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Will gay and bisexual men taking oral pre-exposure prophylaxis (PrEP) switch to long-acting injectable PrEP should it become available?

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Abstract

Oral pre-exposure prophylaxis (PrEP) is highly effective at reducing HIV transmission risk and is CDC recommended for many gay, bisexual, and other men who have sex with men (GBM). We sought to investigate awareness of and preference for using long-acting injectable PrEP (LAI-PrEP) among GBM currently taking oral PrEP ($n=104$), and identify their concerns. About half of GBM had heard of LAI-PrEP, and 30.8% specifically preferred LAI-PrEP. GBM with more concerns about the level of protection and drug half-life of LAI-PrEP had lower odds of preferring LAI-PrEP. Given that daily pill adherence is a challenge for some on PrEP, it is important to investigate the degree to which those on PrEP might consider LAI-PrEP as an alternative.

Keywords

pre-exposure prophylaxis; long-acting injectable; men who have sex with men; HIV

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COMPLIANCE WITH ETHICAL STANDARDS

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INTRODUCTION

According to the 2015 HIV surveillance report issued by the Center for Disease Control and Prevention (CDC), gay, bisexual, and other men who have sex with men (GBM) made up 67% of all new HIV infections in the United States (US), accounting for 84% of all infections among men [1]. Pre-exposure prophylaxis (PrEP) is a promising biomedical HIV prevention strategy currently available to consumers as a once-daily oral pill (Emtricitabine/Tenofovir). Once-daily oral PrEP was approved by the US Food and Drug Administration (USFDA) in 2012 [2] and is now CDC recommended for many GBM at risk for HIV acquisition [3]. Researchers have estimated that there are as many as 7.4 million GBM in the US [4], and data from a national sample of GBM indicated 64% of GBM could meet CDC guidelines for PrEP use [5]. Despite more than 4.5 million GBM potentially meeting CDC recommendations for PrEP use, only 1% of those men had started PrEP by the end of 2015 [6].

Currently being studied as another method of PrEP dosing/administration, long-acting injectable (i.e., LAI-PrEP) is being tested in two Phase 2a clinical trials: HPTN 077 in the United States, Brazil, and sub-Saharan Africa (NCT02178800); and ÉCLAIR in the United States (NCT02076178). In preliminary data from ÉCLAIR, participants were satisfied with LAI-PrEP and would prefer to continue dosing via injectable instead of daily oral PrEP [7]. GBM and transgender women in the US have reported barriers to once-daily PrEP including worries about long-term health effects, potential side effects, incomplete HIV protection, and routine medical check-up requirements [8], and pill burden was identified as a reason for preferring intermittent over daily PrEP among at-HIV risk Kenyan samples [e.g., 9]. Although research is currently limited on the psychosocial implications of LAI-PrEP on HIV prevention, LAI-PrEP could reduce patients' concerns about daily pill adherence—including remembering to take a pill and having pills available when away from home—and HIV pill stigma associated with oral PrEP [10]. The implications of HIV pill stigma are two-fold; others may think a PrEP user is HIV-positive because they are taking medications typically associated with an HIV diagnosis or be shamed because of their PrEP use based on perceptions of sexual risk or promiscuity.

Data from US samples of GBM suggest that LAI-PrEP is preferred over daily oral PrEP. In a US national cohort of 948 HIV-negative GBM, 46% preferred LAI-PrEP, 14.3% preferred once-daily oral PrEP, 21.7% preferred whichever was most effective, 10.1% had no preference, and 7.8% were not interested in either form of PrEP [11]. GBM had concerns about potential long-term health effects and side effects of both once-daily PrEP and LAI-PrEP [11]. Although 5.9% of participants in this study were currently on PrEP, it did not report separately the preferences of those currently taking oral PrEP and those not. In another US national study of 512 GBM that assessed preferences of once-daily oral PrEP, LAI-PrEP, and visible or non-visible implants, 35.5% preferred once-daily PrEP, 34.4% preferred the non-visible implant, a quarter (25.2%) preferred LAI-PrEP, and very few (4.3%) preferred a visible implant [10]. Participants discussed their reasoning for picking each dosing strategy as having to do with convenience, stigma, effectiveness of protection, and dislike/fear of one option over another [10]. Finally, 80.7% of young GBM (18–19 years old) in New York City were willing to use LAI-PrEP, and 79.2% specifically preferred a

