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PrEP Providers in Birmingham, Alabama and New York City, New York Identify Critical Barriers to Newer PrEP Strategies: A Mixed Methods Study

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All authors on this paper meet the four criteria for authorship as identified by the International Committee of Medical Journal Editors (ICMJE); all authors have contributed to the conception and design of the study, drafted or have been involved in reviewing this manuscript, reviewed the final version of this manuscript before submission, and agree to be accountable for all aspects of the work. Specifically, using the CRediT taxonomy, the contributions of each author are as follows: Conceptualization & Methodology: ESK, RS. Funding acquisition: RS. Writing – original draft: ESK; Writing/Revising – All authors.

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Abstract

Young Black and Latino men who have sex with men (MSM) are disproportionately impacted by the United States HIV Epidemic, yet pre-exposure prophylaxis (PrEP) uptake remains low. To understand barriers and facilitators to PrEP uptake and persistence, we utilized a concurrent mixed methods design (quantitative: online surveys, $n = 19$; qualitative: individual interviews, $n = 15$) from providers (e.g., nurse practitioners, clinicians, social workers) at four clinics providing PrEP services in Birmingham, Alabama and New York City. While all providers were comfortable prescribing daily oral PrEP, they had concerns about on-demand PrEP (e.g., complex dosing schedule) and injectable PrEP (e.g., insurance barriers). Provider training is needed to address barriers to providing PrEP modalities beyond daily oral PrEP and increase uptake among young Black and Latino MSM. Policy change is needed to increase uptake of injectable PrEP and offset rising PrEP costs due to changes in the 340B Drug Pricing Program.

Keywords

barriers to PrEP; HIV pre-exposure prophylaxis (PrEP); men who have sex with men; mixed methods; PrEP new formulations

Men who have sex with men (MSM) are disproportionately affected by HIV, with MSM accounting for nearly 67% of new HIV diagnoses in the United States in 2022 (Centers for Disease Control and Prevention, 2024). Black and Latino MSM experience even more pronounced HIV inequities: of all new HIV infections among MSM in the US, 37% were among Black MSM and 33% were among Latino MSM (Centers for Disease Control and Prevention, 2024), despite Black and Latinx people comprising 14% and 19% of the U.S. population, respectively. Further, young Black MSM under 25 years old had the highest percentage of new diagnoses in 2022, at 49%--higher than any other group (Centers for Disease Control and Prevention, 2024).

HIV pre-exposure prophylaxis (PrEP) is highlighted in the Ending the HIV Epidemic initiative as one of their key strategies in preventing new HIV infections. The Food and Drug Administration first approved oral PrEP in 2012 under the brand name “Truvada ©” (tenofovir disoproxil fumarate and emtricitabine), followed by an additional oral PrEP regimen in 2019, Descovy © (tenofovir alafenamide with emtricitabine). “On-demand” PrEP, also referred to as “2-1-1” due to its dosing schedule (taking 2 pills 2–24 hours before sex, 1 pill 24 hours after first PrEP dose, and 1 pill 24 hours later), is another option for MSM engaging in condomless event-driven or non-daily anal sex. While on-demand PrEP has not been approved by the FDA, clinical trial results with MSM demonstrate a relative reduction in HIV risk by 86% (Molina et al., 2015). In fact, several U.S. health departments provide prescription and monitoring guidance to providers, since it has shown demonstrated efficacy. In 2021, the FDA approved an additional form of PrEP, long-acting injectable cabotegravir (CAB-LA), which can be injected intramuscularly every two months. However, extant research suggests that providers’ lack of knowledge about CAB-LA, including how to obtain insurance coverage, is a barrier to its uptake (Keddem et al., 2024).

Despite its efficacy, PrEP uptake remains low across all subgroups in the United States, particularly among youth, Black and Latino people, and people living in the South (Siegler et al., 2018). The national PrEP-to-need ratio, a health equity index that is equal to the number of PrEP users divided by the number of new HIV diagnoses (Siegler et al., 2018), illustrates that Black and Latinx people have the lowest PrEP-to-need ratios by race/ethnicity. Indeed, the literature has identified multiple barriers to uptake and persistence among young Black and Latino MSM such as low interest in PrEP, lack of accurate information about PrEP, stigma related to PrEP use, concerns with PrEP marketing as being for sexual and gender minority people only, and lack of trust in providers (Pichon et al., 2022). At the structural and policy level, primary barriers include cost (regardless of insurance status), education, and accessibility (Ayangeakaa et al., 2023; Kay & Pinto, 2019). Furthermore, as new PrEP formulations enter the market, the burden of managing prior authorizations and other insurance requirements may exceed the time and resources available to PrEP providers (Magnus et al., 2023).

There are additional multilevel barriers experienced by Latino and Black MSM. For Latino MSM, there are concerns about meeting traditional masculine gender role expectations (e.g., machismo), stigma, immigration and language barriers, and lack of culturally informed materials, such as those that integrate peer-led navigation (Dillon et al., 2024; Zapata et al., 2023). For Black and African American MSM, medical mistrust and stigma are prominent barriers highlighted in the literature (Hutchins & Drey, 2024). Given the significant PrEP-related disparities affecting young Black and Latino MSM, coupled with the expanding array of PrEP options there is an urgent need for culturally informed education and tools to support providers in increasing PrEP screening, counseling, and prescribing for these populations.

