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Engaging Healthcare Providers to Implement HIV Pre-Exposure Prophylaxis

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Abstract

Purpose of review—Recent randomized controlled trials have demonstrated that HIV Pre-Exposure Prophylaxis (PrEP) can decrease HIV incidence among several at-risk populations, including men who have sex with men, serodiscordant couples, and heterosexual men and women. As PrEP is a biomedical intervention that requires clinical monitoring and a high level of medication adherence, maximizing the public health effectiveness of PrEP in real-world settings will require the training of a cadre of healthcare providers to prescribe PrEP. Therefore it is critical to understand provider knowledge, practices and attitudes towards PrEP prescribing, and to develop strategies for engaging and training providers to provide PrEP.

Recent findings—A limited number of studies have focused on PrEP implementation by healthcare providers. These studies suggest that some providers are knowledgeable about PrEP, but many are not, or express misgivings. Although many clinicians report willingness to provide PrEP, few have prescribed PrEP in clinical practice. Provider comfort and skills in HIV risk assessment are suboptimal, which could limit identification of individuals who are most likely to benefit from PrEP use.

Summary—Further studies to understand facilitators and barriers to HIV risk assessment and PrEP prescribing by practicing clinicians are needed. Innovative training strategies and decision-support interventions for providers could optimize PrEP implementation and therefore merit additional research.

Keywords

HIV; Prevention; Pre-Exposure Prophylaxis; Provider; Implementation

Introduction

Over the past two years, studies have demonstrated that HIV antiretroviral pre-exposure prophylaxis (PrEP) with oral or topical antiretroviral medications can decrease HIV incidence among several high-risk populations, including men who have sex with men, serodiscordant couples, and at-risk heterosexual men and women in Africa [1–2, **3, **4]. As PrEP is a biomedical intervention that is currently only available by prescription, optimizing the benefits of PrEP in real-world clinical settings will require the engagement and training of practicing clinicians. To implement PrEP successfully, practitioners will

need to identify those persons who are at high-risk for HIV acquisition, elicit patient preferences regarding the use of chemoprophylaxis, and prescribe antiretroviral medications to those patients who choose to utilize this intervention. Providers will also need to deliver appropriate counseling and monitoring to optimize adherence and reduce the likelihood of potential harms that could be associated with PrEP use, such as medication toxicities and increases in risk-taking behaviors. Although well-trained clinicians will be essential to disseminate PrEP, few studies have assessed healthcare provider knowledge, practices, and beliefs regarding this novel biomedical intervention. In this review, we will summarize recent studies that address the readiness and willingness of providers to prescribe PrEP, and we will discuss innovative strategies that may be employed to train healthcare practitioners in the provision of chemoprophylaxis.

What do Healthcare Providers Know and Think about PrEP?

Healthcare practitioners will need to be aware of several recent studies that form the evidence base for PrEP. In 2010, the Centre for the AIDS Program of Research in South Africa-004 (CAPRISA-004) study demonstrated that pericoital administration of a topical vaginal gel containing the antiretroviral medication tenofovir reduced the risk of HIV acquisition by 39% among at-risk South African women [2], the first demonstration that PrEP is efficacious in humans. Later that year, the Pre-Exposure Prophylaxis Initiative (iPrEx) study reported that daily oral administration of a fixed-dose combination tablet containing the antiretroviral medications tenofovir and emtricitabine decreased HIV incidence by 44% among high-risk men who have sex with men [1]. Two subsequent studies have demonstrated the efficacy of daily oral PrEP in preventing heterosexual HIV transmission for African men and women, either in stable HIV discordant relationships or for those who had concurrent or sequential sex partners [**3, **4]. Two other studies focused on African women did not demonstrate oral or topical PrEP efficacy [**5, 6]. These studies raised concerns about the need for meticulous medication adherence and the possibility that mucosal pharmacology (i.e., lower tissue concentrations of drug) and/or local genital tract inflammation might mitigate the protective benefits of PrEP for some high risk women.

