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Representation of Latinos and Blacks in screening for and enrollment into preventive HIV vaccine trials in New York City

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ABSTRACT

Introduction: In the United States, Latinos and Blacks are disproportionately affected by HIV/AIDS, but have been underrepresented in HIV vaccine trials. We assessed screening and enrollment of Blacks and Latinos for preventive HIV vaccine trials conducted in New York City, 2009–2012.
Methods: A retrospective analysis was conducted among 18–50 year old men and transgender women screening for four preventive phase 1 and 2 HIV vaccine trials. Demographic, recruitment, and behavioral/medical eligibility data and outcome of screening were examined. To determine factors associated with enrollment, a multivariable logistic regression analysis was performed.
Results: Among 6077 individuals who provided contact information, 2536 completed a phone pre-screen. 96 (1.6% of recruitment contacts) enrolled. Latinos were 35.7% of recruitment contacts, but 17.7% of those enrolled, whereas Blacks were 22.5% and 32.3%, respectively. Among all Latinos, nearly one third were excluded for being uncircumcised, an eligibility criterion for several studies. In multivariable analysis among potentially eligible potential participants, controlling for age and recruitment method, Latinos were less likely than Whites to enroll in a preventive HIV vaccine trial (aOR 0.52, 95% CI 0.28–0.95) whereas Blacks were as likely as Whites (aOR 0.99, 95% CI 0.59–1.67). Individuals recruited through print advertisements, social media/internet, referral, and other modes were more likely to enroll compared to those recruited through in-person outreach, controlling for age and race/ethnicity.
Conclusions: Targeted outreach has led to substantial inclusion of Latinos and Blacks, with Blacks comprising almost a third of those enrolled in these preventive HIV vaccine trials. Latinos, however, were less likely to enroll compared to Whites. Circumcision status as an eligibility criterion partly accounts for this, but further studies are warranted to address the reasons Latinos decide not to participate in preventive HIV vaccine trials.

1. Introduction

In the United States (US), Blacks and Latinos are disproportionately affected by HIV/AIDS. In 2013, Blacks comprised 46% and Latinos 21% of new HIV diagnoses, despite comprising 12% and 16% of the US population, respectively [1]. New York City (NYC) has one of the largest HIV/AIDS epidemics in the US with an estimated 117,618 people living with HIV/AIDS as of the end of 2013 [2]. In 2013, 42% of new HIV diagnoses were among Blacks and 34% were among Latinos [2]. Historically, however, these groups have been underrepresented in many areas of HIV prevention research. The legacy of the Tuskegee syphilis study, and ongoing racial/ethnic disparities in the US health care system have contributed to this problem [3–5]. Inclusion of these groups in HIV vaccine trials is critical to determine generalizability of trial results and because it is possible that immune responses to preventive HIV vaccines may differ by race/ethnicity [6,7].

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In 1993, US Congress passed a law mandating inclusion of sufficient numbers of women and racial/ethnic minorities into National Institutes of Health (NIH) sponsored clinical trials [8]. From 1988 to 2002, Blacks accounted for only 10.1% and Latinos 4.2% of participants in National Institute of Allergy and Infectious Disease (NIAID) sponsored HIV phase 1 and 2 vaccine trials [9]. The HIV Vaccine Trials Network (HVTN) and NIAID have launched special initiatives such as the Legacy Project [10], the NIAID HIV Vaccine Research Education Initiative (NHVREI), Be The Generation (BTG) and BTG Bridge [11–13] that aimed to increase participation and engagement of historically underrepresented communities in HIV vaccine prevention research.

A substantial body of literature assesses impediments and willingness to participate in preventive HIV vaccine trials [14–28]. Common barriers include mistrust of government, fear of side effects, stigma, uncertainty of vaccine efficacy, study demands, and vaccine-induced seropositivity (VISP) [14,21–23,25,26]. Some studies indicate that Blacks are more likely to mistrust clinical research and the health care system than other groups [24,29]. Altruism is the most commonly reported reason for participation, but others include personal benefits such as access to social services, the possibility of vaccine protection, and financial incentives [14,16,21,22,25,26].

Several studies reported no difference in willingness to participate by race/ethnicity [15,21,24] but others have found variation between groups [16–18,20]. These findings were predominately derived from studies which assessed willingness to participate in HIV vaccine trials or other HIV vaccine related activities without examining actual trial enrollment. To address this, Buchbinder et al. showed that hypothetical willingness did not match actual participation by measuring enrollment among those who had reported prior willingness to participate; Blacks, but not Latinos, were more likely to refuse participation months/years later when given the opportunity to enroll in an actual trial [30]. The literature assessing actual participation by racial/ethnic minorities is sparser. One study examining volunteers screening for an HIV vaccine trial in Atlanta, from 2005 to 2007, found white race to be predictive of enrollment [31].

