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ORIGINAL RESEARCH

Insurance- and medical provider-related barriers and facilitators to staying on PrEP: results from a qualitative study

Alexa B. D'Angelo,[1,2] Javier Lopez-Rios,[1] Anthony W. P. Flynn,[3] Ian W. Holloway,[4] David W. Pantalone,[5,6] Christian Grov[1,2]

[1]Graduate School of Public Health and Health Policy, City University of New York, New York, NY
[2]Institute for Implementation Science in Population Health, City University of New York, New York, NY
[3]Department of Counseling Psychology, University of Wisconsin – Madison, Madison, WI
[4]Department of Social Welfare, University of California, Los Angeles, CA
[5]The Fenway Institute, Fenway Health, Boston, MA
[6]Department of Psychology, University of Massachusetts – Boston, Boston, MA

Correspondence to: Christian Grov, cgrov@sph.cuny.edu

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Abstract

Pre-exposure prophylaxis (PrEP) is a highly effective biobehavioral strategy for preventing HIV acquisition. Although PrEP uptake has increased steadily, discontinuation rates are high among members of key populations like gay and bisexual men (GBM). Understanding the challenges that arise for PrEP users is key to better PrEP implementation and sustained use over time. We report on barriers that arose for PrEP-using GBM, as well as facilitating factors that aided PrEP persistence, with the goal of informing PrEP implementation efforts. In 2015–2016, 103 PrEP-using GBM in NYC completed qualitative interviews about their engagement with PrEP, including their experiences navigating PrEP-related medical care. Interviews were transcribed verbatim, coded, and analyzed thematically. Over half of participants (53%) received their PrEP-related care from their primary care provider (PCP), one-third (33%) from a community-based health clinic, and 13% from multiple medical providers. Emergent themes regarding the barriers and facilitators to PrEP persistence fell into two categories: insurance- and medical appointment-related barriers and facilitators to continued PrEP use. The experiences of PrEP-using GBM can provide useful insights for providers, program developers, and policymakers aiming to improve the implementation of PrEP. To support PrEP persistence, reliable insurance coverage, cost-assistance, and easy appointment scheduling are key to maintenance. Removing insurance- and appointment-related barriers to persistence may prove essential for sustaining use among GBM.

Keywords

Pre-exposure prophylaxis, HIV prevention, Gay and bisexual men, MSM

Implications

Practice: Exploring alternate testing options and less onerous pre-exposure prophylaxis (PrEP)-related clinical practices will help alleviate medical provider-related barriers to staying on PrEP.

Policy: Policymakers who want to improve PrEP persistence should explore policies that prevent prior authorization and mandated pharmacy requirements from acting as barriers to PrEP renewal.

Research: Future research should explore the prevalence of insurance- and medical provider-related challenges facing PrEP users in an effort to gain a more complete picture of barriers to staying on PrEP.

INTRODUCTION

Once-daily [emtricitabine and tenofovir disoproxil fumarate], for use as pre-exposure prophylaxis (PrEP), was FDA approved in 2012, and today is one of the most promising biobehavioral strategies for preventing HIV among key populations like gay and bisexual men (GBM). PrEP users who maintain daily adherence experience over a 90% reduction in HIV acquisition risk [1, 2]. Although there is a growing body of research on the many barriers to *initiating* PrEP use [3–6], there are limited data on the barriers that arise for those attempting to *remain* on PrEP over time. PrEP discontinuation undermines the HIV prevention benefits of PrEP for those at the highest risk for HIV, attenuating HIV prevention efforts on a population level.

