

**A Demographic Analysis of Minority Enrollment into HVTN Preventive HIV Vaccine Clinical Trials in
the United States, 2002-2016**

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Abstract

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Background The inclusion of participants in HIV preventive vaccine trials who identify as a member of a racial, ethnic, sexual, and/or gender minority group continues to be lacking, even though rates of HIV infection are often higher among these groups in the United States. An analysis of enrollment demographics of US HIV preventive vaccine trials from 1988 to 2002 showed that enrollment of minority group members increased over time. To determine more recent trends in minority enrollment, a similar analysis of enrollment in HIV preventive vaccine trials from 2002 to 2016 was undertaken to compare to the former study as well as compare to the current demographic distribution of trial participants to the number of new HIV diagnoses in the US annually.

Methods Participant demographic data of 43 Phase 1 and Phase 2A trials conducted in the United States were examined. Distributions of participants by racial, ethnic, sexual, and gender identity were calculated. The racial/ethnic distribution of participants was compared to that of the former study and over time by US geographic region. Racial and ethnic distributions from 2011 to 2015 were compared to CDC data on the number of new HIV diagnoses in the same time period. Recruitment strategies used by trial sites were reviewed to account for differences in minority enrollment by region.

Results A total of 3,469 participants were included in the analysis. Thirty three percent of all participants identified as a racial/ethnic minority, a significant increase from the previous time period. The proportions of enrollment of Black and Hispanic/Latinx participants were substantially less than their respective proportions of new HIV diagnoses in all regions. No conclusions were able to be made on data regarding sexual orientation and gender identity due to inconsistencies in collection and reporting.

Conclusions Although the proportion of all racial and ethnic minority group members enrolled in HVTN preventive vaccine clinical trials in the US has increased from the previous time period, comparison to data on new HIV diagnoses in the country reflects a need to continue to enhance diversity among the trial participant pools. More standardized data collection for sexual orientation and gender identity is required for any meaningful future analysis of these populations.

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Background

Around the globe, the brunt of HIV is shouldered by marginalized populations who face a disproportionately increased risk of acquiring the infection yet decreased resources and opportunities to access prevention and treatment modalities.¹ In the United States (US), racial, ethnic, gender, and sexual minority communities continue to be overrepresented within the HIV seropositive population compared to their White, heterosexual, and cisgender counterparts. According to the US Centers for Disease Control and Prevention (CDC), African Americans comprised close to half of total HIV incidence and prevalence in the US in 2014, despite representing only 12% of the overall population.² In 2010, Latinxs made up 17% of the US population yet represented approximately a quarter of new and existing HIV diagnoses during the same year.³ Persons identifying as a member of a gender and/or sexual minority community face an exponentially higher risk of HIV infection, even more so if they are also a person of color.^{4,5} The majority of new HIV diagnoses among African Americans and Latinxs are men who have sex with men (MSM), with the highest burden existing among young MSM aged 13-24.^{6,7} Transgender individuals, especially transgender women and people of color, are considered to be one of the most vulnerable groups to HIV infection.^{8,9} A 2011 national survey estimated HIV prevalence among transgender individuals to be four times the national average, and was found to be even higher among transgender individuals of color.¹⁰ A 2016 study by Clark et al. reviewed National HIV Surveillance System (NHSS) data to conclude that of the 2,351 transgender individuals in the US who were identified as being diagnosed with HIV from 2009-2014, 84% were transgender women and over half of this group identified as non-Hispanic African American.⁹ A recent meta-analysis of 29 studies conducted between 1990 and 2003 estimated that 28% of transgender women and adolescents in the US are HIV-positive.¹¹ These studies utilized a variety of data collection methods

including interviews, surveys, and focus groups, and 79% of them utilized venue-based recruitment strategies.

Where an individual resides in the United States can also impact their risk of acquiring HIV. According to the CDC, the southeastern US accounts for the largest proportion of HIV incidence and prevalence; 44% of all individuals known to be infected with HIV are concentrated in this region.¹² States within this region also have some of the lowest rates of HIV testing and linkage to care compared to the rest of the country.¹³ Similar inequalities persist for racial, ethnic, sexual, and gender minorities along the entirety of the HIV care continuum.^{14,15,16}

As alluded to previously, individuals who identify as members of multiple minority communities with regard to race, ethnicity, sexual orientation, and gender identity face an exponentially increased risk of acquiring HIV and can experience even more stigma as well as barriers to prevention, testing, and care than individuals with one minority identity.^{17,18,19,20,21} This is further compounded by age, socioeconomic status, educational attainment, region of residence, substance abuse, and other social stratifiers.^{22,23,24,25,26,27} This is commonly referred to as intersectionality, and there is a growing awareness among researchers and health practitioners of the importance of adopting this lens to address the disproportionate vulnerability to HIV that minority communities encounter.^{28,29}

An essential upstream component to tackling disparities in HIV prevention and treatment is the equitable inclusion of marginalized groups in preventive HIV vaccine clinical trials. Without the participation of individuals from populations at highest risk of HIV infection, trial outcomes lack the ability to be generalizable to the diversity of the US population and relevant to those groups that are most affected. To date, few preventive HIV vaccine clinical trials conducted in the US have attained adequate sample sizes of high risk minorities to perform sub-group analyses that can produce

meaningful results.^{30,31,32} Additionally, it is essential in preventive HIV vaccine trials to detect any physiological responses to the vaccine that are unique to specific groups, especially those at higher risk of HIV infection.³³ Most importantly, efforts to adequately include minority groups in preventive HIV vaccine trials can serve to challenge systemic barriers in access to other prevention interventions as well as treatment and care for HIV seropositive individuals.

Although the necessity of adequate representation of high-risk minority groups is increasingly recognized by the research community, numerous barriers exist for these populations to access and enroll in preventive HIV vaccine trials. Research looking at barriers specific to HIV clinical trials - as well as those involving cancer, chronic disease, and other health conditions – have documented a multitude of factors that can present challenges for recruitment and enrollment. Distrust of research and the motives of clinicians and researchers involved is a barrier identified frequently in the literature and is common to persons of color as well as sexual and gender minorities. The legacy of the Tuskegee Syphilis Study and other research that has caused harm to Black individuals and communities in the US has understandably not been forgotten and continues to influence reluctance to participate in current clinical trials.³⁴ Studies involving Black Americans and other racial/ethnic minorities have revealed common fears about a lack of full disclosure regarding research objectives, inappropriate use of biomedical samples, and the potential for participation being revealed and the resulting stigma, all of which have been informed by the precedent of breaches of ethics and trust in research practice.^{35,36,37,38} This reluctance is also reinforced by an inability to establish trustful provider-clinician relationships due to disparities in access to routine health care and in the lack of representation of minorities in the health workforce.^{39,40} For Latinx individuals in the US, language barriers and fear of

research participation influencing immigration documentation status are additional impediments to hearing about and enrolling in clinical trials.^{41,42}

Many persons that identify as a member of a sexual or gender minority community share similar fears regarding potential exploitation by research as well as the risk of increased stigma due to enrollment, particularly in HIV clinical trials.^{4,43,44} Lesbian, gay, bisexual, transgender, and queer (LGBTQ) individuals also frequently encounter challenges to establishing trusting relationships with clinicians who are not attuned to the unique health care needs of LGBTQ communities.^{4,45} Access to screening, prevention, and treatment services for HIV may be limited for sexual and gender minorities if they exist in spaces that are not LGBTQ-friendly.^{46,47} Additionally, study methodologies and data collection techniques still too often do not appreciate the spectrum of sexual and gender identities that exist, which can exclude individuals and communities that do not characterize themselves within traditional binary constructs.^{48,49}

