High Interest in Preexposure Prophylaxis Among Men Who Have Sex With Men at Risk for HIV Infection: Baseline Data From the US PrEP Demonstration Project

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Background: Preexposure prophylaxis (PrEP) is the first biomedical intervention with proven efficacy to reduce HIV acquisition in men who have sex with men (MSM) and transgender women. Little is known about levels of interest and characteristics of individuals who elect to take PrEP in real-world clinical settings.

Methods: The US PrEP Demonstration Project is a prospective open-label cohort study assessing PrEP delivery in municipal sexually transmitted disease clinics in San Francisco and Miami and a community health center in Washington, DC. HIV-uninfected MSM and transgender women seeking sexual health services at participating clinics were assessed for eligibility and offered up to 48 weeks of emtricitabine/tenofovir for PrEP. Predictors of enrollment were assessed using a multivariable Poisson regression model, and characteristics of enrolled participants are described.

Results: Of 1069 clients assessed for participation, 921 were potentially eligible and 557 (60.5%) enrolled. In multivariable analyses, participants from Miami (adjusted Relative Risk [aRR]: 1.53; 95% confidence interval [CI]: 1.33 to 1.75) or DC (aRR: 1.33; 95% CI: 1.2 to 1.47), those who were self-referred (aRR: 1.48; 95% CI: 1.32 to 1.66), those with previous PrEP awareness (aRR: 1.56; 95% CI: 1.05 to 2.33), and those reporting >1 episode of anal sex with an HIV-infected partner in the last 12 months (aRR: 1.20; 95% CI: 1.09 to 1.33) were more likely to enroll. Almost all (98%) enrolled participants were MSM, and at baseline, 63.5% reported condomless receptive anal sex in the previous 3 months.

Conclusions: Interest in PrEP is high among a diverse population of MSM at risk for HIV infection when offered in sexually transmitted disease and community health clinics.

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INTRODUCTION

In the United States, an estimated 50,000 new HIV infections occur each year,[1] highlighting the urgent need for new prevention strategies. Men who have sex with men (MSM) account for approximately two-thirds of new HIV infections and are the only group in whom HIV incidence has been rising.[2] Transgender women (TGW) also have elevated infection rates; over a quarter in the United States are HIV positive.[3–5]

Preexposure prophylaxis (PrEP) is the first biomedical intervention with proven efficacy to reduce HIV acquisition in MSM and TGW. Iniciativa Profilaxis Pre-Exposicion (iPrEx), a randomized controlled trial, demonstrated a 44% reduction in HIV incidence among MSM and TGW who received once-daily emtricitabine/tenofovir (FTC/TDF) and an estimated >90% efficacy among those with detectable blood drug levels.[6,7] Based on the compelling data from iPrEx and other PrEP trials,[8,9] the US Food and Drug Administration approved FTC/TDF for the prevention of sexually acquired HIV infection in July 2012.[10,11] The Centers for Disease Control and Prevention published PrEP clinical practice guidelines in May 2014.[12]

Modeling studies suggest PrEP could substantially reduce HIV incidence among MSM in the United States and may be cost effective if targeted to the highest risk populations.[13–15] However, little is known about levels of interest and characteristics of individuals who elect to take PrEP in clinical settings. An analysis of pharmacy claims found that between January 2012 and September 2013, only 2319 people filled prescriptions for FTC/TDF PrEP in the United States and almost half were women.[16] Several factors, including perceived low demand for PrEP,[17–19] inadequate access to insurance or health care,[20] lack of provider knowledge or willingness to prescribe PrEP,[21–24] and concerns about adherence,[25] HIV resistance,[26] risk compensation,[27] and cost,[15,20] may explain why there has not been rapid dissemination of this innovation. Demonstration projects have been recommended to address implementation issues and help determine if appropriate and how best to scale-up PrEP.[28,29]

The US PrEP Demonstration Project (The Demo Project) is the first study assessing the feasibility, acceptability, and safety of delivering PrEP to MSM and TGW in sexually transmitted disease (STD) clinics and a community health center. In this article, we describe the proportion of potentially eligible participants who elected to enroll in the study (PrEP uptake) and correlates of uptake and describe baseline demographic and risk characteristics among participants who enrolled.

METHODS

Study Design, Sites, and Population

The Demo Project is a prospective, longitudinal open-label cohort study assessing PrEP delivery in municipal STD clinics in San Francisco (SF) and Miami and a community health center in Washington, DC (DC). All 3 clinics are in metropolitan areas with high HIV incidence[1,30,31] and are experienced in providing sexual health services to at-risk MSM and TGW; the DC clinic also provides primary care services for HIV-uninfected and infected individuals. HIV-uninfected MSM and TGW receiving services or requesting PrEP at the study sites were assessed for participation in The Demo Project. Screening was conducted from September 2012 to November 2013 in SF and Miami and from August 2013 to January 2014 in DC. Enrolled participants were offered up to 48 weeks of FTC/TDF at no charge as part of a comprehensive package of HIV prevention services. This study was sponsored by the National Institute of Allergy and Infectious Diseases and was reviewed and approved by the local institutional review board at each site.