In preparation for our larger study investigating the effect of a novel mobile health (mHealth) intervention (mChoice) on PrEP outcomes among $n = 400$ young MSM ages 18–39 ($\geq 50\%$ Black or Latino) in two Ending the HIV Epidemic priority settings (Birmingham, Alabama [BHM] and New York City [NYC]), we conducted formative work with clinic staff involved in providing PrEP care (hereafter, “providers”). The overarching goal of the five-year mChoice study (2021–2026) is to increase PrEP screening, counseling, initiation, adherence, and persistence by MSM across the three PrEP modalities (daily oral PrEP, on-demand PrEP, and CAB-LA). Participants will be followed for up to 18 months, and PrEP uptake, adherence and persistence will be evaluated. The mChoice app is accompanied by provider training and support, offered prior to implementation as well as throughout our study. Providers will have access to online training modules in PrEP support tools, national PrEP guidelines, and best practices in sexual health. The primary objective of the work described herein was to assess PrEP providers’ knowledge of and attitudes towards PrEP in order to increase PrEP screening, counseling, and prescribing among young Black and Latino MSM. Results of this formative work will enable us to tailor provider training and support around the three PrEP modalities in preparation for implementation of the mChoice trial. Understanding the clinical and cultural knowledge and PrEP prescribing preferences of providers at participating clinic sites will inform analysis of participants’ PrEP choices and changing regimens (or lack thereof) throughout the intervention period. While we recognize the distinct cultural needs and experiences of Black and Latino MSM, we focus on both

populations in our study given disproportionately low rates of PrEP uptake among these groups.

Methods

Design, Sample, and Recruitment

Study procedures occurred in April and May of 2023. We utilized a concurrent mixed methods design (Creswell & Plano Clark, 2011) to collect quantitative and qualitative data from providers at our study sites, including online surveys and individual interviews. Our study sample included four clinic sites providing PrEP services to high numbers of young Black and Latino MSM, two in Birmingham and two in New York City. Eligible providers were those with experience working with young Black and Latino MSM, such as physicians, social workers, nurse practitioners, and PrEP coordinators. Each site principal investigator provided research coordinators with a list of the names and email addresses of providers working directly with young Black and Latino MSM. The research coordinators then emailed the providers to inquire about their interest in participating in our study.

We organized the survey questions and interview guide around the Consolidated Framework for Implementation Research (CFIR), a meta-theoretical determinants framework for assessing multilevel characteristics hypothesized to affect implementation success (Damschroder et al., 2009; Damschroder et al., 2022). We used the original CFIR framework, as CFIR 2.0 (Damschroder et al., 2022) had not been published at the time of study initiation.

Study Procedures

The 30-minute survey was distributed via REDCap (Harris et al., 2019) to 30 participants, and participants ($n = 19$, 63% response rate) received \$75 for their participation. Three trained members of the research team (ESK, SS, MB) conducted the individual structured interviews ($n = 15$) over Zoom. Interviews lasted between 30 and 45 minutes and were audio-recorded and professionally transcribed. Providers received an additional \$75 incentive for completion of the interview. Twelve of the participating providers completed both the survey and the interview, while $n = 3$ completed only the interview and $n = 7$ completed only the survey. Thus, $n = 19$ providers completed the survey, while $n = 15$ completed the individual interview. Both activities required provision of written informed consent via REDCap prior to participation. All study procedures were approved by Columbia University's Institutional Review Board.

Survey Measures

Demographics—To help describe the sample, we queried providers about their job category, years at current organization, and total number of years working with young MSM. We also collected information on location (Birmingham vs. New York City), age, gender identity, race, ethnicity, and education level.

CFIR Items

Inner setting

Organizational culture.: To assess organizational culture (the norms, values, and basic assumptions of an organization, we used the following validated measures (Fernandez et al., 2018): culture overall (9 items, $\alpha = 0.78$), culture stress (perceived stress and strain and role overload at organization, 4 items, $\alpha = 0.68$; higher scores equal higher culture stress), culture effort (the organization values doing good work, 5 items $\alpha = 0.71$), and learning climate (the organization values new ideas, 5 items, $\alpha = 0.95$). Response categories were from 1 (*strongly disagree*) to 5 (*strongly agree*); several items were reverse-coded such that “5” always indicated the strongest level of agreement.

Implementation climate for young MSM.: We measured organization’s commitment to implementing services and programs for young MSM using an adaptation of Fernandez et al.’s validated Implementation Climate Scale (Fernandez et al., 2018), initially developed to assess organizations’ uptake of evidence-based practices (EBPs) for colorectal screening. As an example, “<EBP> to increase colorectal cancer screening rates is a top priority of the clinic” was rephrased to “Implementing programs to improve HIV care outcomes for MSM is a top priority of the organization.” Response categories were coded from 1 (*strongly disagree*) to 5 (*strongly agree*) ($\alpha = 0.79$).

