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Refusal of Daily Oral PrEP: Implementation Considerations and Reported Likelihood of Using Various HIV Prophylaxis Products in a Diverse Sample of MSM

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Abstract

Background: An important subgroup of gay, bisexual, and other men who have sex with men (MSM) with behavioral indications refuse daily oral pre-exposure prophylaxis (PrEP) when recommended by a provider. Emerging HIV prophylaxis products (eg, injectable, event-driven) offer more options to MSM who refuse daily PrEP. In this article, we assess reasons for refusal and likelihood to use various products among MSM who refused PrEP.

Methods: MSM who reported anal sex without condoms or PrEP and refused daily oral PrEP in the past 6 months were recruited through clinics, community venues, and online in Atlanta, Chicago, and Raleigh-Durham. Men were asked their main reason for recently refusing daily PrEP and likelihood of using various PrEP options in the future. Bivariate and multivariable regression models were used to estimate associations.

Results: MSM ($n = 93$; 70% Black, 48% age 18–29 years) reported their main reason for refusing daily PrEP were potential side effects (35%), a daily pill regimen (22%), and not having enough information (18%). Reported likelihood of using PrEP products was 58% for penile gel, 54% for event-driven oral, 52% for injectable, and 50% for daily PrEP. MSM who reported daily regimen as the main reason for refusing PrEP had greater odds of likelihood to use an injectable [adjusted odds ratio (AOR) = 5.21, 95% confidence interval (CI): 1.32 to 20.52]. Younger men (18–29 vs 30+ years) had greater odds of likelihood to use condoms (AOR = 3.40, 95% CI: 1.15 to 10.04) and daily PrEP (AOR = 2.76, 95% CI: 1.06 to 7.16); there were no product preference differences by race.

Conclusion: Most men who refused daily PrEP indicated likelihood of using some form of PrEP in the future.

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This manuscript is in memory of our HIV prevention colleague at CDC, Dr. Dawn Smith.

Keywords

PrEP; prophylaxis; refusal; decline; MSM; gay men

INTRODUCTION

After a decade of approval¹ and recommended use² of daily oral HIV pre-exposure prophylaxis (daily PrEP), challenges to daily PrEP use continue among gay, bisexual, and other men who have sex with men (MSM) at behavioral risk for HIV infection. Issues of reaching MSM³ and educating providers⁴ about addressing perceptions of this highly effective prevention method continue, even in the context of US Preventive Services Task Force Grade A recommendation⁵ and guidelines that recommend daily PrEP for any person who requests it.² Although PrEP use among White MSM has greatly expanded, racial and ethnic minority MSM are less likely to use PrEP.^{6–8}

Despite the many MSM who overcome barriers of PrEP knowledge and related health care access, some men with behavioral indications refuse daily PrEP when offered by a provider.^{9–11} Previous research on this topic in the United States is sparse. A novel longitudinal approach with a small sample of young Black/African American (Black) MSM in 2016–2017 Atlanta¹² found that a variety of issues were involved in decisions to refuse oral PrEP relatively early in PrEP implementation within the United States. Concern for potential side effects, daily pill adherence, cost, and other issues changed over time for some men, with the emphasis on importance of provider–patient dialogue over time to tilt the balance toward acceptance of oral PrEP as a viable prevention option.^{4,12–15}

With new HIV prophylaxis products becoming available,² further behavioral research is needed to understand concerns about using PrEP among MSM in the emerging context of sexual event-driven (ie, 2-1-1 dosing)¹⁶ and long-acting injectable PrEP.¹⁷ In this quantitative analysis, we examine concerns reported by MSM who recently refused provider-offered daily oral PrEP to better facilitate uptake and use of various forms of HIV prophylaxis among MSM.

METHODS

MSM who self-reported unprotected anal sex (ie, without condoms or PrEP use) and refusal of daily oral PrEP recommended by a provider in the past 6 months were recruited for this study primarily through provider referrals but also health clinics, community venues, and online outreach in Atlanta, Chicago, and Raleigh-Durham during 2019. Other eligibility requirements included 18 years or older, cisgender male identification, and a resident of 1 of the 3 metropolitan statistical areas noted. Study procedures were approved and monitored by the CDC Institutional Review Board (Protocol #7031).