Participation in preventive HIV vaccine trials presents an additional challenge due to myths regarding the risk of HIV acquisition from a vaccine. Studies involving persons of color, MSM, and transgender individuals have documented barriers to enrollment in preventive HIV vaccine trials due to perceived potential risks of side effects, including vaccine-induced seropositivity (VISP), a phenomenon in which a person tests antibody positive during routine HIV screening using tests that detect antibodies as a proxy for HIV infection. These antibodies may have been acquired as an immune response to a preventive HIV vaccine product and not because the person is actually infected with HIV.^{50,51,52,53} This is a key component of another barrier to enrollment, which is the inadequate provision of information to potential participants regarding the mechanism of action of a vaccine, the vaccine clinical trial process, and the potential implications of VISP for HIV testing.^{4,54,55} When

education regarding these facets of trial participation are not adequately discussed by research staff or community partners with potential participants, they are more vulnerable to misinformation and myths, such as the vaccine causing HIV infection.^{51,56} Another documented sentiment among traditionally underrepresented populations in research is that beneficial outcomes of clinical trials (i.e., the development of an effective preventive HIV vaccine) will not reach their communities.^{4,57}

These barriers to recruitment into preventive HIV vaccine trials are complex, yet they do not negate the evidence that demonstrates a willingness of underrepresented communities to participate in research.^{58,59,60} Furthermore, altruism as a major motivator to participate in research is common among racial, ethnic, sexual and gender minority groups.^{32,37,60,61,62} It is abundantly clear that efforts to address these barriers would be most successful if directed at encouraging research and clinical institutions to be more engaged with and accessible to communities of color and sexual and gender minorities.

The HIV Vaccine Trials Network (HVTN) is an international collaboration of researchers, clinicians, and community-based organizations and advocates working toward the goal of developing a safe and universally effective HIV vaccine. The HVTN has worked diligently with community and research partners to identify and address the barriers to recruitment and enrollment in their preventive HIV vaccine trials experienced by traditionally underrepresented communities. The HVTN approaches the development and implementation of their preventive HIV vaccine trials through the lens of Community-Based Participatory Research (CBPR). CBPR is a research paradigm in which researchers and communities work as partners throughout each step of the research process rather than in a traditional hierarchical researcher-subject dynamic. CBPR has been shown to be very effective in accessing populations that researchers have experienced as hard-to-reach by engaging them as

experts regarding their communities and the research subject matter.^{63,64} CBPR can also serve to lessen barriers of mistrust towards research among these populations.^{65,66,67}

Clinical Research Sites (CRSs) receive funding through the Division of AIDS at the National Institute of Allergy and Infection Disease (NIAID) to participate in HVTN preventive HIV vaccine trials. Funded CRSs are expected to recruit individuals with low and high behavioral risk profiles for HIV infection from groups that are disproportionately impacted by HIV infection, as well as those that have been traditionally underrepresented in clinical research, which often overlap. Each CRS chooses which group(s) they will focus their recruitment efforts on based on local or national data and submits a Community Engagement Workplan for review by the HVTN Community Engagement Unit (CEU). The CRS's progress with outreach to these individuals and communities is monitored by the CEU and the HVTN Network Evaluation Committee (NEC), with reports provided to the sites quarterly and annually. Other HVTN policies and strategies are implemented by each CRS to increase participation of underrepresented populations. Each CRS has a Community Advisory Board (CAB) comprised of diverse members of the community who are involved in key decision making about recruitment, enrollment, and retention strategies used by the CRS. Advertising and recruitment strategies are tailored to reach targeted communities depending on the needs of each clinical trial, and sustainable partnerships are developed with community-based organizations that provide services to and are trusted by these communities.⁶⁸ The HVTN also promotes diversity within its research and leadership staff and provides cultural awareness training for Network and CRS staff working with participants.^{62,69}

A 2005 study by former HVTN member Gaston Djomand, et al analyzed enrollment data from 55 Phase 1 and Phase 2A NIAID-funded preventive HIV vaccine trials that took place in the US from 1998 to 2002 to characterize the distribution of racial/ethnic minorities within the participant

population.⁷⁰ These trials were conducted by the HVTN and its predecessor network, the AIDS Vaccine Evaluation Group (AVEG). The study found that although minority participant inclusion in Phase 1 trials varied widely from year to year, the overall trend was an increase in the proportion of racial/ethnic minorities enrolled over time. No further analysis of this kind has been undertaken to examine HVTN clinical trial enrollment data since 2002 nor has this type of data been compared to rates of new HIV diagnoses within their corresponding geographical areas.

The purpose of this study was to continue and expand upon the former investigation to describe the demographic distribution of clinical trial participants with respect to race, ethnicity, sexual orientation, and gender identity among HVTN preventive HIV vaccine trials with enrollments in the US from 2002 to 2016. Additionally, we compared the racial and ethnic distributions to regional data on newly diagnosed HIV infections to determine whether the minority groups that are at higher risk of HIV acquisition are adequately represented in these preventive vaccine trials. Finally, any region that identified as having more equitable participation of one or multiple minority groups was explored further to determine whether this could be attributable to specific recruitment and community engagement practices of the CRSs within the region.

The findings of this study will provide HVTN with important information on their progress toward achieving their goal of sufficient inclusion of key minority groups in their trials as well as identify any groups that remain underrepresented. This data could also inform the development of future recruitment practices to ensure that disparities in participation are not perpetuated.

Methods

For this analysis, we extracted from HVTN case report forms (CRFs) the demographics of all HVTN Phase 1 and 2A preventive HIV vaccine trial participants that were enrolled in the US between

May 16, 2002 and June 30, 2016. Eighty participants who enrolled in multiple HIV vaccine trials within this time period were counted once based on their first enrollment. In total, 43 trials were included. These trials were conducted at eighteen different CRSs within fourteen cities. In the analysis, CRSs were divided into four regions as defined by the US Census Bureau to allow for comparison to regional-level data on the annual number of new HIV diagnoses as reported by the CDC:

- Northeast: Boston, MA; Providence, RI; New York, NY; Philadelphia, PA; Rochester, NY
- Midwest: Cleveland, OH; St Louis, MO; Chicago, IL
- South: Birmingham, AL; Atlanta, GA; Baltimore, MD; Nashville, TN
- West: Seattle, WA; San Francisco, CA

Each CRS served participants in the immediate metropolitan area, and, in some cases, the larger surrounding geographic area.

Participants in these HVTN trials were between the ages of 18-60 and HIV seronegative at the time of enrollment. Participants needed to be in overall good health as determined by a physical exam, laboratory tests, and a review of their history for any significant medical conditions and as assessed by the Inclusion/Exclusion Criteria associated with each individual clinical trial. Receipt of an experimental HIV vaccine in the past, or current or recent use of certain immunosuppressive medications and vaccines were criteria for exclusion. Specific eligibility criteria regarding sexual and substance use behaviors related to increased risk of HIV infection varied across trials. Women of reproductive age were required to avoid pregnancy and use an approved method of contraception throughout the duration of the trial in which they were enrolled.

For this analysis, variables used to describe the demographic distribution of minority enrollment participation were race, ethnicity, sex assigned at birth, sexual orientation, and gender

identity. Racial categories included White, Black, Asian, Native Hawaiian/Pacific Islander (NH/PI), Native American/Alaska Native (NA/AN), and Other, with participants able to specify more than one category. Those specifying more than one race group were considered as Multiracial. Ethnicity was defined by identification as Hispanic/Latinx. To allow for comparison to the Djomand, et al analysis as well as CDC data, race and ethnicity were combined and those that identified as Hispanic/Latinx were counted by this identity rather than any race they identified. Additionally, Asian and NH/PI categories as well as Multiracial and Other categories were combined.