Eligibility Criteria

MSM and TGW who were ≥18 years of age, able to speak English or Spanish, HIV negative by self-report, and who reported any of the following sexual risk criteria in the previous 12 months were eligible to screen for The Demo Project: (1) condomless anal sex with ≥2 male or TGW sex partners; (2) ≥2 episodes of anal sex with at least 1 HIV-infected partner; or (3) sex with a male or TGW partner and self-reported history of syphilis, rectal gonorrhea, or rectal chlamydia. Participants had to be HIV negative by a rapid HIV antibody and a fourth generation HIV antigen/antibody (Ag/Ab) test at screening and by a rapid HIV antibody test at enrollment and have a urine dipstick with negative or trace protein and a creatinine clearance ≥60 mL/min within 45 days of enrollment. In addition, participants at the SF site had to have a negative pooled HIV RNA at screening. Participants with a positive hepatitis B surface antigen (HBsAg) and those with serious medical or psychiatric comorbidities, taking nephrotoxic medications, or co-enrolled in other HIV prevention studies or studies of investigational agents or devices were not eligible. Major depressive disorder and bipolar disorder were not exclusionary, unless the participant had active suicidality at the time of screening or was deemed not to have capacity to consent or safely comply with study procedures. Nonsteroidal anti-inflammatory drugs and antihypertensives were not exclusionary. Initially, clients taking nonoccupational postexposure prophylaxis (nPEP) were not eligible to screen or enroll in the study; however, in May 2013, the protocol was amended such that clients could transition into the study seamlessly from nPEP.

Referral, Prescreening, Screening, and Enrollment

Participants could be referred to the study as a self-referral or clinic referral. *Self-referrals* came to the clinic with the expressed interest in seeking PrEP or were referred to the study by their primary care provider. *Clinic referrals* presented to the clinic for sexual health services other than PrEP (eg, HIV/STD testing, STD-related symptoms, nPEP). The process by which clinic referrals initiated prescreening varied slightly by site, reflecting differences in patient flow

and staff capacity. In SF, behavioral eligibility for The Demo Project was assessed by a clinician during the clinic visit as part of a standardized risk assessment administered to all MSM and TGW clinic patients. MSM and TGW who met behavioral eligibility criteria for the study were referred to study staff for prescreening. In Miami, behavioral eligibility for The Demo Project was not assessed by clinic staff. Clinic staff informed MSM and TGW clients about PrEP and The Demo Project and referred all interested patients to the PrEP team for prescreening. In DC, study staff were embedded in the HIV and STD screening programs that take place within the community health center. Study staff directly approached MSM and TGW clients who were seeking services at these programs and offered them the opportunity to prescreen for The Demo Project. At all sites, study staff initiated prescreening by first requesting verbal consent using a standardized script (see Text, Supplemental Digital Content 1, http://links.lww.com/QAI/A609).

Participants who were asked for verbal consent to begin the prescreening process were considered "assessed for participation." Those who gave verbal consent were considered to have "prescreened" and were assessed to see if they met any of the 3 specified behavioral risk criteria. Participants who declined prescreening were asked verbal consent to complete a refusal questionnaire that included reasons for declining and a limited set of questions regarding demographics, whether they had condomless receptive anal sex in the last 3 months, previous PrEP awareness, and HIV risk perception. Participants who did not meet any of the 3 criteria were deemed behaviorally ineligible, were not asked any additional questions, and were referred back to the clinic for ongoing sexual health services. Participants who were behaviorally eligible completed a short additional questionnaire that included an assessment of sociodemographics, whether they had condomless receptive anal sex in the last 3 months, previous PrEP awareness, HIV risk perception, and an assessment for other study eligibility criteria, including major medical comorbidities (eg, chronic kidney disease). Participants who declined at any point during prescreening were asked to complete the refusal questionnaire. Those who were preliminary eligible after completing prescreening were offered the opportunity to screen for the study.

The screening process began with a review of an electronic presentation providing additional background on PrEP and study goals (see Presentation, Supplemental Digital Content 2, http://links.lww.com/QAI/A609), followed by written informed consent and a detailed discussion of the potential risks and benefits of FTC/TDF for PrEP and required study procedures; this process lasted between 20 and 25 minutes. Participants were informed that the study visits would last 1–3 hours (depending on the visit), they would be asked detailed questions regarding their sexual and drug-using behaviors, they would have phlebotomy and an STD screen every 3 months, and they would be remunerated $25.00 for each scheduled study visit. Participants who signed the written informed consent were considered to have "screened." Clients could prescreen or screen for the study multiple times.

Screened participants had a blood draw for HIV, HBsAg, syphilis, and creatinine; sample collection for urine, rectal, and pharyngeal gonorrhea and chlamydia; and completed a detailed interviewer-administered questionnaire regarding demographics and sexual and drug-use behaviors. The enrollment visit was then scheduled 7–45 days after screening. Participants ineligible based on HIV, HBsAg, or kidney function results were referred to appropriate services for care. Participants who met all eligibility criteria and remained interested in participation were dispensed their first bottle of FTC/TDF at the enrollment visit and were considered to have "enrolled." Participants who declined participation during screening or who missed their enrollment visit were asked to complete the refusal questionnaire.

