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RUNNING HEAD: Changes in attitudes toward PrEP over time

Changes in familiarity with and willingness to take PrEP in a longitudinal study of highly sexually active gay and bisexual men

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ABSTRACT

PURPOSE: For gay and bisexual men (GBM), research suggests that familiarity with Pre-Exposure Prophylaxis (PrEP) has been increasing since being approved by the U.S. FDA in 2012. However, it is less clear how willingness to start using PrEP has changed over time. Likewise, some have expressed concerns regarding the potential for risk compensation (i.e., reduced condom use) were one to start PrEP; however, again, it is unclear how these may have been changing over time.

METHODS: We conducted baseline and 12 month assessments with 158 highly sexually active HIV-negative GBM in NYC who were assessed between 2011 and 2014. We examined change over time both between participants (based on when they entered the study), as well as within each participant (over the 12 months of his involvement).

RESULTS: Familiarity with PrEP increased over time (both between and within participants); however, willingness to take PrEP did not change (neither between nor within participants). Few men believed taking PrEP would cause their condomless anal sex (CAS) to increase and this did not change over time. However, a majority believed PrEP would increase *temptation* for CAS, and this did not change over time within participants. Sexual compulsivity (SC) symptomology was associated with higher willingness to take PrEP and perceiving that PrEP would increase one's temptations for CAS. Furthermore, recent CAS was associated with greater willingness to take PrEP, a perception that PrEP would increase one's likelihood to engage in CAS, and a perception that being on PrEP would increase one's temptation for CAS.

CONCLUSIONS: Participants became more familiar with PrEP over time; however, willingness to start PrEP did not change, and this may serve as an opportunity for providers to

discuss PrEP with their patients. Higher risk men were interested in PrEP and pre-existing patterns of sexual behavior may be the primary determinant of CAS while on PrEP.

Introduction

Gay and bisexual men (GBM) continue to be disproportionately affected by HIV in the United States, making up 84% of new infections among men.¹ In July 2012, the United States Food and Drug Administration (FDA) approved once-daily Truvada (emtricitabine/tenofovir disoproxil fumarate) for use as Pre-Exposure Prophylaxis (PrEP) to prevent HIV transmission to HIV-negative individuals. It has been recommended by both the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO).^{2,3} Among GBM, evidence from several studies suggests that familiarity with PrEP has been increasing over time from reported ranges of 11% in 2010-2011⁴ to 54% in 2014.⁵ However, it is less clear how *willingness* to start PrEP has changed over time. Research addressing willingness to start PrEP has varied from 28-80% with most studies reporting 50% or higher.⁴ Anecdotal data suggest that there are multiple barriers to beginning PrEP including stigma attached to using PrEP,⁶ fears around side effects and potential drug resistance to future forms of HIV biomedical prevention.⁷

Likewise, some researchers and popular media outlets have expressed concerns regarding the potential for risk compensation via reduced condom use (i.e., biological risks are decreased due to PrEP and so condom use decreases).⁸ A PrEP demonstration project from three cities (San Francisco, Miami, and Washington D.C.) conducted between 2012 and 2015 that followed participants for 48 weeks found that the average number of anal sex partners declined during follow-up from 10.9 to 9.3, whereas the proportion engaging in condomless receptive anal sex remained stable at 66%.⁹ Although STI incidence was high (90 infections per 100 person-years), it did not increase over time. Only two individuals contracted HIV, both of whom had plasma levels of PrEP consistent with fewer than two doses per week at seroconversion.¹⁰ A recent San Francisco study of men on PrEP reported no new HIV infections over a 2.5 year period, while

more than half of participants had contracted an STI, which suggests low rates of condom use while on PrEP, though rates of condom use prior to beginning PrEP were not reported.¹¹

To provide insights into changes in familiarity with PrEP as well as willingness to start PrEP, we conducted baseline and month 12 assessments with highly sexually active gay and bisexual men assessed between 2011 and 2014. At both time points we assessed for familiarity with PrEP and willingness to start PrEP. In addition, we assessed for perceived effect of PrEP on condomless anal sex (CAS) as well as temptation for CAS.

Method

Analyses for this article were conducted on data from *Pillow Talk*, a longitudinal study of highly sexually active (i.e., ≥ 9 male partners in 90 days) gay and bisexual men in New York City (NYC).¹² Participants were recruited using a combination of strategies: (1) respondent-driven sampling; (2) Internet-based advertisements on social and sexual networking websites; (3) email blasts through NYC gay sex party listservs; and (4), active recruitment in NYC venues such as gay bars/clubs, concentrated gay neighborhoods, and ongoing gay community events.