Eligible and consenting MSM were enrolled and presented with a quantitative, self-administered, computer-based survey assessing their demographic characteristics, sexual risk and prevention behavior, and preferences for emerging future prevention methods among other issues. Specifically, participants were asked 3 key questions for this analysis,

related to their main reason for recently refusing daily oral PrEP, likelihood of using various HIV prophylaxis options in the future, and belief that daily oral PrEP was good for all gay and bisexual men:

1. “What was the MAIN reason you refused PrEP in the past 6 months?” (select one). Response options included:
 - I did not want to take a pill every day.
 - Taking PrEP creates a bad image or reputation.
 - Possible side effects.
 - I did not believe the pill prevents HIV infection.
 - Friends or family did not support it.
 - I did not have enough information at the time.
 - Cost.
 - Other (specify) _____.

Each main reason was coded 1 if selected and 0 if not selected by a participant, and reasons with fewer than 10% of respondent selecting it were combined into a general “other” category.
2. “How likely would you be to use _____ PrEP/condoms to reduce the risk of getting HIV?” was asked separately for each of the following prophylaxis methods: condoms, daily oral PrEP, sexual event-level oral PrEP, long-acting injectable, penile gel, anal gel, and anal suppository. Response options included:
 - Very likely.
 - Somewhat likely.
 - Neither likely or unlikely.
 - Somewhat unlikely.
 - Very unlikely.

Very and somewhat likely to use the method was recoded as 1 or “likely” and compared with very or somewhat unlikely and neither likely nor unlikely recoded as 0 or “not likely.”
3. “Which one of the following statements best reflects your current thoughts about PrEP for gay and bisexual men overall?” (select one)
 - PrEP is not good for any gay or bisexual men to use.
 - PrEP is good for some gay or bisexual men to use.
 - PrEP is good for most gay or bisexual men to use.
 - PrEP is good for all gay or bisexual men to use.
 - I do not know enough about PrEP to answer.

“PrEP is good for all gay and bisexual men to use” was recoded to a dichotomous variable of “yes” vs all other responders combined.

Analysis consisted of bivariate and multivariable logistic regression models of (1) demographic characteristics associated with the most common “main reason” for recently refusing daily oral PrEP offered by a provider and (2) the association of main reasons and demographic characteristics with preferred prevention method. We also analyzed the association of belief that PrEP is good for all gay and bisexual men with their reported likelihood of using prevention products in the future.

RESULTS

Reasons for Recently Refusing Daily Oral PrEP

Our sample of MSM ($n = 93$) was largely Black/African American (70%), young (nearly half were aged 18–29 years), and diverse in education level attained (Table 1). The most frequently reported reason for recently refusing daily oral PrEP from a provider included potential side effects (35%), a daily pill regimen (22%), not enough information on PrEP (18%), and other reasons (25%). Other main reasons were too infrequent for separate analysis and thus were combined as “other,” including cost (9%), taking PrEP creates a bad image or reputation (2%), PrEP does not prevent HIV infection (2%), friends or family did not support PrEP (2%), and other reasons (10%). In a multivariable logistic regression analysis (Table 1), men aged 18–29 (vs 30+) years had lower odds of reporting potential side effects were their main reason for refusing daily oral PrEP [adjusted odds ratio (AOR) = 0.33, 95% confidence interval (CI): 0.13 to 0.86]. Black (vs other) MSM had lower odds (AOR = 0.21, 95% CI: 0.06 to 0.72) of reporting “other” as their main reason for refusing daily PrEP, and men from Atlanta and Raleigh-Durham (vs Chicago) had greater odds of reporting another main reason for refusing PrEP (see Table 1). No other demographic variables were associated with main reasons for recently refusing daily oral PrEP offered by a provider.