Since the publication of these groundbreaking clinical trials, two studies have presented data on practicing clinicians' awareness, practices, and attitudes regarding PrEP provision. An online, cross-sectional survey of generalist and HIV specialist physicians in Massachusetts demonstrated that awareness of topical and oral PrEP was high several months after the release of the iPrEx results, with 80–90% of physicians reporting awareness of these modalities [**7]. HIV specialists were more knowledgeable about PrEP than generalists. More physicians indicated that they would prefer to prescribe topical PrEP (75%) as compared to oral PrEP (25%), primarily because they believed that topical PrEP might have fewer medication-related adverse effects. Although 95% of respondents indicated that PrEP should be available for prescribing if it were a highly effective daily pill, many cited concerns that would decrease their willingness to prescribe PrEP, including medication toxicities, the potential development of drug-resistant virus, limited data on PrEP efficacy, possible decreases in federal funds for other HIV prevention modalities, and potential increases in risk behaviors among PrEP users. Only 4% of the physicians sampled had prescribed PrEP, but requests from patients, additional data on the efficacy of PrEP, or guidelines from normative bodies, such as the Centers for Disease Control and Prevention, the United States Preventive Services Task Force, or specialty professional associations (e.g., the Infectious Diseases Society of America or the HIV Medicine Association), would increase their motivation to provide PrEP [**7].

In a web-based, cross-sectional survey of HIV practitioners recruited through the American Academy of HIV Medicine that was conducted 6 months after the publication of iPrEx results, 43% of HIV specialty care providers reported that they had encountered patient requests for PrEP and 19% of respondents reported that they had prescribed PrEP [**8]. These providers reported similar concerns regarding PrEP provision as compared to the study of Massachusetts physicians, such as the potential development of antiretroviral resistance and possible increases in risky behavior, as well as several additional concerns, including patient non-adherence and cost [**8].

Although the results from the more recent study suggests that PrEP prescribing may be increasingly common among HIV specialists, the apparent increase in PrEP prescribing could also be attributable to differences in the study populations, as both studies were convenience samples recruited from different populations. Further studies, ideally with representative samples of generalist providers and HIV practitioners, are needed to ascertain actual changes in prescribing rates within these groups over time.

Provider perceptions about the effectiveness of PrEP could be an important factor in their willingness to prescribe it. In the American Academy of HIV Medicine study, when HIV practitioners were asked to compare the effectiveness of PrEP to other HIV prevention modalities, including expanded HIV testing, community-level behavioral interventions to reduce high-risk behavior, promotion of condom use, detection and treatment of sexually transmitted infections, and mental health and substance abuse counseling, these providers perceived PrEP to be the least effective method at decreasing HIV acquisition [**8]. This suggests that it will be important to provide practitioners with accurate data on the efficacy of PrEP in comparison to other HIV prevention strategies so that they can make evidence-based decisions about how to integrate PrEP into their delivery of preventive care.

Practitioners are likely to be influenced by more than efficacy data alone when making prescribing decisions about PrEP. In the AAHIVM study, 28% of participants who had prescribed PrEP reported that they had prescribed PrEP to women. Yet, the only available efficacy data for PrEP among women at that time were from the FEM-PrEP study, which was unable to demonstrate efficacy among at-risk African women [**5]. Similarly, 60% of respondents in the AAHIVM study indicated they would prescribe PrEP to a woman who was in a relationship with an HIV-infected man who refused to use condoms, even though results from the Partners PrEP study, the first clinical trial to demonstrate that daily oral PrEP could reduce transmission between members of heterosexual serodiscordant couples [**4], were not yet available. These studies suggest that providers may not always base their prescribing decisions on the best available evidence. Additional studies to understand how providers formulate prescribing decisions about PrEP, including qualitative studies of providers who have faced the point of decision-making about whether or not to prescribe PrEP in real-world practice, could shed light on these intriguing survey results, and thereby inform educational interventions for providers.

