

Implementation of PrEP in STD Clinics and a Community Health Center: High Uptake and Drug Levels among MSM in the Demo Project

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Introduction

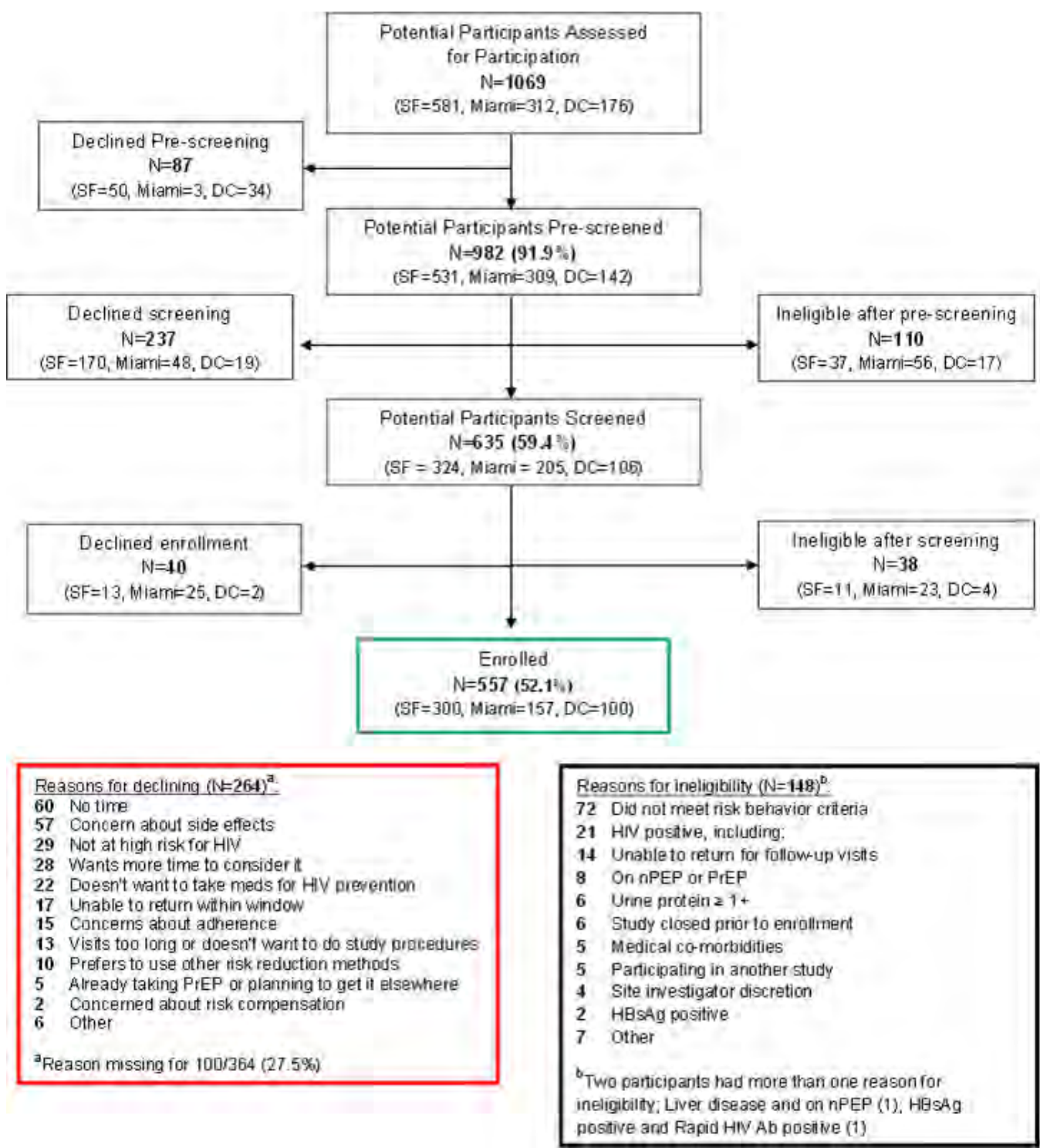
- Pre-exposure prophylaxis (PrEP) has been shown to be safe and efficacious in clinical trials.
- Demand for PrEP and levels of adherence in real world settings are unknown.
- We evaluated PrEP uptake and drug concentrations among men who have sex with men (MSM) and transgender women (TGW) in the first year of a US PrEP Demonstration (Demo) Project.