There is increasing evidence that a significant proportion of GBM who begin a PrEP regimen discontinue the medication shortly thereafter [7, 8]. One observational study of young GBM on PrEP found that younger age and having fewer than three sex partners were associated with PrEP discontinuation [9]. Furthermore, data from publically funded primary care clinics revealed higher discontinuation among Black participants and injection drug users [10]. Currently, there are limited published data concerning the reasons GBM discontinue PrEP, as well as the demographic and behavioral factors associated with discontinuation. One U.S. national study of 1,071 GBM found that 18% of participants reporting having once used PrEP later discontinued [7]. Participants reporting discontinuation were more likely to report lower-perceived risk, loss or insurance or cost issues, leading to discontinuation [7]. Additionally, a longitudinal cohort of 197 GBM found that 33% of participants reported

having discontinued PrEP use within 6 months of initiation [8]. Similarly, participants reported insurance issues as a reason for discontinuation, as well as difficulty in attending PrEP-related medical appointments [8]. Likewise, clinical data from a federally qualified health center in Los Angeles found similar rates with discontinuation, with 32% of PrEP users abandoning the prophylactic within 3 months and 45% discontinuing 6 months post-initiation [11]. In this clinic, patients accessing PrEP without a copay were more likely to continue use over time [11]. Meanwhile, other studies have reported that decreased sexual risk taking and decreased perceived HIV risk were reasons provided for PrEP discontinuation, as well as insurance issues, difficulty attending PrEP-related clinical appointments, and acute medication side effects [7, 8, 11–13]. Taken together, these and other findings highlight the need for data on the factors associated with PrEP discontinuation, as well as a greater understanding of the real-life barriers that occur for GBM attempting to *remain* on PrEP. Understanding the barriers that arise in real life (i.e., outside of research studies) for GBM attempting to renew a PrEP prescription is key to ensuring that PrEP users maintain adherence to their PrEP regimen for as long as needed.

In addition to offering insights into why GBM discontinue PrEP, further research is needed to understand better the strategies and facilitating factors that aid GBM in overcoming the inherent challenges to PrEP persistence. Data from individuals who maintain PrEP usage may provide important insights for informing programming and implementation efforts aimed at sustaining PrEP use among PrEP-eligible GBM over time. Additionally, efforts to scale-up PrEP use to a population level will require a significantly more nuanced understanding of the barriers to PrEP maintenance—and strategies for addressing them successfully—to facilitate maximal PrEP uptake for eligible individuals and current PrEP-taking GBM.

To increase our understanding of the challenges facing PrEP users, as well as the factors the help users overcome barriers to continuing PrEP, we conducted a qualitative study with PrEP-using GBM. We explored topics related to paying for PrEP and related medical costs, as well as attending PrEP-related medical appointments. Our goal was to inform PrEP implementation efforts aimed at sustaining PrEP use over time.

METHOD

Participants and Procedures

Data for this manuscript come from PrEP & Me, a prospective mixed-methods study conducted in New York City about urban GBM's experiences with PrEP. The study and its methodology has been described in detail elsewhere [14–16]. In brief, participants were recruited in 2015–2016 via targeted sampling [17]. Recruitment methods consisted of advertising and preliminary eligibility screening in sexual-minority concentrated neighborhoods and settings (e.g., gay bars, pride events, LGBT community-based venues), and digital recruitment of GBM via social and sexual networking websites/apps, and various social media platforms.

Eligible participants were 18 years or older and male; identified as gay or bisexual; had been taking PrEP for 30+ days but not via a research study that provided the PrEP medication; lived in the New York City (NYC) area so that they could attend in-person study visits, including the qualitative interview; and needed access to the internet to complete online study assessments (data presented elsewhere). One goal of the parent study was to examine the role of club drug use on PrEP adherence. Accordingly, half of the sample self-reported club drug use within the past 30 days. Club drugs included ketamine, MDMA/ecstasy, GHB, cocaine, and methamphetamine. All participants provided evidence of PrEP use by bringing to the study visit their prescription bottle with their name printed on it. Participants were compensated $40 for the assessment that included the semi-structured qualitative interview. All procedures were approved by the IRB of the IRB of the City University of New York.

Measures

Each participant completed an in-person, one-on-one, semi-structured interview that lasted from 30 to 45 minutes. The interview covered a range of topics, including how participants first learned about PrEP and why they decided to begin taking PrEP. Participants were also asked how they pay for PrEP, and about any hurdles they encountered to gaining or maintaining financial coverage for their PrEP prescription and/or PrEP-related medical appointments. These latter questions generated the data presented in this article.

Participants also completed a computerized survey that assessed demographic characteristics that are also reported in this article.