Enhancing Patient-Provider Communication to Identify Individuals who may benefit from PrEP

The benefit-to-risk ratio for utilizing PrEP is likely to be most favorable for those persons at highest risk for HIV acquisition. Therefore, to identify optimal candidates for PrEP, providers will need to assess HIV risk behaviors for individuals they encounter in clinical practice. Numerous barriers to HIV risk assessment exist, including patient and provider discomfort with discussions about sexual orientation [9, 10] and risky sexual and drug using behaviors, and a lack of provider skills in overcoming awkward moments during these potentially sensitive discussions [11]. Suboptimal patient-provider communication about

risky behaviors has been a longstanding barrier to identifying individuals who are at greatest risk for HIV acquisition -- and therefore those persons who are most in need of preventive interventions -- since the beginning of the HIV epidemic [12, 13]. Prior to 2006, guidelines recommended that providers employ risk-based HIV testing, thereby encouraging providers to conduct HIV risk assessments to identify candidates for testing. However, the emphasis on HIV risk assessment decreased in 2006 after guidelines changed and began to recommend that providers engage in universal HIV screening in lieu of risk-based screening [14]. Now, though, a renewed focus on effective risk assessment by providers will be essential to implement PrEP and other novel biomedical prevention interventions for which individualized risks and benefits need to be weighed when making prescribing recommendations (e.g., topical microbicides, voluntary medical male circumcision).

It will be important to support clinicians with training to help them elicit comprehensive sexual histories in a nonjudgmental and culturally-sensitive manner, as current medical training in obtaining sexual histories [*15] and caring for lesbian, gay, bisexual, and transgender (LGBT) persons is suboptimal [*16, *17]. Resources exist to educate providers about how to conduct culturally-sensitive risk assessments for HIV and other sexually transmitted diseases, including written and/or online guidance from the CDC (e.g., "A Guide to Taking a Sexual History" [18]) and organizations that specialize in the care of LGBT persons (e.g., "The Fenway Guide to Lesbian, Gay, Bisexual, and Transgender Health" [19]). Although these resources can support self-directed learning by motivated clinicians, interventions that can enhance risk assessment among the broad array of practitioners who may provide care to individuals at-risk for HIV acquisition are needed.

Computer-assisted self-interviews that allow patients to report data on their sexual and drug-use behaviors may facilitate patient willingness to disclose risky behaviors, as compared to face-to-face contact with clinicians [20, 21], and could therefore circumvent some of the interpersonal barriers to risk assessment. Interventions that incorporate computer-assisted self-interviews have been shown to be acceptable among at-risk MSM in the context of visits with healthcare providers [*22], and studies to assess the acceptability of these interventions among practicing clinicians are being planned [*22].

Several training methodologies have been shown to improve primary care providers' HIV risk assessment skills. These methods include interactive workshops [*23], educational seminars coupled with standardized patient-instructors who provide feedback to providers after office-based encounters [24], written educational materials followed by unannounced standardized patients [25], or objective structured clinical examinations (OSCE) outside of practice settings [26]. Studies to evaluate the effectiveness of standardized patients and office-based interventions in the context of risk assessment for PrEP are warranted. However, these interventions may be costly and time-intensive, and more research is needed to identify additional effective and feasible strategies to educate primary care practitioners in risk assessment [*23].

The Centers for Disease Control and Prevention highlights that multicomponent, systems-based interventions that combine provider education and provider-directed reminders, as well as organizational policies to promote routine risk assessments, may increase behavioral risk assessments and the delivery of preventive services to HIV-infected persons [27]. It is logical to evaluate if similar interventions can also enhance risk assessment practices among providers caring for HIV-uninfected persons. Ascertaining whether clinicians and organizational leaders find these approaches to be acceptable and feasible could help inform the design of interventions to support identification of potential PrEP users.