LAI-PrEP administered by injection every three months [12]. Differences in opinions about LAI-PrEP vary across samples likely because of variability in sampling (i.e., age and geography) and measurement (i.e., PrEP dosing response options differed across studies). Despite substantial evidence of some GBM (of whom, all or most were PrEP-naïve) preferring LAI-PrEP to daily oral PrEP, an understanding of PrEP dosing preferences of *current* oral PrEP users is still unknown. Research is also limited on the identification of potential concerns GBM have for LAI-PrEP and how that could influence their acceptability of it. Determining current oral PrEP users' preferences and concerns about LAI-PrEP could provide meaningful evidence about the possibility of men on oral PrEP transitioning to LAI-PrEP, and what barriers might prevent them from doing so. Matching dosing preferences of current PrEP users has potential to reduce PrEP discontinuation after uptake, encouraging persistence of HIV prevention among those at high-HIV risk.

The purpose of this study was to investigate awareness of and preference for using LAI-PrEP among GBM currently taking daily oral PrEP in an effort to determine if USFDA approved dosing forms of PrEP are meeting current PrEP users' preferences. We examined demographic and potential concerns specific to LAI-PrEP on preferences of oral versus LAI-PrEP. This research fills a critical gap in the literature about the potential of GBM transitioning from oral to LAI-PrEP once commercially available.

METHODS

Data for this manuscript were taken from *PrEP & Me*, a study of GBM who were active PrEP users at the time of enrollment. Participants were recruited from November 2015 to November 2016 via targeted sampling, which included advertising and preliminary screening for the study in gay concentrated neighborhoods and settings (e.g., gay bars, pride events, at LGBT community-based venues) as well as digital recruitment on gay hookup websites and apps, and social media. Those clicking one of our digital ads were routed to a secure online survey that assessed preliminary eligibility criteria. Those deemed preliminary eligible (in any screening setting) were asked to provide contact information for additional telephone-based screening with a member of our research team. Those eligible were scheduled for a face-to-face assessment at our research office.

To be eligible, participants had to 1) be 18 years or older, 2) be cisgender male, 3) identify as gay or bisexual, 4) have been taking PrEP for at least 30 days, but not via a research study that provided the PrEP medication (e.g., demonstration project, clinical trial), 5) reside in the New York City area, and 6) have access to the internet such that they could complete online components of the study (not discussed here). One of the goals of the parent study was to examine the role of club drug use on PrEP adherence, thus half of the sample self-reported club drug use in the last 30 days. Club drugs included ketamine, MDMA/ecstasy, GHB, cocaine, or methamphetamine. All participants provided proof that they were taking PrEP by bringing their PrEP prescription bottle (along with their pills), with their name printed on it, to their study visit. Participants were compensated \$40 for their baseline assessment, which included a computer-assisted self-interview with measures described in the next section. All procedures were approved by the Institutional Review Board of CUNY.

Measures

Demographics, club drug use, and PrEP use—Participants were asked about their age, race/ethnicity, educational attainment, yearly income, and length of time on PrEP. Engagement in club drug use was measured using a 30-day timeline follow-back interview. Individuals were coded as using club drugs if they reported at least one day of use in the past 30.

Description of LAI-PrEP—Participants were presented with the following overview of LAI-PrEP [11]:

Scientists are also working to make a different kind of PrEP that would not require taking a pill every day. Instead, it would involve getting an injection or shot in the muscle of the butt every month or perhaps only every three months. Based on past experiments, scientists believe that this new drug can work similarly to daily oral PrEP to prevent HIV, but conclusive results from human trials have not yet been obtained. We are interested in knowing some of your opinions about this second form of PrEP, which we will call “long-acting injectable PrEP” due to the fact that the injections would last from one to three months.

Concerns about LAI-PrEP—Men were asked about a series of potential worries about using LAI-PrEP with measures adapted from previous research on oral PrEP use [11]. For example, participants were asked “When thinking about whether to take long-acting injectable PrEP, how concerned are you about the possibility of incomplete protection against HIV?” Response categories to all potential barriers to LAI-PrEP ranged from 1 (*not at all concerned*) to 4 (*very concerned*).