Enrollment began in February 2011 and closed in June 2013. Participants were followed for a period of 12 months. Data for this article were taken from the baseline and 12 month visits (the last participant completed his 12 month assessment in June 2014). The project enrolled both HIV-negative and HIV-positive men, though the analyses for this article were limited to HIV-negative men. Of the 376 men who enrolled in the project, 207 (55.2%) were confirmed to be HIV-negative with a rapid HIV antibody test during their baseline assessment—two of these participants tested HIV-positive at their 12-month assessment and were excluded. One of these men was missing necessary data at baseline, 42 individuals did not return for their 12-month

assessment, and four were missing necessary data at the 12-month assessment. Thus, analyses focused on a sample of 158 participants.

Participants and Procedures

To be eligible, participants had to be at least 18 years of age, biologically male and self-identified as male, report nine or more male sexual partners in the prior 90 days, self-identified as gay, bisexual, or some other non-heterosexual identity (e.g., queer), and have access to the Internet. Participants were emailed a link to an Internet-based computer-assisted self-interview (CASI), which included informed consent procedures. Men completed this one-hour online survey at home followed by an in-person baseline appointment and the same procedures were followed for the 12-month assessment. In-person assessments included a structured timeline follow-back (TLFB) interview in which a calendar is used to recall one's daily sexual behavior and substance use.¹³ Final eligibility and enrollment was confirmed during the in-person appointment. All procedures were reviewed and approved by the City University of New York Institutional Review Board.

Measures

Measures used for this article were taken from the baseline and 12-month assessment. Using a computer-assisted survey, participants reported demographic characteristics, including sexual identity, age, race/ethnicity, education, and relationship status. Participants also completed the 10-item Sexual Compulsivity Scale (SCS; $\alpha = 0.91$).^{14,15} The SCS has been shown to have high reliability and validity across multiple studies.^{16,17} A score of 24 was used as a cutoff indicative of experiencing problematic levels of sexual compulsivity.¹⁸⁻²¹

At baseline and month 12, participants were presented with the following brief summary of PrEP:²²

“PrEP (pre-exposure prophylaxis) is a new biochemical strategy to prevent HIV infection. PrEP involves HIV-negative guys taking anti-HIV medications (for example, Truvada) once a day, every day to reduce the likelihood of HIV infection if they were exposed to the virus. The first clinical trial of PrEP indicated that it reduced the likelihood of HIV infection when used in combination with other preventative methods, such as condoms.”

Participants then responded to a series of single-item questions regarding PrEP.

Familiarity with PrEP. Participants were asked how familiar they were with PrEP (*I’ve never heard of it before today; I’ve heard about it, but I don’t really know what it was; I know a little bit about it; I know a fair amount about it; I know a lot about it*). Those indicating they knew a fair amount or a lot were coded as being familiar with PrEP (0 = no, 1 = yes).

Willingness to take PrEP. Participants were asked how likely they would be to take PrEP if it were at least 40% effective and offered to them for free (*“definitely,” “probably,” “might,” “probably not,” “definitely not”*). Those who said they would probably or definitely take it were coded as being likely to take PrEP (0 = no, 1 = yes).

Likelihood of engaging in CAS. Men were also asked how taking PrEP would influence their likelihood to engage in condomless anal sex (*“significantly more likely,” “somewhat more likely,” “would not change,” “somewhat less likely,” “significantly less likely.”*). The variable was dichotomized to reflect those who responded that PrEP would make them somewhat or significantly more likely to engage in CAS (0 = no, 1 = yes).

Temptation to engage in CAS. Men were asked “How do you think taking PrEP would impact your temptation to have sex without condoms?” with Likert-type responses on a 7-point scale. The anchor points were -3 = *“much less tempted,”* 0 = *“no impact,”* and +3 = *“much more*

tempted.” This variable was dichotomized with those indicating 1 through 3 coded as having increased temptation for CAS (0 = no, 1 = yes).

During the TLFB interview, we collected data on CAS with any male partners in the prior 6 weeks (42 days), dichotomized 1 = yes, 0 = no. In addition, we collected data on instances of club drug use (ketamine, MDMA/ecstasy, GHB, cocaine, crystal methamphetamine) in the past 6 weeks, dichotomized 1 = yes, 0 = no.

Analytic Plan

We calculated the month of enrollment during which each participant joined (0 through 27) and created a dichotomous variable indicating the type of visit (baseline = 0, 12-month follow-up = 1). We created a dichotomous variable indicating whether or not each visit occurred after the FDA approval of PrEP on July 16, 2012.