Motivating and Incentivizing Providers to Provide PrEP

With widespread acknowledgement that healthcare systems need to reduce expenditures, including the relatively resource-rich United States [*28], there is increasing attention on incentivizing clinicians to provide cost-effective interventions. Behavioral economists have suggested that coupling financial incentives to the provision of underused, high-value services by providers may be a favorable incentive strategy [*29]. Studies have demonstrated that monetary incentives can improve primary care physician management of disease risk factors for individual patients (e.g., improvement in cardiovascular risk factors [30]). However, few research studies have addressed ways to incentivize providers to deliver HIV prevention interventions. As systems-level changes are likely to demand that clinicians and policymakers prioritize the delivery of high-value services, it will be important to provide these decision-makers with information on the value of specific HIV prevention strategies, including PrEP, relative to other preventive services. Cost-effectiveness analyses can generate estimates of the relative value of different preventive services and could therefore influence policy and prescribing behaviors.

Several studies have modeled the cost-effectiveness of PrEP in different high-risk populations [31, **32, 33–34, **35]. A model based on the 39% efficacy of topical PrEP in CAPRISA-004 predicted that lifelong PrEP implementation among at-risk South African women would be very cost-effective, and even cost-saving under optimistic assumptions, such as 50% efficacy and targeted use among populations with high HIV incidence (i.e., 5%) [**35]. A different model based on data from the HIV epidemic in South Africa also concluded that PrEP would be cost-effective, though this model predicted that PrEP would become less cost-effective relative to a strategy of universal access to testing and treatment for all HIV-infected persons (“Treatment as Prevention”) if antiretroviral treatment is successfully scaled-up to three times its current level. However, as the expected time frame for this degree of scale-up could be several decades or longer, this study concluded that PrEP may have an important role in the near term [34].

A recent modeling study based on data from the iPrEx study explored the cost-effectiveness of implementing daily oral PrEP among MSM in the United States. This study concluded that PrEP would be cost-effective if it were utilized by 20% of MSM at high risk for HIV acquisition, defined as having five or more sexual partners per year, for a 20-year time period [**32]. The study investigators appropriately emphasized that efficient utilization of PrEP among MSM would therefore depend critically on clinicians’ ability to identify high-risk MSM, underscoring the importance of training providers to perform behavioral risk assessments in this population. An additional model suggested that PrEP would be cost-effective for high-risk MSM in New York City [31]. Although a third cost-effectiveness study focusing on MSM predicted that PrEP, if 50% efficacious, would only be attractive from a cost perspective if the price of PrEP decreased substantially [33], this model was based on an assumption of lifetime PrEP use. The results from this model suggest that initiating and discontinuing PrEP in accordance with high-risk periods in a person’s life may be a more efficient strategy for PrEP use. As additional data are accumulated on the effectiveness and potential adverse effects of PrEP in real-world use, and as the cost of the antiretroviral medications that are used for PrEP changes over time, future iterations of cost-effectiveness studies will be helpful in guiding clinician decisions about PrEP provision.

In addition to the use of financial incentives or cost-effectiveness data to influence provider behaviors, behavioral economics, psychology, and social marketing have suggested that providers can be encouraged to perform desired actions in clinical care through the use of subtle interventions known as “nudges.” A nudge is a way “to push gently in order to get someone’s attention” [*36], and the use of nudges to optimize care provision by clinicians

represents a novel approach to improve care delivery. Nudges can include the use of electronic health record reminders and information on peer practices to prompt specific behaviors and decisions [*37, *38, 39]. For example, electronic reminders have been shown to improve cardiovascular disease risk assessment by general practitioners during routine clinical care [40]. Similar reminders could be used to encourage HIV testing and risk assessment to identify potential PrEP candidates. Reminders could also potentially increase the frequency of patient-provider discussions about PrEP and other HIV prevention modalities if every negative HIV test result reviewed by clinicians were coupled with a reminder to reassess risk practices, discuss prevention options, including PrEP when appropriate, with tested individuals.

Providing clinicians with information about their colleagues' practices, known as social norms, can influence clinicians to adjust their prescribing behaviors to conform to those of their peers [41, *42]. If clinicians believe that PrEP would offer benefit to persons in their care, but they are hesitant to prescribe PrEP due to concerns about diverging from normative practices, this approach could facilitate PrEP provision. However, nudge interventions must be employed judiciously, as they have the potential to be counterproductive. It is plausible that clinicians might become inured to an excess of reminders, and they may be uncomfortable recommending PrEP if they perceive that PrEP prescribing is uncommon among their peers. Studies to explore how interventions that are grounded in behavioral economic theory can enhance PrEP implementation would be highly innovative and valuable.

