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ORIGINAL PAPER

Weighing the Options: Which PrEP (Pre-exposure Prophylaxis) Modality Attributes Influence Choice for Young Gay and Bisexual Men in the United States?

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Abstract

Pre-exposure prophylaxis (PrEP) is effective in preventing HIV transmission, but uptake and adherence among young men who have sex with men (YMSM) remains suboptimal. New PrEP formulations may enhance PrEP use, but little is known about their acceptability. We enrolled 39 cis- and transgender YMSM (age 18–34) from Boston, MA; Jackson, MS; Birmingham, AL; and New Orleans, LA, who participated in video-based focus groups ($n=30$) or in-depth interviews ($n=9$) to examine how new PrEP products (e.g., injections, monthly pills, implants) are perceived and might be improved for YMSM. Focus groups were transcribed, coded, and analyzed using grounded theory and content analysis. Nearly half (46%) of participants were Black; 11% identified as Hispanic. Seventy-nine percent were PrEP experienced. Product preference was driven by the desire for flexible, safe, effective, and affordable PrEP options. A majority of participants preferred subcutaneous injections every 6 months or monthly pills dispersed in 3 or 4 doses. Subcutaneous injections and batched monthly pills were favored by those with demanding schedules and those who desired fewer provider visits; monthly pills were more appealing for those who feared needles. Despite broad preferences for longer-acting products for convenience, participants raised concerns regarding side effects and waning protection after missed doses. Participants felt that more education about safety and efficacy profiles of new products could influence their attitudes. These findings suggest that it is important to prioritize YMSM's dynamic lifestyles during product development, and that product safety and efficacy information should be accessible in youth-friendly language.

Keywords YMSM · HIV · PrEP · Product Preference · Next Generation PrEP · Long-Acting PrEP

Introduction

New HIV infections are disproportionately reported among young men who have sex with men (YMSM, ages 18–34) in the United States (US) compared to other sociodemographic groups [1]. Black and Latinx/Hispanic communities are most affected by HIV in the United States [2]. In 2021, Black people accounted for 40% of all new HIV diagnoses in the United States and Latinx/Hispanic people accounted for 29% of all new HIV diagnoses [1, 2]. Furthermore, the Northeast and Southern regions of the United States account for the highest rates and numbers of people with HIV [1, 2]. Thus, new HIV prevention efforts need to focus on YMSM of color, particularly those living in the Northeast and Southern US.

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The antiretroviral fixed dose combination of tenofovir disoproxil fumarate/emtricitabine was first approved as a daily pill by the U.S. Food and Drug Administration for adults in 2012 and then for adolescents in 2018 for use as HIV pre-exposure prophylaxis (PrEP) [3]. Daily oral PrEP is 99% effective in preventing HIV infection among MSM with high adherence [1–5]. However, both PrEP uptake and adherence have been low among young people, and disproportionately lower among young people of color [2, 5–8]. In an open-label study of PrEP use by 18 to 22-year old YMSM, only one-third had protective drug levels at 1 year [5, 8]. PrEP adherence might be even lower for YMSM prescribed PrEP outside research studies, where adherence support may be less intensive. As such, tailored strategies to improve PrEP uptake and adherence for YMSM are needed.

New PrEP formulations may be important tools to promote PrEP uptake and adherence, including among YMSM. HIV prevention scientists are actively developing and testing the efficacy of a variety of new PrEP formulations, including products offering systemic protection (e.g., longer-acting oral formulations, implants, subcutaneous and/or intramuscular injections) or topical protection (e.g., douches, topical gels), as well as products administered on a less than daily basis (e.g. event-driven oral medication, vaccines; implants) [7–10]. Bimonthly intramuscular injectable cabotegravir was found to be superior to daily oral tenofovir disoproxil fumarate/emtricitabine as PrEP in two randomized controlled clinical trials, which led to recent FDA approval [11, 12]. Diverse drug delivery mechanisms and timing could offer choices that are congruent with YMSM's lifestyle and/or sexual practices. For example, PrEP rectal douches may align with anal cleansing practices and behaviors regarded as normative prior to participating in receptive anal intercourse [13, 14] Similarly, infrequent subcutaneous injectable formulations (e.g. every 6 months) or monthly oral may be acceptable by allowing for infrequent clinic visits. Long-acting PrEP might be more compatible with a young person's complex lifestyle where planning for sex or taking a pill every day is unrealistic, and both approaches are under study.