We conducted multilevel modeling examining the effect of between-person enrollment month (0 through 27) and within-person visit type (Baseline vs. 12 month) on PrEP familiarity, willingness to take PrEP, and perceived influence of PrEP on likelihood and temptation to engage in CAS. All models were adjusted for time-invariant covariates (age, White race, sexual identity, and college education or higher which were all measured at baseline), as well as three time-varying covariates (relationship status, whether or not the FDA had yet approved PrEP (i.e., data collected before and after July 2012), and whether or not the participant had engaged in any CAS with a male partner at each assessment point). Throughout the results we distinguish between-person (i.e., time invariant) versus within-person (i.e., time-varying) effects within the multilevel models. In reference to the effect of time, the between-person effect references the time when individuals began the study and can be interpreted as the change in the odds of the outcome for an individual who started the study later than another individual. The within-person

effect of time compares each individual's odds of the outcome after 12 months of being enrolled in the study compared to his own odds at baseline.

Results

As seen in Table 1, the sample was diverse at baseline with regards to race/ethnicity and educational attainment, whereas a majority of the sample was gay-identified and single. At baseline, 22.8% were familiar with PrEP, 46.8% expressed willingness to take PrEP, 25.3% believed PrEP would increase their likelihood to engage in CAS, and 58.2% believed PrEP would increase their temptation to engage in CAS. By the 12-month assessment, the numbers familiar with PrEP and who believed their likelihood of CAS would increase on PrEP had both grown somewhat, whereas the numbers who were willing to take PrEP and who believed their temptation for CAS would increase on PrEP had slightly declined. More than half of the sample had engaged in CAS at baseline and this declined to about half at follow-up, whereas approximately one-quarter had used club drugs at baseline and this increased to nearly 30%. It is worth noting that there was a decline in the number of male partners men reported from baseline to follow-up as well.

After adjusting for both demographic and behavioral characteristics in the model, the odds of being familiar with PrEP increased significantly between participants by 10% per month from the beginning to the end of enrollment but not within participants from baseline to follow-up (see Table 2).. This suggests that individuals who started the study later had greater familiarity with PrEP than individuals who started the study earlier, but each individual's familiarity was unchanged over the 12 months he was enrolled. The adjusted odds of being willing to take PrEP, perceiving that being on PrEP would increase the likelihood of engaging in CAS, and perceiving that being on PrEP would increase temptation to engage in CAS all

remained stable both between and within participants over time. This suggests that individuals who started the study later were no different than individuals who started the study earlier and individuals, on average, did not change over the course of their enrollment.

It is also worth noting the significant associations of covariates within the models. At the between-participant level, gay men had higher odds than bisexual men of being willing to take PrEP, men with at least a college degree had lower odds than men with less education of being willing to take PrEP, and White men had higher odds than non-White men of believing PrEP would increase their likelihood of engaging in CAS. At the within-person level, reporting club drug use during a visit was associated with higher odds of also reporting familiarity with PrEP during that visit. Reporting sexual compulsivity (SC) symptomology was associated with higher odds of reporting willingness to take PrEP as well as perceiving that PrEP would increase one's temptations for CAS during the same visit. Furthermore, reporting CAS prior to a visit was associated with higher odds of reporting during the same visit a willingness to take PrEP, a perception that PrEP would increase one's likelihood to engage in CAS, and a perception that being on PrEP would increase one's temptation for CAS.

Discussion

Pillow Talk was a study of highly sexually active gay and bisexual men—individuals who are excellent candidates for PrEP based on WHO and CDC criteria/guidance.^{2,3,23} Our data demonstrated that individuals who started the study later had higher familiarity with PrEP, though there was no increase in each individual's level of familiarity over the year he was in the study. Willingness to take PrEP was the same regardless of when individuals began the study and also did not change within individuals over the course of their enrollment; however, it is important to note that nearly half of participants were willing to take PrEP if it was free. It may

be that willingness to start PrEP is the result of relatively stable individual-level factors that are more resistant to change over time, such as not believing that one would be an appropriate candidate for PrEP² or stigma attached to using PrEP,⁸ neither of which was measured in this study. The results of this study highlight the need to identify barriers to PrEP uptake amidst increasing familiarity.

