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Response to “Race and the public health impact potential of PrEP in the United States”

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We appreciate the authors’ careful reading of our paper reporting on uptake and characteristics of enrolled participants in the US PrEP demonstration project, and we share the authors’ concerns regarding the potential for disparities in PrEP uptake across race, ethnicity, age, income, geographic region and other factors. The authors raise a number of questions including how we defined race/ethnicity, whether “clinic referred” participants were representative of the populations served at the study sites, and what risk criteria should be used to determine PrEP eligibility across racial and ethnic groups.

Race and ethnicity were assessed using a two-part question based on federal guidelines: “Which ethnic and racial groups(s) do you identify with?: 1) Ethnicity (mark only one): Hispanic/Latino or Non-Hispanic/Latino and 2) Race (mark all that apply): White, Black or African American, Asian, American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, and other, specify.”¹ Participants were not asked to describe which race best describes them. For the purpose of the analysis, we combined race/ethnicity into a single variable. Participants who reported being of Hispanic/Latino ethnicity were classified as “Latino”, regardless of what race they chose. Non-Hispanic/Latino participants who selected only one race were categorized as that race, whereas those who selected multiple races were categorized as “other.” Categorizing race and ethnicity is complex,² and several studies have indicated that the distinction between ethnicity and race is not meaningful to respondents.³⁻⁵ In our study, 31% of Latino participants selected “other” for their race and wrote-in “Latino”. Using a single variable for “ethnicity” with categories that include Latino, non-Latino White, non-Latino Black, non-Latino Asian, and non-Latino other is recommended by the American Anthropological Association⁶ and is common throughout the literature.^{2,7,8}

Of the 354 Latino clients who were assessed for participation in the study, 23 (6.5% of Latino clients and 2.2% of all clients assessed) selected Black as their only race, and an additional six selected Black in addition to one or more racial groups. Among the 62 multi-racial individuals assessed for participation, 14 selected Black as one of their races. If Black race is re-defined as selecting Black as at least one of the races an individual identified with, the number of blacks assessed increases from 90 to 133 (9.2% to 12.4%). While Blacks (defined as anyone who selects Black, alone or in addition to other race and ethnicities) have lower PrEP uptake in bivariate analysis, they are not less likely to choose to enroll in the study after controlling for referral status, site, age, education level, prior PrEP awareness and risk behaviors (aOR 0.89; 95% CI 0.76-1.04).⁹ Some studies have suggested that Black men who have sex with men (BMSM) are more concerned about PrEP side effects than White MSM, however among our sample, Blacks were less likely to report this as a reason for declining participation (26.2% of Whites, 20.5% of Latinos, and 13.0% of Blacks reported a concern about side effects as their reason for declining). Blacks were more likely to report that they “needed more time to think about it” as a reason for declining, compared with Whites (8.3% of Whites, 16.7% of Latinos and 17.4% of Blacks).

We agree that understanding the racial/ethnic make-up of the populations served at the participating clinics would be useful in assessing whether “clinic referred” participants were representative of the clinic populations. While all three clinics are able to report the racial and ethnic make-up of all patients seen at the clinic, only San Francisco City Clinic (SFCC) and Whitman Walker Health (WWH) have available data on the racial and ethnic make-up of HIV-negative MSM and transgender women (TGW). At the Miami STD clinic, sexual orientation or sexual behaviors are not recorded electronically, and the majority of clinic clients are not MSM, thus overall clinic demographics are not reflective of the population eligible for referral to the Demo Project. To approximate the racial/ethnic make-up of HIV-negative MSM seen at the Miami downtown clinic, we used data from a previous record review of 56 HIV-negative MSM who tested positive for pharyngeal gonorrhea or chlamydia in 2012. The table below compares the race/ethnicity of study participants who were “clinic-referred” with HIV negative MSM and TGW seen at the SFCC and WWH sites in a one-year period, and with the subset of HIV negative MSM from the Miami clinic described above.

The race/ethnicity of clinic-referred participants did not differ significantly from those of the respective clinic populations at WWH or the Miami clinic. However in San Francisco, clinic-referred participants were more likely to be Latino or “other”, and less likely to be White or Black, compared with the population of HIV-negative MSM and TGW who were behaviorally eligible for referral to the study team (see Table). The reasons for this are unclear, and may represent differential rates of referral to the study team by clinicians, differential acceptance of the clinician’s referral, or differences in how race/ethnicity were assessed by registration staff at the clinic as compared with the study team.