The lack of data on acceptability of these new products among YMSM may lead to challenges in implementation of next generation PrEP modalities, dampening potential impact among the communities most in need. Achieving consistent and correct use among the product's consumers will require researchers to develop products that are desirable *and* acceptable, both within the context of clinical trials and in the real world [15–17]. Thus, it is crucial that next generation biomedical prevention be designed so that PrEP modalities that not only deliver enough drug to block HIV transmission, but are also a good behavioral fit with the drug's intended end-users. However, YMSM's recruitment in these next generation PrEP studies has been limited and little is known about how YMSM perceive next generation prevention modalities and the factors that influence acceptability of these products in this population. Moreover, available instruments to assess acceptability of and preferences for next generation PrEP products have focused on older adult populations, and few published studies have specifically examined acceptability of these products among young adult MSM [18]. Thus, even if found to be efficacious, the absence of YMSM's perspectives on product characteristics could lead to misgauging their acceptability and could contribute to their adherence challenges once they become available.

Methods

Study Design

To better understand the issues that youth consider when evaluating potential HIV prevention products, we completed 5 video-based focus groups (with 30 participants) and 9 individual interviews with a racially and geographically diverse group of 39 YMSM in Boston, MA; Jackson, MS; Birmingham, AL; and New Orleans, LA, between September 2021 – August 2022. Consent was obtained from participants by trained study staff prior to the focus groups or interview. Additionally, demographic data was collected in a REDCap survey where we collected data on age, education, prior HIV testing, prior PrEP use, and condom use.

In instances where scheduling conflicts prevented full focus group attendance or participants expressed concerns about sharing in groups, individual interviews were scheduled. All focus groups and interviews were conducted online via Zoom, a HIPAA-compliant video-chat platform. All guides, surveys, and measures were reviewed and approved by The Fenway Institutional Review Board before use with human subjects.

Sample Selection

Participants were included in a focus group if they self-reported as an HIV-uninfected YMSM aged 18–34, self-identified as a man or as a person on the trans masculine spectrum, and self-report evidence of sexual behaviors that are associated with HIV transmission and were recruited using both active and passive methods. Additionally, we screened for PrEP use and categorized users as "Ever" vs. "Never" users. Active recruitment was carried out by study staff at all sites by recruiting individuals at organizations and venues where YMSM attend, including sexually transmitted infection (STI) clinics, community-based organizations for

sexual and gender minority young adults, events, and other locations. Passive approaches for recruitment included posting study information via flyers, posters, and palm cards describing the study at various venues.

We determined sample size utilizing thematic saturation. We actively reviewed transcripts of groups as the study progressed to identify recurring themes and ended recruitment after multiple focus groups began to yield little to no new themes from participants.

Study Procedures

Focus groups and interviews ran for a range of 45–120 minutes with the average session lasting 90 minutes. All focus groups and interviews were facilitated by a trained interviewer using a semi-structured, open-ended guide. We explored the following domains in the focus groups:

1. Perceived benefits to PrEP adoption, specifically comparing emerging PrEP modalities (implants, injectables, less frequent peri-coital dosing, daily and monthly oral pills) to once daily oral PrEP (e.g., how YMSM prioritize which approach they prefer, how they think about oral vs. topical vs. systemic PrEP).
2. Perceived risks to PrEP adoption, specifically comparing emerging PrEP modalities to once daily oral PrEP (e.g., prior knowledge of implants, implant sites, side effects, and frequency of replacement; questions about novel approaches, trust in the health care system; concerns about longer duration products).
3. Potential strategies to maximize acceptability of emerging PrEP modalities both in the context of trials and in real-world settings (e.g., potential for fewer clinical care visits).
4. Potential ways to expand access to PrEP (e.g., understanding cost considerations, home self-monitoring).
5. Potential barriers and ways to reduce barriers to adherence of emerging PrEP modalities (e.g., prior experiences of pills, gels, douches, implants, and injections; acceptability of month-long run-in of oral PrEP prior to implants, acceptability of monthly PrEP and implantable PrEP).