Analysis Plan

Interviews were transcribed verbatim, and initial transcripts were independently verified against the original audio file by a second staff member. Using the principles of thematic analysis, members of the research team reviewed the transcripts to code the narratives about participants' experiences engaging in PrEP-related medical care [18]. Thematic analysis is shown to be an effective method for evaluating exploratory qualitative data and has been employed previously in HIV-related research with GBM [19–21]. A coding team comprising the Principal Investigator and the first author developed a codebook from the interview guide and a close-read of a subset of 40 transcripts. One additional staff member was trained to

use the codebook to identify text that represented the codes [22, 23]. The first author initially coded all transcripts, and over 20% of those codes were then independently verified by the second author. The first author also reviewed coded transcriptions for overlap and discrepancies. Any discrepancies were discussed with the coding team and we reached 100% consensus over the application of each code. Throughout the coding process, the team adjusted the codebook to reflect emergent data from the transcripts. Additionally, the first author identified and tracked markers that could relate to PrEP persistence, including the type of medical provider participants received PrEP-related care from, as well as the frequency of PrEP-related medical appointments. The second author reviewed the application of these additional codes as a quality assurance measure.

RESULTS

Table 1 details the self-reported demographic characteristics of the sample. The sample's mean age was 32.5 years old, and nearly half (47%) were men of color. Over half of participants (53%) received their PrEP-related care from their primary care provider (PCP), one-third (33%) from a community-based health clinic, and 13% from multiple medical providers. Of those who described the frequency of their PrEP-related appointments (n = 96), 82% said they attended at least every 3 months, as recommended in PrEP treatment guidelines [24]. The remaining 18% indicated that they attended PrEP-related medical appointments less frequently. Emergent themes regarding the barriers and facilitators to PrEP persistence fell into two salient categories, these were *insurance-* and *medical appointment*-related barriers and facilitators to continued PrEP use. Although GBM is an important population to study due to high rates of HIV acquisition, the results that emerged did not appear to be related to GBM identities but, rather, were largely the result of systemic barriers to medical care, as well as logistical factors that make attending frequent medical appointments difficult.

In total, 39% of participants described insurance-related barriers specifically regarding prescription drug coverage and prescription access. Barriers to filling prescriptions were often attributed to insurance mandates. These included the need for prior authorization from an insurance company before they would renew a prescription, as well as mandates to renew prescriptions via a narrow set of pharmacies, particularly mail-order pharmacies. Both mandates were cited as causing delays in PrEP initiation as well as prescription renewals, causing poorer adherence due to running out of medication between renewals. Participants experiencing prior-authorization delays described arriving at their pharmacy to pick up their PrEP refill, where the pharmacist, who first had to confer with their doctor or insurance company before they could fill the participant's prescription, denied their request.

Table 1| Descriptive demographic characteristics of gay and bisexual men taking PrEP in NYC 2015–2016 [25], N = 103

Characteristics	M ± SD or n (%)
Age	32.5 ± 8.7
Race/ethnicity	
Black	12 (11.7)
Latino	27 (26.2)
White	52 (50.5)
Multiracial	9 (8.7)
Other	3 (2.9)
Education	
High school diploma, GED or less	6 (5.8)
Some college	23 (22.3)
4-year college degree	53 (51.5)
Graduate school	21 (20.4)
Employment	
Full-time	60 (58.3)
Part-time	24 (23.3)
Unemployed	19 (18.4)
Income	
Less than $10,000	13 (12.6)
$10,000–$19,999	7 (6.8)
$20,000–$29,999	14 (13.6)
$30,000–$39,999	11 (10.7)
$40,000–$49,999	14 (13.6)
$50,000–$74,999	22 (21.4)
$75,000 or more	22 (21.4)
Length of time on PrEP	
1–3 Months	15 (14.6)
3–6 Months	23 (22.3)
6–12 Months	27 (26.2)
1–2 Years	28 (27.2)
More than 2 years	10 (9.7)
Missed taking PrEP in the last 90 days?	
Yes	63 (61.2)
No	40 (38.8)
How long ago did you miss a dose? Among n = 63	
Today	1 (1.6)
Yesterday	2 (3.2)
2–3 days ago	9 (14.3)
4–7 days ago	18 (28.6)
2–3 weeks ago	15 (23.8)
4–6 weeks ago	9 (14.3)
7–9 weeks ago	6 (9.5)
10–12 weeks ago	3 (4.8)