We agree and highlighted in the original manuscript that BMSM were less likely to self-refer to the study than White MSM. This likely reflects lower levels of PrEP awareness, and less demand for PrEP, among BMSM in the participating cities. In addition, Black individuals were more likely to be diagnosed with HIV-infection during the screening

process. Of 90 Black individuals assessed for participation, 5 (5.6%) were HIV-positive, compared with 4/411 (1.0%) of Whites, 9/354 (2.5%) of Latinos, 0/57 Asians and 1/69 (1.5%) of those of “other” race ($p=0.053$). We did not actively recruit MSM of color to the study as we were interested in assessing the feasibility of PrEP delivery in our varied clinical settings and interest in PrEP among our clinic populations. However, based on our study findings, we agree with the urgent need to increase PrEP knowledge and interest among BMSM and transgender individuals, two groups that were underrepresented in our study, and to ensure cultural competency of clinics and providers in delivering PrEP to these communities. Diffusion of innovations through communities takes time, and opinion leaders are critical to the process.¹⁰ In our study, 65% of self-referred participants had learned about PrEP from a friend or sex partner. Disseminating information about PrEP to MSM of color and transgender individuals through social marketing and peer-to-peer communication will be critical to increasing uptake.

The authors raise a concern that the provision of free medication and remuneration for study participation may have contributed to PrEP uptake. Compensation was not excessive (\$25.00/scheduled study visit) and was meant to offset opportunity costs related to being in the study. We agree that affordability is critical to PrEP dissemination and this is evidenced by significant differences in PrEP access across our three clinics and jurisdictions. WWH has fully integrated PrEP into its primary care clinic, and now has >200 individuals on PrEP, 11.5% of whom are Black. At SFCC PrEP is now being offered as part of routine sexual health services, and uninsured clients are assisted with applying for a patient assistance program. Over 100 SFCC patients have been initiated on PrEP since the end of the demonstration project, 8% of whom are Black, compared with 3% who enrolled in the Demo Project. Access to PrEP in Miami, while increasing, is still limited. The Miami STD clinic has not integrated PrEP into routine services, and Miami participants were much less likely to report being on PrEP 6-months after study completion, despite being equally likely to express an interest in post-study PrEP use, compared with those in San Francisco (Susanne Doblecki-Lewis, personal communication, April 20, 2015). Cost is a major barrier to PrEP in Miami given the lack of Medicaid expansion and fewer safety net resources. Additional efforts are needed to improve affordability in order to ensure that PrEP is accessible by all individuals at risk.

Finally, the authors question whether the behavioral risk criteria used to determine PrEP eligibility are generalizable, and whether they would adequately identify young BMSM at risk for HIV. We used relatively broad behavioral risk criteria, including condomless anal sex with >1 male or TGW sex partner; > 1 episode of anal sex with at least one HIV-infected partner (regardless of condom use); or having syphilis or rectal gonorrhea or rectal chlamydia in the prior 12 months.⁹ These criteria can be easily implemented in clinical and non-clinical settings, and are consistent with guidelines issued by the Centers for Disease Control and Prevention.¹¹

We chose to launch the US PrEP demonstration project in three diverse clinical settings, in three different metropolitan areas. HIV and STD incidence is high among patients served at all three study sites and 3 of 557 participants were found to have acute HIV infection at the enrollment visit. Other projects focused on younger MSM and BMSM are underway and

will provide critical information about barriers to PrEP uptake among these disproportionately impacted populations.¹²⁻¹⁴ There is a complement of studies planned and moving forward, and we agree with prioritizing those with the highest incidence of HIV for PrEP.

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Table

Race/Ethnicity of HIV-negative MSM seen at the US PrEP Demo Project participating clinics compared with those who were “clinic referred” and assessed for participation in the study

Race/Ethnicity	Study site					
	San Francisco City Clinic		Whitman Walker Health		Miami downtown STD clinic	
	HIV-negative MSM or TGW with a clinic visit in 2013 (N=1107) ^I	“Clinic referred” (N=308)	HIV-negative MSM or TGW with a clinic visit in 2014 (N=4247)	“Clinic referred” (N=93)	HIV-negative MSM with pharyngeal GC or CT in 2012 (N=56)	“Clinic referred” (N=213)
White	602 (54.4)	123 (40)	2336 (55)	45 (48)	6 (11)	17 (8)
Black or African American	88 (8.0)	14 (5)	868 (20.4)	17 (18)	10 (18)	41 (19)
Latino	240 (21.7)	102 (33)	656 (15.4)	22 (24)	40 (71)	149 (70)
Asian	154 (13.9)	36 (12)	315 (7.4)	5 (5.4)	0	1 (0.5)
Other	23 (2.1)	33 (10.7)	72 (1.7)	4 (4.3)	0	5 (2.4)
p-value for comparison of clinic vs. “clinic referred” population	<0.0001		P=0.07		P=0.805	

^I Race/ethnic breakdown shown for MSM or TGW who were eligible for referral to Demo Project staff (in San Francisco, only those who met behavioral risk criteria were referred to PrEP study staff)