During focus groups, a trained note taker was present to take notes about the main themes that emerged, background information about the location and conditions of the focus group or interview (e.g., audio quality, internet connectivity, attendance, etc.), physical reactions (that were discernable over camera for participants who used video) amongst the participants, and specifically for focus groups, rapport among the participants and conflicts/disagreements in participants' responses.

Participants were provided detailed descriptions of the products including available information on differences between administration (e.g., needle comparison, injection site, dosing schedule, etc.) and currently known side effects of the medication (e.g., weight gain, nodules at injection site, gastrointestinal upset, etc.). Visual aids and/or comparisons to existing medication administration techniques (e.g., insulin shots for subcutaneous injections) were used to help ground participants' understanding of the various medication strategies.

Participants were not required to have their cameras on during the focus group/interviews and were instructed to only turn cameras on if they felt comfortable doing so. Within 24 h of completing the interview or focus group, interviewers drafted a 1–2-page summary of the notes and other information about the focus group/interview in full.

Data Analysis

All focus groups/interviews were transcribed and then analyzed using grounded theory and content analysis. Based on the guide, an initial codebook was developed. Multiple analysts then reviewed each transcript and updated the codebook to include emerging themes. Two analysts individually coded each transcript; they then reviewed their codes together and resolved discrepancies through consensus. As data was re-examined, ongoing discussion between analysts and the study investigators allowed for further theorizing and interpretation. MAXQDA software was used to organize, code and summarize transcripts (maxqda.com).

Results

Table 1 gives an overview of the sample characteristics. In brief, mean age was 26 (standard deviation = 4.6) and ranged from 18 to 34 years old. Most participants identified as Gay/Same-Gender loving (51%); bisexual was the next highest endorsed sexual orientation (21%). Most participants were employed full-time (56%). Sites differed in terms of the demographic characteristics. Participants in Birmingham, AL and New Orleans, LA were primarily Black (67% and 83%, respectively), whereas participants in Boston, MA were primarily White (95%). Students comprised half the sample in Boston (50%). People at the southern sites were more likely to be on Medicaid, particularly in Louisiana (67% of Medicaid participants came from the New Orleans site vs. 17% for both Boston and Birmingham).

In focus groups/interviews, a clear consensus emerged. Across all modalities, the subcutaneous injection and monthly pill were most favorably received. Participants were most hesitant about the intramuscular injection and

Table 1 Sociodemographic and behavioral characteristics of focus group/interview participants ($n = 39$)

	Mean	Standard Deviation
Age	26	4.6
Sex partners, number	4.7	3.6
	N	**%**
Male Sex Assigned at Birth	38	97%
Sexual Identity		
Gay, same gender loving	20	51%
Bisexual	8	21%
Queer	7	18%
Other	4	10%
Race		
Black or African American	18	46%
White	19	49%
Other/More than one race	2	5%
Hispanic Ethnicity	4	11%
Highest grade or level of school completed		
High school graduate/GED/Some college	16	41%
Bachelor's degree	10	26%
Post-graduate degree	13	33%
Employment status		
Full-time (30 + hours per week)	22	56%
Part-time (< 30 h per week)	5	13%
Student	11	28%
Unemployed	1	3%
Health Insurance		
Employer/Private	24	62%
Medicaid	12	31%
None	3	8%
STI Diagnosis, past 12 Months	21	54%
PrEP Experienced	31	79%
Likelihood of taking PrEP, next 3 months?		
Not at all likely	3	8%
Somewhat likely	2	5%
Very likely	34	87%

the implant. Primary considerations included relevance to lifestyle (e.g., convenience, flexibility, cost, etc.), efficacy, and side effects. Notably, the way these considerations were weighed impacted preferred modalities.

> "Safety, convenience, affordability are all, like, not neck and neck, but they'd probably rank in that order, but they're all super close." – Boston, MA.

Relevance to Lifestyle

Participant preference was significantly driven by current life circumstances, and because of this, participants desired a level of flexibility in their options and the ability to use a PrEP modality that could be tailored to their present lifestyle. For some participants, busy schedules were cited as the reason for preferring long-acting modalities that had minimal clinic visits.