Due to varying formats of the demographic CRFs during this time period, sexual orientation was only asked of participants enrolled between 2002 and 2007 and then from 2015 to 2016. In addition to categories of homosexual, heterosexual and bisexual, CRFs used in the later two years included additional categories: Queer, Two Spirit, Other and not sure. These were collapsed into the Other category for analysis due to small numbers. 55% of total participants identified their sexual orientation. Similarly, questions regarding gender identity were not uniform on CRFs during this time period. Dependent upon the trial, participants were asked either sex assigned at birth, their gender identity, or both. For this analysis, if sex assigned at birth wasn't available (582 participants), we used the participant's response for gender to code. For these participants, gender was coded as male or female and comments added if the participant was Transgender. We used the comment if present to recode gender. If sex assigned at birth and gender were both ascertained and were discordant (Male/Female or Female/Male), the participant was coded as Transgender.

Proportions of racial/ethnic minority enrollment were examined by year of enrollment and CRS region (described above). Due to missing data and low numbers of those that identified as non-heterosexual and/or non-cisgender, sexual orientation and gender identity results analysis were

limited to a tabulation of proportions within the pooled data. Racial/ethnic minority enrollment on Phase 1 trials was viewed over time to compare to similar analysis done by Djomand, et al.

For comparison of racial/ethnic minority enrollment to regional newly diagnosed HIV infections, comparison data was obtained from the NHSS.⁷¹ Surveillance reports from 2011 to 2015, the most recent five years available, were utilized to compare to enrollment from these same years. CRSs were grouped by these US Census-defined regions for analysis as described previously. Due to a small number of participants in other racial categories, only those participants that identified themselves as Black or Hispanic/Latinx were included. No national-level data exists for HIV diagnoses stratified by sexual orientation or gender identity, thus only the racial/ethnic demographic of enrolled participants was compared to that of data obtained from the CDC.

Lastly, the Senior Community Engagement Project Manager of the HVTN, Ms. Gail Broder, MHS, was consulted to assist with identifying any recruitment practices that CRSs utilized that could have resulted in more equitable enrollment of minority communities compared to other sites. As one of the leaders of the CEU, information Ms. Broder provided was informed by her institutional knowledge and involvement in oversight of the CRSs, specifically with their efforts to recruit from underrepresented populations. Additionally, annual reports from HVTN's NEC, the monitoring and evaluation body for all CRSs, were reviewed for all CRSs between the years 2006 and 2015 to determine if any practices or facets of specific CRSs resulted in better representation of minority participants as evidenced by this analysis.

Analyses was performed using Stata, Version 14. Chi square testing was used to compare proportions of racial/ethnic minority enrollment between Djomand, et al and the current study.

The study is covered by the HVTN's approval from the Fred Hutchinson Cancer Research Center Institutional Review Board (IRB).

Results

Overall trends and comparison to Djomand, et al findings

A total of 3,469 participants were included in this analysis (Table 1). 3,038 (88%) of participants were enrolled in 41 Phase 1 trials, and 431 (12%) were enrolled in 2 Phase 2A trials. 1,565 participants (45%) identified as female at birth. The majority of participants (52%) were between the ages of 20 and 29, with a median of 27 years (interquartile range: 23, 37 years). Across all years and CRSs, 67% of enrolled participants identified as White, 17% identified as Black, 8% identified as Hispanic/Latinx, 3% identified as Asian or Native Hawaiian/Pacific Islander, 0.3% identified as Native American/Alaska Native, and 4% identified as Multiracial or Other. Of the 1,907 participants that were asked their sexual orientation, 71% identified as heterosexual, 22% as homosexual, 6% as bisexual, and 0.9% as Other. A total of 21 participants (0.6%) identified as transgender and 14 (0.4%) identified as Other.

When comparing the distribution of both Phase 1 and Phase 2A trial participants by race/ethnicity enrolled from this time period to those enrolled from 1988 to 2002 as presented by Djomand, et al, the proportion of White participants decreased while the proportion of racial and ethnic minority participants increased ($p < 0.0001$) (Figure 1a and 1b).

Table 1: Enrollment demographics by trial phase and enrollment region

Characteristic	N (%)						
	Phase			Region			
	Total (N=3469)	1 (N=3038)	2A (N=431)	NE (N=1416)	MW (N=194)	S (N=1176)	W (N=683)
Age							
< 20	230 (6.3)	188 (6.2)	42 (9.7)	124 (8.8)	18 (9.3)	57 (4.9)	31 (4.5)
20-29	1789 (51.6)	1547 (51.0)	242 (56.2)	736 (52.0)	99 (51.0)	614 (52.2)	340 (49.8)
30-39	786 (22.7)	694 (22.9)	92 (21.6)	268 (19.0)	51 (26.3)	284 (24.2)	183 (26.8)
40-49	601 (17.3)	553 (18.2)	48 (11.1)	263 (18.6)	25 (12.9)	202 (17.2)	111 (16.3)
50 +	63 (1.8)	56 (1.9)	7 (1.6)	25 (1.8)	1 (0.5)	19 (1.6)	18 (2.6)
Sex at Birth							
Female	1565 (45.1)	1364 (44.9)	201 (46.6)	633 (44.7)	70 (36.1)	569 (48.4)	293 (42.9)
Male	1904 (54.9)	1674 (55.1)	230 (53.4)	783 (55.3)	124 (64.0)	607 (51.6)	390 (57.1)
Gender Identity							
Female	1536 (44.3)	1336 (44.0)	200 (46.4)	627 (44.3)	70 (36.1)	567 (48.2)	272 (39.8)
Male	1898 (54.7)	1668 (54.9)	230 (53.4)	780 (55.1)	124 (63.9)	606 (51.5)	388 (56.8)
Transgender	21 (0.6)	20 (0.5)	1 (0.2)	7 (0.5)	0 (0.0)	2 (0.2)	12 (1.8)
Other	14 (0.4)	14 (0.7)	0 (0.0)	2 (0.1)	0 (0.0)	1 (0.1)	11 (1.6)
Sexual Orientation							
Bisexual	121 (3.5)	108 (3.6)	13 (3.0)	44 (3.1)	7 (3.6)	24 (2.0)	46 (6.7)
Heterosexual	1352 (39.0)	1217 (40.1)	135 (31.3)	492 (34.8)	118 (60.8)	562 (47.8)	180 (26.4)
Homosexual	417 (12.0)	385 (12.7)	32 (7.4)	148 (10.5)	35 (18.0)	121 (10.3)	113 (16.5)
Other	17 (0.5)	17(0.6)	0 (0.0)	5 (0.6)	1 (0.5)	3 (0.3)	8 (1.2)
Unknown	1562 (45.0)	1311 (43.2)	251 (58.2)	727 (51.3)	33 (17.0)	466 (39.6)	336 (49.2)
Race							
Asian	102 (2.9)	93 (3.1)	9 (2.1)	56 (4.0)	3 (1.6)	18 (1.5)	25 (3.7)
Black	600 (17.3)	511 (16.8)	89 (20.6)	217 (15.3)	31 (16.0)	321 (27.3)	31 (4.5)
Latinx	267 (7.7)	236 (7.8)	31 (7.2)	154 (10.9)	8 (4.1)	37 (3.2)	68 (10.0)
Multiracial	124 (3.6)	116 (3.8)	8 (1.9)	52 (3.7)	0 (0.0)	20 (1.7)	52 (7.6)
Native American/ Alaska Native	9 (0.3)	8 (0.3)	1 (0.2)	4 (0.3)	3 (1.6)	2 (0.2)	0 (0.0)
Native Hawaiian/ Pacific Island	10 (0.3)	10 (0.3)	0 (0.0)	1 (0.1)	0 (0.0)	2 (0.2)	7 (1.0)
White	2332 (67.2)	2042 (67.2)	290 (67.3)	917 (64.8)	147 (75.8)	772 (65.7)	496 (72.6)
Other	22 (0.6)	19 (0.6)	3 (0.7)	15 (1.1)	2 (1.0)	4 (0.3)	1 (0.2)
Unknown	3 (0.1)	3 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.4)
Total	3469	3038	431	1416	194	1176	683

