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**HIV pre-exposure prophylaxis (PrEP) uptake and retention among men
who have sex with men in a community-based sexual health clinic**

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ABSTRACT

In a community-based clinic serving men who have sex with men (MSM) in San Francisco, California, this study characterized key steps of the PrEP cascade and identified correlates of retention in care. In total, 344 patients were evaluated for PrEP. Three-fourths (78%) of those who sought PrEP services initiated PrEP. The overall cumulative incidence of discontinuing PrEP at 13 months was 38%. Men with a sexually transmitted infection (STI) were 44% less likely to be retained (adjusted hazard ratio [aHR] 0.56, 95% confidence interval [0.33-0.95]). Comprehensive retention efforts for men with STIs are crucial to optimize the benefits of PrEP.

Keywords: HIV pre-exposure prophylaxis, PrEP, men who have sex with men, retention in care, PrEP cascade

INTRODUCTION

The pre-exposure prophylaxis (PrEP) cascade is a framework for identifying gaps in the care continuum. It involves a series of steps that includes a medical evaluation for PrEP eligibility, initiating PrEP, and retention in PrEP services [1,2]. The cascade provides measureable benchmarks from which we can evaluate the implementation of PrEP programs and inform the development of interventions to optimize engagement. Literature describing PrEP implementation and retention in care outcomes in clinical settings are growing. A study of patients in an integrated healthcare system in Northern California reported a dramatic increase in demand for PrEP since the program started in 2012 [3]. A recent study by Chan et al. [4] that examined PrEP programs at community clinics in Rhode Island, Mississippi, and Missouri also noted high uptake with approximately 60% of patients retained at six months. However, risk factors for discontinuing PrEP services are not well understood and further research is needed to characterize the steps of the cascade in other clinical settings.

In the HIV treatment literature [5], stimulant and unhealthy alcohol use are well-known challenges to retention in care among men who have sex with men (MSM). Stimulant use and unhealthy drinking are prevalent among MSM [6] and recognized as two of the most important drivers of HIV infection because of their well-documented association with condomless sex [7-9]. However, little is known about whether stimulant use and unhealthy drinking are barriers to optimizing the PrEP cascade in MSM. To address these gaps in knowledge, we characterized the PrEP cascade and identified correlates of retention in PrEP services at a community-based sexual health clinic serving MSM. We hypothesized that stimulant and unhealthy alcohol use will be associated with poor retention in PrEP clinical services.

METHODS

We abstracted the medical records of all consecutive patients screened for PrEP eligibility between November 2014 and August 2015 at a nurse-led community-based clinic that provides free sexual health services in San Francisco, California. Patients either self-referred or were offered PrEP by clinicians because of known risk factors (e.g., diagnosis of sexually transmitted infection [STI]). Patients completed a self-administered questionnaire during their clinical intake. The form assessed relevant risk behaviors in the last 12 months, including condomless sex, sex while high or intoxicated, sex with an unknown serostatus partner, the total number of sex partners, and types of drugs used. Any self-reported use of stimulants (i.e., powder cocaine, crack-cocaine, and methamphetamine) was assessed. Self-reported binge drinking (i.e., ≥ 5 alcoholic beverages on a single occasion) in the last 30 days was also assessed.

PrEP eligibility was based on CDC guidelines [10]. However, a prescription for PrEP was provided upon request even in the absence of apparent HIV risk, given that risk behaviors are sometimes underreported. The cost of the medication for PrEP (emtricitabine-tenofovir disoproxil fumarate) was dependent on the patient's insurance coverage. Benefit navigators were available onsite to help patients access medication assistance programs that can offset out of pocket costs. Navigators also assisted patients without insurance apply for coverage.

