HIV: Current Research

Extended Abstract

# A Demographic Analysis of Racial/Ethnic Minority Enrollment into HVTN Preventive Early Phase HIV Vaccine Clinical Trials Conducted in the United States, 2002-2016

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## Abstract

Racial/ethnic minority communities in the United States are overrepresented among new HIV diagnoses, yet their inclusion in preventive HIV vaccine clinical trials is inadequate. An analysis of enrollment demographic characteristics from US preventive HIV vaccine clinical trials from 1988 through 2002 showed that enrollment of racial/ethnic minority groups increased. We analyzed enrollment in preventive HIV vaccine clinical trials from 2002 through 2016 and compared our data with data from the previous study, described demographic characteristics of trial participants, and assessed how well this distribution reflected the racial/ethnic distribution of new HIV diagnoses in the United States.We examined data on demographic characteristics from 43 Phase 1 and Phase 2A preventive HIV vaccine clinical trials conducted in the United States and compared the results with those of the previous study. We also compared racial/ethnic distributions from 2011 through 2015 with Centers for Disease Control and Prevention data on the number of new HIV diagnoses during the same period. Of 3469 participants, 1134 (32.7%) identified as a racial/ethnic minority, a 94% increase from the previous period (634/3731; 17.0%). Percentage annual enrollment of all racial/ethnic minority participants fluctuated from 17% to 53% from mid-2002 to 2016. Percentages of new HIV diagnoses among the general population were 1.9 to 2.9 times the percentage enrollment of black participants and 1.3 to 6.6 times the percentage enrollment of Hispanic/Latino participants in clinical trials for the same period.Although enrollment of racial/ethnic minority groups into HIV vaccine clinical trials has increased, it is not proportional to the number of new HIV diagnoses among these groups. To enhance recruitment of racial/ethnic minority groups, the HIV Vaccine Trials Network has prioritized community partnerships and invested resources into staff training.

**Keywords:** HIV, vaccine, clinical trials, minority, research participation

Our analysis demonstrates that the enrollment of persons from racial/ethnic minority groups in Phase 1 and Phase 2A HVTN preventive HIV vaccine clinical trials during 2002-2016 was greater than enrollment in HIV vaccine clinical trials during 1988-2002.

Research on barriers to participation in clinical trials generally, including barriers that are specific to HIV vaccine clinical trials, has documented several factors that can present challenges for recruitment and enrollment of racial/ethnic minority groups: distrust of research and the motives of researchers disparities in access to routine health care, the underrepresentation of racial/ethnic minority groups in the health and research workforce and subsequent lack of cultural humility in many clinical environments, and language, geographic, and cultural barriers; as well as perceived risks of potential side effects or social harms, including vaccine-induced seropositivity. Vaccine-induced seropositivity is the phenomenon of testing reactive on HIV testing kits because of antibodies generated by an HIV vaccine rather than because of antibodies generated by HIV infection. Use of tests that detect HIV virus can detect true HIV infection; however, these tests are not commonly the first line of testing used in public health settings, potentially requiring participants to obtain HIV testing through study sites after study completion.

Although these barriers to recruitment are complex, they do not negate the evidence that shows a willingness to participate in research among members of racial/ethnic minority communities. Furthermore, altruism as a major motivator to participate in research is common among persons from racial/ethnic minority groups.

By prioritizing partnerships with and leveraging expert feedback from racial/ethnic minority communities and community-based organizations throughout the research process, the HVTN has implemented various strategies to facilitate increased racial/ethnic minority awareness of and involvement in preventive HIV vaccine research. These strategies include increasing diversity among staff members and providing cultural responsiveness training to all employees, using persons from racial/ethnic minority groups as models in advertising, and providing support and technical assistance to CRSs and their community-based partners to promote the mutual exchange of ideas and expertise. These efforts likely contributed to the

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increase in racial/ethnic minority enrollment in the early 2000s and sustained levels in later years. Although we had originally hoped to do so, we were unable to include participants' self-reported information on sexual orientation and gender identity in our analysis because of several changes in the collection of demographic information during the study period. These changes resulted in missing data on sexual orientation and gender identity for participants enrolled in trials that did not collect these data. This limitation also exists in HIV surveillance at the state and national levels; to date, HIV surveillance systems have not routinely collected data on sexual orientation or gender identity of HIV-diagnosed persons. Currently, Washington State is considering adding questions on gender and sexual orientation to its collection of data on newly diagnosed HIV infections. In 2007, the HVTN's demographic case report form was redesigned to adopt the recommendation of CDC to use the 2-step approach: collecting data on sex assigned at birth and self-identified gender. In addition, in 2015, the HVTN added a standardized question to improve the collection of data on sexual orientation. Across the HVTN, all participants are asked, "How do you identify your sexual orientation?" Responses include: gay/lesbian/homosexual, bisexual, queer, 2-spirit, straight/heterosexual, additional category, specify, not sure, and prefer not to answer. These important revisions in data collection will allow for more robust collection and analyses of data on gender identity and sexual orientation.

Our inability to make any conclusions from the data on sexual orientation and gender identity also prevented us from exploring how the intersectionality of race, ethnicity, sexual orientation, and gender identity informs disproportionate vulnerability to HIV infection and barriers to recruitment in preventive HIV vaccine clinical trials. Intersectionality is essential when discussing health disparities because persons with multiple devalued identities may face an increased risk of acquiring HIV and more barriers to prevention, testing, and care than persons with one devalued identity. Pursuing research and engaging in activities that maintain the integrity of an intersectional framework provide a more accurate representation of the burden of HIV that, in turn, enables a more effective and informed delivery of resources into communities most affected by HIV.

## Conclusions

Persons in the United States who identify as members of a racial/ethnic minority group have a complex set of barriers that impede awareness of, access to, and enrollment into HIV vaccine clinical trials. This low enrollment contributes to a dearth of data on differences in immunogenicity, adverse effect occurrence, and reactivity to candidate vaccines among racial/ethnic minority subgroups.Although enrollment of racial/ethnic minority groups into HIV vaccine clinical trials conducted by the HVTN has increased, it still lags behind the proportional representation of new HIV diagnoses among these groups. To promote racial/ethnic minority group participation, the HVTN has prioritized identifying new and strengthening existing partnerships in racial/ethnic minority communities and has invested resources into training HVTN staff members on cultural responsiveness, implicit bias, and health disparities. Despite extensive efforts by the HVTN to reach out to racial/ethnic minority communities, it is unlikely that enrollment in HVTN preventive early phase HIV vaccine clinical trials will be proportional to regional data on the number of new HIV diagnoses among racial/ethnic minority groups, because early phase trials are designed to enroll populations with low behavioral risk for HIV infection. However, comparison of enrollment with these national data can serve as a yardstick for improving the recruitment of racial/ethnic minority groups overall.