Methods

- From September 2012 to January 2014, HIV-uninfected MSM and TGW attending STD clinics in San Francisco and Miami and a community health center in Washington, DC, were assessed for eligibility and interest in participating in The Demo Project.
- Clients were approached in clinic while receiving services or self-referred to the program.
- Individuals who declined were asked their reasons for declining.
- Enrolled participants were offered up to 48 weeks of open-label emtricitabine/tenofovir.
- Uptake was measured as number of enrolled participants/potentially eligible participants, overall and by covariates.
- Predictors of PrEP uptake were assessed using multivariable poisson regression.
- Tenofovir diphosphate (TFV-DP) levels in dried blood spots (DBS) were assessed in a random sample of participants at the 4 week visit using LC/MS/MS.

Results

Figure 1. Patient flow diagram



Individuals Assessed for Participation

- Almost all assessed were MSM; only 14 (1.4%) were TGW.
- Individuals assessed for participation 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 lower risk behaviors compared with those in DC or San Francisco (p<0.05).
- 63.0% assessed were clinic referrals; 37.0% were self-referrals.
- 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).

Table 1: PrEP uptake by site, sociodemographics, PrEP knowledge, and risk behaviors

GROUP	Assessed (N%)	OUTCOME			Percent uptake among potentially eligible ^A
		Ineligible (N%)	Declined (N%)	Enrolled (N%)	
Overall	1069	147	365	557	60.4
Site [†]					
SF	581 (54.4)	48 (32.4)	233 (64.0)	300 (53.9)	56.3
Miami	312 (29.2)	79 (53.4)	76 (21.0)	157 (28.2)	67.4
DC	176 (16.5)	21 (14.2)	55 (15.1)	100 (18.0)	64.5
Referral status [†]					
Clinic-referral	628 (63.0)	56 (70.0)	314 (87.2)	258 (46.3)	45.1
Self-referral	369 (37.0)	24 (30.0)	46 (12.8)	299 (53.7)	86.7
Age [†]					
18-25	228 (23.1)	20 (25)	96 (27.4)	112 (20.1)	53.9
26-35	391 (39.6)	33 (41.3)	149 (42.5)	209 (37.5)	58.4
36-45	218 (22.1)	16 (20.0)	68 (19.4)	134 (24.1)	66.3
>45	151 (15.3)	11 (13.8)	38 (10.8)	102 (18.3)	72.9
Race/Ethnicity [†]					
White	411 (41.9)	28 (35.4)	117 (33.8)	266 (47.8)	69.5
Latino	354 (36.1)	27 (34.2)	135 (39.0)	192 (34.5)	58.7
Black	90 (9.2)	14 (17.7)	36 (10.4)	40 (7.2)	52.6
Asian	57 (5.8)	5 (6.3)	26 (7.5)	26 (4.7)	50
Other [*]	69 (7.0)	5 (6.3)	32 (9.3)	32 (5.8)	50
Education level [†]					
≤ High school	181 (18.4)	24 (30.0)	75 (21.6)	82 (14.7)	52.2
> High school	803 (81.6)	56 (70.0)	272 (78.4)	475 (85.3)	63.6
# male condomless anal sex partners, last 12 mo [†]					
0-1	175 (18.0)	78 (57.0)	37 (13.4)	60 (10.8)	61.9
2-5	454 (46.8)	30 (21.7)	163 (59.1)	261 (46.9)	61.6
>5	342 (35.2)	30 (21.8)	76 (27.5)	236 (42.4)	75.6
# episodes anal sex with HIV+ partner, last 12 mo [†]					
0-1	557 (57.4)	114 (82.6)	188 (68.1)	255 (45.8)	57.6
2-5	137 (14.1)	7 (5.1)	35 (12.7)	95 (17.1)	73.1
>5	277 (28.5)	17 (12.3)	53 (19.2)	207 (37.2)	79.6
Prior PrEP awareness [†]					
No	408 (41.4)	36 (45.0)	198 (56.9)	174 (31.2)	46.8
Yes	577 (58.6)	44 (55.0)	150 (43.1)	383 (68.8)	71.9