Empowering Patients and Providers to make Informed Decisions about PrEP

The Institute of Medicine and the Patient Protection and Affordable Care Act have emphasized the importance of patient-centered healthcare [*43, *44]. Within this framework, the decision to utilize biomedical interventions such as PrEP should be made by informed patients after discussions with knowledgeable healthcare providers. Providers can play a critical role in helping patients approach the decision to use PrEP by providing them with evidence about its anticipated benefits in the context of their personal risk for HIV acquisition. Providers will need tools to help them accurately risk stratify individuals with respect to HIV acquisition and communicate this degree of risk to patients in a comprehensible and nonjudgmental manner. Clinicians will also need to elicit each patient's personal values regarding the pros and cons of using PrEP, and then help patients to make decisions regarding PrEP use that align with these personal values.

Patient decision aids are tools that have been shown to facilitate informed decisions in clinical medicine by preparing patients to engage in this personalized decision-making process with their providers [*45]. These decision aids can take the form of pamphlets, videos, or web-based tools that describe the options available for important healthcare decisions. Patient decision aids can help patients consider the available options from a personal point of view, and they can empower individuals to make decisions that are congruent with their values. As randomized, controlled trials have demonstrated that patient decision aids can optimize the decision-making process in other areas of preventive medicine [45], the development of patient decision-aids to help at-risk individuals decide whether PrEP would be congruent with their values and lifestyle are warranted.

Patient testimonials could also help individuals decide whether or not to utilize PrEP. One recent innovative consumer tool was developed by the Chicago AIDS Foundation, which includes video interviews of individuals who have initiated PrEP (<http://myprepexperience.blogspot.com/2012/05/new-frontier.html>).

These patient-oriented tools can be complemented by provider-oriented tools to help clinicians decide whether PrEP would be beneficial for individuals they encounter in practice. Risk-prediction models are point-of-care tools that use patient-derived data to estimate an individual's risk of important clinical events, and they can help clinicians to accurately risk stratify patients for these events in real-time. These models have fundamentally altered risk assessment in numerous areas of preventive medicine, such as the use of the Framingham Risk Score to predict myocardial infarction in preventive cardiology [46], and they have great potential to improve risk assessment in HIV prevention. Risk-prediction models that use patient-reported data on sexual and substance-use behaviors to estimate the risk of HIV acquisition for individual MSM have been created and validated [47, **48], and they could help providers to identify individuals who are likely to benefit from PrEP. Studies to test the acceptability and utility of HIV risk-prediction models in clinical practice are needed.

Conclusion

Healthcare providers will play a critical role in implementing PrEP. Although recent studies suggest that some clinicians are aware of PrEP and are potentially willing to provide this novel intervention, PrEP prescribing appears to be uncommon. Developing innovative strategies that motivate providers to identify persons at high-risk for HIV acquisition and then prescribe PrEP to those persons who have made an informed decision to utilize this novel intervention represent critical areas of future research.

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Key points

- Since 2010, several randomized, controlled trials have demonstrated that HIV antiretroviral pre-exposure prophylaxis (PrEP) can reduce HIV incidence in several high-risk populations
- Practicing clinicians will play a critical role in implementing PrEP by identifying high-risk persons who may benefit from this strategy and then prescribing chemoprophylaxis to these individuals
- Recent studies suggest that some practicing clinicians are aware of PrEP and are willing to prescribe it, but few of them have prescribed chemoprophylaxis
- As patient-provider communication about HIV risk behaviors is suboptimal, training providers to engage in effective behavioral risk assessments will be critical to successfully identify individuals who are likely to benefit from PrEP
- Important areas of future research include developing interventions that motivate and/or incentivize clinicians to discuss PrEP with high-risk persons, employing risk-prediction models to produce individualized HIV risk assessments, and creating clinical decision aids that support informed, patient-centered decisions regarding PrEP utilization