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A Clinical Home for Pre Exposure Prophylaxis (PrEP): Diverse Health Care Providers' Perspectives on the “Purview Paradox”

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Abstract

Background—One barrier to wider PrEP availability is uncertainty about the most appropriate providers and practice settings for offering PrEP.

Methods—We conducted in-depth interviews with 30 clinicians—primary care and HIV specialists—in the NYC region to explore issues related to PrEP roll-out, including who should provide it and in what settings.

Results—A diverse group favored offering PrEP in non-HIV specialty settings in order to reach high-risk HIV-negative individuals. Yet for each clinical skill or ancillary service deemed important for providing PrEP—knowledge of the medications, ability to assess and counsel around sexual risk behavior, and ability to provide support for retention and medication adherence—participants were divided in whether they thought primary care providers/practices could achieve it. Five participants strongly favored providing PrEP in HIV care practices.

Conclusion—Although there may be multiple “homes” for PrEP, implementation research is needed to identify the most effective delivery approaches.

Keywords

Pre Exposure Prophylaxis (PrEP); Biomedical HIV Prevention; Healthcare Provider; Implementation

INTRODUCTION

Oral pre-exposure prophylaxis (PrEP) was approved by the FDA in July 2012 for individuals at high risk for HIV infection, but its uptake has been slow. A 2013 survey of over half (55%) of the pharmacies in the U.S. by Gilead Sciences, whose drug, Truvada® (TVD), is the only antiretroviral treatment currently approved for PrEP, found that 1,774 individuals received prescriptions of TDA as PrEP between January 2011 and March 2013(1). A 2014 update using the same methods to track prescriptions between January 1, 2012 and March 31, 2014, reported that 3253 individuals received PrEP, with the total number of new starts increasing significantly over this period, and the proportion of prescriptions to women declining from 53.9% in the first half of 2012 to 26.7% in the first quarter of 2014(2).

Numerous difficulties to widespread PrEP implementation have been identified by public health researchers(3–5), but the questions of who should ideally prescribe PrEP and in what types of settings have received limited attention(5, 6). In a 2012 focus group study with HIV care clinicians to explore their perceived barriers and facilitators to PrEP implementation, Krakower and colleagues(6) coined the term the “purview paradox” to describe one of the barriers identified: although primary care settings, which provide care to HIV-negative persons, seemed to be a logical home for PrEP, these HIV care clinicians raised concerns about whether primary care providers were able and willing to manage patients on PrEP, a theme that was also identified in interviews conducted by Arnold et al. (5), among California providers and public health officials. Notably, the most recent pharmacy-based survey found that 68% of PrEP prescriptions were written by five specialties (internal medicine, family practice, infectious diseases, nurse practitioners, and physician assistants) (2), but it provided no information on these providers’ preparedness or comfort levels with prescribing TVD as PrEP.

In the present study we explored more extensively, and among diverse clinicians, views concerning what type/s of providers can best prescribe and manage PrEP, what skills and abilities are necessary, and in what types of settings this prevention strategy should be offered. With the release of findings from two additional studies showing that TVD-based PrEP is efficacious among MSM(7, 8), addressing these questions is especially urgent.

METHODS

This study was a collaborative effort among investigators from the HIV Center for Clinical and Behavioral Studies, the New York/New Jersey AIDS Education and Training Center, and Gay Men’s Health Crisis. All interviews were conducted in late 2012 or early 2013. Eligible study participants were practicing clinicians in the greater New York City metropolitan area. We aimed to include clinicians caring for men who have sex with men (MSM), injection drug users (IDUs), and high risk heterosexual women and men from a range of specialties and practice settings including primary care physicians with specialization in general internal medicine or family practice; infectious disease specialists; emergency medicine physicians; and obstetrician-gynecologists. To recruit participants, co-investigators and members of an expert panel established for this study made initial contact

with potential clinicians in their respective settings and networks to gauge interest. If the clinician was willing to participate, s/he was contacted by the project director to schedule an interview. The protocol was approved by the New York State Psychiatric Institute/Columbia University Department of Psychiatry IRB.