Reported Likelihood of Using PrEP Modalities in the Future

Men reported how “likely” they were to use various prevention methods in the future including from most to least common (Table 2): condoms (70%), a penile gel (58%), sexual event oral PrEP (54%), long-acting injectable (52%), daily oral PrEP (50%), and an anal gel (47%). In multivariable logistic regression analysis, not having enough information as a reason for refusing daily oral PrEP recommended by a provider was consistently associated with preferring every listed HIV prophylaxis method besides daily oral PrEP (see Table 2). MSM who reported a daily pill regimen as their main reason for refusing daily oral PrEP had greater odds of being likely to use long-acting injectable PrEP (AOR = 5.21, 95% CI: 1.32 to 20.52). In addition, men aged 18–29 (vs 30+) years had greater odds of reporting they were likely to use condoms (AOR = 3.40, 95% CI: 1.15 to 10.04) or daily oral PrEP (AOR = 2.76, 95% CI: 1.06 to 7.16) in the future.

Belief that Daily PrEP is Good for all Gay and Bisexual Men

MSM respondents indicated that PrEP is good for all (41%), most (19%), some (24%), or not any (3%) gay or bisexual men to use, whereas 13% reported they did not know enough about PrEP to say. Controlling for demographic variables of race, age, and city, men who believed PrEP to be good for all gay and bisexual men (vs all other respondents) had a greater odds of reporting likelihood of using daily oral PrEP (AOR = 6.44, 95% CI: 2.35 to 17.63; not in tables). Younger (18–29 vs 30+ years) men had greater odds of believing that PrEP was good for all gay and bisexual men (AOR = 4.81, 95% CI: 1.91 to 12.11); age and city were not associated with the belief that PrEP was good for all men.

DISCUSSION

A decade into daily oral PrEP as a viable HIV prevention method for MSM, some men with behavioral indications continue to refuse to use it when offered to them by a provider. We found potential side effects, a daily pill regimen, and lack of adequate information about PrEP to be top reasons for refusing daily PrEP in a diverse sample of MSM. These findings are similar to previous hypothetical studies of MSM who had not been offered PrEP but said that they would not use daily oral PrEP if offered by a health provider.^{4,12–15} Unlike many of the earlier hypothetical studies among men who had not been offered PrEP, however, MSM in our study who refused PrEP had fewer concerns about access and cost. Advancements in cost coverage over the past decade (eg, Medicaid expansion, federal and drug company medication assistance programs, and federal clarification that insurers must pay for all PrEP-related costs) are helping to ease financial concerns among MSM,^{18–20} however not universally for states that have not expanded Medicare. Stigma of using PrEP was also not a common primary reason for men refusing PrEP²¹ as it was earlier in the era of PrEP implementation, as social norms adjust when more MSM use PrEP.^{22,23}

Among the top reasons for refusing daily oral PrEP recommended by a provider were potential side effects.^{4,12–14,24} Provider training and social marketing efforts are needed to inform MSM about research on type and frequency of potential side effects and framing those side effects in perspective with other common medications prescribed by providers. Daily adherence is understandably a concern for some MSM who refuse daily PrEP; however, since late 2021,² providers may prescribe oral event-driven or long-acting injectable PrEP as alternatives to a daily adherence regimen. Provider training and community education on these new PrEP modalities may also be needed, as well as training on facilitating sexual health discussions with patients for a wider range of health providers who may serve MSM,²⁵ and discussions that should continue over time to ensure successful PrEP adherence and persistence or necessary adjustments.