> I did have a couple of instances where there was a prior-authorization needed and it delayed me getting the medication... (Age 28, Latino, 3–6 Months on PrEP)
>
> There were a lot of insurance hurdles. Oh, and obstacles and prior-authorization, and waiting for different

offices to call each other, which sort of galvanized me more and more as an advocate." (Age 25, White, 1–2 Years on PrEP)

It's a pain in the ass. Pre-approvals, repeat phone calls from my doctor to re-certify, and all this stuff. I don't know how it happened, but essentially I think there was a mix-up at one point, and I actually ended up having – I have one month's buffer in my supply which is really good because sometimes there'll be a week delay between when my doctor can redo this whole stupid process. So, yeah, there are barriers. The biggest one is my insurance company, it's not [my personal] money." (Age 37, White, 6–12 Months on PrEP)

Mail-order pharmacy mandates arose as another insurance-related barrier to PrEP persistence, with some reporting discomfort receiving PrEP via mail due to privacy concerns. However, more often participants cited mandated mail-order pharmacies as a threat to adherence. For example, some mail-order pharmacies require carefully timed prescription re-orders to ensure that refilled prescriptions arrive in time to maintain adherence, creating a challenge for some. Additionally, delivery delays by mailing services acted as barriers to maintaining consistent PrEP use. Nevertheless, concerns about mail-order pharmacies were not endorsed by all users, with some participants expressing appreciation for the convenience of receiving their prescription through the mail in lieu of an in-person pharmacy visit.

The only issue I've ever run into was that they wanted to basically force me to go through a mail-order pharmacy, and I wasn't really comfortable with that. I had to get some sort of exception or waiver so that I could go and pick it up at my [local] pharmacy… It's what the insurance companies do. They pay less for it if you go through *this* [mail-order] company. And so, they tell you, "You have to go through this company." (Age 46, Black, 1–2 Years on PrEP)

When I first was getting it, it was tough because… my insurance stopped giving it to me because, I guess you have to at a certain point switch to a mail pharmacy. I guess it's cheaper [for them], so I basically had a period of time where I was freaking out because I couldn't get the mail service pharmacy to deliver on time." (Age 30, Other, 1–2 Years on PrEP)

Several participants described high out-of-pocket prescription costs and lab fees as burdensome, and a challenge for maintaining PrEP use. Out-of-pocket expenses generally included high copayments or deductibles, as well as lab tests not covered by insurance. However, in one case, a lapse in insurance coverage caused high out-of-pocket costs for maintaining PrEP during the break in coverage. Participants experiencing high out-of-pocket costs reported searching for cost assistance programs to maintain their PrEP use.

It's becoming an issue because my insurance only covers half of the quarterly STI testing. So, I owe this lab $250 for part of that testing and I think, over the long term, that may become an issue. And it's something I'm trying to figure out how do I deal with it." (Age 48, Multiracial, 1–2 Years on PrEP)

There was actually a period of time where I fell through the cracks for a week, so I paid retail price for the medication. It was like sixty or seventy dollars a pill or something, it was like $300 for a week, it was harsh."(Age 50, White, More than 2 Years on PrEP)

Participants also reported challenges to maintaining their PrEP prescription as a result of job and insurance plan changes, which in turn made it difficult to continue taking PrEP uninterrupted. Some reported insurance changes because of job termination or job switches. Others described situations in which employers altered the insurance plan or provider that they offered to employees, which subsequently lead to a cascade of insurance-related barriers to continuing their PrEP prescription. These included barriers to gaining coverage through a new plan and/or the addition of bureaucratic barriers to care (e.g., prior-authorization). Furthermore, one participant described a government-subsidized insurance termination, which impeded his ability to remain on PrEP.