Implementation climate for evidence-based practices.: We assessed the organizational environment for implementing EBPs via the validated Implementation Climate Scale (Ehrhart et al., 2014), which included six three-item subscales: 1) focus on EBP (the organization prioritizes use of EBPs, $\alpha = 0.97$), 2) educational support for EBP (organizational support for implementing EBPs, $\alpha = 0.94$), 3) recognition for EBP (how staff who use EBPs are regarded by others in the organization, $\alpha = 0.87$), 4) selection for EBP (the extent to which organization selects staff based on EBP experience, $\alpha = 0.95$), 5) selection for openness (the organization hires open and adaptable staff, $\alpha = 0.98$), and 6) rewards for EBP (financial incentives for use of EBP, $\alpha = 0.56$). Response categories were from 1 (*not at all*) to 5 (*very great extent*).

Implementation leadership.: We measured implementation leadership, which assesses leaderships’ attitudes towards EBPs, using the Implementation Leadership Scale (Smith et al., 2020). Response categories for the six items were from 1 (*strongly disagree*) to 5 (*strongly agree*), $\alpha = 0.89$.

Outer setting

Patient needs and resources.: We used a validated five-item scale (Kegler et al., 2018; McMenamin et al., 2010) to measure the extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by each organization. Response categories were 1 (*strongly disagree*) to 5 (*strongly agree*), $\alpha = 0.81$.

Qualitative Measures

The interview guide comprised four domains of the original CFIR framework, including intervention characteristics, outer setting, inner setting, and characteristics of individuals. Given the formative focus of this data collection, we did not explore process. Questions explored PrEP services for young Black and Latino MSM at providers' clinics, such as current PrEP options, perceptions of clinic readiness for increasing PrEP services, and external drivers of clinical care.

Analysis

Quantitative—We obtained descriptive statistics for providers' demographic characteristics, including number and percent for categorical variables and means and standard deviation (*SD*) for continuous variables. For the CFIR items, we calculated scale and subscale means and *SDs*, as well as Cronbach's alpha to assess reliability. Respondents who chose the "prefer not to respond" option for the CFIR items were not included in generating the means. The analysis was conducted in SPSS. Given the small sample size ($n = 19$), we did not conduct bivariate analyses.

Qualitative—Three coders with research experience in HIV prevention (first three authors) independently read through each transcript, after which the team debriefed and created a preliminary codebook based on the CFIR framework. We applied a directed content analysis, using deductive coding to analyze the data (Hsieh & Shannon, 2005). Analysts also assigned valence (positive or negative influence on implementation) to each code. Any coding differences were reconciled through processes of weekly meetings to establish coding consistency. Each analyst brought unique backgrounds and expertise, thus increasing trustworthiness of the analysis. Approximately 50% of transcripts were double-coded to further increase coding reliability. The data was analyzed and organized in Microsoft Excel. The primary analyst, (first author), collated all notes and organized by CFIR domain and construct. Valence was used to further categorize themes into barriers and facilitators. As there were 15 interviews and four sites, we compiled results as a whole rather than stratifying by site. However, regional differences between Birmingham and New York City were noted.

Results

Quantitative

Provider Characteristics—Most providers who completed the survey were medical providers (e.g., clinician, nurse practitioner, etc.; 79%), had spent an average of six years ($SD = 5.2$) at their current organization, and had a mean age of 37 ($SD = 8.5$) (Table 1). While most identified as White (79%) and non-Hispanic (84%), a range of diverse gender identities were represented, including cisgender women (45%), cisgender men (30%), transgender men (10%), non-binary (10%), and another identity not included (5%). One provider had a bachelor's degree while the rest had either a masters (47%) or doctorate (47%). Fifty-eight percent of providers practiced in New York City and 42% in Birmingham.

CFIR Characteristics

Within the inner setting, survey results (Table 2) indicated favorable organizational cultures at providers' organizations, with the exception of culture stress, which was fairly high ($M = 3.82$, $SD = 0.73$). Providers indicated that there was good leadership support for implementation of EBP (M = 4.02, $SD = 0.72$). Implementation climate for young MSM was also favorable, although selection for implementation of EBPs was moderate ($M = 2.93$, $SD = 1.40$). Within the outer setting, organizations were well aware of, and responded to, the needs of their patients ($M = 4.0$, $SD = 0.70$).

Cronbach's alpha values demonstrated moderate to good reliability, except for the Rewards for EBP ($\alpha = 0.56$) scale.

Qualitative

A diverse range of organizational characteristics, provider attitudes, and experiences with PrEP were discussed. Inner and outer setting domains were most heavily covered. Table 3 illustrates barriers and facilitators to implementation according to their corresponding domain and construct/subconstruct, along with accompanying representative quotes to characterize the themes. Additional illustrative quotes are provided below beneath each construct, organized by participant number and geographic location. Thus, for example, 'P3 (BHM)' is Participant 3 and works at an organization in Birmingham. Given the small number of providers at each site, we do not provide identifying information such as gender or age to protect provider confidentiality.

Intervention Characteristics

Providers discussed their perceptions of the three PrEP modalities, as well as pros and cons of each.

