one state (Washington) actually pays for the medications directly. But in many cases, such options are simply lacking. No level of patient acceptability or provider training will be effective in increasing PrEP implementation if patients cannot afford to take the medication. There are movements to decrease the cost of PrEP medication in the United States,⁸⁰ including by asking the National Institutes of Health to break the manufacturer's patent; advocates draw attention to the high price paid to purchase the medication in the United States compared with that in other countries, including medication purchased by the US government as part of foreign aid,⁸¹ and to the fact that the research that established PrEP efficacy was publicly funded through the National Institutes of Health. In just April through June of 2018, HIV product sales for the manufacturer of the only FDA-approved product for PrEP were \$3.7 billion, and the company's net income for this 3-month period was \$1.8 billion.⁸² Concerted, honest, and vigilant efforts to lowering the cost of PrEP medication, which would, in turn, facilitate the launch of full-service, publicly funded PrEP programs, may be the single most important component of next-wave implementation strategies for GBMSM.

Moving toward integration: research–practice partnership. We argue that next-wave PrEP implementation must focus on the integration of PrEP as a central part, not only of the HIV prevention and care continuum but also of sexual health and primary care more broadly. Increasing patient demand, enhancing provider demand and competency, and

improving health systems capacity require innovative strategies that directly address the key lessons already described. However, one of the persistent challenges in accelerating the pace of innovation in health care is the creation of systems for integrating research findings into practice settings. Researchers may present to providers at scientific conferences or give scientific updates at grand rounds, but such presentations rarely give providers specific strategies for applying new findings to their practice and, as such, contribute to staggering lags in translation.⁸³ Clinic directors or administrators are asked to implement guidelines based on emerging clinical trials data, but such guidelines rarely come with an implementation guide for their integration into already overburdened practice or setting.

Next-wave PrEP implementation requires the development of strategies to integrate research findings—including the five major lessons already mentioned—into clinical practice in a way that is relevant, “culturally competent” (i.e., acknowledges the specific context within which providers work), and useful. This work requires collaborative partnership between researchers with experience in implementation science and agencies that coordinate and oversee implementation in a particular jurisdiction.

In 2013–2014, just as first-wave public health support for PrEP was beginning to grow both nationally and locally, the New York City (NYC) Health Department and the Hunter HIV/AIDS Research Team (HART) launched a collaboration to develop evidence-based implementation strategies focused on increasing PrEP uptake among GBMSM in NYC. We present our experiences hereunder as an example of one model for this type of partnership that could be replicated specifically to address implementation issues in the next wave. This collaboration began with a series of traditional data presentations and updates to Health Department staff, but moved quickly into conversations about what specific tools and strategies were needed to address first-wave developmental concerns. It became clear that our primary objective was capacity building within practice settings.

The *PrEP Program Implementation Workshop* was designed not as an in-service for clinicians, but to train medical directors and clinic administrators on the specifics of PrEP implementation and the integration of a PrEP program into their clinical settings. The training is delivered over 2 days, 1 month apart, to sets of “institutional pairs” (i.e., a medical director and a clinic administrator from the same institution). The workshop engages leadership from clinical centers around the city as a forum for identifying and addressing operational concerns, and provides them with specific protocols, materials, and templates that they can adapt to their practice. Day 1 of the training consists of a PrEP primer, a discussion of the components of an optimal PrEP program, and guidance to support take-home assignments around developing a tailored PrEP protocol and clinic action plan. Day 2 consists of review of the draft protocols, mechanisms of paying for PrEP (specific to the NYC context), and resources available to support them in their ongoing PrEP-related work. The materials and strategies presented to workshop participants integrated three crucial components that relied on the research–health department partnership: (1) findings from the scientific literature, synthesized for a practice audience and consistently updated to reflect emerging research; (2) implementation experience and findings from HART's work on

SPARK, the first PrEP demonstration project in NYC; and (3) deep knowledge of the practice environments of workshop attendees, based on the health department's experience funding and working with them on HIV prevention programs before PrEP implementation.