Measures

Diagnostic Testing

HIV testing was conducted using both a rapid HIV antibody (Clearview Stat-Pak [SF] or Clearview Complete [Miami, DC]) and a fourth generation HIV Ag/Ab test (Architect; Abbott Diagnostics, Abbott Park, IL). In addition, participants in SF were screened for acute HIV using pooled RNA at both screening and enrollment, as is standard practice at the clinic.[32] In Miami and DC, an individual HIV RNA assay (Aptima; GenProbe, San Diego, CA [Miami] or TaqMan V2.0; COBAS [DC]) was conducted at the enrollment visit. Acute HIV was defined as having a negative rapid HIV antibody test and a positive RNA pool, individual HIV RNA, or fourth generation HIV Ag/Ab test. Serologic testing for syphilis was conducted using a venereal disease research laboratory or rapid plasma reagin test. Screening for gonorrhea and chlamydia was conducted using nucleic acid amplification tests (Aptima Combo-2; GenProbe).

Sociodemographics and Sexual and Drug-Use Behaviors

Demographic and risk behavioral data were collected by trained interviewers using standardized questionnaires. Prescreening included an assessment of sociodemographics, sexual risk behaviors (the 3 behavioral risk eligibility criteria described above and whether they had condomless receptive anal sex in the last 3 months), previous PrEP awareness, and HIV risk perception. Screened participants were asked additional questions regarding sociodemographics (zip code of residence, living situation, employment and insurance status, income, housing/food instability), drug use, and sexual risk behaviors [number of anal sex partners and episodes in the past 3 months, by condom status (with or without a condom), partner HIV serostatus (positive, negative, or unknown), and position (insertive or receptive)].

HIV Risk Perception and PrEP Awareness

We measured HIV risk perception using a cognitive assessment of risk ["How likely do you think you are to get HIV in the next year?" (scale, 0%–100%)][33]; 5% was used as a cutoff based on a post hoc analysis of a risk perception threshold for predicting uptake. Participants were asked whether and where they had heard about PrEP. Participants who reported having heard of PrEP from someone other than

a staff person at the clinic were deemed as having previous PrEP awareness.

Statistical Analyses

Descriptive statistics were used to characterize participants assessed, those who were potentially eligible, and those who declined or enrolled. Continuous variables were expressed as mean with SD or medians with interquartile ranges (IQRs), and categorical variables were expressed as percentages. Unadjusted between-group comparisons used χ^2, Fisher exact, *t*, *F*, Wilcoxon, and Kruskal–Wallis tests as appropriate.

PrEP uptake was calculated as the number of participants enrolled divided by the number of potentially eligible clients assessed. For participants who prescreened multiple times, risk covariates and outcome from the last prescreening attempt were included. We used unadjusted analysis to assess associations of uptake with sociodemographic and risk covariates. Factors associated with PrEP uptake ($P < 0.05$) in bivariate analyses were included in a multivariable Poisson model with robust standard errors.[34] Poisson regression was used to obtain risk rather than odds ratios, which are potentially misleading with common outcomes. In checking the final model, we tested for interactions of both study site and referral status with other covariates and assessed linearity of the association of uptake with age, the only continuous covariate. Secular trends in self-referral were assessed using an unadjusted logistic model. All statistical analyses were performed using STATA version 13.1 (College Station, TX).

RESULTS

Individuals Assessed for Participation

Demographic and risk characteristics of individuals assessed for participation in The Demo Project are summarized by site and referral status in Table 1. Of 1069 clients assessed, 41.9% were white, 36.1% Latino, and 9.2% black (Table 1). Almost all were MSM; only 14 (1.4%) were TGW. Individuals assessed in Miami were younger, more likely to be Latino, had lower education level, were less likely to have heard of PrEP or be self-referred, and reported fewer condomless sex partners or anal sex episodes with an HIV-positive partner compared with those in DC or SF ($P < 0.05$ for all pairwise comparisons). Most (63%) individuals assessed were clinic referrals, 39.6% of whom had previously heard of PrEP. Self-referrals were older, more likely to be white, had a higher education level, and higher reported sexual risk behaviors and risk perception compared with clinic-referred participants (all $P < 0.05$). Differences between clinic and self-referrals remained significant after adjustment for site. The proportion of clients who were self-referred increased throughout the study period (from 29.9% in the first 3 months to 52.6% in the last 3 months; $P < 0.0005$, test for trend). Screening outcomes and main reasons for ineligibility and declining are shown in Figure 1.