Evidence strength and quality—All providers were aware of the scientific evidence for PrEP's efficacy, including both oral and injectable PrEP. As a Birmingham provider enthusiastically explained, "We trust PrEP. We know that it works." (P3, BHM)

Relative advantage—Advantages of certain PrEP modalities over others were noted. CAB-LA may allow men who experience intimate partner violence to use PrEP more discretely than oral PrEP options:

And I do think it's important to recognize, MSM, there's a lot of domestic violence. And partner violence. ... And in those individuals where that is a potential, doing that injection where there's not a pill bottle sitting in your house, and nobody knows you're on it, may decrease that risk of having that.

(P13, BHM)

A Birmingham provider noted that online PrEP services may be beneficial for younger patients who might not want to come to the clinic. However, three of the providers (20%) had reservations about PrEP modalities outside of daily oral PrEP, particularly 2-1-1 PrEP, and expressed concerns about their patients' ability to adhere to the schedule correctly: "I get a little nervous because some people are sort of like making up their own on-demand

PrEP regimens that they just sort of heard about through the grapevine” (P8, NYC). Concerns about PrEP persistence associated with CAB-LA were also raised:

So, it’s very important that if you, if we go down this route, that you understand that you know you need to get this shot. You know as prescribed, because if you miss it, then your risk goes up.

(P13, BHM)

Design quality and packaging—Providers had several suggestions about ways to create culturally informed PrEP marketing and services, primarily highlighting the appeal of digital content and social media in engaging younger patients. Employing email or text-based communication (as opposed to phone calls) which supports implementation of the mChoice app:

I think one of the things that would be really helpful is to have a little bit more flexibility in how we engage the folks. I don’t want to talk on the phone. My clients don’t want to talk on the phone. ... The ability to engage through text message or through email ... or even through social media sites can be really, really comfortable.

(P3, BHM)

Providers felt their clinics could do a better job engaging with racially and ethnically diverse patients, highlighting the need for more diverse PrEP materials (e.g., video ads that are “more representative of the population that we see here”) that are translated into multiple languages in order to meet the needs of a diverse range of clients. However, providers also discussed the need to not “re-stigmatize” patients by focusing advertising materials on only certain populations:

Making sure that marketing is very representative of the populations you’re trying to reach while still being mindful that you don’t want to accidentally re-stigmatize that population because now we’re just associating them HIV.

(P3, BHM)

Providers also suggested making changes in the waiting room areas to demonstrate support for diversity:

I just feel like maybe even in the waiting room, if we just had artwork representing all different cultures, colors, and different backgrounds, I think that in itself would say enough.

(P9, NYC)

Outer Setting

All CFIR outer setting constructs were discussed, and both facilitators and barriers were noted.

Needs and resources of those served by the organization—Providers in both locations were highly familiar with the needs of their PrEP patients and, for the most part,

prescribed oral PrEP according to patient choice (e.g., daily oral vs. on-demand). This was not as much the case for CAB-LA due to external barriers, but providers were still cognizant of its efficacy. The importance of patient-centered PrEP care was emphasized:

I very much believe in a shared decision-making process; understanding each aspect of the nuances of the various PrEP modalities, whether that's side effects, adverse effects; whether that is safety profile; whether that is efficacy. I think we live in a time right now where currently marketed PrEP agents are all highly effective, so it's more of a matter of getting the right safety adverse effect profile; the right convenience profile.

(P10, BHM).

In another example of demonstrating a strong commitment to meeting patients' needs, one clinic in New York City regularly examined their sexually transmitted infection testing data to ensure they were reaching patients who could benefit from PrEP. However, providers in both Birmingham and New York City noted that their organizations did not adequately serve the needs of their Latinx patients, noting that while they had Spanish-speaking patients (particularly in New York City), they did not have sufficient Spanish-speaking staff. Only one of the New York City clinic's reported having sufficient Spanish-speaking staff to meet the needs of their patients.

External policy and incentives—This CFIR construct was heavily discussed in interviews and was solely couched as a barrier. Extra-organizational barriers included lawsuits for Truvada®, which increased patient concerns around PrEP's safety, and the adverse effect of the release of generic PrEP and changes in Gilead's patient assistance program on clinics that depend on pharmaceutical reimbursements to provide PrEP to underinsured and uninsured patients. Gilead ended its Advancing Access patient assistance program as of January 1, 2022 (Gilead, 2021), which made it more difficult for clinics to assist clients with accessing PrEP. In addition, the release of generic PrEP made it more difficult to facilitate client PrEP access for some clinics who depend on pharmaceutical reimbursements from the 340B program (Health Resources and Services Administration, 2019), as only brand name drugs are eligible for reimbursements.

Providers also discussed challenges with insurance coverage for youth and for CAB-LA. In fact, insurance barriers for CAB-LA were so challenging that some providers dissuaded their patients from taking it:

Mostly I don't bring it up [CAB-LA] because it feels like I can't really offer it, so I don't want to confuse anybody. And they'd be like, "oh yes, that sounds way better," and I'm like, "oh yes, it does, but you can't have it."