> "I mean I think a lot of these questions around method of intake deal with convenience. They just deal with like what is the most convenient for you as an individual. Which some of us, taking a daily pill is like more of a hassle because we're at two jobs. For me it's like I work independently, uh, like sort of when I want to so it's like it-it's a different-my-it's just a different lifestyle, uh, intake is different for me." – New Orleans, LA.
>
> "I think that more so just like my life, my career, just like how busy I am would you know, just like that would mainly affect, um, you know, which method I would want to take." – New Orleans, LA.

For many participants, their current financial situation, and therefore comparative costs of each modality, was an essential consideration.

> "Like if my favorite option was, like, prohibitively expensive, then I would – I would go with something else…[If] the twice-a-year injection would be not super-expensive, and then I think that would-that would be something that I would choose. But if it was expensive, then I might consider, like, okay, do the-the daily pill or monthly pill instead." – Boston, MA.

Additionally, participants took time between visits into consideration when assessing how they would maintain their regular testing schedule. Some participants showed concern about the ramification for longer dosing windows, like lapses in testing and breakthrough infections, while others felt they would have the self-efficacy to maintain their routine testing.

> "But from, like, a population health standpoint, what concerns me is that if we're gonna target, like, low access groups with these long-acting things so they don't have to interface with the medical system as frequently, if they have to then take up a year and a half of adherence to daily PrEP to prevent, like, breakthrough infections, people can't access PrEP already for any number of reasons, from like, PrEP stigma to just, like, structural barriers of, like, affordability." – Boston, MA.
> "I was just going to say if I chose a six-month shot, and we're only getting tested every six months, um, I would probably do a check-in with either an urgent care or my provider to do like a quick STI panel just to-just to know my status. I like to-I like to know that. I like-so, I would probably still get tested even before the six months." – New Orleans, LA.

Drug Efficacy Concerns

A common concern across modalities was the efficacy of the drug, particularly as it related to the current standard.

> "For me to change my regimen I think the effectiveness would need to be greater of a newer regimen, ah, or at least the same, ah-ah, compared to ah-ah, the current [daily pill] regimen." – Jackson, MS.
> "I think that top for me is also convenience but maybe a close second is just the trustworthiness and, um, I-you know, I feel like I got into PrEP kind of late, so it feels like an established thing that my friends are fine on. So, I would be hard pressed to be the first to sign up for a new kind."– Boston, MA.

Additionally, there was a clear desire to better understand the duration of efficacy (i.e., does this drug protect me over the entire described timeline?) and consequences of nonadherence or delayed use (i.e., in the event of a missed dose, how long am I protected until my next one?) for newer modalities.

> I think when we were talking about the monthly option, we were talking about this concern of, like, the effectiveness waning towards the end of, like, whatever period we're talking about. I think maybe that concern is a bit magnified for me here when we're talking about six months. And like, am I gonna be covered fully all the way through? Six months feels like a really long time." – Boston, MA.
> "My only concern of course would be like, you know, like I'm not gonna lie, um, in the back of my mind like, you know, taking a pill every day like, you know, you kind of have that like safety net-that safety net of feeling like, you know, okay I'm secure because I know for sure I took my medicine seven days straight like, you know, and I been taking it. And I miss the dosage like what's now my window before now I have to get that dosage? Like is it a week, is it two weeks 'efore you have to get that dosage. So that will be nice to know as well." – New Orleans, LA.

Similarly, participants discussed considerations of misapplication (i.e., what happens if it is not administered correctly?) and potential consequences.

> "I trust the science that if it-if it's supposedly as efficacious as the daily pill, like I'll believe that. I just, with my experience with SubQ injections like, um, I don't know if they-if they're not administered correctly, they're not gonna be effective. And then you have only two opportunities in the entire year, so it seems very important to get it-get it right, to make sure that the medication was injected correctly." – Birmingham, AL.

Side Effect Concerns

Because the side effects of some of the newer or emerging modalities are not fully known, many participants, despite showing interest in (and even preference toward) some of the options, were clear about their desire to know more about what potential effects they might experience.