^AExcludes those who were found ineligible during screening process

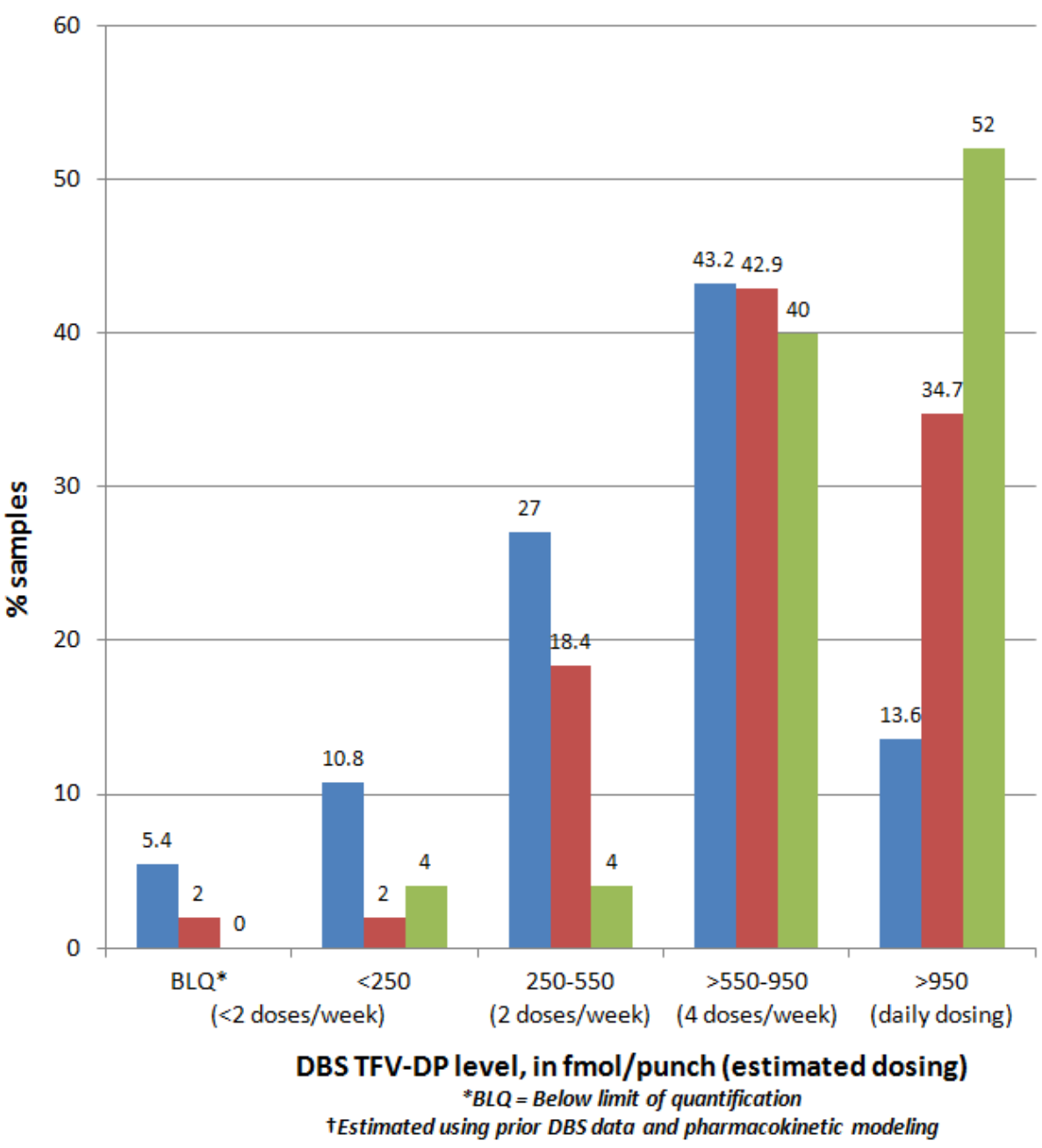
[†]p<.05 for difference in % uptake

^{*}Includes: Native Hawaiian or Pacific Islander (6), American Indian or Alaska Native (1), and multi-race (62)

Table 2: Predictors of PrEP uptake

CHARACTERISTIC	Bivariate RR (95% CI)	Adjusted RR (95% CI)
Site		
SF	1	1
Miami	1.20 (1.07-1.35)	1.53 (1.33-1.75)
DC	1.15 (1.0-1.32)	1.33 (1.2-1.47)
Age, per 10 year increase	1.10 (1.05-1.16)	1.04 (0.99-1.09)
Race/Ethnicity		
White	1	1
Latino	0.85 (0.76-0.95)	0.97 (0.85-1.1)
Black	0.76 (0.61-0.95)	0.84 (0.68-1.04)
Asian	0.72 (0.54-0.95)	0.88 (0.68-1.14)
Other	0.72 (0.56-0.93)	0.82 (0.68-0.99)
Education level		
≤ High school	1	
> High school	1.22 (1.04-1.43)	1.09 (0.94-1.26)
# episodes anal sex with HIV+ partner, last 12 mo		
0-1	1	1
2-5	1.27 (1.11-1.45)	1.17 (1.02-1.33)
>5	1.38 (1.25-1.53)	1.22 (1.09-1.36)
Referral status		
Clinic-referral	1	1
Self-referral	1.92 (1.74-2.12)	1.48 (1.32-1.66)
Prior PrEP awareness		
No	1	1
Yes	2.91 (2.2-3.84)	1.56 (1.05-2.33)

Figure 2: DBS TFV-DP levels at week 4, by study site



- DBS from 136 participants were tested.
- 98% had TFV-DP detected.
- Median TFV-DP levels were higher in SF than in Miami and DC (975, 658 and 812 fmol/punch respectively, p<0.001).
- Most participants (77%) had a TFV-DP level consistent with taking at least 4 doses/week (≥550 fmol/punch) (92% SF, 57% Miami, 78% DC, p<0.001).

Limitations

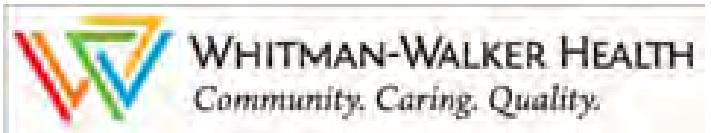
- The process by which clients were referred from clinic staff to study staff varied slightly across the sites and may partially explain site differences in uptake, if clinic staff selectively referred clients to the PrEP team.
- Sociodemographic and risk behavior data were not available for all participants who declined participation.
- Results may not be generalizable to clients offered PrEP in other clinical settings.

Conclusions

- Interest in PrEP is high among a diverse population of MSM when offered as part of a comprehensive prevention program in STD and community health clinics.
- Drug concentrations at week 4 are high among MSM in the Demo Project.
- In multivariable analyses, PrEP uptake was associated with site, being self-referred, having prior PrEP awareness, and reporting higher risk sexual behaviors.
- Despite limited advertising and outreach, there were a significant number of self-referrals to the study in both San Francisco and Washington, DC, reflecting built-up demand in the community for PrEP.
- However, relatively few TGW and young MSM of color were assessed for participation and enrolled in this study. Additional strategies to increase community awareness of PrEP and engage these populations in PrEP programs are urgently needed.
- Appropriate PrEP uptake among those at highest risk, coupled with high adherence, will help maximize the cost-effectiveness and public health impact of PrEP.



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