(P5, NYC)

Another provider, who was so frustrated by insurance challenges that they were "ready to leave medicine," shared that their organization had hired a full-time employee "just to do the insurance authorizations." (P7, NYC). They also discussed concerns about the dissolution of their clinic's 340B program, yet highlighted their continued commitment to advocating for PrEP patients' health:

And we're going through all these drug formulary changes in New York State right now. They just got rid of our 340B program. And so, there's a lot of policy changes that are affecting us right now. But we're very mission-driven and very mission-focused and very much... Like we're going to continue offering PrEP no matter what.

(P7, NYC).

These quotes highlight the time-consuming and often infuriating difficulties that providers faced with insurance companies in their efforts to prescribe patients CAB-LA.

Finally, the chilling effect of police presence at the clinic, particularly for Black and Latinx patients, was discussed in Birmingham:

One of the things that I don't like about our clinic is that we do have police presence. ... I feel like many folks—especially folks of color—have had negative experiences or perceived potential for negative experiences with the police. So, I just wonder ... you see the policeman standing at the front door ... do I really want to go?

(P3, BHM)

Inner Setting

Providers described their networks and communications, culture, and implementation climate, and readiness for implementation.

Networks and communications—Providers described methods employed by their clinics to effectively provide streamlined services to their patients, including the important role of front desk personnel: “Our front desk now knows ... oh, you said the word ‘PrEP,’ let me send you to [name of provider].” (P3, BHM)

Culture—Clinics had varying levels of staff diversity, with all but one of the clinics having mostly White staff. A Birmingham provider discussed the tremendous impact that having a Black PrEP coordinator had on their clinic:

If we're going to sit there and try to promote this to a community that definitely I don't match and I'm not part of, then we need to hire people or have people on staff that can relate to that. ... Our PrEP Coordinator is a Black MSM. And that significantly has helped increase those numbers in that population. Because it's more relatable. ... Our retention, prior to doing that, was probably 35%. Now, we're up to like in the 90s as a result. So, it's really made a difference.

(P13, BHM)

A NYC provider shared that their organization provided both HIV and primary care on-site, noting the positive impact that this status-neutral approach had on decreasing stigma.

Implementation climate—Providers' discussions of their implementation climates were unanimously positive. A BHM provider expressed interest in increasing PrEP services at their clinic to become more “status neutral” (compatibility), while providers from both

locations shared that their clinics regularly provided cultural competency, antiracism, and HIV prevention and treatment trainings to staff (learning climate). One of the Birmingham organizations incentivizes employees who refer and link individuals to PrEP (organizational incentives and awards):

So, we have an incentive program with our employees, if they were to refer someone here for PrEP, they scan a QR code, they bring their QR code here. That employee gets the incentive, but that's one way that people come.

(P4, BHM)

Readiness for implementation—While clinics had favorable leadership engagement, some faced resource limitations. Several providers discussed having limited time to meet with their patients during short 15-minute visits, as well as a shortage of clinic staff:

So, screening-wise, we are a little bit more reactionary in our approach, at least for right now. And that's largely due to staffing. I would love to be more proactive, but you know we're just like everywhere else, limited by the number of staff we have.

(P4, NYC)

However, other providers shared that their organizations had a good clinic flow and were able to spend more time with patients while keeping wait times down.

Characteristics of individuals

Providers discussed knowledge and beliefs about the Intervention (facilitator) and self-efficacy (mixed—both barrier and facilitator).

Knowledge and beliefs about the intervention—Providers were universally knowledgeable about daily oral PrEP. However, they had varying levels of knowledge about the other two PrEP modalities. One provider was unaware of on-demand PrEP. Regarding CAB-LA, most providers were fairly knowledgeable in prescribing and counseling practices ($n = 12$; 80%), with remaining providers having less familiarity with how to prescribe it to patients:

Personally, I'm not as knowledgeable to injectable PrEP, just not, you know, having more knowledge of it. I know usually with new medications it tends to be a lot more challenging to get, but I'm not as knowledgeable, so which is why I haven't really prescribed it.

(P1, NYC)

Self-efficacy—While all providers were comfortable with daily oral PrEP, attitudes toward on-demand PrEP and CAB-LA varied. Three of the providers (20%) were hesitant to prescribe on-demand PrEP due to complexities of the dosing schedule and underscored the importance of patient education:

I have to give them a graphic because it's confusing to just explain it. And also the fact that if people are doing 2-1-1 more than four times [a month], they might as well be on daily PrEP because they're already kind of taking lots of pill in a

week. So, I give them a picture. A conversation isn't enough. I need to give them a handout to take home with them.

(P6, NYC).

Providers also had mixed attitudes on prescribing CAB-LA. One concern was that patients would seroconvert early in the process:

You know I think by starting on the oral route too is it gives us the opportunity to get them started, and you know we're not withholding any type of PrEP while we navigate through any barriers. You know, my concern would be that they might seroconvert before you know they had a chance to get started.

(P4, BHM)

Other concerns were lack of insurance coverage and lack of adequate knowledge.