For example, as one participant commented about the monthly pill:

> "I would just wanna know, like, if something were to happen, and you like, forget for, like, I don't know, a week, and then you take it on a completely different time, like, does that really affect you? Like, are there really bad side effects for not taking it at the same time every month? I would just wanna know that." – Boston, MA.

For some PrEP experienced participants, their past experience of side effects with the daily pill was used as a benchmark for what was acceptable; typically, if the side effects were similar in nature to the daily pill, participants were willing to endure them for the benefit of the drug.

> "I didn't have any with my current regimen even when I first began. And I was on the same version of the medication then. And if the side effect profile is essentially similar with the monthly pill then it is for the daily pill, then I don't think I would be concerned with side effects from the monthly pill versus the daily dose." – Jackson, MS.

Conversely, some participants who were newer to PrEP noted hesitancy in pursuing new drugs due to limited experience with their current regimen and the desire to become more familiar with the daily pill before moving forward with new options.

> "I feel like minus the upper respiratory infection, I feel like just-the side effects, or the-the potential side effects, are similar, the risks to the once-a-day pill so I would still rather the once-a-month pill to try it out." – New Orleans, LA.

These priorities were sometimes offset by personal aversions, such as fear of needles or foreign objects placed in one's body.

> "It doesn't-at least for me-me, because I just don't like needles. Um, I'd much rather-and if I were to do… the injection, it would be [a] very, very dire situation. Like, I absolutely needed it, or like, I was at risk, or something along those lines."– Boston, MA.
>
> "I will say, yeah, the implant just really sounds like a bad option. So, even if it was [cheapest], I don't know if I would do it…." – Boston, MA.

Discussion

This study enrolled a geographically diverse sample of YMSM (aged 18 to 34) and found a general interest in the development and use of novel antiretroviral PrEP modalities to prevent HIV infection, without major differences across geographic locations. There were a range of priorities expressed regarding preferred PrEP modalities. Across all modalities, the subcutaneous injection and monthly pill were favorably received. There was less enthusiasm for intramuscular injections and very few endorsed the use of a long-acting implant. However, there was still interest in these modalities despite participants not preferring them, so it is possible that, given the appropriate modifications, YMSM may find them personally acceptable.

We found that adaptability, affordability, accessibility, and flexibility were most important to YMSM with regards to preferred novel PrEP modality. The overarching theme in all focus group conversations was the need to prioritize the development of new modalities that consider the diversity of young adults' sometimes transient and fast-paced lives, allowing for disruptions due to work, school and travel. Participants also highlighted that as new modalities are developed, it will be important to create easily understood product safety and efficacy information to help assuage concerns around side-effects and duration of protection. Additionally, making sure that there is adequate information around product acquisition and administration to ensure patients understand exactly how medications will be delivered and what is expected of them regarding visits and follow-up procedures.

Our data are of particular interest since earlier work using online surveys of MSM found that some preferred injectable intramuscular PrEP to oral modalities [19] and others preferred daily oral medication. This study demonstrates a strong interest in subcutaneous injections and a monthly oral pill and provides qualitative context for participant decision making. These data are particularly salient as clinical trials are underway to assess the efficacy of lenacapavir given subcutaneously every 6 months and MK-8527 used as a single monthly pill, both for HIV prevention [20].

Affordability of prescriptions and medical appointments has consistently been a stated barrier to PrEP uptake by YMSM irrespective of their interest in the products [21–23]. This is consistent with comments from our focus group participants interested in a broader menu of PrEP options but were concerned that new products might be prohibitively expensive. Participants also expressed concerns that insurance coverage for new modalities may be an additional barrier to accessing these options. Even though insurance may be a cost mitigating mechanism for some patients, YMSM may be reluctant to utilize PrEP if they use parental insurance and have privacy or outing concerns [24]. Because

YMSM are likely to discontinue or not access PrEP due to the additional burdens of having to navigate complex and costly medical systems, removing these barriers may have a significant impact on product preference [25–27]. Because PrEP utilization is facilitated when offered at no, or low cost [27, 28], our findings affirm that as new products are being developed, mechanisms that offload the financial burdens for patients may not only influence product preference but may also facilitate product uptake. However, we must go beyond solely financial barriers and look to address other social and structural barriers to PrEP access for YMSM [29, 30].