Awareness of and preference for LAI-PrEP—We assessed two outcome measures associated with LAI-PrEP. First, participants were asked how familiar they were with LAI-PrEP with response categories from “I’ve never heard of it before today” to “I know a lot about it.” Participants were coded as aware of LAI-PrEP if they had indicated any level of familiarity above never hearing about it. Next, men were asked about their preference for LAI-PrEP versus oral PrEP with response categories of “LAI-PrEP,” “daily oral PrEP,” “either LAI-PrEP or daily PrEP no – preference,” and “LAI-PrEP or daily PrEP – whichever is more effective.” Men were coded as preferring LAI-PrEP if they specifically selected it, whereas those who selected daily oral PrEP, no preference, or whichever is most effective were coded as not preferring LAI-PrEP.

Statistical Analyses

We conducted bivariate analyses on both outcomes using chi-squared comparisons and logistic regressions. Demographic, club drug use, and length of time on PrEP were tested for associations with LAI-PrEP awareness. Both club drug use and time on PrEP were then tested within multivariable logistic regressions, adjusting for age, race/ethnicity, education, and income, on LAI-PrEP awareness. We then assessed preference for LAI-PrEP using multivariable logistic regressions for each variable including each LAI-PrEP concern, club drug use, and time on PrEP, adjusting for age, race/ethnicity, education, and income.

RESULTS

Half (50.0%) of the 104 GBM in this sample were White, most (71.2%) had a Bachelor's degree or more of education, and 42.3% made more than \$50,000 annually in income. Mean age of men in this sample was 32.5 years old and 63.5% of men had been on oral PrEP for less than a year. By design, half (51.9%) of the men engaged in club drug use. Half (51.9%) of the men had at least heard of LAI-PrEP previously. About one-third (30.8%) specifically preferred LAI-PrEP, and the remaining men preferred oral PrEP (26.9%), whichever most effective (34.6%), or had no preference (7.7%). Participants had the lowest amount of concern regarding fear/dislike of needles associated with LAI-PrEP ($M = 1.75$, $SD = 1.10$, range: 1–4), with the majority (61.5%) having no concern at all. Similarly, men leaned toward having less as opposed to more concern about returning for medical check-ups and injections every three months ($M = 1.79$, $SD = 1.00$, range: 1–4), with 54.8% having no concern about these quarterly medical visits. On average, men had a moderate amount of concern regarding long-term health effects of LAI-PrEP ($M = 2.63$, $SD = 0.97$, range: 1–4), and most (87.5%) expressed some level of concern (i.e., *a little concerned* or more). Similar to the concern about long-term health effects, men had a moderate amount of concern about the potential side effects of LAI-PrEP ($M = 2.71$, $SD = 0.91$, range: 1–4), with most (93.3%) endorsing some level of concern. The next most highly endorsed concern was about the possibility that HIV protection might wear off if the participant does not return on time for the next scheduled injection ($M = 2.76$, $SD = 1.00$, range: 1–4); 87.5% of men expressed some concern above none at all. Finally, men had the most about concern about incomplete HIV protection with LAI-PrEP ($M = 3.10$, $SD = 0.92$, range: 1–4). Nearly all (93.3%) expressed some level of concern about incomplete protection, and 40.4% of all men were very concerned about it.

In bivariate analyses, men with less than a Bachelor's degree had higher odds of preferring LAI-PrEP compared to those with more education. Preference for LAI-PrEP was significantly associated with the two most highly endorsed concerns. Concerns about incomplete HIV protection and possibility of protection wearing off were both associated with lower odds of LAI-PrEP preference.

In analyses adjusted for demographic characteristics, men who have been on PrEP longer than a year had nearly 10 times the odds of being aware of LAI-PrEP compared to men who more recently initiated oral PrEP within the past year. Men on PrEP longer also had higher odds of LAI-PrEP preference ($p = 0.10$), but the p -value was above the predetermined $\alpha = 0.05$ cutoff. Club drug users did not significantly differ from non-users in awareness of or preferences for LAI-PrEP. Men with more concern about incomplete HIV protection using LAI-PrEP and more concern that LAI-PrEP protection would wear off over time had lower odds of preferring LAI-PrEP. Preferences were not associated with other LAI-PrEP concerns, including concerns about long-term health effects, potential side effects, returning for medical check-ups and injections every 3 months, or dislike of needles. Table 1 describes complete results of all analyses.