Few men believed taking PrEP would cause their CAS to increase and we did not find evidence that this changed over time. A majority of participants believed PrEP would increase *temptation* for CAS, but this also did not appear to change over time. These findings suggest the importance of investigating differences between *temptation* and *likelihood* as well as their impact on actual changes in CAS among men before and after they start PrEP. Furthermore, although risk compensation is of concern for STIs, it also remains important for researchers to both investigate and acknowledge the intrinsic benefits of CAS such as increased sexual pleasure and feelings of connectedness.^{24,25} Likewise, researchers must acknowledge the relative risks of STI transmission and treatment versus HIV transmission and treatment.

The results of this study should be understood in light of their limitations. To be eligible for *Pillow Talk*, men had to report at least 9 male partners in the prior 90 days. This sample represents, by definition, a priority population for PrEP; however, these men do not represent all GBM. One strength of our study was the assessment of changes between baseline and 12 months; however, we recognize that both a longer assessment window and/or more incremental assessment points would have benefited this study. It would be important to replicate this study today in light of emerging data highlighting consistently the effectiveness of PrEP in community-based settings.^{9,11} Furthermore, we acknowledge that by virtue of asking participants about PrEP we are in-fact exposing them to information about PrEP, and this may have

contributed to our findings regarding increased knowledge over time. We did not assess where or how participants were learning about PrEP, and thus cannot attest to the magnitude of test-retest effects attributable to this study. Enrollment for this study began before data on clinical trials regarding PrEP's effectiveness were available. Thus, we used a conservative estimate of 40% effectiveness when describing PrEP to participants. This number was in line with initial data on PrEP's effectiveness;²⁶ however, early findings included individuals who were prescribed PrEP but did not have detectable levels of PrEP in their bloodstream (i.e., were not taking PrEP). We now know that PrEP is much more effective when taken as prescribed¹¹ and this new-and-emerging information will likely have a significant impact on men's decisions to use PrEP today. In essence, were revised estimates of effectiveness presented to participants, we might have observed different values for both uptake as well as the perceived impact on CAS.

We do not have data on reasons why individuals were unwilling to take PrEP and our findings indicate that enough individuals were unwilling to do so that further consideration is warranted, perhaps through qualitative methods like semi-structured interviews and/or focus groups. The results of this study concerned hypothetical PrEP initiation. As PrEP continues to diffuse as a new prevention strategy, it is important to continue to investigate how PrEP will affect both perceived and actual sexual behaviors of GBM. Our measure of temptation to have sex without condoms did not specify anal sex; however, we believe strongly that participants understood this to mean anal sex. Finally, sexual behavior decreased among participants in our study over time, and this was controlled for in our analyses, but we did not have data as to why behavior decreased. It may be that because frequency was so high at baseline we observed a statistical regression toward the mean.

Conclusion

Gay and bisexual men became more aware of PrEP as enrollment for *Pillow Talk* continued in time, and this may be largely a result of the recent growth of both traditional and social media campaigns to promote PrEP education and dissemination (e.g., myPrEPexperience.blogspot.com, whatisPrEP.org, PrEPforsex.org, #TruvadaWhore on Twitter and Facebook); however, the actual effect of PrEP promotion campaigns was not measured in this study. Nevertheless, in this study, willingness to use PrEP did not change over time. To what extent was stagnant willingness to start PrEP a result of combined concerns regarding effectiveness, access, side effects, and fear of stigma? The potential for risk compensation seemed low (and unchanged over time); however, participants' temptation for CAS as a result of PrEP was high. Data gathered from men before and after starting PrEP are necessary to discern the actual impact of PrEP in real world settings, and we suggest that researchers weigh the intrinsic benefits associated with CAS in the event of risk compensation.

With the expansion of PrEP uptake, some have expressed concerns regarding risk compensation; however, less is mentioned about behavioral disinhibition. Risk compensation could be conceptualized as between subjects differences in cognitions and attitudes that differentially predict engagement in CAS (e.g., level 2 predictor); whereas, behavioral disinhibition could be conceptualized as changes in behaviors on average over time (e.g., between and within subjects changes in outcomes over time). Our findings suggest a need to collect data on and assess for risk compensation as well as behavioral disinhibition.