Interviews, lasting 1–1 ½ hours, were conducted by one of the co-investigators or the project director, in person or on the telephone, and were audiotaped and subsequently transcribed. The interview team trained together to ensure consistency in interviewing. Participants also documented their practice setting, medical specialty and any additional training, and characteristics of their patient population. At the completion of the interview, study participants were reimbursed \$85.

The interview guide was developed by the team and reviewed by the expert panel. Topics included knowledge of PrEP and prescribing guidelines; prior experience prescribing PrEP; skills needed to implement PrEP in one's practice, and challenges anticipated; perceptions of peers' opinions of PrEP; intentions to implement PrEP and, if so, to whom; anticipated training needs; and preferences for continuing education modalities. To ensure all participants had basic knowledge of PrEP, we sent them educational materials before the interview and read a standardized script providing basic information before beginning the interview.

The content of the transcribed interviews was coded into global topic areas, using a codebook that was developed by the team and tested by team members on 6 interviews, discussed, and revised. Coding was conducted in pairs; each person coded independently and then met with his/her partner to review and resolve inconsistencies. Final codes were applied to documents using a computerized qualitative program (Atlas.ti), after which we produced coding reports for each global code. Two or more team members read each report, identified sub-codes, and created coding grids to document content and quotes by participant so that any patterns by participant characteristics could be identified. These were summarized and jointly discussed among the research team.

For this analysis, we focused on the narratives for the code "who should prescribe". Typically, this text was in response to the lead interview questions "What kinds of providers do you think should be prescribing PrEP?" and "What are the prerequisites for providers to be able to implement the prescription of PrEP successfully? What should they know, what should they be able to do?"

RESULTS

Study Participants

Of the 30 participants, 24 were physicians, four were nurse practitioners, and two were physician assistants. All nurse practitioners and physician assistants were specialized in primary care for HIV patients. Among the physicians, five were trained in family medicine and 11 in internal medicine, of whom eight also specialized in infectious diseases; five were trained in obstetrics and gynecology, two in pediatrics, and one in emergency medicine. Seventeen participants practiced at least part-time in a setting specializing in care of HIV+

people and 13 worked in other settings (general primary care or family practice, family planning, urgent care clinic used by MSM, college clinic, adolescent medicine, addiction primary care, or ob-gyn setting). Seventeen worked in an academic medical center or affiliated site. Seven of the 30 providers had prior experience prescribing PrEP; these seven were diverse with respect to training background and practice setting.

A Home for PrEP?

The crux of the dilemma about who should prescribe and manage patients on PrEP emerged sharply in these interviews. Study participants noted that whereas infectious disease and HIV specialists are experienced in prescribing antiretrovirals and providing the adherence support for patients taking these medications, such clinicians typically do not care for HIV-negative patients. Participants viewed this dilemma in different ways. In their initial response to the question “what kinds of providers do you think should be prescribing PrEP?”, nine participants stated primary care physicians or practices; five indicated HIV providers; seven said either group could do so, depending on their skill and training; three responded by indicating settings (such as STD-, adolescent- or MSM-focused clinics) where high-risk individuals would be seen; four said any physician, and two did not reply or were unsure. Four of the five who endorsed HIV providers were themselves practicing in an HIV specialty setting. However, of the nine participants who endorsed primary care providers, five practiced in HIV settings and four did not, and of the 14 who did not strongly endorse either HIV specialty or primary care settings, eight practiced in an HIV setting and six did not. Therefore, on this “first pass” response, the majority—including both HIV specialists and non-specialists—thought that primary care settings, or at least *not* HIV specialty settings, were well suited to providing PrEP.