Between October 2014 and March 2018, the workshop was delivered 8 times to 148 participants representing >50 institutions citywide, including all clinical institutions comprising the NYC PlaySure Network,⁸⁴ a citywide collaborative of clinical and nonclinical partners focused primarily on addressing barriers to PrEP access among priority populations. Among 34 attendees of the first four workshops (held between October 2014 and December 2015) surveyed electronically between 3 and 12 months after workshop completion (34% response rate), 77% started the development of a new PrEP protocol or policy as a result of the meeting, and 33% named a PrEP champion. Furthermore, 67% reported changing their approach to PrEP provision in some way, including changes to clinic infrastructure, changes to policies or programs, and increased willingness to prescribe PrEP.⁸⁵

Another product of the Health Department–HART collaboration was a 1-day *Best Practices in PrEP Education and Counseling* training for PrEP navigators and counselors. This training was developed to build the capacity of front-line staff in both clinical and nonclinical settings alike to support access to PrEP,⁸⁶ recognizing that inconsistent and/or insufficient messaging about PrEP to those who might benefit poses a barrier. In this training, after an introductory section providing a primer about PrEP (e.g., efficacy, mechanism, and side effects), staff were taught to normalize PrEP as part of sexual health, and to focus on agency and empowerment using a strengths-based approach. The diverse staff who attended included navigators and other individuals providing outreach and education about PrEP in nonclinical settings, and any nonclinicians supporting all aspects of PrEP delivery in clinical settings. This was also a required training for navigation staff and supervisors of the clinical organizations comprising the PlaySure Network. From 2015 to 2018, the Best Practices Workshop was delivered 33 times to 574 individuals from >50 different institutions. Data derived from pre- and post-training knowledge assessments from 2017 to the present showed improvements in knowledge and confidence in conducting such education and counseling.

The public health–academic partnership that led to the development of these two trainings provided a foundation on which the entire PrEP implementation plan in NYC rests. Without clinical sites that have fully reoriented to improving access to PrEP, and without a knowledgeable, empowered workforce, PrEP access would remain fettered. Both courses provided a mechanism for research findings to be implemented citywide in short order, and for clinical trial and implementation research data to be leveraged to inform and promote practice in a concrete and timely way. This collaboration became the cornerstone for a larger PrEP strategy in NYC characterized by four major activities to support PrEP, including (1) promoting PrEP to potential users (e.g., social marketing/media and an online directory of PrEP providers citywide); (2) promoting PrEP to potential providers (e.g., public health detailing to clinicians, plus trainings); (3) supporting PrEP provision in diverse practice models through patient navigation and establishing intersite referral net-

works; and (4) comprehensive PrEP-related monitoring and evaluation.⁸⁷ We believe that the marked increase in PrEP prescribing in the jurisdiction that outpaces implementation elsewhere⁸⁸ can be attributed, at least in part, to the success of this partnership. This model for research–practice partnership that develops training and concrete materials to facilitate implementation and then disseminates those resources through networks could be replicated across different jurisdictions to accelerate diffusion of empirical findings into clinical settings, although modifications to this model, such as telementoring of community medical providers,⁸⁹ may be more appropriate in other contexts where geography limits in-person support. The rise of diverse provider-to-patient telehealth interventions, many of which also leverage public health–academic partnerships, may support PrEP implementation in the same settings.⁹⁰

As we begin the third phase of PrEP implementation, leveraging the initial PrEP implementation experience since 2012, it is instructive to reflect on the themes that can inform integrative PrEP implementation moving forward. Our review proposes that we jettison traditional notions of “eligibility assessment” and instead focus on helping patients to identify a plan for how best to maintain sexual health, shifting the focus from solely provider-directed information elicitation to a tailored discussion of appropriate options. Given the limitations of a focus on risk perception to increase PrEP uptake, it seems we should stimulate demand by seeking strategies that appeal to patients directly about the benefits of PrEP for their overall well-being. The equivocal data on risk compensation suggest that we must cease hand-wringing about potential increases in STIs and maintain laser focus on the primary desired outcome of an HIV prevention strategy: HIV prevention. Data on PrEP persistence suggest that we should critically reflect on the demands placed on patients for monitoring and engagement in clinical care for prevention, particularly now that we are well past the initial clinical trials, with years of data from demonstration projects to assuage initial concerns, and greater recognition of the barriers ongoing, frequent clinical contact may present for some of the patients who might benefit most from PrEP. And finally, our review leads us to conclude that we must fully acknowledge the barriers introduced by lack of insurance and related financial concerns, and increasingly invest public monies to facilitate PrEP rollout. In NYC, where PrEP rollout has been largely successful, a research–practice partnership has supported developing a community-based PrEP workforce and built health systems capacity more broadly. Wide dissemination of such workshops and trainings, particularly those that embrace these lessons learned from implementation to date, may be one relatively low-resource approach to support this third wave of implementation, allowing us to embrace an integrated approach that centers sexual health and values the lives of GBMSM.

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