Figure 1a: Participant distribution by race/ethnicity (N=3731) - Djomand, et al

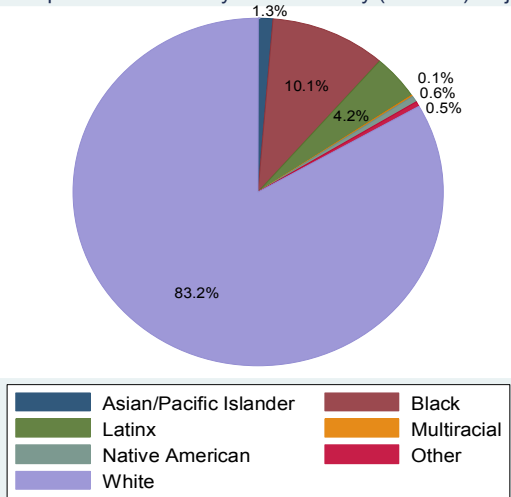
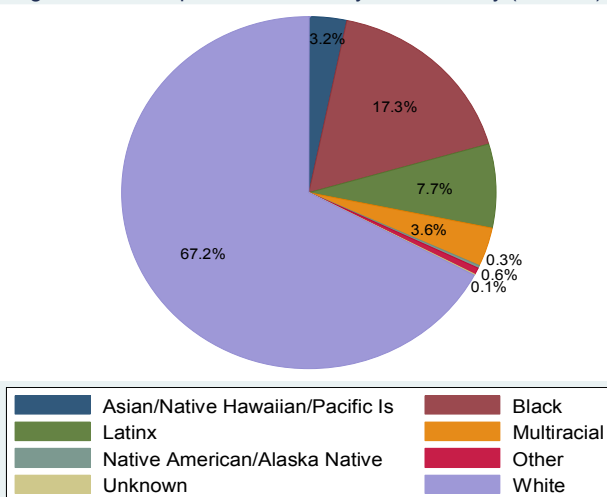


Figure 1b: Participant distribution by race/ethnicity (N=3469)



When the distribution of Phase 1 and Phase 2A trial participants enrolled between 2002 and 2016 was disaggregated by race/ethnicity and year of enrollment, the percent enrollment of all racial/ethnic minorities was between 17 and 40% for all years except for 2008. Lower percent enrollments were observed earlier in this time period: 2002, 2003, and 2004 had 17, 18, and 27% minority enrollment, respectively. After 2004, the percentage of minority enrollment generally increased to between 30 and 40% for subsequent years. In 2008, racial/ethnic minorities represented 53% of all enrolled participants (Figure 2). Black participants were the only racial/ethnic minority

Figure 2: Racial/ethnic minority enrollment over time (N=3466)

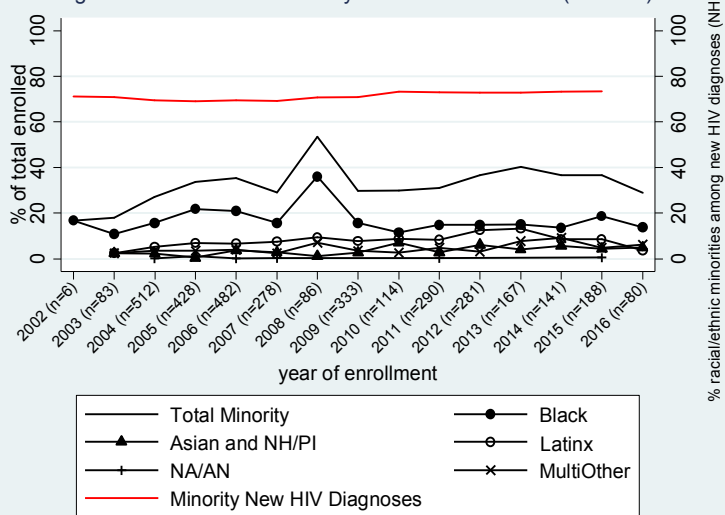
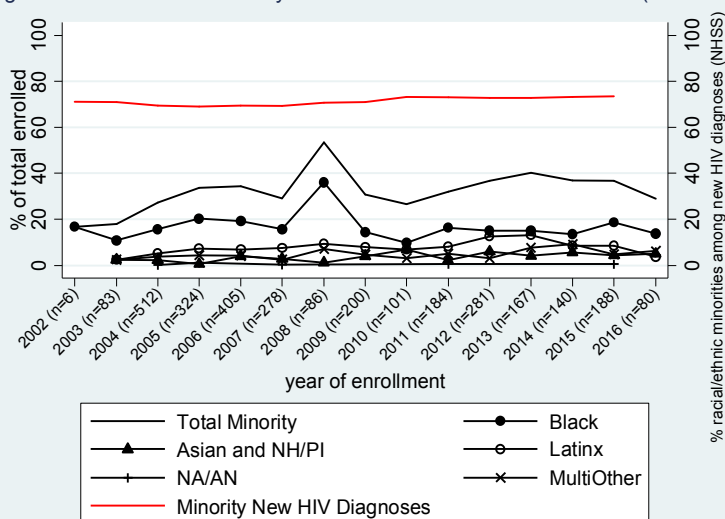


Figure 3: Racial/ethnic minority enrollment over time: Phase 1 trials (N=3035)



group that surpassed 20% of total enrollment for any year, which they did in 2005, 2006, and 2008. Unlike Djomand, et al, who reported a significant increase in racial/ethnic minority participation in Phase 1 trials across time, there were no upward nor downward trends observed in the current data. Enrollment of each racial/ethnic minority group remained fairly steady throughout the time period. This was observed when looking at both Phase 1 and Phase 2A trials as well as limiting to just Phase 1 trials, as was done with the Djomand, et al analysis (Figure 3).

Regional trends and comparison to HIV new diagnoses

When stratified by region, 1416 (41%) of participants were enrolled in the Northeast, 194 (6%) in the Midwest, 1176 (34%) in the South, and 683 (20%) in the West. Per review of the NEC annual reports and consultation with the CEU regarding inclusion of underrepresented populations among the CRSs during this time period, all sites prioritized recruitment of Black participants while approximately a quarter targeted Latinx individuals for participation as well. There was no specific effort towards recruiting sexual/gender minorities at any site in these phase 1 and 2A trials, although these individuals were eligible for enrollment if they met the inclusion/exclusion criteria for any given study. Each region was characterized by distinct trends in participation in HVTN preventive HIV vaccine trials during this time period as well as in levels of enrollment of racial/ethnic minority groups (Figures 4a-h).