PrEP Uptake and Correlates

Table 2 shows the disposition of assessed individuals overall and by demographic and risk characteristics. Overall PrEP uptake was 60.5% and varied by referral status, site, age, race/ethnicity, education, previous PrEP awareness, self-perceived risk, and reported risk behaviors (all $P < 0.05$, Table 2). In multivariable analyses, participants from Miami or DC, those who were self-referred, those with previous PrEP awareness, and those reporting >1 episode of anal sex with an HIV-infected partner in the last 12 months were more likely to enroll, whereas those of "other" race/ethnicity were less likely to enroll (Table 3). There were no significant interactions between study site or referral status and other covariates (all $P > 0.05$). Although participants who declined PrEP had lower reported risk behaviors and a lower median HIV risk perception score (15, IQR: 5–50, vs. 30, IQR: 10–50), a substantial proportion of those who declined PrEP reported risk factors associated with HIV acquisition: 61.6% reported condomless receptive anal sex in the last 3 months, 27.5% reported >5 condomless anal sex partners, and 43.0% self-reported a history in the last 12 months of syphilis, rectal gonorrhea, or rectal chlamydia. Only 46 (13.3%) of potentially eligible self-referrals declined participation: 23 were passive refusals (did not return for screening or enrollment and were unresponsive to outreach), 5 did not have time, 5 had concerns about side effects, 5 found another place to access PrEP, 2 had concerns about adherence, 2 said that the study visits were too long or they did not want to do the study procedures, and 4 listed other reasons for declining participation.

Participants Enrolled

The mean age of enrolled participants was 35 years; 47.8% were white, 34.5% Latino, 7.2% black, 4.7% Asian, and 5.8% other; 98.4% were MSM and 8.5% identified as bisexual. Most reported working full time (61.9%) and 15.9% were unemployed; 34.2% reported an annual income of less than $20,000 and 29.6% of ≥$60,000. About two-thirds had health insurance (62.6%), and 53.0% had a primary care provider. Approximately 4% had participated in a previous PrEP study, 3.1% had used PrEP outside of a study, and 15.1% had a sexual partner taking PrEP (42% of these partners were enrolled in The Demo Project). Almost all participants had tested for HIV in the last year (94.8%). The most commonly reported main reason for enrolling in the study was "to protect myself against HIV" (66.6%), "to help fight the HIV epidemic" (14.9%), and "because my partner has HIV and I want to avoid getting HIV" (10.4%). Although only 4.7% reported "to make it safer for me to have sex without condoms" as their main reason for enrolling, 58.9% included it as one of several reasons for enrolling (see Table, Supplemental Digital Content 3, http://links.lww.com/QAI/A609).

Baseline Sexual Behaviors, Drug Use, and STDs Among Enrolled Participants

Risk characteristics of enrolled participants are shown in Table 4. Of the participants, 58.2% reported poppers, crack, cocaine, methamphetamine, or club drug use in the past 3 months. More than half of participants did not have a primary partner, whereas 32% of self-referred and 14% of clinic-referred participants had an HIV-positive partner. The median

TABLE 1. Characteristics of Clients Assessed for Participation, Overall and by Site and Referral Status

	Overall*	Site*			Referral Status*†	
Characteristic	**N = 1069**	**SF (n = 581), n (%)**	**Miami (n = 312), n (%)**	**DC (n = 176), n (%)**	**Clinic (n = 628), n (%)**	**Self (n = 369), n (%)**
Site‡						
SF	581 (54.3)				315 (50.2)	252 (68.3)
Miami	312 (29.2)				216 (34.4)	46 (12.5)
DC	176 (16.5)				97 (15.5)	71 (19.3)
Referral status‡§						
Clinic referral	628 (63.0)	315 (55.6)	216 (82.4)	97 (57.7)		
Self-referral	369 (37.0)	252 (44.4)	46 (17.6)	71 (42.3)		
Age‡§						
18–25	228 (23.1)	107 (19.0)	91 (35.1)	30 (18.0)	172 (27.8)	56 (15.2)
26–35	391 (39.6)	223 (39.7)	87 (33.6)	81 (48.5)	244 (39.4)	147 (39.8)
36–45	218 (22.1)	135 (24.0)	49 (18.9)	34 (20.4)	125 (20.2)	93 (25.2)
>45	151 (15.3)	97 (17.3)	32 (12.4)	22 (13.2)	78 (12.6)	73 (19.8)
Gender‖						
Male	969 (98.3)	550 (98.0)	258 (99.6)	161 (98.0)	605 (98.1)	364 (98.6)
TGW	14 (1.4)	10 (1.8)	1 (0.4)	3 (1.8)	11 (1.8)	3 (0.8)
Race/ethnicity‡§						
White	411 (41.9)	292 (52.2)	25 (9.7)	94 (57.7)	185 (30.2)	226 (61.4)
Latino	354 (36.1)	144 (25.8)	180 (69.5)	30 (18.4)	273 (44.5)	81 (22.0)
Black	90 (9.2)	22 (3.9)	44 (17.0)	24 (14.7)	72 (11.8)	18 (4.9)
Asian	57 (5.8)	47 (8.4)	3 (1.2)	7 (4.3)	42 (6.9)	15 (4.1)
Other¶	69 (7.0)	54 (9.7)	7 (2.7)	8 (4.9)	41 (6.7)	28 (7.6)
Education level‡§						
≤High school	181 (18.4)	88 (15.7)	77 (29.7)	16 (9.8)	128 (20.8)	53 (14.4)
>High school	803 (81.6)	474 (84.3)	182 (70.3)	147 (90.2)	487 (79.2)	316 (85.6)
No. male condomless anal sex partners, last 12 mo‡§						
0–1	175 (18.0)	46 (8.7)	100 (32.8)	29 (20.9)	86 (16.1)	25 (6.8)
2–5	454 (46.8)	245 (46.5)	150 (49.2)	59 (42.5)	294 (55.0)	159 (43.1)
>5	343 (35.2)	236 (44.8)	55 (18.0)	51 (36.7)	155 (30.0)	185 (50.1)
No. episodes anal sex with HIV+ partner, last 12 mo‡§						
0–1	557 (57.4)	239 (45.4)	247 (81.0)	71 (51.1)	357 (66.7)	135 (36.6)
2–5	137 (14.1)	93 (17.6)	19 (6.2)	25 (18.0)	70 (13.1)	67 (18.2)
>5	277 (28.5)	195 (37.0)	39 (12.8)	43 (31.0)	108 (20.2)	167 (45.3)
Condomless receptive anal sex, last 3 mo‡§						
No	347 (35.3)	154 (27.6)	130 (50.2)	63 (38.0)	242 (39.2)	105 (28.6)
Yes	636 (64.7)	404 (72.4)	129 (49.8)	103 (62.1)	374 (60.7)	262 (71.4)
Previous PrEP awareness‡§						
No	408 (41.4)	170 (30.4)	171 (66.0)	67 (40.4)	373 (60.4)	35 (9.5)
Yes#	577 (58.6)	390 (69.6)	88 (34.0)	99 (59.6)	245 (39.6)	332 (90.5)
HIV risk perception‡§						
≤5%	241 (25.2)	132 (24.6)	56 (21.7)	53 (32.9)	176 (29.4)	65 (18.3)
>5%	714 (74.8)	404 (75.4)	202 (78.3)	108 (67.1)	423 (70.6)	291 (81.7)