Despite access to free PrEP in many states that have public and private medication assistance programs, some literature suggests that PrEP may still be inaccessible to YMSM [26, 30]. Throughout focus group conversations, YMSM noted the importance of having flexible and adaptable medication regimens to add convenience to their lives. Many YMSM noted having schedules that make it difficult to adhere to their current daily regimen and valued products that reduced the chance of missing doses by requiring fewer office visits and dose administrations. School, work, and leisure travel were all notable factors that participants endorsed as potential barriers to maintaining their PrEP. This is consistent with literature on emerging adulthood (described as 18–25 years old) which explores the difficulties adolescents and young adults face as they assume more responsibility, develop their identity, and begin depending less on parents and have increasing self-reliance [31].

Logistical (e.g., travel times, work/class schedules, on-site testing availability, etc.) and structural challenges (e.g., long appointment times due to overtaxed healthcare facilities, lack of transportation/inadequate public transportation infrastructure, medical/pharmacy [32–36] deserts, insurance disparities, etc.) have a significant impact on PrEP utilization [21–23, 27, 36–38]. Participant preference may be driven by how many logistical burdens a particular product can remove, and as noted by participants this goal is often closely considered with cost. Additionally, some participants noted long-acting medications like subcutaneous injections or monthly oral pills were popular due to the length of time between doses and infrequency of provider visits. This longer duration between doses may be what potential patients are looking for when seeking to ease logistical difficulties when trying to access PrEP.

However, it is still important to consider specific clinic visit schedules strategies for new modalities in conjunction with the overall duration between doses. Visits to the clinic (and the associated considerations like cost, insurance, travel, social support, time between STI testing, etc.) factored into participant preferences for longer-acting modalities; some participants noted concerns maintaining testing routines and the potential ramifications for reduced medical encounters. As such, providers should consider the benefits of consistent social support and communication, including remote engagement, from care teams to reduce lapses in adherence and/or any other adverse outcomes [16].

Lack of information, or the desire for more information, has been noted as a potential barrier for PrEP uptake and could have an impact on the success and utilization of upcoming modalities [17]. Previous work in the field has also indicated that balancing medical jargon and casual language for product descriptions and reducing redundancy are essential elements that may improve the comprehension for YMSM engaging with new medical products [19]. Furthermore, being able to compare new product information with existing knowledge of and/or experience with well-known products (e.g., insulin shots, hormonal implants, daily pill regimen) may be useful in grounding user understanding, aiding in any assessments made about benefits and drawbacks of new medications [21]. Ensuring information about products is accessible and easy to understand is one potential path to bolstering YMSM's trust in the efficacy of new modalities, making them more likely to engage in new products. Previous studies have documented YMSM's concerns about PrEP efficacy and side-effects [17, 19, 39]. Developers of new PrEP modalities must contend with deep-rooted concerns of community mistrust and research inaccessibility. Engaging in meaningful community partnerships, increasing transparency in the research and development process, and disseminating study findings in accessible and innovative ways may help future investigators mitigate these issues as the market for biomedical prevention methods continues to grow.

It is important to note that because this is a convenience sample these responses are not generalizable to the broader MSM population. However, our focus groups provide insight into what some members of the community find important regarding new prevention products. Additionally, we acknowledge the complexity and potential difficulty of making comparisons between existing and hypothetical products. Further, many participant concerns were rooted in lack of information about side effects and efficacy. Despite these limitations, we believe that grounding participant knowledge with detailed descriptions of the products and providing analogous examples from existing treatment options of other illnesses produced generative and informative discussion.

Conclusion

Our findings suggest that it is important to prioritize the development of new modalities that account for YMSM's desires for PrEP options that are accessible and flexible enough to meet the needs of their life at different points in time and that can easily be transitioned to a new modality if necessary or desired. Additionally, as new modalities are developed, it is important to prioritize accessible and easily understood product safety and efficacy information to help assuage concerns.

Developers of new PrEP modalities may potentially influence product preference by considering the myriad ways that YMSM must navigate their lives distinct from their heterosexual peers. Furthermore, they should keep in mind that this group is directly impacted by structural inequities that impose challenges to obtaining and maintaining optimal care.

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