Strangely enough, I didn't think it would be that big of a deal. But it was a huge big deal, when my insurance transferred [from one company to another] and the new prescription insurance company wouldn't pay for PrEP. … Right now, I'm in the process of appealing the decision and my pharmacist thinks that they'll probably end up approving it, although that is not yet 100% set in stone. If I find out that, you know, either my insurance isn't going to cover it or whatnot, I don't know what I'm going to do. (Age 37, White, 3–6 Months on PrEP)

A significant minority (29%) of participants reported systemic challenges related to attending quarterly PrEP-related medical visits. These included difficulty scheduling appointments with their physician due to limited appointment availability (e.g., no after-work or weekend availability, long delays between scheduling and available appointments), as well as physician staff turnover. "Sometimes, [as he has difficulty scheduling appointments], I was supposed to have to have an appointment in September but they were all booked up, so I have it in October" (30362, Age 30, White). On the other hand, some participants described personal barriers to attending PrEP appointments and, thus, maintaining seamless PrEP prescriptions. Personal barriers impeding PrEP-related appointments included busy work schedules, frequent travel plans, and competing priorities, which made attending quarterly medical visits difficult.

> Work—that's the thing. Work changes my schedule all the time. … My job is very demanding. And, even though I have a [medical] appointment, sometimes I want to meet a work deadline, [and that comes] before my health, for some reason." (Age 27, Latino, 1–2 Years on PrEP)

Participants also reported facilitators to continued PrEP use. Although participants expressed a range of challenges they encountered in attempting to maintain PrEP adherence, many also offered examples of facilitating factors that aided their overcoming barriers that arose. Cost-related facilitators were endorsed by 96% of participants. The most frequently reported cost-related facilitators to PrEP access were consistent insurance coverage for PrEP and medication cost-assistance programs. Although some participants described lapses in insurance coverage, most experienced consistent coverage for PrEP prescriptions and many noted that they experienced no insurance barriers to PrEP initiation. Both participants with private insurance as well as those with government-subsidized plans expressed consistent coverage for their PrEP prescriptions.

> I was really kind of surprised, I mean, because I'm on Medicaid and you know sometimes they are really just outlandish with their requirements… but this was not an issue at all. I was really surprised that I didn't even get a prior-authorization issue." (Age 46, White, 3–6 Months on PrEP)
>
> My insurance pays for most of it and then there's like a $3 copay, so it's pretty sweet." (Age 21, Latino, 6–12 Months on PrEP)

Participants also described frequent use of cost-assistance programs, as important cost-related facilitators to PrEP use. These programs included Gilead's Copay Coupon Card program [26], for individuals with private insurance, as well as The Gilead Advancing Access® program [26], which provides cost assistance for individuals who are un- or under-insured. Additionally, participants described several other funding sources which they used to cover the cost of their PrEP prescriptions, including The Patient Access Network and local health departments [27]. Many participants who endorsed the use of a cost-assistance program expressed that, without financial assistance, they would not have been able to keep up with the cost of their PrEP prescription. Others noted that they appreciated the discount on the medication. In addition, some participants reported financial support from family members or partners for covering PrEP-related medical expenses.

"The copay for PrEP is covered completely by the Gilead copay assistance program, so I literally pay $0 for my PrEP. It's only the doctor's visits that I have to worry about, which my parents' insurance, again, takes care of that." (Age 24, Other, 6–12 Months on PrEP).

> I kept talking to different organizations about their programs and they kept trying to find me a program that would help me with the co-pay that wouldn't mess up my other drugs, you know, my other prescription plan. Finally, I found the Patient Access Network that provides the copay. So now I'm getting it for free. (Age 61, White, 6–12 Months on PrEP)

In addition, 10 participants reported that scheduling their quarterly PrEP-related medical appointments was an easy and convenient process. In these cases, some participants received reminder emails about quarterly appointments or alerts through a medical app or patient portal into their electronic medical records. However, for others, it was not always clear *why* scheduling and attending their PrEP-related appointments were easy. Several participants described personal factors that facilitated their PrEP use, including advanced knowledge of the healthcare system, payment support options, and insurance company policies. Lastly, some participants (11%) expressed that their health was their top priority and, thus, worth investing time and effort to address.