The Northeast region accounted for the largest number of CRSs, and most of the sites participated in at least half of the enrollment years during this time period. In the Northeast, enrollment of racial/ethnic minority participants remained below 20% for all groups throughout the time period, except for a spike in Black participant enrollment in 2008 up to 36%. This appears to be driving the increase seen in the aggregate data during the same year. Upon review of the NEC reports from the Northeastern CRSs and consultation with the CEU, this spike is most likely attributable to two

changes that occurred during this year. First, one of the CRSs in the Northeast began enrolling in 2008 (NE 7). This CRS had a long-standing history of community engagement through well-established partnerships with several community-based organizations (CBOs) from previous research the site had conducted. The leadership of this CRS was committed to reaching and recruiting traditionally underrepresented populations in their area. After 2008, enrollment at this site fluctuated between 1% of total enrollment in this region in 2009 and 38% in 2013 (compared to 46% in 2008). The second factor that was identified by the CEU was that around this year, NIAID began to provide financial support to CBOs located in the same cities as the CRSs, as well as several national organizations, through the Be The Generation initiative. Activities funded through this program included capacity building and information sharing between the CBOs and their respective CRSs in order to promote the mutual exchange of ideas and expertise to enhance racial/ethnic minority awareness of and involvement in preventive HIV vaccine research. At least one CBO per CRS city was awarded funding through this project. Because the Northeast contains the most CRSs, this could have been a component in the spike seen in racial/ethnic minority enrollment in 2008; however, this growth wasn't sustained in future years nor did any other region experience the same trend in this year.

In the Midwest, there were only three CRSs who participated in the HVTN preventive HIV vaccine trials under analysis in vastly different time periods. MW 1 enrolled from 2014-2016, MW 2 enrolled from 2002-2006, and MW 3 enrolled from 2012-2013. There was no enrollment in this region from 2007 to 2011 for Phase 1 and Phase 2A trials. Additionally, the Midwest sites had less enrollment slots allocated to them, thus their enrollment numbers throughout the time period were lower compared to the other regions. In 2006 and 2013, there were marked increases in percent enrollment of all racial/ethnic minority participants, which appear to align with an increase in the number of Black

Figure 4a: Number of enrolled participants: Northeastern sites (N=1416)

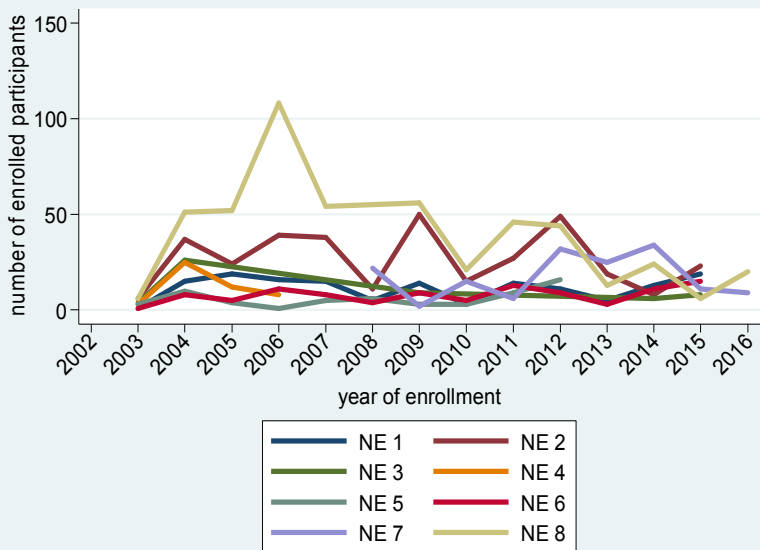


Figure 4b: Racial/ethnic minority enrollment over time - NE (N=1416)

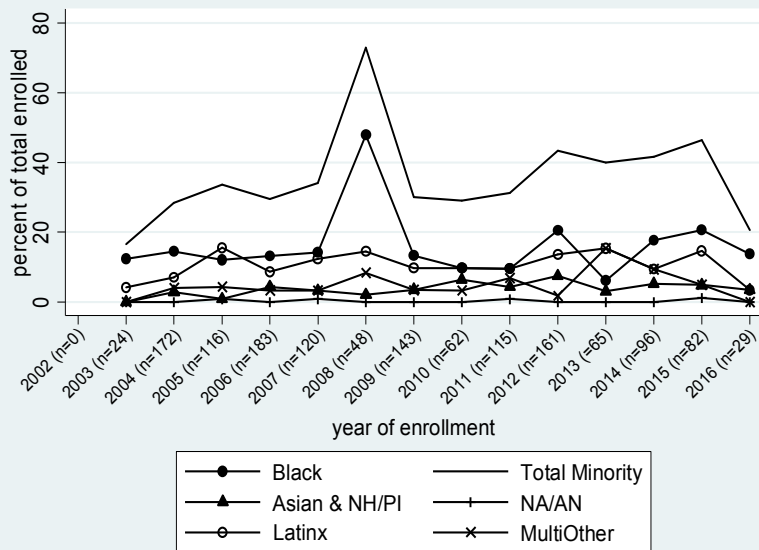


Figure 4c: Number of enrolled participants: Midwestern sites (N=194)

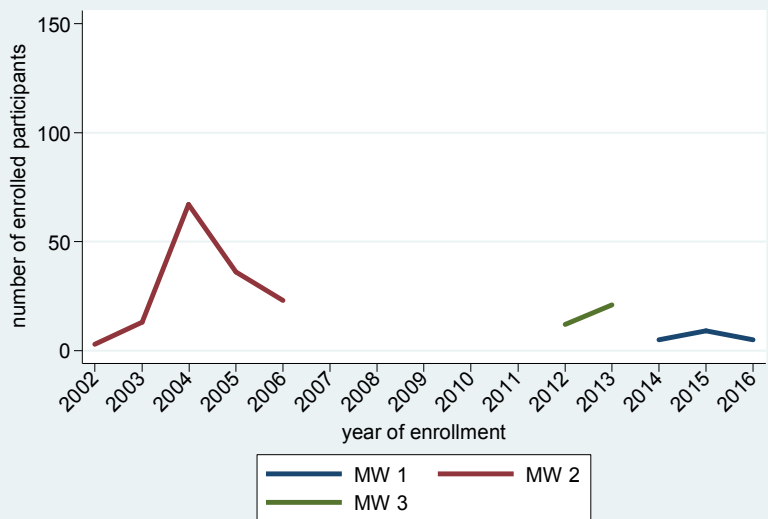
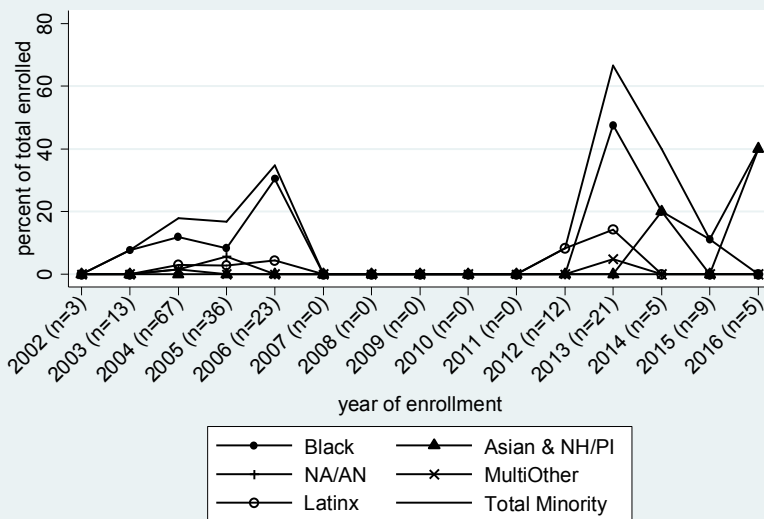


Figure 4d: Racial/ethnic minority enrollment over time - MW (N=194)



participants during these two years. Otherwise, percent enrollment of racial/ethnic minorities varies throughout the time period from 0% to 20%. The 2013 NEC report for CRS MW 3 commended this CRS's diversity of their CAB, advertising and recruitment activities that were accessible to the minority population they were targeting, and continual efforts to nurture their CBO partnerships. These strengths and resulting impact on minority enrollment were reaffirmed by the CEU.