Below we examine the two more extreme positions—that PrEP should remain in primary care and that PrEP belongs in specialty settings. We then explore participants’ assessments of whether primary care providers had, or could obtain, the requisite knowledge, skills and support for providing PrEP, and show how these assessments served to qualify some participants’ views that primary care settings were the most appropriate “home” for the provision of PrEP. We close with a discussion of some organizational options proposed by participants. Illustrative quotations are followed by the participant’s training, but not practice setting, to preserve confidentiality.

“People Who Don’t Have HIV are Not Going to HIV Providers”: Primary Care Providers Should Prescribe PrEP

Both HIV specialists and primary care providers thought that primary care settings were good sites for provision of PrEP first and foremost they are where high risk, HIV-negative people could be identified. As one internist stated,

...because you [...] need to cast a wide net to be able to get all the patients that are high risk [...] when you’re only talking about people who do HIV medicine you’re not able to get those patients who are high risk. [P8 – Internal medicine with HIV certification]

And as another infectious disease specialist noted,

they're [the primary care physicians] the ones who are going to be seeing the patients, right? It's not the HIV providers. People who don't have HIV are not going to HIV providers. So, you've got to -- it has to be everybody, really. [P11 – Internal medicine/infectious disease]

An internist completing a fellowship in infectious diseases referred specifically to the difficulties HIV specialists would face if they prescribed PrEP to the partners of their HIV+ patients, given that these partners were not their own patients.

I mean, it's hard from the HIV partner side in trying to prescribe PrEP to a person who's not even your patient. So in that light, the HIV negative patient, their PCP should definitely be prescribing it and be educated about how to prescribe it. [...] I think it's difficult for the HIV physician to prescribe it for someone who's not their patient, like just legally. [P4 – internal medicine/infectious disease]

“Everyone Should Come to See a Specialist”: HIV Providers are Best-Positioned to Prescribe PrEP

A well-articulated alternate position to the view that “PrEP is primary care” was that HIV specialists should prescribe PrEP. The argument turned chiefly on the need for skills and knowledge that are not routinely practiced by primary care providers. Participants' prior experience with HIV-positive patients who were poorly managed by primary care providers was another reason for supporting PrEP as part of HIV specialty care.

...the people outside our clinic or outside our field who are doing primary care with HIV, by and large are not very competent, just to use a word. They're not familiar. They have minimal knowledge, and even though they may be treating some people, have probably some prejudice, or at least ambivalence. So we unfortunately will see people from time to time who have been treated -- you know, they were given a pill and they said “come back in a year,” and they come to us and they're not well, and, you know. So I don't, personally, in that area, feel too comfortable with primary care really doing HIV. [...] I think everybody should come to see a specialist, and we're the only game in town, so I think they should come to see us. That's not just out of loyalty; I just think this is what we do. [P16 – non-physician clinician]

Apart from outright “patient mismanagement”, experience obtained through regular use of knowledge and skills was thought to be critical for good care by another infectious disease specialist. Although s/he did not believe PrEP *needed* to be prescribed by a specialist, this participant argued that more than training was necessary for primary providers to successfully offer PrEP; clinicians also had to stay abreast of developments and have a significant patient base in order to maintain high quality care.

Well, I mean, I don't think you have to have infectious diseases training, or even special HIV training. But like most areas of medicine, people provide better care when they have an interest and a fair amount of experience in an area. And there are lots of general internists that provide HIV care, and do a great job of it because they're very interested in it, they keep up in it. You know, but it's a moving and complex field, and, you know, I think the general kind of practice that has a few

patients on the side often provides an inferior level of care. I think PrEP certainly falls in the same area. [P26 – Internal medicine/infectious disease]

For another participant the option of specialty care made sense in a place like New York City, where it was widely available.

... it also depends on where you're practicing. If you're in New York and you have access to HIV specialists, I think why not leave it in their hands. But if you're out in the middle of nowhere, it's just you. [P28 - obstetrician-gynecologist]

What Knowledge and Skills Do Providers Need to Be Able to Offer PrEP?