We previously assessed enrollment of Latinos and Blacks into HIV vaccine trials at two research sites in NYC and reported that once engaged in the screening process, they were enrolled at similar proportions [32]. To add to the limited literature on actual participation, we examined the screening and enrollment process for phase 1 and 2 HIV vaccine trials to assess recruitment and enrollment of Latinos and Blacks.

2. Methods

2.1. Study population

The Columbia University HIV Vaccine Research Site, a NIAID-funded HVTN site, is located in northern Manhattan, a predominantly Latino community [33]. The site conducts both phase 1 and 2 HIV vaccine trials using a variety of recruitment approaches. All recruitment and community education strategies are developed in partnership with the New York Blood Center Project Achieve. The target population consisted of HIV-negative individuals screening for HIV vaccine studies at the site between June 1, 2009 and March 1, 2012.

In this retrospective analysis we included screening data for persons 18–50 years old, who were screening into one of four HVTN trials outlined in Table 1 [34]. Women were excluded because they comprised approximately 7% of persons screening for vaccine trials at the site and were ineligible for the phase 2b study; transgender men, and those with missing data on gender, were also excluded. In addition, those missing data on race/ethnicity or an outcome status, or still undergoing screening at the time of analysis were excluded.

2.2. Recruitment, screening, and enrollment

Individuals were recruited using multiple strategies such as newspaper/magazine advertisements, flyers, referrals from prior/current participants, in-person outreach at events, health fairs, and banner ads on social media websites such as Facebook and Craigslist. For the phase 2b study, participants were recruited by in-person outreach (including Spanish-speaking recruiters, who explained the study, answered questions, and completed contact cards) at bars/clubs, and through national, local, and site-specific advertising campaigns on a study website (www.hopetakesaction.org), Craigslist, Facebook, and sexual networking websites including adam4adam and Manhunt. Individuals responding to web-based or social media ads completed online contact cards. Contact card information (including race/ethnicity) for all recruitment contacts was entered into a database. Follow-up calls were made by staff within 24–72 h of initial contact; three attempts were made to reach everyone and all interactions were recorded. While individuals reported all methods/sites of recruitment, they were asked to identify one as the primary source of recruitment.

The next step for those who could be reached and agreed was the phone pre-screen questionnaire (PSQ) to determine preliminary eligibility based on self-reported behavioral, medical, and circumcision criteria. This questionnaire was conducted in either English or Spanish depending on the volunteer's preference. Preliminarily eligible individuals were invited to visit the site for HIV vaccine education (HVE) when behavioral and medical eligibility was confirmed, and preventive HIV vaccines, the clinical research process, and the study were explained. Generic screening informed consent was completed at this visit (in preferred language English or Spanish); blood samples were drawn for HIV testing, Adenovirus5 and/or Adenovirus35 antibodies, and general laboratory tests.

If the individual remained interested, a general study visit (GSV) with a physical exam was scheduled. Upon completion of this step, if still eligible and interested, the volunteer was offered the opportunity to sign a protocol-specific consent form (in English or Spanish), and an enrollment visit was scheduled. The entire screening process, from the point of first contact to enrollment, took place over three to five visits in the course of several weeks. Screening could stop at any stage prior to enrollment; reasons were captured via standardized questions and recorded in the database.

2.3. Statistical analysis

Participants were classified as in-screening (still in any phase of the screening process), screening-stopped (regardless of the reason or stage when screening was terminated, includes those who signed screening informed consent but did not enroll), or enrolled in a trial. The primary outcome was enrollment into an HIV vaccine trial and the main independent variable was self-reported race/ethnicity. Race was collected as White, Black/African-American, Asian/Pacific Islander, Native American/Alaskan Native, or other. Individuals could choose one or more categories as appropriate, and also recorded whether or not they were of Latino or Hispanic ethnicity. All persons regardless of race who self-identified as Latino or Hispanic were classified as Latino. For analysis, race/ethnicity was categorized as a four level variable: (1) White, (2) Latino, (3) Black, and (4) Other (includes Asian/Pacific Islander, Native American/Alaskan Native, multiracial, and other). The 255 participants with missing race/ethnicity were excluded from the analysis

Univariate analysis to describe the study population was performed. Proportions of different racial/ethnic groups at various