In the South, despite varying levels of participation among the CRSs during the enrollment period, the percent of enrollment of all racial/ethnic minority groups combined remained above 20%.

This was largely attributable to levels of enrollment of Black participants, which also remained above 20% for all years except 2013 and 2014. According to the NEC, CRSs S1 and S3 maintained consistent participation among Black individuals throughout this time period due to the large Black populations in the cities in which they are located as well as both CRSs directing significant resources and staff towards recruiting Black individuals. Conversely, the CEU noted that throughout CRS S5's involvement with HVTN Phase 1 and 2A trials, they struggled to meet their goals for inclusion of any non-White

Figure 4e: Number of enrolled participants: Southern sites (N=1176)

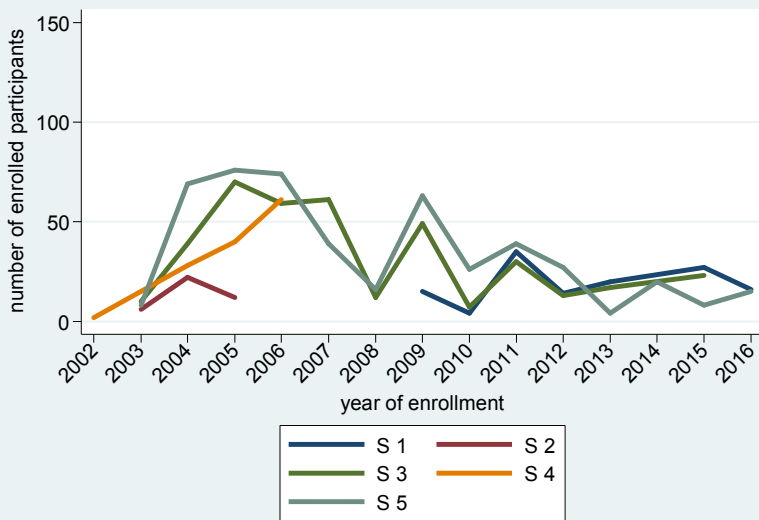


Figure 4f: Racial/ethnic minority enrollment over time - S (N=1176)

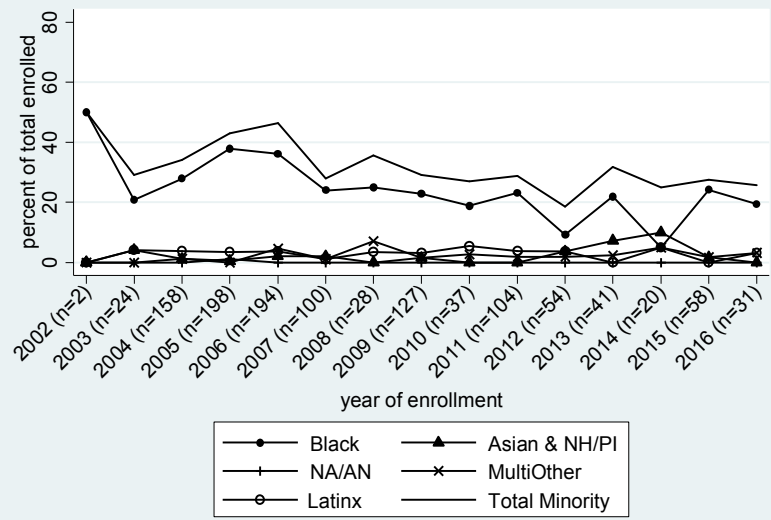


Figure 4g: Number of enrolled participants: Western sites (N=683)

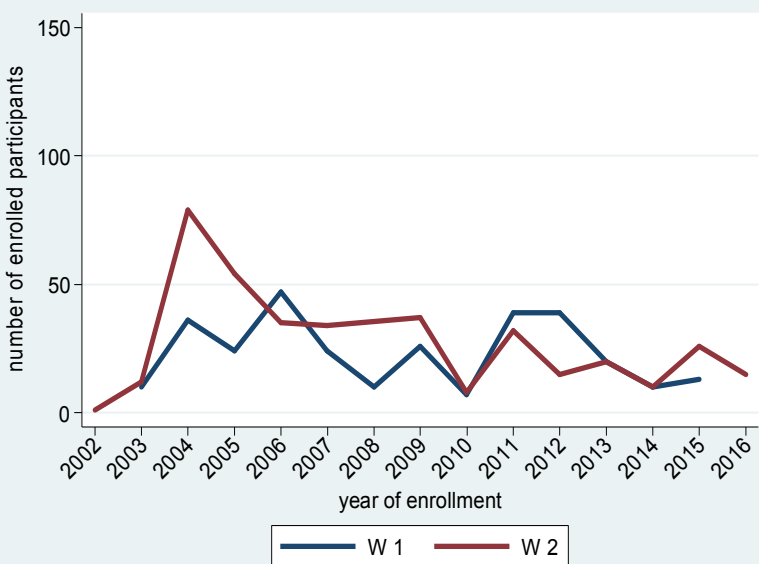
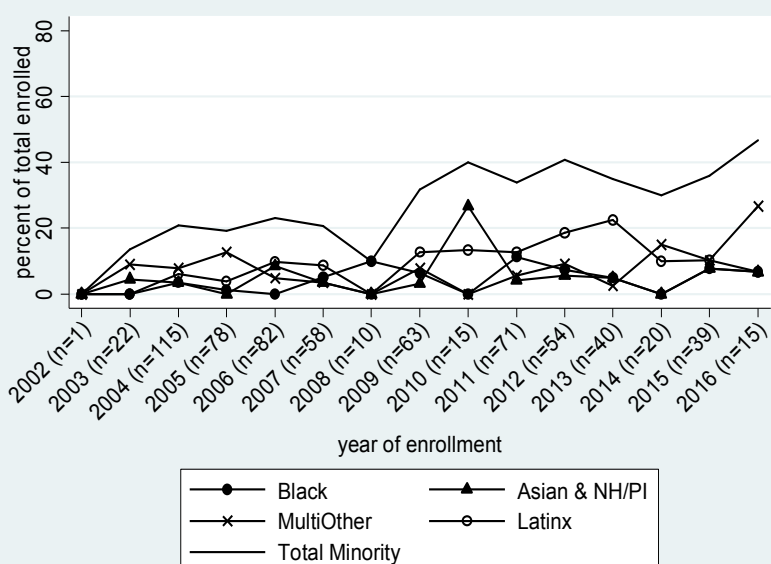