DISCUSSION

The aim of this paper was to explore the barriers to continuing PrEP among GBM in NYC. Understanding the challenges facing PrEP-using GBM is key for addressing issues of discontinuation and gaps in usage in this critical population. Although participants experiencing barriers to maintaining their prescription did not represent the majority, participants for whom this was part of their experience provided important insights into the challenges that arise for PrEP-using GBM in real life. Insurance-related challenges were the most frequently endorsed barriers to PrEP, particularly with regard to mandated (mail-order) pharmacies and prior-authorization, both of which resulted in delays in starting PrEP as well as renewing prescriptions, which resulted in gaps in medication adherence.

Insurance companies mandate prior-authorization requirements to ensure that prescribed medications are medically necessary. Prior-authorization requirements are applied to expensive drugs as a cost-containment strategy that encourages alternate medication options through the creation of barriers to high priced pharmaceuticals [28, 29]. However, these requirements often act as barriers to care by delaying patient's prescriptions or refills. The American Medical Association (AMA) recently reported that 92% of care delays can be attributed to prior-authorization issues [30]. According to an AMA survey of 1,000 providers, prior-authorization delays led to a one-day prescription delay for 64%

of patients, with 30% experiencing a reported delay of three days or more [30]. For GBM using PrEP, a delay of three days or more has the potential to significantly decrease the medication's HIV prevention power [31].

Significantly, one study found that prior-authorization requirements for non-preferred medications were associated with *complete* discontinuation of bipolar disorder medication in patients attempting to refill their prescriptions [32]. We could identify no published data concerning whether prior-authorization requirements lead to *complete* discontinuation of PrEP. However, future research should explore the potential for prior-authorization policies to lead to PrEP delays or discontinuation among GBM, as well as other key populations. Prior-authorization policies clearly present a threat to PrEP adherence and persistence. That said, legislative efforts to remove barriers to PrEP use are already underway in several states, and include removing prior-authorization requirements for PrEP. For example, in 2019, California passed legislation allowing pharmacists to furnish PrEP without a physician's prescription, and removed prior-authorization requirements for PrEP [33]. Additionally, in June 2019, the U.S. Preventive Services Task Force designated PrEP as a Grade A drug, effectively mandating most insurance companies to cover it without cost-sharing [34, 35]. However, Grade A recommendations do not remove barriers to access like prior-authorization, leaving room for further improvements in the removal of systemic barriers to PrEP [34]. Legislation aimed at removing barriers to continued PrEP use, including prior-authorization, could support PrEP users in maintaining consistent use; over time, maintaining their protection against HIV infection. Furthermore, by promoting greater flexibility in PrEP access, such legislation could facilitate PrEP-using GBM who adopt alternative dosing strategies, such as on-demand dosing (i.e., 2-1-1 dosing), whereby PrEP is taken only around episodes of condomless sex. Although on-demand dosing has yet to gain FDA approval, early data suggest that it is effective at protecting GBM from contracting HIV [36, 37].

Pharmacy mandates also arose as an insurance-related barrier, with some describing pharmacy mandates as an inconvenience, and others expressing that the required use of mail-order pharmacies led to prescription delays. Some participants described discomfort about receiving PrEP via mail due to the potential for delivery challenges, including delays because of holidays or inclement weather, providing additional challenges to maintaining PrEP adherence over time. On the other hand, some participants described mail-order pharmacy use as convenient, and appreciated not needing to pick-up their prescription in-person. Receiving mail-order prescriptions requires that patients maintain stable housing and be able to receive packages by mail. Although not a theme that arose among our participants, research suggests that LGBTQ youth experience higher rates of housing instability and homelessness [38]. Unstable housing and homelessness are also associated with a higher risk for HIV, potentially making unstably housed GBM a particularly vulnerable population that could benefit from PrEP use. Thus, unstably housed and homeless GBM represent a population that may be blocked from PrEP use in the event of a mandated mail-order pharmacy requirement. Given the variety of views expressed by our participants, as well as the potential for mandated mail-order pharmacies to impede access to PrEP among vulnerable GBM, PrEP-users should be given the option (but not mandated) to utilize mail-order pharmacies should it be more convenient for them than typical in-person pharmacy pick-up.