*Columns may not sum to total because of missing data for those who were found to be ineligible or who declined PrEP.
†Referral status missing for 72/1069 assessed clients.
‡$P < 0.05$ for comparison by site.
§$P < 0.05$ for comparison by referral status.
‖Three participants reported gender as "other": "genderqueer" (1), "all the above" (1), and "both as a male and a transgender female" (1).
¶Includes native Hawaiian or Pacific Islander (6), American Indian or Alaska Native (1), and multirace (62).
#Thirty-five self-referred participants had only heard of PrEP from a staff person at the clinic and thus did not meet the definition of "previous PrEP awareness."

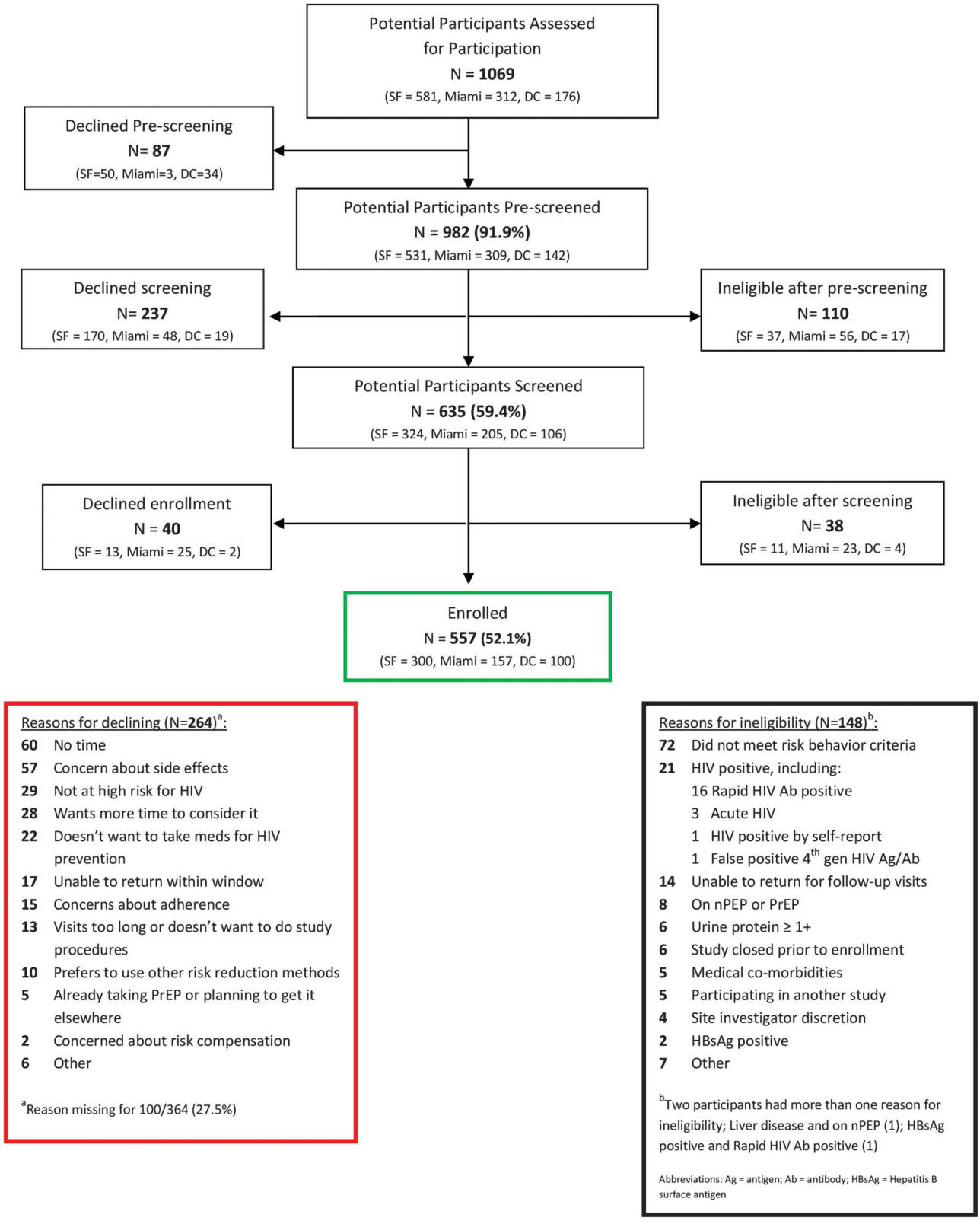

FIGURE 1. Study flow diagram.

TABLE 2. PrEP Uptake, Overall and by Selected Characteristics

Group	Assessed*, n (%)	Potentially Eligible*†, n (%)	Outcome		Percent PrEP Uptake‡
			Declined*, n (%)	Enrolled, n (%)	
Overall	1069§	921	364	557	60.5
Site‖					
SF	581 (54.4)	533 (57.9)	233 (64.0)	300 (53.9)	56.3
Miami	312 (29.2)	233 (25.3)	76 (21.0)	157 (28.2)	67.4
DC	176 (16.5)	155 (16.8)	55 (15.1)	100 (18.0)	64.5
Referral status‖					
Clinic referral	628 (63.0)	572 (62.4)	314 (87.2)	258 (46.3)	45.1
Self-referral	369 (37.0)	345 (37.6)	46 (12.8)	299 (53.7)	86.7
Age‖					
18–25	228 (23.1)	208 (22.9)	96 (27.4)	112 (20.1)	53.9
26–35	391 (39.6)	358 (39.4)	149 (42.5)	209 (37.5)	58.4
36–45	218 (22.1)	202 (22.2)	68 (19.4)	134 (24.1)	66.3
>45	151 (15.3)	140 (15.4)	38 (10.8)	102 (18.3)	72.9