Mixed Methods

The quantitative and qualitative findings closely aligned. Overall, providers spoke about their organizations favorably (inner setting). They were also highly aware of the needs of their patients (patient needs and resources, $M = 4.0$, $SD = 0.70$), although qualitative interviews revealed areas where more organizational change was needed (e.g., expanded language services; more diverse staff). Constructs related to the implementation climate were favorable, particularly the Implementation Leadership Scale ($M = 4.02$, $SD = 0.72$), illustrating that providers felt supported by clinic leadership in both learning about and implementing PrEP and evidence-based services. This was also demonstrated in the qualitative data, where providers discussed both a considerable knowledge on the provision of daily oral PrEP, with most knowledgeable about other PrEP modalities as well. However, culture stress ($M = 3.82$, $SD = 0.73$) was high at our study sites, as evidenced in providers discussing large workloads exacerbated by challenges with insurance companies and 340B.

Discussion

This formative work elucidates providers' knowledge of and attitudes towards multiple PrEP modalities and helps provide a roadmap for implementation of the mChoice intervention to increase PrEP uptake and persistence among Black and Latino MSM. Applying CFIR as a framework, we uncovered key barriers and facilitators to implementation that underscore the importance of pre-implementation work. Clinics in our study are generally prepared and resourced to expand and increase PrEP services among MSM; however, key outer setting barriers were identified. To our knowledge, this is the first study that explores providers' attitudes towards and experiences with all three PrEP modalities in both New York City and Birmingham, Alabama.

While providers were highly familiar with the clinical evidence supporting PrEP's efficacy, three providers (20%) were not comfortable prescribing on-demand PrEP. These providers shared concerns that on-demand PrEP does not adequately protect patients against HIV acquisition, citing its complex dosing schedule and room for patient error. To our knowledge, ours is the first study to elicit PrEP providers' feedback on on-demand PrEP. Yet, a recent survey conducted with MSM found that adherence to a 2-1-1 regimen was

high (> 84%) and patients appreciated the opportunity to take fewer pills (Camp & Saberi, 2021), suggesting that some of the concerns reported by providers in our study may be unfounded. Regarding CAB-LA, all providers shared enthusiasm for integrating it into their clinics, although three desired additional education on this newest PrEP modality. Providers discussed how CAB-LA was superior to oral PrEP and felt that it was a good option for patients who needed to take PrEP discreetly, particularly those experiencing intimate partner violence. However, all providers encountered such immense challenges with insurance that they were unable to reliably offer it to their patients, a finding which is corroborated in the literature (Keddem et al., 2024). CAB-LA is not covered under most insurance programs, a prominent barrier to its uptake (Zapata et al., 2023).

Another key outer setting barrier involved the impact of PrEP policy changes on PrEP revenue. Providers shared that their clinics depend on funds from the 340B Drug Pricing Program to offset the costs of prescribing PrEP to underinsured and uninsured patients. Since 2010, 340B entities have been able to contract with retail pharmacies who dispense 340B-discounted drugs to covered patients (Health Services and Resources Administration, 2018). Whenever patients with insurance at 340B entities fill prescriptions for 340B-eligible drugs, the entity is able to keep the delta (reimbursement for the average manufacturer's price of the drug minus the discounted 340B price), with the goal of using these drug rebates to invest in patient services' and "stretch scarce federal resources as far as possible" (Health Resources and Services Administration, 2019). While clinics have long used this method as a way to offset the costs of purchasing PrEP for patients without insurance (Killelea et al., 2022), the end of Gilead's Advancing Access patient assistance program, in addition to the release of generic PrEP, has cut off critical funding streams and led to millions of dollars of losses for some clinics, particularly in states such as Alabama that have not expanded Medicaid (Straube, 2023).

While some clinics had a racially diverse staff, others noted that providers at their clinics were mostly White. All but one of the clinic sites lacked enough Spanish-speaking staff to adequately serve the needs of their Latinx patients, despite having large numbers of Spanish-speaking patients, and depended on external interpreter services. Indeed, lack of culturally and linguistically informed resources for Spanish-speaking patients has been recognized as one of the top barriers in increasing PrEP uptake among Latino MSM (Zapata et al., 2023). Yet, a provider at a Birmingham clinic, which had recently hired a Black MSM PrEP coordinator, spoke about the dramatic and positive impact that this individual had on increasing visit adherence among PrEP patients, underscoring the importance of racial diversity in clinic staff (Quinn et al., 2019). This finding also emphasizes the significant impact of programs led by individuals who represent the communities they serve.

Much has been written about health disparities along the HIV prevention and treatment continua in the U.S. South, which bears the brunt of the domestic HIV epidemic (Centers for Disease Control and Prevention, 2024); however, there were few notable differences between Birmingham and New York City clinics. Clinic police presence was also raised as a barrier to accessing care in Birmingham, particularly for Black and Latinx patients. Black and African American patients are more likely to be targeted by security than White patients

in healthcare settings (Valtis et al., 2023) underscoring the importance of creating healthcare spaces that are safe and welcoming to all patients.