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Table 1.
Demographic and background characteristics of the sample ($N = 158$)

	Baseline		12-Month	
	<i>n</i>	%	<i>n</i>	%
Race/Ethnicity				
Black	24	15.2	--	--
Latino	19	12.0	--	--
White	93	58.9	--	--
Other/multiracial	22	13.9	--	--
Sexual Orientation				
Gay	132	83.5	--	--
Bisexual	26	16.5	--	--
Educational Attainment				
Less than a bachelor's degree	46	29.2	--	--
Bachelor's degree	62	39.2	--	--
Graduate degree	50	31.6	--	--
Relationship Status				
Single	134	84.8	114	72.2
Partnered	24	15.2	44	27.8
Familiar with PrEP				
No	122	77.2	107	67.7
Yes	36	22.8	51	32.3
Willing to take PrEP				
No	84	53.2	87	55.1
Yes	74	46.8	71	44.9
Likelihood of CAS on PrEP				
No	118	74.7	113	71.5
Yes	40	25.3	45	28.5
Temptation for CAS on PrEP				
No	66	41.8	77	48.7
Yes	92	58.2	81	51.3
Any CAS				
No	63	39.9	78	49.4
Yes	95	60.1	80	50.6
Any club drug use				
No	118	74.7	111	70.3
Yes	40	25.3	47	29.7
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Age	34.8	12.2	--	--
Number of male partners	12.2	8.2	6.6	6.2

Note. Race/ethnicity, sexual orientation, educational attainment, and age were assessed once and fixed over time.

Table 2.
Longitudinal models examining predictors of PrEP-relevant factors

	PrEP Familiarity			Willingness to Take PrEP		
	B	AOR	95% CI	B	AOR	95% CI
Between-Participant Factors (Level 2)						
Age	0.03	1.03	0.99, 1.06	-0.01	0.99	0.97, 1.02
White race (ref = non-White)	-0.41	0.66	0.31, 1.44	-0.06	0.94	0.50, 1.76
Gay (ref = bisexual)	0.82	2.28	0.80, 6.45	0.93	2.53*	1.11, 5.74
College degree (ref = no)	-0.26	0.77	0.34, 1.75	-0.92	0.40**	0.21, 0.77
Month of enrollment	0.10	1.10**	1.02, 1.19	0.04	1.04	0.98, 1.10
Within-Participant Factors (Level 1)						
Partnered (ref = single)	-0.36	0.70	0.30, 1.64	-0.55	0.58	0.29, 1.17
Club drug use (ref = no)	0.89	2.44*	1.12, 5.30	0.11	1.12	0.59, 2.12
SC symptomology (ref = no)	-0.40	0.67	0.33, 1.37	0.62	1.86*	1.04, 3.32
FDA approved PrEP (ref = no)	0.32	1.37	0.47, 3.98	-0.52	0.59	0.25, 1.42
Any CAS reported (ref = no)	0.27	1.31	0.66, 2.61	0.79	2.21**	1.25, 3.91
12-month assessment (ref = baseline) ^b	0.48	1.61	0.78, 3.35	0.35	1.42	0.73, 2.77
	Likelihood of CAS on PrEP			Temptation for CAS on PrEP		
	B	AOR	95% CI	B	AOR	95% CI
Between-Participant Factors (Level 2)						
Age	-0.02	0.98	0.95, 1.01	-0.03	0.97	0.95, 1.00
Gay (ref = bisexual)	0.39	1.47	0.57, 3.84	0.39	1.47	0.59, 3.64
White race (ref = non-White)	1.04	2.82**	1.33, 5.98	0.42	1.53	0.75, 3.09
College degree (ref = no)	0.21	1.23	0.57, 2.69	0.73	2.08	0.99, 4.38
Month of enrollment	0.03	1.03	0.96, 1.10	0.03	1.03	0.97, 1.10
Within-Participant Factors (Level 1)						
Partnered (ref = single)	-0.16	0.85	0.39, 1.83	0.43	1.54	0.71, 3.32
Club drug use (ref = no)	0.10	1.11	0.54, 2.29	0.04	1.04	0.50, 2.14
SC symptomology (ref = no)	0.30	1.35	0.69, 2.63	0.84	2.32**	1.21, 4.44
FDA approved PrEP (ref = no)	-0.49	0.61	0.22, 1.69	0.82	2.28	0.87, 5.95
Any CAS reported (ref = no)	1.71	5.51***	2.65, 11.46	1.27	3.57***	1.91, 6.66
12-month assessment (ref = baseline) ^b	0.65	1.91	0.87, 4.18	-0.66	0.52	0.25, 1.07

Note. * $p \leq 0.05$; ** $p \leq 0.01$; *** $p \leq 0.001$; ^a Between-person time was coded as the month of the participant's enrollment (0 through 27) which was mean centered and time invariant (i.e., constant for the same participant over time); ^b Within-participant time was dichotomously coded as the month of the assessment (BL = 0, 12M = 1) and was time-varying (i.e., differed for the same participant over time). Age and month of enrollment were both mean centered.