Gender					
Male	969 (98.3)	891 (98.6)	343 (98.3)	548 (98.4)	61.5
TGW	14 (1.4)	13 (1.4)	6 (1.7)	7 (1.3)	53.9
Race/ethnicity‖					
White	411 (41.9)	383 (42.5)	117 (33.8)	266 (47.8)	69.5
Latino	354 (36.1)	327 (36.3)	135 (39.0)	192 (34.5)	58.7
Black	90 (9.2)	76 (8.4)	36 (10.4)	40 (7.2)	52.6
Asian	57 (5.8)	52 (5.8)	26 (7.5)	26 (4.7)	50.0
Other	69 (7.0)	64 (7.1)	32 (9.3)	32 (5.8)	50.0
Education level‖					
≤High school	181 (18.4)	157 (17.4)	75 (21.6)	82 (14.7)	52.2
>High school	803 (81.6)	747 (82.6)	272 (78.4)	475 (85.3)	63.6
No. male condomless anal sex partners, last 12 mo‖					
0–1	175 (18.0)	97 (11.6)	37 (13.4)	60 (10.8)	61.9
2–5	454 (46.8)	424 (50.9)	163 (59.1)	261 (46.9)	61.6
>5	342 (35.2)	312 (37.5)	76 (27.5)	236 (42.4)	75.6
No. episodes anal sex with HIV+ partner, last 12 mo‖					
0–1	557 (57.4)	443 (53.2)	188 (68.1)	255 (45.8)	57.6
2–5	137 (14.1)	130 (15.6)	35 (12.7)	95 (17.1)	73.1
>5	277 (28.5)	260 (31.2)	53 (19.2)	207 (37.2)	79.6
Condomless receptive anal sex, last 3 mo					
No	347 (35.3)	316 (35.0)	133 (38.4)	183 (32.9)	57.9
Yes	636 (64.7)	587 (65.0)	213 (61.6)	374 (67.2)	63.7
Previous PrEP awareness‖					
No	408 (41.4)	372 (41.1)	198 (56.9)	174 (31.2)	46.8
Yes	577 (58.6)	533 (58.9)	150 (43.1)	383 (68.8)	71.9
HIV risk perception‖					
≤5%	241 (25.2)	220 (25.0)	110 (33.1)	110 (20.1)	50.0
>5%	714 (74.8)	659 (75.0)	222 (66.9)	437 (79.9)	66.3

*Columns may not sum to total because of missing data for those who were found to be ineligible or who declined PrEP.