Most participants argued that clinicians providing PrEP needed specific skills and supports. These included knowledge of the medications, skills in sexual risk assessment, and the ability to monitor and closely follow patients and provide adherence support. Participants differed in whether they viewed these as strengths of primary care providers, weaknesses that were remediable, or as critical limitations.

“It has to be someone who really understands the drugs.”—Participants uniformly believed that anyone prescribing PrEP had to understand the nature of the drugs, their potential side effects, and how to monitor patients for them. As a primary care provider specializing in HIV care noted,

[...]So I don't know if it has to be an HIV specialist necessarily, but it has to be someone who's really familiar with the drug. How to look for Fanconi syndrome. Understand the potential toxicity and so on. [P21 – non-physician provider]

Some thought that obtaining this knowledge was a relatively simple matter that any clinician could master with training, noting that “*we certainly, in primary care, use medications that are much more complex.*” [P11- internal medicine/infectious disease]

Another internist strongly challenged the idea that prescribing these medications required a specialist, even while acknowledging that others might object if community providers prescribed PrEP.

There has been such an effective exceptionalization of HIV [...] clearly it's not that difficult a medication to give, and it's not any [...] more difficult than most medicines that community providers give, but I just -- I would think that there would be pushback from them [community providers] doing it. [P12-Internal medicine]

On the other hand, those who believed that managing PrEP and keeping abreast of new drug developments required more extensive experience were concerned that some primary care providers do not feel competent to use ARVs.

I have seen sometimes that some of the primaries aren't as comfortable, or don't really know what these meds are or aren't, and aren't very comfortable with them. So I'm kind of concerned if you say, well let's just open it up to primary. Although that's certainly the best way to get it out there. I would -- like I said, I would almost

be more comfortable seeing it become a part of any of the HIV-dedicated programs. [P3 – Non physician provider]

How to talk about sex. “It’s not just saying, ‘Hey, you should have safe sex. Use condoms.’ We have to go deeper.”—Besides knowledge of ARVs, sexual

history-taking and risk reduction counseling were judged to be extremely important skills for providing PrEP. Clinicians needed to be comfortable, as well as non-judgmental, in asking about sexual behavior.

They have to be able to speak openly with patients about sexual risks and in language that, in a way that puts patients at ease and promotes their candid response to questions so that you can properly evaluate their risk. [P22 - Family medicine specialist]

HIV providers were perceived to have comfort and skill discussing sexual behavior, as described by a clinician whose practice was in primary care for HIV+ patients.

... HIV providers are pretty savvy with the whole concept of risk reduction and safer sex. So, being able to have that open conversation, I think, is a skill set that HIV providers are more comfortable with than non-HIV providers. [P18 – Non physician provider]

Could primary care providers also do this? One participant elaborated on concerns about primary care providers’ ability to take a thorough sexual history and their consistency in doing so.

...I’m pretty sensitive to how hard it is to get ... primary care doctors to have really ... frank, detailed discussions about risk behavior with their patients.... [P30 – Internal medicine with HIV training]

Task-shifting was suggested as one approach to address this.

[...] maybe taking ... the screening or assessment part out of the doctor’s hands and letting patients... do that in some other way, and then letting the doctor follow up ... might be more effective. [P30 - Internal medicine with HIV training]

By contrast, a family medicine physician with HIV certification argued that “...the major effort should be to train providers to do a really good risk assessment in terms of sex, sexuality.” S/he continued,

Because the other part, you know, the dose, and how do you have to monitor the labs, is easy. (After probe about what providers needed to know): one is that part (risk assessment), two is how you’re going to reinforce this message with a patient, that even though they’re going to be taking the medication, it’s not 100% effective. [...] and it’s not just saying, “Hey, you should have safe sex. Use condoms.” We have to go deeper. “What’s going on? Why is it difficult for you to use a condom? What are the difficulties of the situation?” [P5 – Family medicine with HIV certification]