Follow-up visits were scheduled every 1-3 months. Clinicians authorized a 30-day prescription refill for patients who missed a follow-up appointment, allowing them to reschedule their visit without any lapses in coverage. Clinicians verified PrEP initiation at the first follow-up visit. Those who did not return for their first follow-up were considered to not have started PrEP. Retention in care was defined

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as patients presenting for their follow-up appointments. Patients who did not return within 30 days of a scheduled follow-up visit after PrEP initiation was verified and had no evidence of transferring care were considered to have discontinued PrEP and no longer retained in the program. For this retrospective clinical cohort, we collected medical record data up to 13 months of follow-up after men initiated PrEP. When noted in the medical record, we abstracted the reasons for why patients did not return for their follow-up visit.

PrEP uptake was calculated as the number of patients who returned for their 1-month follow-up divided by the total number who were medically evaluated for PrEP. The cumulative incidence of PrEP discontinuation at 13 months was estimated using the Kaplan-Meier estimator [11]. Differences in the cumulative incidence of PrEP discontinuation across strata of stimulant use and binge drinking were tested using the log-rank test of equality. Cox proportional hazard regression with robust standard errors was used to identify factors associated with time to PrEP discontinuation. Analyses were conducted using Stata 14 (College Station, TX).

RESULTS

A total of 344 patients were medically evaluated for PrEP between November 2014 and August 2015. The median age was 31 years (interquartile range [IQR] 12) and the median number of sex partners in the last 12 months was 10 (IQR 14). Most identified as gay or bisexual (99%), White (65%), and non-Hispanic (74%). Approximately 60% (208/344) reported using illicit substances in the last 12 months at their enrollment visit, of whom 44% (92/208) reported using stimulants. Half (50%) of all patients reported binge drinking in the last 30 days and slightly over half (59%) reported having sex while either high or intoxicated. Most patients reported engaging in condomless anal sex in the last 12 months (95%) and nearly

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one-third reported having sex with an unknown serostatus partner (31%). At enrollment, 12% (40/344) were diagnosed with rectal gonorrhea or rectal chlamydia and 3% (10/344) tested positive for syphilis.

Of the 344 patients who were evaluated for PrEP, 331 (96%) received a prescription to start the regimen. All of the individuals who received a prescription for PrEP were MSM. In total, 76 (22%) did not start PrEP (Figure 1). Of these, 23/76 (30%) did not start PrEP because of issues with cost or insurance coverage. The demographic characteristics and risk behaviors of those who did not start PrEP were not significantly different from those who initiated PrEP ($p>0.05$).

Among the 268 patients who initiated PrEP, median follow-up time was 389 days (range 112-488; due to the 30-day grace period allowed for rescheduling visits, some patients had longer follow-up times). The overall incidence of dropout was most pronounced around seven months after enrollment. The cumulative incidence of discontinuing PrEP services at four months was 4% and approximately 21% at seven months. At 10 months, the cumulative incidence of PrEP discontinuation was 29% and at 13 months, cumulative incidence was 38%.

Reasons documented in the medical record for PrEP discontinuation are summarized in Figure 1. The cumulative incidence of PrEP discontinuation at 13 months among stimulant users was 43% compared to 36% among non-users ($p=0.82$) and 42% among binge drinkers compared to 33% among those who denied unhealthy alcohol use ($p=0.53$). In the multivariable Cox proportional hazards model, men diagnosed with an STI (i.e., rectal gonorrhea, rectal chlamydia, or syphilis) at baseline were 44% less likely to be retained in the PrEP program (adjusted hazard ratio [aHR] 0.56, 95% confidence interval [0.33-0.95]). Stimulant

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use (aHR 1.00, [0.64-1.57]) and binge drinking (aHR 0.93, [0.64-1.37]) were not significantly associated with retention in PrEP clinical services.

DISCUSSION

We observed high uptake among individuals who were medically evaluated for PrEP at a nurse-led community-based sexual health clinic for MSM. Approximately 78% of patients started PrEP, consistent with reports from other clinical settings [3,4]. In a study of PrEP programs at clinics in Rhode Island, Mississippi, and Missouri, Chan et al. [4] found that medication cost generally had minimal impact on PrEP access. However, among patients in Mississippi, nearly 30% noted medication copayment as a barrier to obtaining PrEP. In our sample, structural barriers related to cost and issues with insurance coverage remained challenging for some individuals despite the availability of benefit navigators. Nearly one-third of those who did not initiate PrEP described cost or insurance issues as the reason for not starting.