†Potentially eligible participants were those not found to be ineligible during prescreening or screening; some potentially eligible participants declined further participation before having a complete assessment of eligibility.

‡% Uptake = no. enrolled/no. potentially eligible.

§Thirty-seven participants prescreened twice and 2 participants prescreened 3 times. Data were abstracted from the last prescreening attempt.

‖$P < 0.05$ for difference in % uptake.

number of male anal sex partners was 5 (IQR: 2–10) and the median number of episodes of condomless anal sex was 7 (IQR: 2–20), both in the past 3 months. Almost two-thirds reported at least 1 episode of condomless receptive anal sex, including 23.7% with any HIV-positive partners. More than one-quarter (27.5%) were diagnosed with an STD at baseline, 4.3% with early syphilis, and 16.6% with rectal gonorrhea or chlamydia. Higher HIV risk perception was associated with

TABLE 3. Predictors of PrEP Uptake

Characteristic	Bivariate RR (95% CI)	aRR (95% CI)
Site		
SF	1.0	1.0
Miami	**1.20 (1.07 to 1.35)**	**1.53 (1.33 to 1.75)**
DC	**1.15 (1.0 to 1.32)**	**1.33 (1.2 to 1.47)**
Age, per 10-yr increase	**1.10 (1.05 to 1.16)**	1.04 (0.99 to 1.09)
Race/ethnicity		
White	1.0	1.0
Latino	0.85 (0.76 to 0.95)	0.97 (0.85 to 1.1)
Black	**0.76 (0.61 to 0.95)**	0.84 (0.68 to 1.04)
Asian	**0.72 (0.54 to 0.95)**	0.88 (0.68 to 1.14)
Other	**0.72 (0.56 to 0.93)**	**0.82 (0.68 to 0.99)**
Education level		
≤High school	1.0	
>High school	**1.22 (1.04 to 1.43)**	1.09 (0.94 to 1.26)
No. male condomless anal sex partners, last 12 mo		
0–1	1.0	1.0
2–5	1.0 (0.84 to 1.18)	1.05 (0.89 to 1.24)
>5	**1.22 (1.03 to 1.45)**	1.13 (0.96 to 1.33)
No. episodes anal sex with HIV+ partner, last 12 mo		
0–1	1.0	1.0
2–5	**1.27 (1.11 to 1.45)**	**1.17 (1.02 to 1.33)**
>5	**1.38 (1.25 to 1.53)**	**1.22 (1.09 to 1.36)**
Referral status		
Clinic referral	1.0	1.0
Self-referral	**1.92 (1.74 to 2.12)**	**1.48 (1.32 to 1.66)**
Previous PrEP awareness		
No	1.0	1.0
Yes	**2.91 (2.2 to 3.84)**	**1.56 (1.05 to 2.33)**
HIV risk perception		
≤5%	1.0	1.0
>5%	**1.33 (1.15 to 1.53)**	1.07 (0.95 to 1.21)

CI, confidence interval.
Bold values are statistically significant, p<0.05.

TABLE 4. Drug and Sexual Risk Behaviors and STD Prevalence Among Enrolled Participants (n = 557)

Drug and Sexual Risk Behaviors	n (%)
≥5 drinks per day when drinking	64 (11.5)
Drug use, past 3 mo	
Poppers or other inhalants	258 (46.3)
Powder cocaine/crack	112 (20.1)
Methamphetamines	83 (14.9)
Club drugs*	129 (23.2)
Erectile dysfunction drugs†	175 (32.1)
Marijuana	244 (43.8)
Injected drugs last 3 mo	10 (1.8)
Has primary partner	
Yes, HIV positive	132 (23.7)
Yes, HIV negative	129 (23.2)
Yes, unsure of HIV status	6 (1.1)
No	290 (52.1)
No. male condomless anal sex partners, last 3 mo	
0	75 (13.5)
1	117 (21.0)
2–5	233 (41.8)
6–9	59 (10.6)
≥10	71 (13.1)
No. male condomless anal sex episodes, last 3 mo	
0	77 (13.8)
1	27 (4.9)
2–5	130 (23.3)
6–9	75 (13.5)
≥10	248 (44.5)
Condomless anal sex, last 3 months	
None	77 (13.8)
Insertive only	126 (22.6)
Any receptive	354 (63.6)
Condomless receptive anal sex, last 3 mo	
None	203 (36.5)
With HIV-negative only	147 (26.4)
With unknown serostatus	75 (13.5)
With any HIV positive	132 (23.7)
Any female condomless anal or vaginal sex partners	12 (2.2)
Exchange sex last 3 mo	30 (5.4)
Perceived likelihood of getting HIV in next year	
<5%	110 (20.1)
5%–25%	152 (27.8)
26%–50%	196 (35.8)
>50%	89 (16.3)
Prevalence of STDs	
Early syphilis	24 (4.3)
Primary	5 (0.9)
Secondary	9 (1.6)
Early latent	10 (1.8)
Gonorrhea (any site)	86 (15.4)
Chlamydia (any site)	75 (13.5)
Rectal gonorrhea or chlamydia	92 (16.6)

*Ecstasy, gamma-hydroxybutyrate, or ketamine.
†Recreational use of medications to enhance erectile dysfunction, including sildenafil, vardenafil, and tadalafil.

higher reported risk behaviors, including number of condomless anal sex partners and episodes (P for trend < 0.0001) and having condomless receptive anal sex with HIV unknown status or HIV-positive partners ($P < 0.0001$).