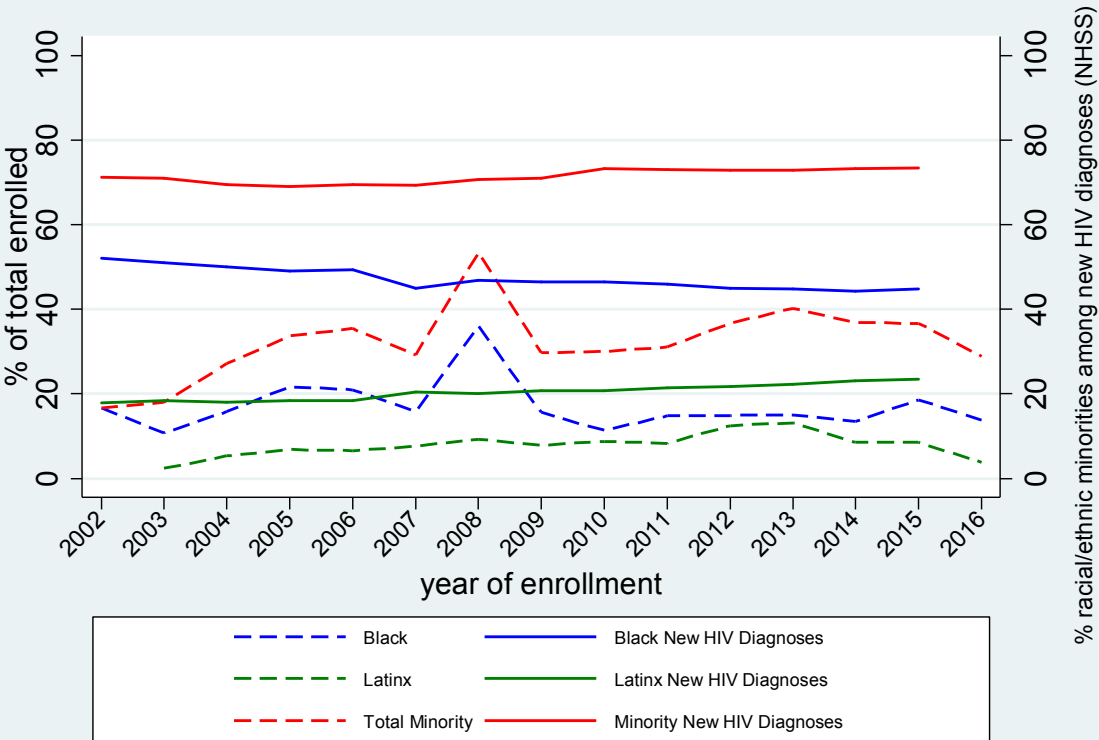
Figure 4h: Racial/ethnic minority enrollment over time - W (N=680)



groups due to the location of the CRS (private university) and the subsequent inaccessibility of the site for many communities of color. For all Southern sites, participation of other racial/ethnic minority individuals, including Hispanic/Latinxs, remained under 10% during the time period.

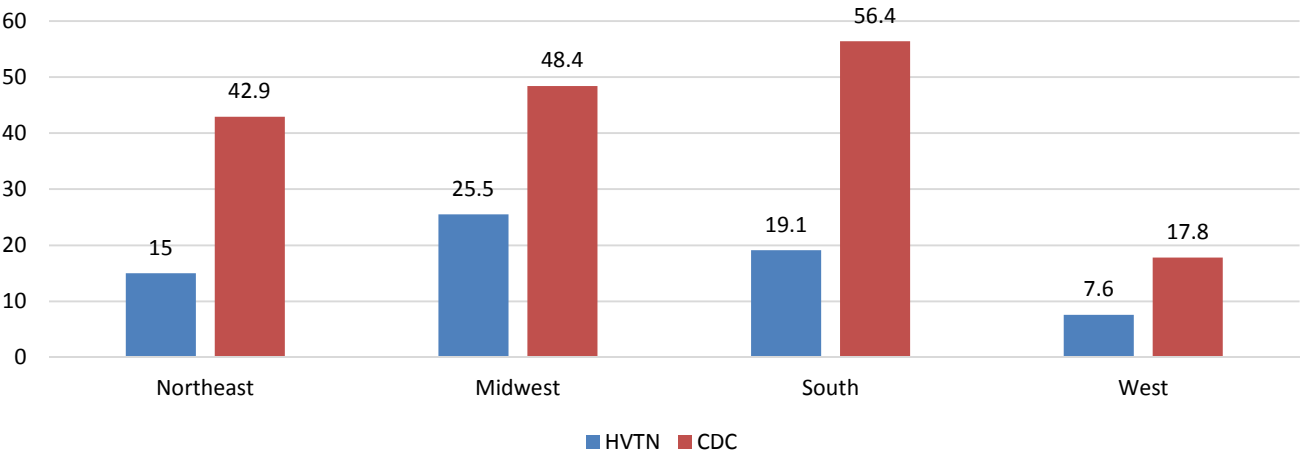
The West has only two CRSs; however, each maintained their participation in HVTN trials throughout the entire enrollment period. Like the Midwest, they also had lower enrollment numbers in Phase 1 and Phase 2A trials compared to the Northeast and South due to fewer allocated participant slots than these two regions. The West is the only region that had a notable percentage of participants that identified as Multiracial or Other. Additionally, Hispanic/Latinx enrollment generally increased over time and reached almost 25% in 2012 and 2013.

Figure 5: Racial/ethnic minority enrollment over time vs % racial/ethnic minorities among new HIV diagnoses



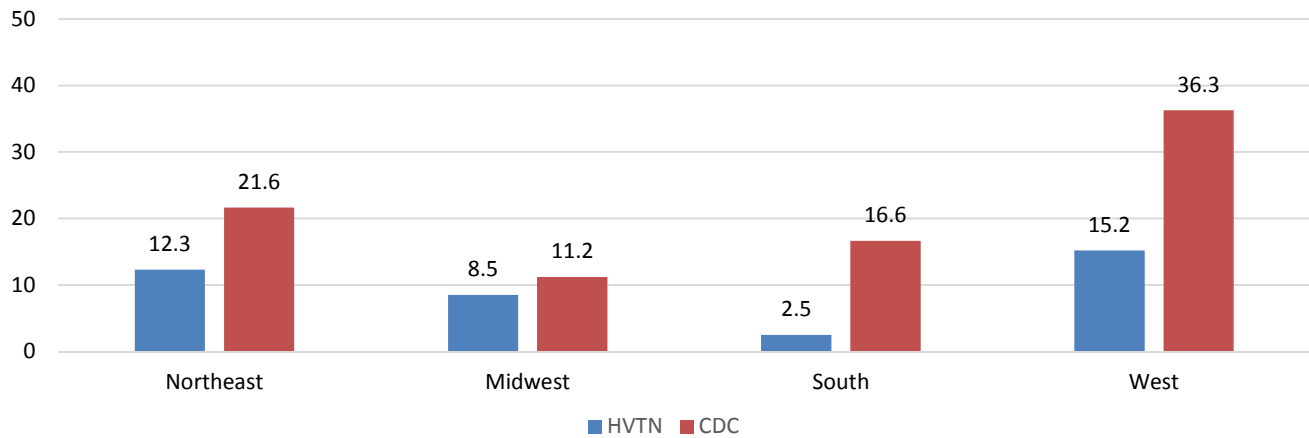
As reported by the NHSS, from 2002 to 2016 racial/ethnic minorities accounted for between 69 and 73% of newly diagnosed HIV infections, far above the percentage of enrollment of any racial/ethnic minority group into Phase 1 and Phase 2A HVTN preventive HIV vaccine trials in any year between 2002 and 2016 as well as all groups combined (Figure 2). This is further elucidated when extracting just Black and Hispanic/Latinx enrollment and comparing them to the number of new HIV diagnoses among each group (Figure 5). When comparing percent enrollment in Phase 1 and Phase 2A HVTN preventive HIV vaccine trials of Black participants in each region to the region’s number of new HIV diagnoses annually among this same population from 2011 to 2015, the proportion of the number of HIV diagnoses among Black individuals ranged from two to four times the percent enrollment of Black participants in HVTN trials, with the greatest disparity in the South (Figure 6). With regard to

Figure 6: Total proportion of Black HVTN participants vs Number of New HIV Diagnoses in US Black population 2011-2015 (NHSS)



Hispanic/Latinx individuals, the burden of HIV diagnoses was almost two to five times that of the percent of Hispanic/Latinx trial enrollees. The South was responsible for the largest gap seen between trial enrollment and the number of new HIV diagnoses among this group (Figure 7).