Several participants described insurance plan terminations or reduced coverage for PrEP as significant barriers to maintaining PrEP-use over time. Nevertheless, most participants reported that their insurance was successfully covering their PrEP medication. That said, USPSTF's Grade A recommendation will likely *increase* insurance coverage of PrEP without cost-sharing, alleviating the cost of PrEP for many users [35]. However, approximately 13% of insured individuals have plans that were "grandfathered" prior to ACA implementation, and thus remain exempt from Grade A requirements, including requirements to cover preventive services [39]. In this study, many who struggled to obtain or maintain insurance coverage for PrEP reported participation in cost-assistance programs such as Gilead's Advancing Access Program and The Patient Access Network Foundation. However, far more common was the use of Gilead's Copay Card program to assist with the copays and deductibles associated with their PrEP prescription. Although Gilead offers financial assistance to patients, thus shifting some of the cost of PrEP from the individual, the high overall cost of PrEP acts as a significant barrier to ensuring PrEP access to for GBM at risk of HIV acquisition. Currently, Gilead charges $1,600–2,000/month for Truvada [emtricitabine and tenofovir disoproxil fumarate] [40]. The high cost of PrEP poses significant barriers to scaling up PrEP to the population level, given that, at its current price point, universal access in the United States is not feasible [41]. Patient advocacy groups have been generating pressure to bring down the cost of PrEP through several avenues [42, 43]. These include pressuring the CDC to exercise its competing patent rights, as well as the NIH to discontinue Gilead's patent for Truvada as PrEP, allowing generic formulations to enter the market [44, 45]. In response to organized efforts, and a congressional oversight committee hearing [46], the Department of Health and Human Services filed a

patent infringement suit against Gilead Sciences in November 2019 [47]. Efforts to bring down the cost of PrEP are still underway and are likely to affect access to PrEP in the foreseeable future. Bringing down the price of PrEP is key to achieving universal access to PrEP through scaled-up implementation efforts and programming.

GBM experiencing appointment-related barriers, reported challenges scheduling PrEP-related medical appointments for a range of reasons. Barriers to scheduling and attending quarterly PrEP-related medical appointments arose as a result of both limited physician availability and hours, as well as busy personal lives, frequent travel and inflexible work schedules. Although some of these factors are outside of the control of medical providers, providing reminder emails and encouraging other creative reminder systems may be useful for PrEP users in improving attendance at quarterly appointments. For example, several studies have demonstrated that reminder emails, texts, and phone calls boost attendance rates at medical appointments [48–51]. Applying similar logic, PrEP users would likely benefit from consistent reminder systems regarding their quarterly check-up appointments. In fact, one participant mentioned that reminders from their provider helped them schedule and attend PrEP-related medical appointments. However, removing clinical barriers to PrEP may require more substantive policy changes, including relaxing clinical guidelines for quarterly visits under certain circumstances and implementing alternate options for lab workups in lieu of in-person testing [45, 52]. Indeed, HIV experts have suggested that at-home testing could potentially alleviate some of the burden created by quarterly follow-up appointments [52]. Furthermore, pilot data from a feasibility study of home-testing for PrEP users found the alternate protocol to be highly acceptable to participants [53]. CDC guidelines recommend biannual renal testing for PrEP users, which remains important for monitoring kidney functioning during continued PrEP use. Thus, offering the option of at-home HIV testing could alleviate half of quarterly in-person PrEP-related medical appointments for users demonstrating reliable adherence to PrEP. Furthermore, identifying alternate avenues for renal testing (lab testing, clinic testing etc.) could prove useful for patients experiencing barriers to primary care physician appointments. Exploring alternate testing options and less onerous PrEP-related clinical practices may prove integral for sustaining PrEP use among GBM over time.