DISCUSSION

Prior research has assessed preferences and concerns regarding LAI-PrEP in samples of GBM not currently taking PrEP, but these prior data offered little assessment of whether GBM currently taking oral PrEP would transition to LAI-PrEP. In this study, about one-third of GBM currently taking oral PrEP would prefer LAI-PrEP, suggesting some men could change dosing forms after Phase 3 clinical trials are completed. Once clinical trials have completed, even more GBM could prefer LAI-PrEP if it is shown to be more efficacious than oral PrEP because another third of men preferred the dosing form most effective against HIV transmission. Most notably, more men in this sample preferred LAI-PrEP compared to daily-oral PrEP (i.e., the strategy they were currently using), indicating current USFDA approved dosing forms of PrEP are not meeting many current PrEP users' preferences. This research adds to a growing body of research supporting the acceptability and preference of LAI-PrEP dosing [10–12]. LAI-PrEP could help increase PrEP uptake among those who do not find a once-daily pill acceptable or who find difficulty maintaining daily pill adherence after initiation of oral PrEP. After all, GBM reported convenience as the most highly reported reason for choosing LAI-PrEP in prior research [10].

GBM who have initiated oral PrEP still had concerns about LAI-PrEP that influenced their preferences of using it over once-daily oral dosing. Mainly, men who worried about the level and longevity (i.e., drug half-life) of HIV protection using LAI-PrEP had lower odds of preferring long-acting injectables. This evidence differs from prior reports of mostly PrEP-naïve GBM, which found concerns about long-term health effects and the potential side effects of LAI-PrEP as the largest barriers to injectable (and oral) PrEP dosing uptake [11]. Similar concerns about both LAI-PrEP and oral PrEP were reported by PrEP-naïve GBM in prior research, but men who have already initiated PrEP overcame those initial barriers. Men in our study could have found oral PrEP tolerable; thus, they were no longer worried about these health concerns. Nonetheless, mostly PrEP-naïve GBM still had a moderate level of concern regarding incomplete protection against HIV, but this did not differentiate preference between oral and LAI-PrEP in prior research [11].

LAI-PrEP has promise for increasing uptake and minimizing barriers for oral PrEP users, but a surprising finding of our research was that nearly half of these oral PrEP users had not heard of LAI-PrEP. However, LAI-PrEP is not yet available for use outside of participation in a clinical trial, but that does not preclude interventions from increasing awareness about the growing science around alternative forms of PrEP dosing currently under study to increase uptake once available if shown to be efficacious. Men who worry about having to take a pill every day or have concerns about HIV pill or PrEP stigma [12] could be earlier adopters of LAI-PrEP once available, as could men currently on oral PrEP who would prefer injectable PrEP or experience difficulty with oral PrEP persistence. We found a marginally significant difference—perhaps because of the sample size—in LAI-PrEP preferences by length of time on PrEP in our multivariable model; men who were on PrEP longer had higher odds of LAI-PrEP preference, indicating the potential maintenance burden of daily oral PrEP and need for long-acting dosing alternatives.

This research is not without limitation. First, the relatively modest sample size and recruitment of men only from New York City, including half of whom are club drug users, may limit the generalizability of our findings. Second, the modest sample size resulted in large confidence intervals for some of our odds ratios because of small cell sizes, reducing the precision of these estimates. Third, we provided some information about LAI-PrEP to participants to better inform their answers; however, perceptions may change when given more thoroughly detailed information with a different mechanism (e.g., from a clinician) or different information based on dosing protocols under current study (e.g., two shots instead of one or two month dosing intervals instead of three). Finally, we do not yet know how effective LAI-PrEP is, how long protection lasts, how much it will cost, and whether insurance will pay for it; further qualitative study is needed to explore more fully the nuanced perceptions of LAI-PrEP not possible in a quantitative survey. Thus, continued study of perceptions of LAI-PrEP is warranted as findings from clinical trials are reported, USFDA approval is granted, and CDC recommendations for use are made.