Figure 7: Total proportion of Latinx HVTN Participants vs Number of New HIV Diagnoses in US Latinx population 2011-2015 (NHSS)



Discussion

Individuals in the US that identify as a member of a minority group with respect to race, ethnicity, sexual orientation and/or gender identity continue to be disproportionately vulnerable to acquiring HIV as well as to poorer outcomes once infected. These inequities are further exacerbated by the intersectionality of individuals with multiple minority identities. This is a result of a complex set of barriers that impede access to prevention, screening, and treatment. One important barrier is the inadequate representation of minority groups in HIV preventive clinical trials, which could limit knowledge of and access to effective prevention and treatment strategies.

This analysis demonstrates that the participation of racial/ethnic minority groups in HVTN preventive HIV Phase 1 vaccine trials has increased when compared to the enrollment period analyzed by Djomand, et al. However, despite the HVTN's mindful approach towards inclusion of racial/ethnic minority groups, disparities in enrollment of racial/ethnic minority groups still persist compared to the number of new HIV diagnoses annually in the country and when viewed by region.

Although causation cannot be established by this study, site-specific recruitment practices were identified with the assistance of the HVTN Community Engagement Unit and review of the NEC annual reports that could explain findings regarding trends of minority enrollment observed in enrollment in

Phase 1 and 2A trials. Overall, it appeared that CRSs that established strong partnerships with CBOs that served the underrepresented populations they were targeting seemed to be more effective in enrolling individuals from those populations into their trials. The effectiveness of this strategy in recruiting racial/ethnic, sexual, and gender minority participants into HIV prevention and treatment clinical trials has been well documented in the literature.^{72,73,74,75} The extent to which racial/ethnic minorities are enrolled at each CRS is informed by the priorities of the leadership of each CRS, racial/ethnic diversity among CRS staff and CAB members, and the ability of the CRS to make accommodations for participants who could experience barriers in access to the site (ie, operating on evenings and weekends, locating the site in a place accessible by public transit). These factors were also cited in many studies on HIV preventive clinical trials. Minority representation among CABs, research staff, and clinicians that mirror that of the ideal participant pool is important to establish trust with potential participants and allay fears of exploitation or abuse.^{4,Error! Bookmark not defined.,41} Hiring staff that can communicate with participants in their native language or have similar lived experiences is also essential to good participatory research practice.^{39,76,77} Advertising and recruitment activities at community events or in community spaces frequented by minority groups is another key strategy to increase the diversity of those enrolled.^{78,79,80} For the CRSs in the HVTN, these factors are very site-specific and depend on the amount and type of staff a CRS can employ, the setting in which they are located, and the resources available to gain access to the underrepresented population they are targeting.

Limitations

There are some known limitations of this study. A major one was the inability to include data on sexual orientation and gender identity beyond the initial demographic analysis. Several changes in

what information was collected from participants during study enrollment over the time period of analysis resulted in almost half of participants not being asked their sexual identity. In a large majority of cases, gender identity could not be adequately ascertained. Even when specific questions were included in the CRFs, it is known that fear of stigma and historically poor access to research opportunities could have posed further challenges to recruitment.^{4,81,82} This limitation reflects a larger one regarding current HIV surveillance methods utilized by most state and municipal health agencies, which do not routinely collect data on sexual orientation or gender identity of HIV diagnosed individuals. Findings from a comprehensive review of the most current HIV surveillance report of each state's Department of Health (DOH) revealed that no state currently collects data on sexual orientation. MSM status of male respondents is ascertained by each state, but this does not provide information on these respondents' sexual orientation, nor does it reflect distinctions between cisgender and transgender men. There are only nine states that have data on Transgender status for persons with a new HIV diagnosis. This has resulted in the absence of reliable state and national-level data on HIV prevalence and new HIV diagnoses among those that identify as a sexual or gender minority. There is growing recognition of the importance of quantifying this burden in a standard way. For example, Washington state plans to transition to a new reporting system in 2017 that will allow for the collection of data regarding sexual orientation and gender identity of any individual newly diagnosed with HIV.⁸³ This would enable a more effective and informed delivery of resources and programs into these communities.

The inability to make any conclusions from the data on sexual orientation and gender identity also prevented us from exploring any analysis of intersectionality. This is essential when discussing any type of health disparity, as it can have a dramatic impact on outcomes involving participants that

identify as part of multiple minority communities. To determine the extent to which intersectionality further impedes recruitment and enrollment of these individuals into HVTN preventive vaccine trials, it would be valuable to repeat this analysis once more robust data on sexual orientation and gender identity of HVTN participants is available.

It is known that some participants do not live in the metropolitan area where their CRS is located. Because this presented a challenge in comparing HIV incidence data to enrollment data on a CRS level, a regional comparison was undertaken. This approach limited us from detecting site-specific differences in minority recruitment patterns. A more in-depth analysis would be required to be able to fully understand what specific recruitment practices have made a measurable difference in recruitment persons from minority groups. Differences in the number of CRSs included in each region as well as the number of trials that each CRS enrolled in undoubtedly affected the distribution of racial/ethnic minority participation. Additionally, the distribution of the burden of HIV incidence within a specific region could be different from the demographic distribution of a CRS's catchment area. For example, metropolitan areas in the South such as Birmingham and Atlanta have a much smaller population of Hispanic/Latinx residents compared to that of Miami. Although this is the case, it is still important for HIV preventive vaccine trials to work towards adequate inclusion of participants from racial/ethnic and sexual minorities, no matter the location of the trial site.

Phase 2B trials, which are conducted with individuals who report higher HIV risk profiles to determine the efficacy of a vaccine, were not included in this analysis. This excluded additional enrollment data from several CRSs. According to the CEU, there are certain CRSs that had difficulty achieving adequate racial/ethnic minority participation in the Phase 1 and 2A trials they were involved in, yet are successfully enrolling persons of color and other minority groups into current Phase 2B

trials. Phase 2B trials were not included in order to compare the findings to those of the Djomand, et al study. Additionally, Phase 2B trials have different inclusion/exclusion criteria than Phase 1 and 2A trials. This would have created further limitations of this analysis. Examining enrollment data from Phase 2B trials in the future would certainly enhance the evaluation of enrollment performance by these CRSs and provide more information on successful recruitment strategies for inclusion of racial/ethnic minority communities.

The HVTN has continued to be a leader in prioritizing community-based approaches to recruiting participants in their preventive HIV vaccine trials. This analysis shows that since 2002, enrollment of racial and ethnic minority groups has increased, although it still lags behind the annual number of new HIV diagnoses among these groups. Comparing HVTN preventive HIV vaccine trial enrollment data to regional-level data on the number of new HIV diagnoses could be a valuable metric in future evaluations to measure how well CRSs are meeting their goal of inclusion of minorities, though with the caveat that this data may not represent the landscape of HIV diagnoses where the CRSs are located. Furthermore, more robust data collection concerning participants' sexual and gender identities is essential to effectively characterize these communities in relation to participation in preventive HIV vaccine trials and, on a national scale, determine HIV incidence more accurately. With HVTN's continued commitment to engaging minority communities throughout the research process, minority representation in their HIV preventive clinical trials should continue to improve.

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