Adherence support: “The HIV doctors have that issue for breakfast every morning.”—Maintaining close follow-up of patients on PrEP and providing adherence support were seen as challenges that primary care providers – and primary care practices – might have difficulty meeting. HIV clinicians were seen as experienced in medication adherence counseling and in having the supportive services necessary to address retention. For example, after stating that the provision of PrEP should *NOT* be limited to HIV specialists, this adolescent specialist raised a concern around primary care providers’ capacity for delivering adherence support.

that’s not without concern that [...] the HIV physicians are used to dealing with the adherence issue, whereas the primary care docs, while they may have certain familiarity with the adherence issue in day-to-day practice of general medicine, there’s less at stake [...]. If you’re prescribing anti-hypertensives, people may be not adherent, but they’re not going to become resistant to the medication. They’re also not going to potentially transmit a resistant virus to someone else. So ... the HIV doctors... have kind of the -- have that issue for breakfast every morning. [P29 – Pediatrics/Adolescent medicine]

A related concern raised by this participant was around ensuring regular follow-up of patients.

I think the concept of regular follow-up is something that is more ingrained in an HIV provider’s head, in terms of regular, ongoing visits. [...] And, ... people outside, people in general medicine, especially for a younger and more sexually active population, may not have that much desire to see their doctors as frequently as people with HIV end up having to see their doctor. So, that’s another concern. [P29 – Pediatrics/Adolescent medicine]

Even though the provider cited above supported the delivery of PrEP in primary care practices, a number of other participants highlighted adherence support and retention services as factors rendering HIV practices superior settings for providing PrEP. As stated by one, adherence and retention are challenges “*where primary care providers may not be the best skilled, or have the most time.*” [p27 - Emergency medicine]. *S*he went on to explain that HIV clinics provide access to support services such as mental health, care coordination, etc. and that might therefore be better places for managing patients on PrEP.

So I think even though it makes more sense that it’s primary care providers of all types, I think that ultimately, what we should be really thinking of is expanding the responsibilities of HIV providers who understand this disease much better than primary care providers, and having them really be the gatekeepers. [P27 - Emergency medicine]

Mixed Models Might be the Best Approach to Providing PrEP

A few participants alluded to combined approaches in which primary care providers would partner with or have access to HIV specialists. For example, an HIV care provider who thought that PrEP should be in the domain of HIV specialty clinics said this when asked about how a general practitioner should respond if a patient requested PrEP.

If they [the patient] saw [...] the HIV physician once, and then followed up with their [primary care] doctor, that would be fine. But there's got to be someone involved, even if it's a one-time-a-year thing, who is in this field for a while, and is, you know, considered an HIV specialist. [P6 – Non-physician provider]

Another HIV specialist who thought that “a family practice setting ... that has experience with this population, let's say a high-risk population, [providers] with the education, with the background,..., with the training might be a setting” continued by describing an approach in which primary providers have access to specialty practices.

Certainly our setting [a large medical center]. You know, we have an infectious disease practice, HIV practice. ... community health, family practice kind of settings as long as they have those pieces in place. [P23 – Infectious disease]

Finally, several participants believed that locations where high-risk people present for care, such as STD clinics or addiction treatment sites, would be good places to introduce PrEP. However, they also noted that these “drop-in” sites presented a challenge in that regular follow-up was not a standard part of this model of care.

I think it's also worth thinking about...other settings that... are less medical but... have better access to people who are at high risk. [...]Like a harm-reduction program, you know, bathhouses, STI clinics. But the problem is, with those programs, they tend to have not great follow-up with people. It's more of, like, the drop-in model. [P30 – Internal medicine with HIV training]

Another participant suggested that at least the STD or urgent care providers “should be aware, offer, providing information about where and how to find it [PrEP].” [P22 – Family medicine] This participant also thought that intravenous drug user settings would be good places for introducing PrEP. This view—that PrEP information and/or screening should be offered in sites frequented by large numbers of high-risk individuals—implies a mixed model, whereby screening would be conducted in one site and potentially eligible individuals would be referred elsewhere for prescription and management.