Although stimulant use and binge drinking are known correlates of difficulties with HIV disease management [5], the modest associations with poorer retention in PrEP clinical services were not statistically significant. Others have reported similar findings in open label studies [12,13], but our results are among the first to demonstrate that MSM who use stimulants and engage in binge drinking display comparable rates of PrEP initiation and retention in PrEP clinical services. Men who use stimulants or engage in unhealthy drinking may be more aware of their risk profile and are more motivated to mitigate HIV risk. In fact, earlier PrEP studies have found that uptake and adherence were higher among persons who exhibited greater risk for acquiring HIV [12,13]. Overall, retention declined over time. We observed a marked drop in retention around seven months after enrollment with a

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cumulative incidence of PrEP discontinuation of approximately 21%. In their study of PrEP programs across three states, Chan et al. [4] noted an approximate 40% drop in retention around the same time. Important contextual factors, like attitudes towards PrEP, social marketing, and availability of resources, may partly account for the differences in retention observed between studies. Regardless, these findings underscore the need for interventions to sustain care engagement over time.

Individuals diagnosed with a rectal STI or syphilis at baseline were significantly less likely to be retained in PrEP clinical services. Clinicians may have been more likely to refer patients diagnosed with any STI during routine screening for PrEP than those who self-referred. Those with an STI may have lower intrinsic motivation or less perceived HIV risk than those who self-referred, which may explain poorer rates of retention. Because STI diagnoses like syphilis significantly increase the risk of HIV seroconversion [14], comprehensive interventions like PrEP adherence counseling, motivational enhancement, and navigation support services may help optimize PrEP retention in these individuals.

This study has important limitations. First, we were unable to fully evaluate reasons for PrEP discontinuation. It is possible that some patients moved away, transferred care, selected a different HIV prevention method, or had a change in their risk profile. All of these situations can be considered appropriate discontinuations of PrEP from the clinic's service. Second, substance use was captured using a questionnaire that asked patients about behaviors in the last year and we were unable to screen for alcohol and substance use disorders. Additionally, self-reported drug and alcohol use may be biased by social desirability. However, the clinic is known in the community as a sex-positive environment and staff are trained to provide nonjudgmental care to minimize underreporting of risk behaviors.

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Third, our use of data collected as part of routine clinical practice limited our ability to accurately capture other relevant factors like medication adherence. Fourth, it is important to recognize the current clinical context where PrEP roll-out is in its early stages. Most individuals seeking PrEP are early adopters. Further, this study was conducted in San Francisco where there has been a strong public health campaign to increase PrEP awareness and uptake. Individuals in our sample are likely a select group that are well-informed and more intrinsically motivated to engage in PrEP services.

Despite these limitations, this study provides important insights for PrEP implementation. Findings underscore the continued role of structural barriers to PrEP uptake such that difficulties with cost were reported by one-third of MSM who did not initiate PrEP. The high prevalence of STIs as well as binge drinking and stimulant use provide some indication that PrEP delivery is reaching MSM who are at greatest risk of HIV seroconversion. However, important challenges remain. Less than half of those who started PrEP were ultimately retained in PrEP clinical services at the end of our study and men with a rectal STI or syphilis were 44% less likely to be retained. Findings will inform efforts to optimize the delivery of PrEP clinical services with MSM.

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Figure 1. The pre-exposure prophylaxis (PrEP) cascade at a community-based sexual health clinic serving men who have sex with men (MSM). Patients were followed up to 488 days from enrollment. Of those who sought PrEP services, 268 (78%) initiated PrEP. Cost was the most commonly cited reason for not starting PrEP. Among those who initiated PrEP, 127 (47%) were retained in the program at the end of follow-up.