CONCLUSION

Nearly half of the PrEP-using GBM in this sample had not heard of LAI-PrEP previously, but many men currently on oral PrEP appeared interested in transitioning to LAI-PrEP should it become available. GBM in this sample still had concerns about the level of protection and drug half-life of LAI-PrEP, but other concerns typically associated with oral PrEP uptake were not applicable to LAI-PrEP preferences among these current oral PrEP users. Transitioning men from once-daily oral PrEP to long-acting injectables is an encouraging avenue to increase PrEP persistence among those at high-HIV risk who experience pill burden and/or adherence issues. Findings about HIV protection and longevity of HIV protection from ongoing clinical trials will likely influence whether oral PrEP users consider LAI-PrEP.

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Table 1

Demographics, PrEP use characteristics, club drug use, and barriers about long-acting injectable pre-exposure prophylaxis (LAI-PrEP) and their associations with awareness and preference for using LAI-PrEP (n = 104)

Categorical Variables	Aware of LAI-PrEP - Yes (Ref: No)					Prefer LAI-PrEP - Yes (Ref: No)						
	n	Column %	n	Row %	χ^2	AOR †	95% CI	n	Row %	χ^2	AOR †	95% CI
Race/Ethnicity					1.9					0.3		
Black	13	12.5	5	38.5				4	30.8			
Latino	27	26.0	15	55.6				8	29.6			
White	52	50.0	29	55.8				17	32.7			
Other/Multiracial	12	11.5	5	41.7				3	25.0			
Education					0.5					5.0**		
Less than Bachelor's degree	30	28.9	14	46.7				14	46.7			
Bachelor's degree or more	74	71.2	40	54.1				18	24.3			
Income					0.5					2.6		
Less than \$20k per year	20	19.2	11	55.0				9	45.0			
\$20k to \$49k per year	40	38.5	22	55.0				12	30.0			
\$50k or more per year	44	42.3	21	47.7				11	25.0			
Engages in club drug use					0.0					0.1		
No	50	48.1	26	52.0				16	32.0			
Yes	54	51.9	28	51.9		1.02	0.41–2.54	16	29.6		1.19	0.43–3.30
Length of time on PrEP					17.5***					1.0		
Less than 1 year (1 to 12 months)	66	63.5	24	36.4				18	27.3			
More than 1 year (1 year or more)	38	36.5	30	79.0		9.89***	3.38–28.95	14	36.8		2.24*	0.86–5.87
Continuous Variables	M	SD	OR	SE				OR	SE		AOR †	95% CI
Age (Range: 21–61 years old)	32.5	8.7	1.00	0.02				1.01	0.02			
Concern about the long-term effects on my health (Range: 1–4)	2.6	1.0						0.99	0.22		0.97	0.61–1.54
Concern about the potential side effects (Range: 1–4)	2.7	0.9						0.91	0.21		0.85	0.51–1.41
Concern about the possibility of incomplete protection against HIV (Range: 1–4)	3.1	0.9						0.47***	0.11		0.45***	0.27–0.76

Categorical Variables	Aware of LAI-PrEP - Yes (Ref: No)					Prefer LAI-PrEP - Yes (Ref: No)						
	<i>n</i>	Column %	<i>n</i>	Row %	χ^2	AOR †	95% CI	<i>n</i>	Row %	χ^2	AOR †	95% CI
Concern about having to return for medical check-up and injection every 3 months (Range: 1–4)	1.8	1.0	0.78	0.18				0.78	0.18		0.72	0.44–1.18
Concern about possibility that LAI-PrEP might “wear off” if I don’t return on time for next injection (Range: 1–4)	2.8	1.0	0.62**	0.14				0.62**	0.14		0.55**	0.33–0.90
Concern about my fear/dislike of needles (Range: 1–4)	1.8	1.1	0.82	0.17				0.82	0.17		0.77	0.49–1.21

Notes:

* *p* 0.10;

** *p* 0.05;

*** *p* 0.01;

† adjusted for age, race/ethnicity, education, and income.