Although some of the challenges experienced by participants led to gaps in PrEP use, many reported having overcome obstacles to maintaining their PrEP prescription and medical appointments. In one case, a participant described his motivation to become a PrEP advocate after experiencing insurance-related barriers. Similarly, several participants expressed that while maintaining their PrEP prescription was not always an easy process, protecting their health was worth the additional effort. Although these participants expressed an admirable commitment to protecting their health and the health of their sexual partners, sustaining PrEP use over time should not require the fierce willpower displayed by this subgroup of participants. Ultimately, sustained PrEP-use should be feasible for GBM, without requiring extraordinary skill, knowledge or effort to maintain the regimen.

Limitations

Data for this study were taken from open-ended, qualitative, semi-structured interviews in which participants recalled their experiences paying for PrEP and attending their PrEP-related medical appointments. This open-ended approach illuminated the challenges most salient for the participants, offering an in-depth exploration of barriers faced by participants attempting to maintain their PrEP use over time. However, we may have missed less salient barriers to sustained PrEP use due to our approach. Therefore, there may be additional issues for GBM hoping to maintain their PrEP prescription that our interviews did not identify. Qualitative methods are used for hypothesis generation and not hypothesis testing and, thus, an adequately powered quantitative study would be needed to assess the true prevalence of the multitude of challenges facing PrEP users. PrEP researchers would benefit from both open-ended and closed-ended approaches to investigating the challenges faced by PrEP users attempting to maintain use over time.

Overall, participants in this study were well-educated, employed, and made a living wage. This set of characteristics was perhaps emblematic of those who could gain access to PrEP when this study was conducted. That said, it is important to note that higher un- and under-insurance rates among people of color and low-income individuals, and variable Medicaid access dependent on the state of residence, mean that PrEP access differs by race and ethnicity, employment and income status, as well as state of residence [54–56]. Furthermore, structural barriers to PrEP persistence may also disproportionately impact people of color and low-income individuals who face greater structural barriers to medical care; thus, research on populations from a range of socioeconomic statuses is warranted to assess the burden of systemic barriers to PrEP persistence.

Our data were collected in 2015–2016, when PrEP was beginning to be adopted on a larger scale in NYC [57]—at a time and in a location where substantial resources were being implemented to increase PrEP adoption. Thus, our findings may not generalize to other locations and, as we have highlighted, the landscape for PrEP access is rapidly changing.

Additionally, we believe that many of our participants could best be classified as "early adopters." It may be that both GBM on PrEP at the time, as well as GBM willing to participate in a research study about their PrEP use, are different from those adopting PrEP today. Additionally, participants in this study were generally highly adherent, thus challenges reported by this group may be different than those experienced by less adherence PrEP-using GBM. Furthermore, we observed a subgroup of participants who were determined to overcome barriers to remain on PrEP. These participants displayed high levels of health prioritization and may also be more likely to participate in a research study about sexual health and PrEP use. These participants may also be different from those initiating PrEP today.

Finally, we were unable to identify data reporting similar barriers and facilitators to continue PrEP among other key populations of PrEP users. However, our findings did not appear to be specifically related to GBM's identities or unique experiences; therefore, we can hypothesize that similar barriers may exist for other PrEP users. Nonetheless, further research is needed to confirm whether other key populations experience similar insurance and medical appointment-related barriers to PrEP persistence.

CONCLUSION

Although most participants reported consistent and reliable insurance coverage for their PrEP-prescription, many described barriers to prescription renewal as a result of mandates by their insurance provider. Insurance mandates may threaten the consistent use of PrEP over time by creating obstacles to obtaining one's prescription and seamlessly maintaining adherence to PrEP. Additionally, some participants described difficulty in attending quarterly medical check-ups. Difficulty attending PrEP-related medical appointments was largely attributed to busy personal schedules combined with limited physician availability. These challenges may hinder participants from obtaining the medical clearance needed for providers to refill PrEP prescriptions for eligible GBM. Efforts to improve PrEP implementation among GBM should work to remove barriers to prescription renewals and medical appointments in an effort to support PrEP use over time. Furthermore, PrEP's ability to prevent new HIV infections will likely rely on removing the barriers faced by PrEP-using GBM in an effort to sustain protection from PrEP for those at risk for HIV.

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Compliance with Ethical Standards

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Ethical Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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