DISCUSSION

Through in-depth interviews with primary care clinicians as well as HIV specialists practicing in primary and specialty care settings, we identified multiple and sometimes contrasting perspectives on what is the best setting for offering and managing PrEP. We found that although many clinicians believed that PrEP should be provided in places where high-risk HIV-negative individuals are most likely to access medical care, for each clinical skill or ancillary service deemed important for providing PrEP in a high quality manner—knowledge of the medications, ability to assess and counsel around sexual risk behavior, and ability to provide support for retention and medication adherence—participants were divided in whether they thought this could be achieved by non-HIV providers and practices. Some believed that primary care providers could master and integrate the skills and obtain the needed supports through training and access to specialists when necessary, whereas others, although supporting in principle the provision of PrEP in primary care settings, were less sanguine about the feasibility of such approaches, highlighting the limitations of primary

care settings and primary care providers. Notably, these divisions did not align tightly with training or practice setting. Although the majority of participants who advocated providing PrEP in HIV specialty settings themselves practiced in such settings, a diverse group of providers favored offering PrEP in non-HIV special settings. These findings highlight that the PrEP “purview paradox” is real and likely has no simple solution.

A strength of this study is that we included a diverse sample of clinicians, including those providing HIV care as well as those not specializing in or providing HIV services. Additionally, we were able to shape our interview guide to elicit providers’ in-depth views on issues that had been identified in other studies. We explicitly queried participants about the type of provider they thought was best suited to prescribe PrEP and the skills they deemed necessary to do so. The rich and diverse responses allowed us to undertake a nuanced examination of this issue and to examine whether opinions tended to map onto training and practice setting. A limitation was that although we recruited a diverse sample, we did not set specific targets (e.g., by practice setting, specialty, patient population); as a consequence, the sample includes a larger number of academic-affiliated physicians than might be considered ideal. Also important to recognize is that this study was conducted in a large urban metropolitan region with high HIV prevalence and wide availability of HIV specialty services.

Based on these findings, we believe that it will require creative experimentation to identify the best approaches to increase access for those who could benefit from PrEP. The CDC and NIH-funded demonstration projects are an important step(9, 10). Further insights to resolve the PrEP “purview paradox” call for the use of implementation science to test whether and how well different models achieve effective dissemination of this proven intervention to those most at risk. These different models might include capacitating HIV providers and practices to serve HIV-negative individuals at high risk, and build the skills of non-HIV specialized providers to assess HIV risk, prescribe ARVs for PrEP, and manage adherence and side effects. Indeed, our participants offered some suggestions, including linking primary care providers with an HIV specialty “mentor” and screening in one setting (e.g., primary or GYN care setting) and referring to another setting (e.g., infectious diseases specialty practice)(11). Another suggestion was to shift responsibilities for HIV risk assessment from medical providers to other professionals in the health care setting who could be trained to conduct screening assessments and/or undertake in-depth conversations with patients about these issues.

The providers we interviewed identified some specific skills they thought necessary for those who would prescribe PrEP need to have. This will require training and education, a critical prerequisite for every innovation in any field of medicine. Some of these skills, such as sexual history-taking are arguably important for individual and public health more generally, beyond the issue of HIV risk. The roll-out of health care reform under the Affordable Care Act, particularly with the emphasis on preventive medicine and primary care in community health centers, provides impetus for expanding provider understanding of HIV and HIV prevention at this level. Ultimately, a public health approach to HIV prevention and sexual health would view PrEP as one of many tools that should be available to people who are at high risk for HIV infection, wherever they are seeking medical care.

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