Most MSM with behavioral indications who refuse daily oral PrEP offered by a provider reported that they are likely to use daily PrEP or other emerging prophylaxis methods in the future. This is promising for providers and health officials to continue to message and discuss PrEP options with their MSM patients despite their initial reluctance to use PrEP. Provider education on emerging HIV prevention products is a critical next step to inform ongoing discussions with MSM about the best PrEP alternatives for them²⁵ while considering that optimal prevention methods for an individual may change over time.²⁶

This study of MSM who refused daily oral PrEP recommended by a provider represents a first quantitative study on a unique sample that we are aware of, and, further, focused largely on Black MSM in 3 US cities. Given the small sample size ($n = 93$), some of the odds ratios have relatively wide CIs and are not entirely stable. Nevertheless, these results give practical direction to next steps for messaging for racial and ethnic minority HIV-negative MSM who are reluctant to use daily oral PrEP. More research is needed in larger samples of MSM who refuse PrEP offered by a provider to better understand the intricacies of why they refuse PrEP now and what are their intentions for HIV prevention in the future—especially in a new era of multiple available PrEP modalities. Another limitation is the hypothetical nature of multiple PrEP modalities at the time of the study, when only daily oral PrEP was available and recommended in the United States. Now that long-acting injectable and event-driven PrEP are available modalities; actual behavior can be assessed for those options and daily oral PrEP when offered by a provider. Nonetheless, our 2019 study of several products that would be available in the future provides insight into potential alternative preferences and relevant prevention messaging for MSM.

Implementation of daily oral PrEP has its challenges; some of those persist over time (eg, daily regimen, concern for side effects),^{27–29} while other challenges are being addressed (eg, cost, access).^{5,16,26,30} The advent of new HIV prophylaxis methods brings a greater variety of prevention opportunities for MSM, particularly men who have refused daily PrEP, although injectable and event-driven PrEP may have their own challenges for uptake and adherence. Most men who refuse daily PrEP when offered by a provider still indicate a likelihood of using some form of PrEP in the future. This is promising for HIV prevention providers and public health officials, indicating a need to continue to discuss and offer PrEP products to MSM under their care over time, further addressing the Ending the HIV Epidemic in the US initiative.³¹

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Characteristics of Gay, Bisexual, and Other Men Who Have Sex With Men and Their Main Reason for Refusing Daily Oral PrEP Offered by a Health Care Provider, 3 US Cities in 2019 (n = 93)

Characteristic	Main Reason for Refusing PrEP Offered by a Provider									
	Potential Side Effects			Daily Pill Regimen			Not Enough Info			Other
	n (%)	n (%)	AOR (CI)	n (%)	n (%)	AOR (CI)	n (%)	n (%)	AOR (CI)	
Overall	93 (100)	33 (35)	—	20 (22)	—	—	17 (18)	—	23 (25)	
Race/ethnicity										
Black/African American	65 (70)	23 (35)	1.44 (0.51–4.10)	15 (23)	1.18 (0.34–4.08)	14 (22)	2.40 (0.54–10.63)	13 (20)	0.21 (0.06–0.72)*	
Other (ref)	28 (30)	10 (36)		5 (18)		3 (11)		10 (36)		
Age group, yrs										
18–29	45 (48)	11 (24)*	0.33 (0.13–0.86)*	13 (29)**	1.66 (0.55–5.10)	9 (20)	1.27 (0.39–4.18)	12 (27)	1.59 (0.52–4.80)	
30+ (ref)	48 (52)	22 (46)		7 (15)		8 (17)		11 (23)		
City/MSA										
Atlanta	35 (38)	14 (40)	0.63 (0.21–1.89)	9 (26)	0.78 (0.23–2.63)	6 (17)	0.72 (0.19–2.77)	6 (17)	3.19 (0.84–12.14)**	
Raleigh-Durham	24 (26)	8 (33)	0.69 (0.19–2.61)	4 (17)	0.54 (0.12–2.45)	4 (17)	0.53 (0.10–2.85)	8 (33)	5.04 (1.05–24.23)*	
Chicago (ref)	34 (36)	11 (32)		7 (21)		7 (21)		9 (26)		

Other race/ethnicities include Hispanic/Latino, White, and mixed. Multivariable logistic regression analysis models included all variables in each column. AOR, adjusted odds ratio; CI, 95% confidence interval; —, not applicable; MSA, metropolitan statistical areas.

* *P*, 0.05.

** *P*, 0.10.

TABLE 2.