DISCUSSION

Despite early reports of slow PrEP uptake in the United States,[35–37] we show high levels of interest in PrEP among MSM offered PrEP as part of a comprehensive prevention program in STD clinics and a community health center. Almost half of eligible clinic-referred clients, most of whom had never heard of PrEP, and 87% of self-referrals enrolled in The Demo Project. PrEP uptake was high across sites, age groups, race/ethnicities, and levels of education. These findings are consistent with a number of previous surveys of MSM conducted before[38,39] and after[19] the release of iPrEx results indicating high levels of willingness to use PrEP if

efficacious and provided at low or no cost.[39,40] This suggests that previous "slow uptake" may have been because of a lack of PrEP knowledge and availability, and efforts to facilitate both can lead to high uptake of PrEP among at-risk MSM.

Rates of self-referral to the study were high in SF and DC and increased throughout the enrollment period at all 3 sites. A substantial proportion (15%) of participants reported having a sexual partner on PrEP, with almost half of these enrolled in The Demo Project, suggesting the potential influence of peer referrals in driving PrEP uptake. However, black and Latino MSM, younger individuals, and those with a lower educational level were less likely to self-refer, and very few TGW were assessed for participation. These findings highlight the importance of reaching out to these populations, to increase PrEP awareness and interest, and to ensure that PrEP is available at sites where young MSM of color and TGW seek sexual health services. In adjusted analyses, blacks and Latinos were no less likely to enroll than whites, suggesting PrEP uptake can be high in these individuals when provided information and access to PrEP. Reasons for lower PrEP uptake among those of other race/ethnicity are unclear; this was a heterogenous group and included multirace individuals.

A substantial number of participants who declined PrEP reported not having enough time for participation. Whether the time required to access PrEP outside of a study would also be a deterrent is unclear, and strategies for optimizing the efficiency and convenience of delivering PrEP are needed. Concern about side effects was also a common reason for declining, a finding reported in previous acceptability surveys.[40] These results underscore the importance of accurate community education regarding the safety profile and tolerability of FTC/TDF PrEP when taken by HIV-uninfected individuals.[6,8,9] Although participants who declined PrEP had lower reported risk behaviors and lower perceived risk of HIV acquisition than those who enrolled, their risk behaviors and self-reported STD history still reflected substantial HIV risk. Risk assessment tools could be used to assist individuals in making more accurate assessments of their HIV risk and selecting from a range of HIV prevention tools, including PrEP.[41,42]

Modeling studies suggest that the uptake of PrEP among those at highest risk of HIV will maximize the cost-effectiveness[15,43] and public health impact of PrEP.[44] The cohort of participants who enrolled in The Demo Project reported high rates of recreational drug use, condomless receptive anal sex, and had a high prevalence of early syphilis or rectal infections; all factors strongly associated with HIV acquisition.[6,45–47] Furthermore, 20 individuals were diagnosed with HIV infection during the screening process, including 3 with acute HIV. These findings show that MSM at high risk for HIV acquisition are interested in PrEP and highlight the role that PrEP programs play in identifying those with undiagnosed and early HIV infection and those at risk for HIV acquisition who may benefit from PrEP. Although interest in PrEP was high among our cohort, additional strategies to increase PrEP uptake and coverage may be required to maximize population-level impact.[15]

There are several limitations to our study. First, the process by which clients were referred from clinic staff to study staff varied by site and may have led to an overestimate of uptake for clinic referrals in SF and Miami, where some clients declined before assessment by the PrEP team. Second, sociodemographics, risk behavior data, and reasons for declining were not available for all participants who declined, and differential patterns in missing data may have biased the results. Third, questionnaires on sexual and drug risk behaviors were interviewer administered and may be subjected to social desirability bias. Finally, these results may not be generalizable to clients offered PrEP in other clinical settings, without the commitment required of a clinical study, or when there are some cost or other barriers to accessing PrEP clinical services and medication.

Overall, our findings illustrate substantial interest in PrEP among a diverse population of MSM at elevated risk for HIV infection when offered in STD clinics and a community health center and highlight the role that these clinics play in expanding PrEP access nationwide. Additional strategies are needed to increase community awareness about PrEP and engage TGW and young MSM of color in PrEP programs. Additional PrEP demonstration projects are underway to evaluate the feasibility, acceptability, and safety of PrEP delivery in a variety of populations.[48] As adherence to PrEP is critical to its effectiveness,[7] this and other PrEP demonstration projects will evaluate this important PrEP implementation outcome in longitudinal follow-up. Appropriate PrEP uptake among those at highest risk, coupled with high adherence, will help maximize PrEP's public health impact.

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