Our study is not without limitations. While providers were prompted to explore the provision of PrEP as it relates to Black and Latino MSM, few discussed the barriers these patients face in accessing and utilizing PrEP in clinical settings or provided a nuanced description of the unique challenges Black versus Latino MSM experience. Providers more often spoke about PrEP in their clinics more broadly, without attention to racial or cultural considerations. We collected data from providers who were already providing PrEP, thereby facilitating implementation of mChoice. Providers located in clinics that do not support the provision of PrEP or who lack the infrastructure needed to do so would likely have had much different clinical experiences. Due to a small study sample, we were unable to assess differences in CFIR measures between geographic locations or other associations, and our descriptive survey findings should additionally be interpreted with caution. We also included providers from just four clinics in two states, whose experiences may not be generalizable to other locations. In addition, we did not have data on patient perspectives regarding PrEP access and uptake. The views expressed by providers may or may not overlap with their patients.

In conclusion, our mixed methods study informs implementation of mChoice, a multisite trial for young Black and Latino MSM, and highlights barriers and facilitators within key CFIR domains. Our study also provides valuable clinical insight for nurses, other practitioners, researchers, and policymakers into providers' attitudes towards and experiences with multiple PrEP modalities, including daily oral, on-demand, and injectable PrEP. Other clinics and providers can integrate some of the successful organizational strategies into their own practices, such as incentivizing employees who refer and link individuals to PrEP and increasing racial and cultural diversity among providers and other clinic staff to better meet the needs of diverse patients. Additional guideline-informed provider training is needed to address barriers to providing different PrEP modalities, particularly CAB-LA. Structural changes (particularly around medication costs) are needed to support providers in offering newer PrEP modalities like CAB-LA, for which health insurance coverage is challenging. Policy change is also needed to offset the rising costs of PrEP due to changes with the 340B Drug Pricing Program.

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Data Accessibility Statement

The authors will make data available upon request.

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Key Considerations

- While PrEP providers demonstrate high confidence and comfort with daily oral PrEP, there is less comfort with newer modalities (e.g., injectable PrEP).
- Clinics demonstrate strong implementation climates with regular staff training in cultural competency and HIV prevention. However, high workplace stress and limited patient visit times constrain service delivery.
- Rising PrEP costs and 340B program changes are the primary challenges facing PrEP service delivery.
- Increasing PrEP delivery will require a multi-faceted approach focusing on both structural and organizational changes. This includes expanding provider training on newer PrEP modalities, addressing insurance barriers particularly for injectable PrEP, diversifying clinical staff, and creating more culturally informed environments.

Table 1:
Provider Demographic and Job Characteristics of PrEP Providers in BHM and NYC ($N = 19$)

Variables at Baseline	Mean	SD
Age	37.7	8.5
Number of years working at current organization	6.2	5.2
Number of years working with young MSM	8.2	6.9
	n	%
Site		
BHM	8	42.1
NYC	11	58.0
Gender*		
Cisgender woman	9	45.0
Cisgender man	6	30.0
Transgender man	2	10.0
Non-binary	2	10.0
Something else not listed	1	5.0
Race*		
Black or African American	1	5.3
White	15	79.0
American Indian or Alaskan Native	1	5.3
Asian	1	5.3
Native Hawaiian or Other Pacific Islander	1	5.3
Prefer not to answer	1	5.3
Ethnicity		
Not Hispanic or Latino	16	84.2
Hispanic or Latino	3	15.8
Education		
Bachelor's degree	1	5.3
Master's degree	9	47.4
Doctoral or professional degree	9	47.4
Work Position*		
Behavioral health provider	2	10.5
Medical provider	15	79.0
Case manager	2	10.5
Linkage to care specialist	1	5.3
Outreach specialist/educator	2	10.5
Administrator	3	15.8
Supervisor	2	10.5
Study team member	1	5.3

Note. BHM = Birmingham, Alabama; NYC = New York City, New York

* Participants could choose more than one answer

Table 2.
Organizational Characteristics of Clinics Providing PrEP Services in Birmingham and New York City

CFIR domain	Scale or subscale	Mean (SD) α
Inner setting	Culture	3.31 (0.78) $\alpha = 0.85$
	Learning climate	3.43 (1.03) $\alpha = 0.95$
	Culture stress	3.82 (0.73) $\alpha = 0.68$
	Culture effort	3.82 (0.60) $\alpha = 0.71$
	Implementation Leadership Scale	4.02 (0.72) $\alpha = 0.89$
	Implementation climate for Young MSM	3.72 (0.74) $\alpha = 0.79$
	Focus on EBPs	3.70 (1.17) $\alpha = 0.97$
	Educational support for EBPs	3.22 (1.05) $\alpha = 0.94$
	Recognition for EBPs	3.07 (1.27) $\alpha = 0.87$
	Selection for EBPs	2.93 (1.40) $\alpha = 0.95$
	Selection for openness	3.45 (1.24) $\alpha = 0.98$
	Rewards for EBP	1.23 (0.73) $\alpha = 0.56$
Outer setting	Patient needs and resources	4.0 (0.70) $\alpha = 0.887$

Note. EBP = Evidence-based practice, MSM = Men who have sex with men

Means Range: 1–5

Table 3:

Representative Provider Quotes Illustrating Barriers and Facilitators to Increasing PrEP Uptake and Persistence among Young Black and Latino MSM at Clinics in Birmingham and New York City

CFIR domain, construct, and subconstruct	Representative quotes
Intervention characteristics	
Evidence strength and quality	<u>Facilitator:</u> From an efficacy standpoint, we're going to stand by the PrEP products. They've been tested. They've been tried. Real world is even better efficacy than controlled trials. (P3, BHM)
Relative advantage	<u>Barrier:</u> One of the things I do not do is I really discourage the PrEP on-demand. We don't really do that in our practice. Because I feel that having that conversation, basically puts in the mindset of our patients that, oh, ok, well I can just go out and have sex, and just do this PrEP on-demand thing. (P13, BHM) <u>Facilitator:</u> I think some of the online things have been great for the younger community. I guess some of them, MISTR, Q Care Plus—things like that have been great. They can do it from their own house. (P15, BHM)
Design quality and packaging	<u>Barrier:</u> Our office right now is very bare. ... There's nothing on the walls. There's not a lot of signage. And the signage that we do have is typically just in English or in Spanish. ... Although there is a predominately Hispanic population, we do see a lot of patients of other ethnicities. And so I do feel like if we could have a few more inclusive, language-inclusive signs available, not just in the waiting areas, but also in the rooms, it would be ideal. (P9, NYC) <u>Facilitator:</u> I think social media has been really influential. They all talk to each other, so if you can get one out there who is willing to say, hey, I am on PrEP, talk to me about it, that's huge. (P3, BHM)
Outer setting	
Needs and resources of those served by the organization	<u>Barrier:</u> There's definitely a lot of Spanish speakers [among our patient population]. We have, there's only one NP [nurse practitioner] here that speaks Spanish, so the other providers, like myself, I don't speak Spanish. (P2, NYC) <u>Facilitator:</u> We've done QI/QA projects looking at folks testing positive for other STIs, and making sure that at every treatment visit, if someone's not living with HIV, diagnosed, on treatment, off treatment, whatever, and they're not on PrEP, that they're counseled on PrEP. (P6, NYC)
External policy and incentives	<u>Barrier:</u> I'm just trying to get as many people on Cabotegravir as possible. And insurance has made it nearly impossible to get anyone on. And I think that's the biggest barrier right now to PrEP access is the way we pay for medicine in this country, which is ridiculous. (P7, BHM)
Inner setting	
Networks and communications	<u>Facilitator:</u> We partner with a pharmacy in our building. And a lot of times, we use them for dispensing the medication. So they have a big part in our care team as well I would say. (P14, BHM)
Culture	<u>Barrier:</u> When all of your leadership is cis White; gay, maybe. You don't see yourself represented, why would you want to receive services there. I worry about us in that sense from a community perspective. With HIV people really have little choice in terms of what's available in the area ... our staff is very White. (P3, BHM) <u>Facilitator:</u> We also collocate our HIV care with our primary care. And all of our nurse practitioners and primary care, like our internal medicine PCPs can manage HIV care patients, just integrated in the clinic with other patients. And so there's not this kind of like separate physician stigma that can be associated with that. All of our patients, HIV positive or negative, can come in and get care from all the providers. (P11, NYC)
Implementation climate	
Compatibility	<u>Facilitator:</u> I think that if we want to really think of being more of a status neutral clinic, in that you know we're able to easily adapt to doing a prevention visit, versus seeing someone living with HIV. You know I think people might be open to having more interaction with all things, prevention. (P4, BHM)
Learning climate	<u>Facilitator:</u> We've started doing monthly HIV 101s, just for staff. We have new staff who are brought on all the time. (P3, BHM)
Readiness for implementation	
Leadership engagement	<u>Facilitator:</u> One of our providers has taken the lead as our champion since our medical director has left. (P3, BHM)
Available resources	<u>Barrier:</u> Yeah, so the biggest challenge would be, you know having time blocked off to see a patient for 15 minutes to talk specifically about PrEP. And also, to tell the patient, hey, like I can't talk to you about anything else because I don't have time. (P2, NYC)

CFIR domain, construct, and subconstruct	Representative quotes
	<u>Facilitator:</u> We have a really quick turnaround on most of our lab draws, so we are able to get folks if they want to do PrEP. We actually have space ... time to see them. We try to get them in as soon as possible. Everyone gets in either next available or at their convenience. (P10, BHM)
IV. Characteristics of individuals	
Knowledge and beliefs about the intervention	<u>Facilitator:</u> One, you know I think Aprelude, the injectable, is statistically superior than the oral medication. But as far as the oral medication goes, you know they're both equally effective and incredibly safe. (P4, BHM)
Self-efficacy	<u>Barrier:</u> I mean, honestly, I will prescribe [daily oral] PrEP to anybody who asks for it. I think that should be the standard really for PrEP, because there is a lot of trauma in the gay community around HIV. (P5, NYC) <u>Facilitator:</u> I haven't really been offering the injectables at all. One, because I'm not really well-versed in the injectable PrEP therapy. It's fairly new. (P9, NYC)

Note. NYC = New York City; BHM = Birmingham, Alabama; P = participant.