Gay, Bisexual, and Other Men Who Have Sex With Men Who Refused Daily Oral PrEP From a Health Care Provider: Likelihood to Use Condoms, Daily Oral PrEP, and Other PrEP Products in the Future, 3 US Cities in 2019 (n = 93)

Characteristic	Likely to Use HIV Prevention Product in Future											
	Condoms			Daily Oral PrEP			Sexual Event Oral PrEP			Injectable PrEP		
	n (%)	AOR (CI)	n (%)	n (%)	AOR (CI)	n (%)	n (%)	AOR (CI)	n (%)	AOR (CI)	n (%)	AOR (CI)
Overall (n = 93)	64 (70)	—	46 (50)	—	50 (54)	—	48 (52)	—	53 (58)	—	43 (47)	—
Main reason refused PrEP												
Daily pill regimen (n = 20)	14 (70)	1.62 (0.41–6.43)	8 (40) *	0.34 (0.09–1.31)	13 (65)	2.87 (0.78–10.53)	13 (65)**	5.21 (1.32–20.52) *	11 (55)	1.25 (0.36–4.36)	8 (40) **	0.90 (0.25–3.22)
Potential side effects (n = 33)	23 (72)	2.78 (0.77–10.08)	11 (34)	0.37 (0.11–1.23)	15 (47)	1.40 (0.44–4.44)	17 (53)	2.43 (0.72–8.16)	17 (53)	1.14 (0.37–3.54)	12 (38)	0.95 (0.30–3.03)
Not enough info (n = 17)	14 (82)	4.36 (0.83–22.76)**	13 (76)	2.09 (0.47–9.18)	12 (71)	4.09 (1.00–16.75) *	11 (65)	4.92 (1.17–20.66) *	13 (76)	3.54 (0.84–14.96)**	13 (76)	4.79 (1.12–20.59) *
Other (n=23), ref	13 (56)		14 (61)		10 (43)		7 (30)		12 (52)		10 (43)	
Race/ethnicity												
Black/African American (n = 65)	45 (70)	0.79 (0.25–2.48)	34 (53)	1.25 (0.42–3.71)	33 (52)	0.47 (0.17–1.35)	34 (53)	1.04 (0.36–2.97)	35 (55)	0.56 (0.20–1.57)	31 (48)	0.85 (0.30–2.40)
Other (n = 28), ref	19 (68)		12 (43)		17 (61)		14 (50)		18 (64)		12 (43)	
Age group, yrs												
18–29 (n = 45)	36 (80) *	3.40 (1.15–10.04) *	28 (62) *	2.76 (1.06–7.16) *	26 (58)	1.40 (0.56–3.48)	20 (44)	0.47 (0.18–1.21)	26 (58)	1.09 (0.44–2.69)	24 (53)	1.83 (0.72–4.61)
30+ (n = 48), ref	28 (60)		18 (38)		24 (51)		28 (60)		27 (57)		19 (40)	
City/MSA												
Atlanta (n = 35)	24 (69)**	2.79 (0.80–9.71)	17 (49)	0.78 (0.27–2.30)	20 (57)	0.89 (0.32–2.44)	20 (57)	0.52 (0.18–1.48)	21 (60)	0.92 (0.34–2.54)	15 (43)	1.20 (0.42–3.38)
Raleigh-Durham (n = 24)	12 (52)	0.69 (0.20–2.41)	13 (57)	1.28 (0.37–4.45)	13 (57)	1.46 (0.44–4.82)	14 (61)	1.35 (0.39–4.65)	13 (57)	1.08 (0.33–3.53)	12 (52)	1.70 (0.51–5.68)
Chicago (n = 34), ref	28 (82)		16 (47)		17 (50)		14 (41)		19 (56)		16 (47)	

Other race/ethnicities include Hispanic/Latino, White, and mixed. Multivariable logistic regression analysis models included all variables in each column. AOR, adjusted odds ratio; CI, 95% confidence interval; –, not applicable; MSA, metropolitan statistical areas.

* *P*, 0.05.

** *P*, 0.10.